

FRONT PAGE - COMPANIES & MARKETS
Weldon to leave J&J helm after turbulent tenure

By Alan Rappeport in Boca Raton, Florida
440 words
22 February 2012
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13
English

William Weldon will retire this year as chief executive of Johnson & Johnson, marking an end to a tenure that has been marred by a string of product recalls.

The US healthcare company said yesterday that Mr Weldon, 63, would be replaced by Alex Gorsky, a J&J veteran currently serving as executive vice-chairman of medical devices and diagnostics. Mr Gorsky will take over the top job after the company's shareholder meeting in April.

J&J said the decision to replace Mr Weldon was part of a multi-year succession planning process. The selection was widely considered a two-person race since December 2010, when Mr Gorsky and Sheri McCoy, head of pharmaceuticals, were named to serve alongside Mr Weldon in an expanded chairman's office.

"I look forward to the transition of leadership and to a bright future for Johnson & Johnson," Mr Weldon said in a statement.

Mr Weldon has been J&J's chief executive since 2002 and his two most recent predecessors retired by the age of 64. The last several years have been especially challenging because of recalls and lawsuits that have tarnished the company's reputation.

In 2010, the company's sales were cut by $900m because of problems with its over-the-counter drugs. Lawsuits related to its marketing of an anti-psychotic drug and faulty hip replacement devices continue to weigh on its results.

Mr Weldon has been criticised for being overly aggressive in cutting costs and for a decentralised management approach.

Les Funtleyder, an analyst and fund manager at Miller Tabak, said he did not think Mr Weldon would have retired so soon had the over-the-counter drug problems been behind the company.

"This was expected, although it seems a bit earlier than the Street assumed," Mr Funtleyder said.

Mr Gorsky joined J&J in 1988 as a sales representative and worked up through marketing in the drugs business. In 2004, he joined Novartis as chief operating officer, where he worked for four years before returning to J&J. Analysts at Barclays Capital said Mr Gorsky's background could signal that J&J will put more emphasis on medical devices and diagnostics. J&J said Ms McCoy will report to Mr Gorsky and be responsible for pharmaceuticals, consumer groups and information technology and that Mr Weldon will remain as chairman of the board.

J&J shares rose 0.08 per cent to $65.09 in after-hours trading.

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FT FINANCIAL TIMES

COMPANIES - ROUND-UP
Weldon to step down as chief executive of J&J; pharmaceuticals

252 words
22 February 2012
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English

William Weldon will retire this year as chief executive of Johnson & Johnson, marking an end to a tenure that has been marred by an embarrassing string of lawsuits and product recalls.

The US healthcare company said yesterday that Mr Weldon, 63, will be replaced by Alex Gorsky, executive vice-chairman of medical devices and diagnostics.

Mr Gorsky, who joined J&J as a sales representative in 1988, will take over after the company's shareholder meeting in April.

J&J said the decision to replace Mr Weldon was part of a multi-year succession planning process. The selection was widely considered a two-person race since December 2010, when Mr Gorsky and Sheri McCoy, head of pharmaceuticals, were named to serve alongside Mr Weldon in an expanded chairman's office.

"I look forward to the transition of leadership and to a bright future for Johnson & Johnson," Mr Weldon said in a statement.

In recent years Mr Weldon, who has been chief since 2002, has had to manage a string of recalls and lawsuits that have tarnished J&J's reputation.

In 2010, group sales were cut by $900m due to problems with its over-the-counter drugs. Lawsuits related to marketing of an anti-psychotic drug and faulty hip replacement devices continue to weigh on results .

J&J shares rose 0.08 per cent to $65.09 in after-hours trading.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
Product recall fees dent J&J earnings

By Alan Rappeport in New York
495 words
25 January 2012
Financial Times
FTFT
USA Ed2
16
English

healthcare

New signs of life in device business

Charges related to litigation and product recalls led to a steep decline in fourth-quarter earnings at Johnson & Johnson, the US healthcare company.

Bill Weldon, chief executive, said the company still faced economic headwinds, including high unemployment, rising healthcare costs and currency volatility. But he said ageing populations around the world represented an opportunity for the company, while there were new signs of life in its device business.

"Populations in the developed world are ageing rapidly, and we consume more healthcare as we grow older," Mr Weldon said. "Our investments continue to be aligned with these market opportunities."

Mr Weldon has been working to rehabilitate J&J's image and replenish its product pipeline after embarrassing and costly recalls of drugs such as Tylenol and Motrin.

Last week, the company agreed to pay $158m to settle charges that it improperly marketed Risperdal, an anti-psychotic drug, in Texas. J&J is facing similar charges in other states.

Although J&J's medical device business has been struggling in recent years, Mr Weldon said that declining utilisation of procedures requiring devices appeared to be reaching a trough.

"The people that need this elective surgery are not having it done because they're unemployed, they've lost insurance," Mr Weldon said. "But you can only put these procedures off for so long. And there's going to be a bolus of people that will come back into the market over time."

Les Funtleyder, healthcare analyst and fund manager at Miller Tabak, noted that signs of the medical device industry bottoming out could signal that the US economy was stabilising, because procedures such as hip and knee replacements are highly correlated to employment.

In spite of those positive signs, J&J is still recovering from a difficult stretch of recalls and lawsuits, which continue to hit its bottom line. It said yesterday its net income during the last three months of 2011 fell by 88.8 per cent from the previous year to $218m, or 8 cents a share. The sharp decline reflected $2.9bn in charges related to litigation, settlements and recalls.

Sales in the quarter were up 3.9 per cent year-on-year to $16.3bn. For the year, sales were up 5.6 per cent to $65bn, ending two years of declines. During the fourth quarter, US sales fell 3.4 per cent year-on-year, while international sales rose 10.2 per cent. The drugs business showed the fastest growth, followed by medical devices and consumer products. The results were better than Wall Street analysts' expectations and the company's shares were unchanged on the day. However, some investors were concerned about J&J's weaker than expected 2012 outlook which projected earnings of $5.05 to $5.15 a share for 2012.

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FT FINANCIAL TIMES

J&J earnings hit by litigation and recalls

By Alan Rappeport in New York
299 words
24 January 2012
Financial Times (FT.Com)
FTCOM
English

Charges related to litigation and product recalls led to a steep decline in fourth-quarter earnings at Johnson & Johnson, the US healthcare company.

J&J said on Tuesday that its net income during the final three months of last year fell by 88.8 per cent from the prior year to $218m, or 8 cents a share. The sharp decline reflected $2.9bn in charges related to litigation, settlements and recalls.

Meanwhile, sales were up 3.9 per cent year-on-year to $16.3bn. For the year, sales were up 5.6 per cent to $65bn, ending two years of declines.

"We delivered solid results for 2011, built on the strong growth of our recently launched pharmaceutical products, and continued the steady momentum of new product approvals across all our businesses," Bill Weldon, chief executive, said in a statement.

During the fourth quarter, US sales fell 3.4 per cent year-on-year, while international sales were up 10.2 per cent. J&J's drugs business showed the fastest growth, followed by medical devices and consumer products.

Mr Weldon has been working to rehabilitate J&J's image and replenish its pipeline after embarrassing and costly recalls of products such as Tylenol and Motrin.

Last week the company agreed to pay $158m to settle charges that it improperly marketed Risperdal, an antipsychotic drug, in Texas. J&J is facing similar charges in other states.

J&J's results were better than Wall Street analysts' expectations, but the company's shares slipped in pre-market trading due to a weaker than expected 2012 outlook. It projected earnings of $5.05 to $5.15 a share for 2012.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
Johnson & Johnson plaintiffs shrug off report into mismanagement claims

Jack, Andrew Rappeport, Alan
718 words
25 July 2011
Financial Times
FTFT
Asia Ed1
16
English

HEALTHCARE

News analysis

Independent directors' findings leave lawyers unimpressed, write Andrew Jack and Alan Rappeport

Plaintiffs threatening legal action against Johnson & Johnson have shrugged off a report from the US healthcare group that dismisses suggestions of systemic or board-level failures behind recent damaging product recalls, aggressive marketing claims and regulatory settlements for paying bribes.

Their comments followed a filing last week by J&J of findings by a committee of its independent directors that attributed manufacturing quality failures at its McNeil consumer healthcare division to cuts, internal management tensions, frequent executive turnover and distractions caused by the integration of businesses acquired from Pfizer.

It argues that there was no breach of fiduciary duty but describes mid-level managerial failures and an instance of bribe-giving in Greece in which senior executives were complicit.

The report, endorsed by the board in mid-July and filed by J&J in response to shareholder lawsuits seeking damages for mismanagement, provides a rare insight into the internal workings of the company.

Don Haviland, a lawyer representing J&J customers who were denied refunds for recalled Tylenol pain relief products, maintained that the recall problems went all the way to the top.

"[Chief executive William] Weldon came in with a plan to cut," he said. "He outsourced too much, cut back on quality control and we're seeing the results of that."

James O'Brien Jr, an attorney representing Oral Cancer Prevention International in a $400m lawsuit against J&J, said that the report showed "an element within Johnson & Johnson that does not seem to follow good corporate governance", adding: "I don't think their counsel would let them accept blame publicly. That would just open them up to more claims."

Analysing the problems at McNeil that has led regulators to close two sites, the report points to a hiring freeze and concludes that the subsidiary "had a string of successive leaders in a short period of time who may not have had sufficient understanding of what was taking place at the plant level". It highlights "a lack of attention to product quality by some non-quality personnel" and argues "periodic headcount freezes and an emphasis on production volume may have contributed to this situation. In addition, some equipment was outdated and insufficient."

Responding to one of several US legal actions related to marketing of its products, the report describes a "doctor for a day" programme used until 2003 that was developed by the sales force and "not . . . management" of Ortho-McNeil, a J&J subsidiary, by which doctors were paid to accompany sales reps selling its Topamax epilepsy treatment on visits to other doctors.

It rejects claims of "systematic non-compliance" with rules forbidding drug companies from marketing products "off label", beyond authorised indications.

But it concedes that "one area of potential improvement" would be for the company to review marketing plans and strategies ahead of programmes targeting doctors likely to prescribe drugs off-label.

Describing "isolated incidents" of bribes, it concedes that when J&J acquired the De Puy medical device company in 1998, its partner Medec, a Greek distributor, did "make improper payments to surgeons to induce sales".

Certain De Puy staff and "potentially" its worldwide chairman maintained the corporate relationship with Medec "while keeping the sales practice at arms length" until 2005.

J&J's medical devices chairman, who was said to have ultimate responsibility for De Puy through the reporting chain, retired on the same day the company formally notified the authorities of the practice in 2007, but the report concluded that it was not in the interests of the company to pursue potential claims for breach of fiduciary duty against either executive.

It says the company's Polish division also made sponsorship payments to doctors "intended to influence pending tender offers" until an inquiry in 2006; and in Romania until 2007 it found staff had arranged cash, gifts and travel "in exchange for prescriptions for select J&J products".

J&J said in a statement: "The company's management takes the shareholder concerns and criticisms very seriously and appreciates that the special committee has given these matters careful consideration."

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
J&J suffers as recalls push profits lower

By Alan Rappeport in New York and Andrew Jack in London
533 words
20 July 2011
Financial Times
FTFT
USA Ed1
20
English

healthcare

Second quarter net income falls 20%

Results better than analysts' forecasts

Johnson & Johnson, the US healthcare and consumer company, said on Tuesday that its second-quarter profits slid as it faced steep costs related to lawsuits and product recalls.

Net income at J&J declined by 20 per cent to $2.8bn, or $1 a share, compared with $3.45bn, or $1.23 a share in the same quarter of 2010.

In spite of the decline, earnings were better than Wall Street analysts had projected. The company's shares ended the day down 0.5 per cent.

Last month, J&J said that it would close its slumping drug-coated stent business and concentrate on other areas of the cardiovascular market, as it looked to narrow its focus.

That restructuring resulted in a $549m after-tax charge.

The company has been working to put a troubling year of product recalls behind it and replenish its pipeline of drugs.

J&J had to recall brands such as Tylenol and Motrin , close a plant and restructure its operations last year because of problems with its products.

On Monday, J&J filed a report in federal court from a special committee it appointed to investigate the recalls that found "no breach of fiduciary duties by current Johnson & Johnson officers and directors".

Consumer sales rose by 4 per cent globally, with a 12.4 per cent increase internationally helping to offset an 8.5 per cent decline in the US.

A weaker US dollar helped boost overseas sales at J&J, which makes products ranging from baby powder to bandages.

J&J's sales rose by 8.3 per cent to $16.6bn. Demand picked up in each of its divisions, led by a 12.2 per cent jump in pharmaceuticals - its second largest division.

"Our recently launched pharmaceutical products continued to achieve strong growth and contributed to our solid second-quarter results," said William Weldon, chief executive.

Separately on Tuesday, Novartis, the Swiss drugmaker, said that sales of its patented drugs helped pharmaceutical revenue rise 8 per cent to $8.3bn in the second quarter.

Sandoz, Novartis's offpatent generic arm, reported an increase in net sales of 25 per cent to $2.5bn in the quarter, with volume growth offsetting price cuts.

The company moved to placate investors by lifting a cap on dividends and completing a $5bn share buy-back programme in the second quarter, even as it reported earnings up 7 per cent to $1.13 a share, ahead of expectations.

The company's move on dividend payments follows the finalisation of its $51.4bn cash and share purchase last year of Alcon , the specialist eyecare business, which raised net company debt to $22bn and caused a 7 per cent dilution in capital.

Novartis reported net income up 12 per cent to $2.7bn for the second quarter on sales 27 per cent higher to $14.9bn.

The results helped lift the shares by up to 4 per cent in midday trading.

Document FTFT000020110720e77k00042

FT FINANCIAL TIMES

J&J profits slip on steep recall costs

By Alan Rappeport in New York
383 words
19 July 2011
Financial Times (FT.Com)
FTCOM
English

Johnson & Johnson, the US healthcare and consumer company, said on Tuesday that its second-quarter profits fell by 20 per cent, as it faced steep costs related to lawsuits and product recalls.

Net income at J&J declined to $2.8bn, or $1 a share, from $3.45bn, or $1.23 a share in the same quarter of 2010. In spite of the decline, the results were better than Wall Street analysts had projected, and the company's shares rose 0.6 per cent to $67.13 in pre-market trading.

Last month, J&J said it will close its slumping drug-coated stent business and focus on other areas of the cardiovascular market, as it looked to narrow its focus. That restructuring resulted in a $549m after-tax charge.

J&J's sales rose by 8.3 per cent to $16.6bn. Demand picked up in each of its divisions, led by a 12.2 per cent jump in pharmaceuticals - its second largest division

"Our recently launched pharmaceutical products continued to achieve strong growth and contributed to our solid second-quarter results," William Weldon, chief executive, said. "We received several new product approvals across our businesses, which will benefit patients around the world and drive future growth."

The company has been working to put a troubling year of product recalls behind it and replenish its pipeline of drugs. J&J had to recall brands such as Tylenol and Motrin, close a plant and restructure its operations last year because of problems with its products.

On Monday, J&J filed a report in federal court from a special committee it appointed to investigate the recalls that found "no breach of fiduciary duties by current Johnson & Johnson officers and directors".

Consumer sales rose by 4 per cent globally, with a 12.4 per cent increase internationally helping to offset an 8.5 per cent decline in the US. A weaker US dollar helped boost J&J's overseas sales.

Mr Weldon told the Financial Times last month that he is unlikely to retire until at least next year, as he supervises the relaunch of products withdrawn after last year's recalls.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
Pharma chief says J&J is on the road to recovery

Jack, Andrew Rappeport, Alan
680 words
20 June 2011
Financial Times
FTFT
Asia Ed1
14
English

Interview

William Weldon

Johnson & Johnson chief executive

Drugs group looks ahead after last year's recalls, write Andrew Jack and Alan Rappeport

The chief executive of Johnson & Johnson is unlikely to step down at least until next year, as he supervises the relaunch of consumer products withdrawn after a damaging series of recalls that hit the US-based healthcare group in 2010.

In an interview with the Financial Times, William Weldon stressed his group was performing strongly in all divisions, with previous quality control problems and the need for a new drugs pipeline now taken in hand, meaning external macroeconomic factors were more important in determining future growth.

Mr Weldon said he would personally oversee the resolution of troubles with products made at three factories, as he vigorously defended his management of problems with brands including Motril and Tylenol that led to a "consent decree" signed last March with US regulators.

"I think that we want to get the consent decree behind us," said Mr Weldon. "We want to get the products back in the marketplace. There are certain things that I want to make sure we're doing and getting done that I wouldn't want to burden somebody with.

"We feel by the second half of this year, and early next year, we'll have the products back on the market."

His comments follow the appointments in December of Alex Gorsky and Sheri McCoy as vice-chairmen to work alongside Mr Weldon, 62. They are seen as the most likely candidates to emerge as Mr Weldon's successor in a race expected to heat up over the coming months.

"The natural transition would be over time that these people get developed and one day I ride off into the sunset, and one of them goes into my position," he said. "I think we're in as good a shape as we've ever been in as you go forward."

He rejected criticisms that J&J's decentralised approach to management, or pressures to cut costs, had led to the group's problems, most seriously highlighted at its Fort Washington factory in Pennsylvania, where a mouldy smell affecting several product lines triggered a recall - although no proven health problems for consumers - and a sharp drop in sales.

"The issues, as I see them, weren't a function of cost-cutting," he added. "We didn't reduce expenditures or cut heads in those areas. It was just not paying attention to some of the details."

He said the company had launched detailed inspections and concluded there was no systematic failure across the group, with serious quality control issues in just three of its 120 plants. "We have very few observations that

have to be dealt with that are significant. We've got in the high-90s [of sites] where there are no issues. So we feel really good about it."

Instead, he argued that the solution, backed up by $100m in fresh investment, lay in better future assurance "making sure that we're following our [standard operating procedures]. It does come back to making the right investments, making sure you have the right people . . . And you want to be able to share best practices".

He defended J&J's decentralised and diversified businesses, which have helped maintain strong investor support, because they "allow us to develop extraordinary leaders. Being broadly based allows us to really be able to move into any area in healthcare and be able to see it and understand it."

"No matter where you look at our business, we feel very good about it," he said. "I think the challenge for all of us is the external environment, whether it's the sovereign debt in Europe or unemployment here in the US."

He would not comment on continuing regulatory issues that include a threat by the Food & Drug Administration to consider criminal penalties related to the way the group handled the consumer health recalls.

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FT FINANCIAL TIMES

J&J to close drug-coated stent unit and shut plants

By Alan Rappeport in New York and Andrew Jack in London
430 words
15 June 2011
Financial Times (FT.Com)
FTCOM
English

Johnson & Johnson said on Wednesday it will close its slumping drug-coated stent business and focus on other areas of the cardiovascular market, as it looks to narrow its focus after a year of embarrassing product recalls.

The company will take a restructuring charge of $500m-$600m in the second quarter of this year because of the move. It will also cut up to 1,000 jobs with the closure of manufacturing plants in Ireland and Puerto Rico and the consolidation of a research centre in California.

J&J will stop making its Cypher coronary stents and will cease work on the Nevo stent that it was developing. Analysts at Leerink Swann projected that J&J's drug-eluting stent business would generate $400m in sales this year and account for 10 per cent of the market.

"Due to evolving market dynamics in the drug-eluting [drug-coated] stent business, we see greater opportunities to benefit patients and grow our business in other areas of the cardiovascular device market," said Seth Fischer, chairman of Cordis Corporation, J&J's vascular technology unit. The stent business has been suffering due to a slowdown in technology advances and a weak economy that has deterred patients from expensive medical procedures.

In its first quarter, J&J's sales of Cypher stents fell 41 per cent year on year and its market share fell from 12 per cent to 10 per cent. J&J said it will continue to focus on cardiovascular care through its Biosense Webster and Cordis businesses, which generated $1.9bn in sales last year. Analysts at UBS project the move will reduce J&J's earnings per share by about 1 per cent in 2012 and beyond, but called it a "reasonable strategic decision" because of the overall drag the business was having on the company's revenues.

Shares of J&J slipped 1.03 per cent to $66.41 in midday trading on Wednesday.

The decision comes as J&J is working aggressively to revive its business after a troubled 2010 when its sales were cut by $900m due to recalls of over-the-counter drugs.

Rick Wise, analyst at Leerink Swann, said: "This is just a pragmatic decision because the current market is not thrilling and pricing is under pressure, they don't want to keep pouring money into a bet that's not paying off."

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FT FINANCIAL TIMES

HEALTHCARE
Deal could be just what doctor ordered

By Alan Rappeport in New York
621 words
19 April 2011
Financial Times
FTFT
Asia Ed1
19
English

News analysis

US company has been left bruised by product recalls and bribery claims, says Alan Rappeport

A successful bid for Synthes, the Swiss medical device maker, could be timely medicine for Johnson & Johnson after a year plagued by product recalls and bribery allegations.

Healthcare analysts are optimistic that if the talks between the companies lead to a deal, J&J will become the leading participant in the fast-growing medical trauma market.

It will solidify its dominance in orthopaedics and gain increasing power when dealing with hospitals.

"The last couple of years have been challenging for J&J," said Rick Wise, an analyst at Leerink Swann, noting the company's series of recalls and the impact of the tough economy.

"What better time to make a major strategic move?"

Last year J&J took after-tax charges of $922m due to lawsuits related to its DePuy ASR replacement hip, which was recalled, and other product liabilities and litigation.

Recalls were a drag on the company in its latest quarter, pulling sales back by 30 per cent.

Earlier this month, J&J agreed to pay $70m to US regulators after admitting "improper payments" to healthcare employees in Greece, Poland and Romania connected to the sale of medical devices, and kickbacks to the former Iraqi regime of Saddam Hussein.

Synthes specialises in plates, screws, saws and drills surgeons use when repairing skulls and spines.

Wells Fargo analysts estimate that if J&J acquires Synthes, its share of the orthopaedic market would grow to 28 per cent, and medical devices would account for 46 per cent of its overall sales, up from 40 per cent.

Synthes controls about 50 per cent of the market for trauma devices.

As with J&J, Synthes has had its share of problems.

Last October, Synthes and Norian, its subsidiary, agreed to pay $24m in penalties after US authorities charged them with wrongfully conducting trials of a bone cement device on human subjects, and misleading the Food and Drug Administration.

But Synthes has proved to be highly profitable, and last year group sales rose 8.6 per cent to $3.69bn while net profits increased nearly 25 per cent to $908m.

The $6bn market for trauma-related products has been growing at an average rate of 10 per cent over the past five years, and companies that sell pharmaceuticals have been looking to devices as a way to blunt losses from forthcoming patent expirations.

At a healthcare conference last month, Michael Mahoney, J&J's chairman of medical devices and diagnostics, underscored the importance of the device business.

He said healthcare reform legislation could provide a boost, as more insured patients require treatment.

He noted, however, that device prices remained under pressure and that the looming medical device tax would pose challenges.

"A major acquisition and use of cash would bring operational and expense synergies," Ben Yeoh, analyst at Atlantic Equities, said.

Larry Biegelsen, a healthcare analyst at Wells Fargo, suggested that such a merger could trigger further consolidation in the medical device industry as smaller rivals became acquisition targets.

He projected that a $20bn deal would add up to 5 per cent to J&J's earnings from 2012 to 2014.

Acquiring Synthes would please J&J investors by putting its $28bn in cash to good use.

"J&J has a lot of cash that was earned and is held outside the US," Mr Wise said.

"It certainly could be enhancing to the company's sales, margins and returns to take low-earning cash and redeploy it to a high- margin business."

Document FTFT000020110419e74j0000y

FT FINANCIAL TIMES

J&J first quarter profits slide 23%

By Alan Rappeport in New York
497 words
19 April 2011
Financial Times (FT.Com)
FTCOM
English

Johnson & Johnson, the US healthcare company, offered a brighter outlook for the year in spite of a steep drop in profits during a quarter that was plagued by consumer product recalls.

Weak sales of over-the-counter drugs were a drag on the consumer business, with US sales falling nearly 14 per cent. Dominic Caruso, J&J's chief financial officer, said that the business was "dramatically impacted" by the recent suspension of activity in a Pennsylvania manufacturing centre, which the Food and Drug Administration has partially taken over.

However, Mr Caruso noted that the first quarter was likely to be the toughest of the year for the consumer unit and that there were signs of improvement beyond the rash of recalls.

Investors and analysts were hoping to learn more about J&J's takeover talks with Synthes, the Swiss medical device maker that acknowledged on Monday that discussions about a combination were taking place.

"They have a lot of resources and they look for businesses that would be a good fit in the existing J&J empire," said David Toung, analyst at Argus Research, noting that Synthes' expertise in medical tools would fill a need for J&J.

J&J continued to avoid any discussion the talks, but in a call with analysts, Dominic Caruso, chief financial officer, emphasised the importance of the medical device business to J&J's portfolio.

"We think we already are a major player," Mr Caruso said. "And obviously where we don't have sufficient scale, we'd love to increase the scale over time in the appropriate manner."

Mr Caruso also stressed the importance of expanding the business overseas to countries such as China and India, where healthcare services remain less advanced than in the US. International sales already account for about half the company's total sales.

International sales rose by 7.3 per cent in the first quarter, while US sales slipped by 0.6 per cent. Overall, the company's revenues rose to $16.2bn, beating Wall Street analysts' projections.

J&J said that the financial health of the US consumer remained diminished from the recession, with spending still below levels seen prior to the downturn. According to Mr Caruso, in many cases premium consumer brands are losing market share to less expensive private label store brands.

With such a strong international focus, the weaker US dollar was an important factor in J&J lifting its outlook. The company raised its full-year earnings per share guidance to between $4.90 and $5 from $4.80-$4.90 previously.

During the first quarter, net income was $3.5bn, or $1.25 a share, down from $4.5bn in the same period a year ago.

J&J booked $271m of charges related to its DePuy ASR, a hip replacement which had to be recalled.

Document FTCOM00020110419e74j004v2

FDA to impose tough rules on J&J factories

By Jeremy Lemer in New York
399 words
11 March 2011
Financial Times (FT.Com)
FTCOM
English

US officials on Thursday said they would impose a tough new regulatory regime on three factories operated by a subsidiary of Johnson & Johnson, in an effort to bring the drugmaker's practices into compliance with the law after a series of product recalls.

The Food and Drug Administration said it had imposed a "consent decree" on J&J's McNeil-PPC subsidiary and two of its offices to force the company to improve its manufacturing standards.

Over the past two years McNeil has recalled hundreds of thousands of units of liquid medicines such as children's Tylenol, Motrin, and Benadryl products due to defective manufacturing processes.

In April 2010, McNeil shut its large facility in Fort Washington, Pennsylvania and the company will not be able to reopen the plant until it receives a certification from an independent expert and finally the FDA.

Under the terms of the order, McNeil will also have to allow independent consultants to inspect its other sites in Las Piedras, Puerto Rico, and Lancaster, Pennsylvania and follow an agreed plan to bring the plants into compliance with the rules.

The recalls cost J&J millions of dollars in lost sales from its consumer products, which make up about 25 per cent of its $62bn annual revenues.

If J&J's unit fails to comply with the decree, the company could face fines of up to $10m a year and the whole enhanced review process could take years to complete. J&J said the stringent regulatory scrutiny will last for a period of at least five years.

"This is a strong, but necessary, step to ensure that the products manufactured by this company meet federal standards for quality, safety and purity," said Deborah Autor, director of the office of compliance in the FDA's Center for Drug Evaluation and Research.

In a statement McNeil said that the terms of the consent decree recognised "the progress made in remediation efforts to date, and are consistent with the commitments the company has made" as part of an action plan it submitted in July.

The consent decree was filed by the US Department of Justice's Office of Consumer Litigation and the US Attorney's Office for the Eastern District of Pennsylvania, and requires approval by the courts.

Document FTCOM00020110311e73b000um

FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
Product recalls weigh on Johnson & Johnson

By Andrew Jack in London
423 words
26 January 2011
Financial Times
FTFT
USA Ed1
16
English

HEALTHCARE

Increasing product recalls depressed US sales at Johnson & Johnson by nearly 30 per cent in the fourth quarter, as the healthcare group issued 2011 earnings guidance that was below market expectations.

Combined with the continued decline in global demand, currency devaluations and a one-off legal settlement, net earnings fell to $1.9bn for the final quarter of 2010 from $2.2bn in the same period a year earlier. Overall group sales fell from $16.6bn to $15.6bn.

William Weldon, chairman and chief executive, called 2010 "a challenging year". He said "we will continue to see near-term pressures on the business for 2011" as he unveiled full-year earnings guidance of $4.80-$4.90 per share.

That was below a market consensus of close to $5 per share, and depressed the group's shares by more than 2 per cent in mid-afternoon trading in New York.

J&J has been hit by dozens of withdrawals of brands such as Tylenol and Motrin, including a fresh one in January, forcing the company to close a plant and launch internal restructuring under pressure from regulators and politicians.

It said it was "on schedule" to meet objectives set out in a comprehensive action plan submitted to the US Food and Drug Administration to respond to manufacturing concerns, and was continuing audits of its suppliers.

Mr Weldon said: "We have made a commitment to restoring these products to the levels of quality and compliance that consumers expect of J&J."

He said that despite the economic climate, the company had maintained a strong credit record and fresh cash flow, issued low-cost bonds and continued launching new products.

US sales for the consumer business were down 19 per cent for the full year to $5.5bn, and fell 29 per cent to $1.2bn for the last three months of 2010. Global consumer sales, including the US, were down 15 per cent in the quarter to $3.6bn.

Colleen Goggins, head of consumer healthcare, announced her early retirement in September.

The company took after-tax charges of $922m during the year to cover litigation concerning its DePuy ASR replacement hip, which was recalled. Arbitration hearings in a dispute over its rheumatoid arthritis drug Remicade, triggered by Merck's takeover of its partner Schering Plough last year, have been completed and a decision could come in the first half of this year.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
J&J criticised over action on painkiller

By Andrew Jack in London
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Financial Times
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London Ed3
25
English

'Phantom recall'

Johnson & Johnson, the healthcare group, failed to swiftly and adequately inform regulators about a withdrawal of its products from shops across the country last year, a top US official said.

Joshua Sharfstein, deputy commissioner of the Food & Drug Administration, told a Congressional hearing on Thursday that the US group "did not fully disclose the likely scale of the action or the way that the company was intending to proceed" in removing the painkiller Motrin from shelves.

His comments came as the House Oversight Committee reopened hearings into J&J's involvement in a "phantom recall" - whereby the company commissioned a contractor to discreetly purchase all stocks of one variety of Motrin, without informing shopkeepers or making its action public.

Bill Weldon, the head of J&J, told the hearings that McNeil, its consumer products subsidiary that makes Motrin, "should have handled things differently" and that his group had "let the public down". He also laid out details of a $100m remediation plan which includes strengthening quality controls and the firing of a number of executives.

Colleen Goggins, worldwide head of the group's consumer arm, recently decided to resign, saying she had been considering retiring and the remediation plan helped her decision.

With the approach of the US midterm elections, both the Republican and Democrat political parties have taken increasingly partisan positions around the J&J recall. Democrats led by Ed Towns, head of the committee, have proposed tough new legislation to give the FDA greater powers to force companies to withdraw medicines.

But leading Republicans on the committee highlighted underlying weaknesses at the FDA, arguing that it had known of but failed to adequately respond to J&J's problems, meaning that greater authority might not make a difference.

Mr Sharfstein admitted that regulators had been slow to react in their handling of the product recall after it became aware of a manufacturing problem in November 2008. Final withdrawals were made in August 2009.

Both J&J and the FDA have stressed that their investigations had not identified any serious side effects caused to the public by the product.

Mr Sharfstein said companies had no legal requirement to notify the FDA when they are launching a drug recall, and when one takes place, the agency "does not have legal authority to approve the manner in which the firm conducts the recall or to direct the firm to adopt a different recall strategy".

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
Report into J&J recalls looms

By Andrew Jack in London
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15
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pharmaceuticals

Chief reacts to product withdrawals

'There is potential' for criminal action

An internal report into the manufacturing problems over the past year that tarnished some of Johnson & Johnson's best-known products should be completed later this month, Bill Weldon, chief executive, said.

Mr Weldon told the Financial Times that the study, which includes scrutiny by executives and external experts, would help prevent repetition of the wide-ranging withdrawals of 40 household brands made by its McNeil Consumer Healthcare division, such as the cough medicine Tylenol.

In a rare interview since the problems emerged, he stressed remedial measures while conceding that "there is potential" still ahead for criminal action against the company triggered by official probes in recent months, including a review by Congress and by the Food Drug Administration, which criticised the group's slow reaction and said it had referred the matter to its office of criminal investigation.

The problems at McNeil's factories led to thousands of products being recalled and the suspension of manufacturing at the factories concerned.

Internal documents scrutinised during hearings by the congressional oversight committee highlighted an apparent "phantom recall", with J&J employees requesting an external consultant to discreetly buy back supplies of the painkiller Motrin from retailers without revealing any details of a withdrawal.

J&J said: "McNeil kept the FDA informed of its actions and removed the product from the market in a compliant manner. However, the concerns highlighted by the congressional committee have identified that, moving forward, we will look for ways to do things differently."

The group has since replaced a number of senior executives, cut more than 300 employees at the plants that have been shut pending investigations, and estimated that lost sales alone will amount to $600m during this financial year. McNeil has hired a new vice-president of operations, a new plant manager and a head of quality at its Fort Washington factory.

While J&J has said there were no cases of ill health caused by the use of the products under scrutiny, Mr Weldon said the problems had been "most disheartening . . . we've let the people who use our products down. This is a very difficult situation".

He said J&J, which has long operated with arm's length subsidiaries, had restructured so it now had an executive responsible for the supply chain across the group reporting directly to him. It has pledged to implement a single framework to cover manufacturing, quality and compliance.

"We hope we will never experience this again."

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COMPANIES - INTERNATIONAL
Drugmakers start to realise watchdog has learnt to bite

By Andrew Jack in London
712 words
31 May 2010
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Asia Ed1
18
English

News analysis

FDA has become swifter and tougher on errant US healthcare groups, writes Andrew Jack

If Johnson & Johnson underestimated long-simmering concerns about the manufacturing quality of leading drug brands including Tylenol as recently as February this year, it has since realised that US regulators mean business.

After the Food & Drug Administration demanded a meeting with senior management and began considering criminal sanctions, the company launched what Congressman Edolphus Towns, chairman of the House Committee on oversight and government reform, dubbed "the largest recall of children's medicine in history".

J&J has been drawn directly into the spat in spite of its policy of arm's length management of subsidiaries such as McNeil Consumer Healthcare, the producer of the affected products.

Yet it is only one of a number of prominent healthcare groups with production problems that have been highlighted recently by increasingly active US regulators inspecting their home market.

While the share price impact on J&J has so far been modest, the financial consequences may include fines and the need for greater investment in manufacturing - as well as longer term damage to corporate reputation and market positioning.

Michael Druckman, a partner with the law firm Hogan Lovells in Washington DC and former FDA employee, says: "The new administration . . . have set out pretty explicitly that the FDA would be more aggressive in enforcement and is putting more resources into inspections."

In mid-May, Genzyme, a producer of high-priced drugs for extremely rare genetic diseases, unveiled a settlement with the FDA after months of shortages triggered by the identification of viral contamination and small particles of steel and rubber in its medicines.

The agreement includes a $175m upfront fine and threats of confiscation of up to 18.5 per cent of future sales and $15,000 a day in penalties per drug if it did not meet the goals of a multi-year remediation plan.

Genzyme has lost market share to its rival, Shire, and last week Carl Icahn, the billionaire activist investor, called for the resignation of Henry Termeer, chief executive.

The upsurge in attention on drug manufacturing was triggered in 2008 when the FDA was alerted to reports of deaths among patients using heparin, a blood-thinning agent, made by Baxter.

The company, and other producers, ultimately identified a contaminant introduced into the raw ingredients by Chinese suppliers, sparking intense debate over the quality of imported medicines.

Subsequently, the FDA called for an import ban on a number of generic drugs made in India by Ranbaxy and destined for the US market after raising concerns during inspections over inadequate quality assurance procedures, which are still not resolved.

But while the agency has since opened offices in India and China and tightened co-operation with other drug regulators to improve foreign inspections, many of its concerns - and the problems subsequently raised - remain within the US.

Since 2008, a shift in regulatory philosophy under the Democrats, supported by increased funding, has triggered greater activity.

The FDA has hired 700 new investigators, the largest such increase in almost four decades. During the first half of its current fiscal year, it has issued 378 warning letters to manufacturers raising concerns, compared with 473 such letters for the entire previous 12 months. It has become swifter and tougher in following up concerns raised during its audits.

If more aggressive FDA scrutiny has picked up violations that previously existed but went undetected, outsourcing and cost cuts within the pharmaceutical industry may also have played a role in intensifying the problem.

But producers including J&J have played down the impact of quality problems on the health of patients and stressed that their own controls have identified and rejected products with flaws even before they were distributed to pharmacies.

Several members of the House's oversight committee at last week's J&J hearings called for enhanced FDA powers, including greater authority to seize documents and the power to demand product recalls.

As public scrutiny grows, and the FDA's investment in inspections gathers pace, the probes are likely to grow at home as well as abroad.

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COMPANIES - INTERNATIONAL
J&J pressed over 'phantom recall'

By Andrew Jack in London
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10
English

PHARMACEUTICALS

Memo obtained by Congressional panel

Pressure is growing on Johnson & Johnson to explain whether it sought to conceal a recall of children's medicines in the US by requesting that a contractor discreetly buy suspect stocks from retailers.

The group has pledged to provide more information to the Congressional committee on oversight and government reform.

The committee has obtained an internal memorandum instructing a company to purchase on J&J's behalf all packs of a variety of Motrin IB caplets, a pain relief medicine, to send back to the manufacturer.

The document, pictured below, is dated June 12 last year. It tells employees of "WIS . . . on behalf of Johnson & Johnson" to "quickly enter each store, find all of the Motrin product described, make the purchase transaction, secure the receipt, and leave."

It reads: "You should simply 'act' like a regular customer while making these purchases. There must be no mention of this being a recall of the product! "

The memo follows concerns identified as early as late 2008 at J&J's Puerto Rico factory about the "dissolution profile" of the chemicals in Motrin which risked reducing its potency.

However, a formal recall of the product only took place in a month later, while subsequent actions by the Food & Drug Administration sparked further withdrawals including tens of millions of packs of Motrin, Tylenol and other products made in its Pennsylvania factory at the end of last month.

Testifying before Congress on Thursday, Colleen Goggins, worldwide chairman of the consumer group of J&J, described manufacturing problems with the company's products, including the presence of tiny metal particles in some bottles, as "unacceptable", but claimed that none had caused safety problems.

She said J&J had used a third-party contractor to purchase packets of Motrin primarily sold in petrol stations but the Puerto Rico office of the FDA had been informed of its action.

"There was never any intent to mislead," she said.

Rep Edolphus Towns, chairman of the House committee, said the FDA had only learnt about the problems afterwards and exp-ressed concern about the "phantom recall" described in the memo.

He said the activities it described, compounded by other actions by J&J, "paints a picture of a company that is deceptive, dishonest and has risked the health of many of our children."

Ms Goggins said J&J took the problems very seriously and had since removed six "key executives" responsible for over-the-counter sales and production.

While some contaminants were found in products, including bacteria and tiny metal particles, and there were medicines with greater concentrations than agreed with regulators, she said most had been identified during quality control and not distributed for sale.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
US regulator eyes action against J&J on medicine recall

By Andrew Jack in London
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23
English

pharmaceuticals

US regulators are considering criminal action against Johnson & Johnson because of manufacturing lapses that led to the recall of nearly 200m bottles of Tylenol and other children's cough medicines.

Josh Sharfstein, principal deputy commissioner of the Food & Drug Administration, told a hearing of the congressional committee on oversight and government reform in Washington that his agency was considering sanctions including "seizure, injunction and criminal penalties".

The hearing followed intensifying actions by the agency against McNeil Consumer Healthcare and J&J, its parent, after what it believed was a "pattern of non-compliance" and a reluctance to act swiftly and tell regulators of problems, including tiny metal particles in its products.

It comes at a time of growing FDA enforcement efforts triggered by production problems in the US by pharmaceutical companies, including Baxter and Genzyme, as well as J&J.

J&J ultimately recalled more than 68m individual bottles of cough mixture made in its Puerto Rico factory last year, and a further 136m bottles from its Fort Washington plant in Pennsylvania last month.

There have been more than 770 reports of sideeffects in children who were taking the products, although Mr Sharfstein said the FDA had so far identified no cases in which manufacturing problems had caused the health problems, rather than the effects of the medicine itself.

Mr Sharfstein said the agency's concerns had led to an "extraordinary" meeting last February when it went above the heads of McNeil's management to speak directly to senior executives at J&J about a "culture of non-compliance".

Some consumers had identified smells in products from its Puerto Rico plant as early as 2008, but it took more than a year before the company launched a product recall.

The committee highlighted one case in which McNeil employees allegedly conducted "phantom" recalls by buying suspect batches in shops rather than making a public recall.

The hearings highlighted weaknesses with the FDA's current powers, including its inability to impose the recall of medical products and limited ability to gain access to records or to fine companies.

Colleen Goggins, worldwide chairman of J&J's consumer group, conceded that there had been "quality process deficiencies" that she called "unacceptable", while playing down the health risks of the manufacturing problems that had been identified.

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FT FINANCIAL TIMES

COMPANIES - INTERNATIONAL
J&J warned after drug contamination

By Stephanie Kirchgaessner in Washington
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USA Ed2
09
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PHARMACEUTICALS

FDA says failure to mount proper probe

Group recalls leading products

The Food and Drug Administration accused Johnson & Johnson of failing properly to investigate the contamination of some of its top selling over-the-counter drugs even though customers began complaining about the tainted products in 2008.

The US drugmaker responded to the regulator's "warning letter" by recalling tens of millions of bottles of drugs, including Tylenol and Motrin, that had been shipped to the Americas, United Arab Emirates and Fiji.

The move expanded an earlier recall of the Tylenol arthritis pill that was initiated in December after customers reported an unusual mouldy odour emanating from the products.

The drugmaker said it believed the smell was related to a chemical used on wood pallets used to transport and store product packaging material.

In a sharply worded letter the FDA said J&J had prematurely closed an initial investigation into the matter in 2008 after it ruled out one potential cause of the problem and later failed to alert the FDA once it realised the likely source of the contamination was the chemical tribromoanisole (TBA).

J&J said it had learnt of a small number of cases in which users of the tainted drugs had experienced nausea, stomach pain, vomiting and diarrhoea.

The recall emerged as the Department of Justice separately announced it was suing J&J and two subsidiaries for allegedly paying bribes to Omnicare, one of the largest pharmacy groups in the US serving nursing home patients.

The DoJ accused J&J of paying millions of dollars in kickbacks to Omnicare to entice the company to purchase and recommend J&J drugs, including Risperdal, an anti-psychotic medication, to elderly patients.

The government further alleged that J&J knew Omnicare pharmacists reviewed care home patients' charts monthly and made recommendations to patients' physicians that were accepted by the doctors "80 per cent of the time". J&J viewed such pharmacists as an "extension of [J&J's] sales force", the government said.

J&J denied any wrong-doing yesterday and said it would address the matter in court.

"We believe airing the facts will confirm that our conduct, including rebating programmes like those the government now challenges, was lawful and appropriate," it said.

Central to the allegations is the US government's claim that J&J wrongly made agreements with Omnicare that entitled the pharmacy group to higher rebates as long as Omnicare implemented programmes to increase prescriptions from J&J.

Omnicare reached a $98m settlement with the DoJ in November 2009.

J&J shares yesterday fell 1.5 per cent to $64.14.

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Document FTFT000020100116e61g00053

Search Summary

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