IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CITY OF STERLING HEIGHTS GENERAL EMPLOYEES' RETIREMENT SYSTEM, *et al.*, Plaintiffs,	)	
v.	)	No. 11 C 8332
HOSPIRA, INC., THOMAS E. WERNER, CHRISTOPHER B. BEGLEY, F. MICHAEL BALL, and JAMES H. HARDY, JR., Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

This is a federal securities class action against Hospira, Inc., F. Michael Ball, Thomas E. Werner, Christopher B. Begley, and James H. Hardy, Jr. Plaintiffs have brought this action on behalf of themselves and all person or entities who purchased or acquired shares of Hospira between February 4, 2010 and October 17, 2011 (the "Class Period"). Plaintiffs allege that Defendants engaged in a fraudulent scheme to artificially inflate Hospira's stock price during the Class Period. Defendants have moved to dismiss the Amended Consolidated Class Action Complaint (the "Complaint"). (R. 75.) In response, Plaintiffs moved to strike Exhibits D, and O-V from Defendants' memorandum accompanying their Motion to Dismiss, as well as "all references to and assertions based upon those materials" in the memorandum. (R. 90, Pls.' Mot. to Strike.) For the reasons discussed below, the Court grants Defendants' Motion to Dismiss in part without prejudice and denies in part Defendants' Motion to Dismiss. The Court also grants Plaintiffs' Motion to Strike.

FACTUAL ALLEGATIONS

I. The Parties

The Court appointed Plaintiffs Sheet Metal Fund, KBC Asset Management NV, Laborers Funds, and Roofers Fund to serve as Lead Plaintiffs in this case. (Am. Compl. ¶¶ 17-20.) Each Plaintiff allegedly purchased Hospira stock at artificially inflated prices during the Class Period and suffered an economic loss "when the true facts about the Company's business and financial condition were disclosed and the stock price resultantly declined." (*Id.* ¶¶ 17-20.)

Defendant Hospira, formed in 2004 from a spin-off from Abbott Laboratories, "is a U.S.-based global pharmaceutical and medical device company headquartered in Lake Forest, Illinois, and describes itself as the world's leading provider of injectable drugs and infusion technologies." (*Id.* ¶¶ 35, 39.) Its products are "used by hospitals, clinics, long-term care facilities, and home healthcare providers." (*Id.* at ¶ 35.) In 2011, it had $4.1 billion in sales. (*Id.*)

Hospira conducts business primarily in three segments: 1) the Americas, including the United States, Canada, and Latin America; 2) Europe, the Middle East, and Africa; and 3) Asia Pacific, including Asia, Japan, Australia, and New Zealand. (*Id.*) Hospira markets products in each of these segments in three general categories: 1) specialty injectable pharmaceuticals ("SIP"), "which include approximately 200 injectable generic drugs that provide customers with lower cost alternatives to name brand products;" 2) other pharmaceuticals, including large volume intravenous ("IV") solutions and nutritional products and solutions for cleaning wounds and surgical sites; and 3) medication management systems, "which include electronic pumps to deliver IV fluids and medications to patients and other offerings to support the pumps." (*Id.* ¶

36.) Hospira's Rocky Mount, North Carolina facility is among Hospira's largest facilities, producing "approximately 100 different injectable pharmaceuticals–or roughly half of Hospira's entire SIP portfolio" and "account[ing] for 25% of [Hospira's] $4 Billion in annual revenue." (*Id.* ¶¶ 37, 38.)

Defendant F. Michael Ball has served as the Chief Executive Officer ("CEO") of Hospira since March 28, 2011 and the Director of the Board since March 2011. (*Id.* at ¶ 22.) Defendant Thomas E. Werner is the Chief Financial Officer and Senior Vice President of Finance of Hospira. (*Id.* at ¶ 23.) Defendant Christopher Begley is the Executive Chairman of the Board of Hospira, and served as Hospira's CEO until March 28, 2011. (*Id.* at ¶ 25).[1] Defendant James H. Hardy, Jr. served as the Senior Vice President of Operations from January 2011 until his departure from Hospira in April 2012. (*Id.* at ¶ 24.) Previously, Mr. Hardy served as Corporate Vice President, Supply Chain, from 2009 through 2010. (*Id.*)

II. Factual Allegations

Plaintiffs allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5. Plaintiffs contend that throughout the Class Period, while Defendants were "promising" to address issues raised by the FDA following inspections of Hospira's facilities, "they were actually making the problems worse by gutting quality control efforts through cost cutting aimed at boosting short-term profitability." (*Id.* at ¶ 3.)

In August of 2009, following an inspection of Hospira's Morgan Hill, California facility, the U.S. Food and Drug Administration ("FDA") issued a warning letter to Hospira. (*Id.* ¶¶ 116, 145.) The August 2009 Warning Letter raised issues "related to Hospira's corrective action

[1] The Court adopts the Complaint's practice of referring to Defendants Ball, Werner, Hardy, and Begley collectively as "Defendants." (Am. Compl. ¶ 26.)

plans with respect to the failure of certain AC power cords . . . used on certain infusion pumps and related products." (*Id.* ¶ 145.)

In March of 2009, Hospira began Project Fuel, an initiative "with the stated purpose to increase shareholder value through the purported optimization of Hospira's operations." (*Id.* ¶ 45.) Defendants stated that Project Fuel would accomplish this goal by (1) identifying and eliminating underperforming and duplicative units and non-strategic assets; and (2) "reducing Hospira's global workforce by 10% through a 'de-layering' of its management structure, a consolidation of certain functions, and a 'heightening' of the Company's focus on 'process improvement.'" (*Id.* ¶ 17.) According to Plaintiffs, Project Fuel's "reduced operating budgets and slashed workforces . . . wreak[ed] havoc on Hospira's already declining quality control efforts, especially at Rocky Mount – the Company's largest facility." (*Id.* ¶ 47.) As a result, Project Fuel exacerbated Hospira's problems, including "quality and equipment failures, rejected products, production delays, and re-inspection delays." (*Id.* ¶ 59.)

In January of 2010, an FDA inspection of Hospira's Rocky Mount facility revealed significant problems with Hospira's quality control and drug validation processes. (*Id.* ¶ 4.) On April 12, 2010, the FDA issued a warning letter to Begley "identifying numerous violations of the Federal Food, Drug, and Cosmetic Act and its implementing regulations." (*Id.* ¶¶ 4, 107.) With respect to the Rocky Mount facility, the April 2010 Warning Letter noted the following: Hospira (1) "did not have adequate written procedures for production and process controls designed to assure that the drug products it manufactured had the identity, strength, quality, and purity they were purported to have"; (2) "had failed to adequately validate the mixing processes for certain products"; and (3) "had failed to submit adverse events reports to the Agency." (*Id.* ¶ 108.) The April 2010 Warning Letter also identified "Current Good Manufacturing" issues at

Hospira's Clayton, North Carolina facility. (*Id.* ¶ 107.) The April 2010 Warning Letter allegedly showed that Hospira had failed to address the concerns raised about Hospira's facilities in the FDA's August 2009 Warning Letter. (*Id.* ¶ 4.) Plaintiffs allege that Defendants "were well aware of the Company's significant and varied operational deficiencies, particularly at Rocky Mount." (*Id.* ¶ 8.)

Following a May/June 2011 inspection of Rocky Mount, on June 17, 2011, the FDA issued a Form 483 to Hector Jimenez, the Director of Quality at Rocky Mount, identifying 18 "manufacturing and quality control deficiencies." (*Id.* ¶ 112.) On August 4, 2011, the FDA issued another Form 483 addressed to Jonathan Waldron, Rocky Mount's Vice President of Operations, following a July/August 2011 inspection. The August 2011 Form 483 allegedly cited three deficiencies: (1) "Hospira's failure to thoroughly review the failure of a batch or any of its components;" (2) "the Company's laboratory controls not including the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards"; and (3) "the quality control unit's failure to fully follow applicable responsibilities and procedures, which resulted in numerous product lots being released for distribution despite having failing in-process and/or finished product results." (*Id.* ¶ 114.)

Plaintiffs allege that from February 2010 through July 2011, Defendants knowingly or recklessly made various misleading or false statements or omitted statements of material fact regarding Project Fuel and Hospira's quality control issues, remediation efforts, and relationship with the FDA in Hospira's SEC filings, press releases, on conference calls, and at investor conferences. (*Id.* ¶¶ 142-219.) Defendants Begley and Werner also signed certifications for certain filings attesting that the filings complied with the requirements of the Exchange Act and

that the information in them "fairly presented . . . the financial condition and results of the operations of the Company." (*Id.* ¶ 145.) Plaintiffs contend that these alleged misrepresentations hid information from the market and "buoy[ed Hospira's share price, allowing Defendants Begley and Werner to line their pockets during the Class Period with nearly $27 million in combined proceeds from unusual and suspicious insider stock sales." (*Id.* ¶ 220.)

After Hospira's disclosures at a September 7, 2011 "Investor Day," Hospira's stock price fell "approximately 13%, from a close of $45.61 on September 7, 2011, to a close of $39.51 on September 13, 2011." (*Id.* ¶¶ 221, 225.) Specifically, Plaintiffs allege that these disclosures revealed "the seriousness of Hospira's quality control and facility deficiencies at Rocky Mount," "the scope and cost of remediation efforts necessary to fix the problems," and "the fact that Project Fuel was not improving quality but was working against it." (*Id.* ¶ 225.) On October 18, 2011, Hospira "issued a press release announcing disappointing preliminary financial results for the third quarter of 2011." (*Id.* ¶ 234.) Plaintiffs allege that the press release also revealed for the first time "that Rocky Mount's operational woes were inhibiting service as inventory was not sufficient to make up for decreased production capacity." (*Id.* ¶ 234.) On November 28, 2011, RBC Capital Markets published a report concluding that "Hospira's manufacturing issues are far greater than investors realize and will take a minimum of 2-3 years to resolve." (*Id.* ¶ 243.) The Report also noted that based upon its authors "more recent conversations with experts," they were "inclined to believe a consent decree is more likely than not, which could have significant commercial implications for Hospira." (*Id.*) As a result, Hospira's stock price fell "approximately 9%, from a close of $30.98 on November 28, 2011, to a close of $28.17 on November 29, 2011, on unusually heavy trading volume." (*Id.* ¶ 246.)

III. Alleged False or Misleading Statements

Plaintiffs allege that from February 2010 through July 2011, Defendants made various misleading or false statements or omitted statements of material fact regarding Project Fuel and Hospira's quality control issues in Hospira's SEC filings, on conference calls, and at investor conferences.

A. February to March 2010[2]

On February 4, 2010, Hospira issued a press release announcing fourth-quarter and full-year 2009 financial results, which "was also filed with the SEC on [a] Form 8-K that same day." (Am. Compl. ¶ 142.) The release quoted Begley as stating that Hospira has "made significant progress on many fronts, including . . . advancing Project Fuel, our corporate-wide optimization initiative." (*Id.* ¶ 142.) The release further quoted Begley as stating, "Looking forward, we expect 2010 to be another good year of growth for Hospira." (*Id.*) On a February 4, 2010 conference call with analysts, Begley stated, "We kicked off Project Fuel, a corporate wide optimization initiative to drive long-term profitable growth and increase[] shareholder value, and we met the commitments we set forth for 2009." (*Id.* ¶ 143.) Begley noted that Hospira was "aggressively driving transformation throughout the organization" and that Project Fuel and other efforts would "optimize [Hospira's] productivity." (*Id.*)

In response to a question about the extent to which "FDA policy ke[pt] [him] up at night, given all the regulatory submissions [Hospira's] got pending?," Begley answered, "we've got a very good relationship with the FDA, and we'll continue to work very closely with the FDA. . . .

[2] Because Plaintiffs allege that Defendants repeated the same allegedly misleading statements at numerous times, the Court, while considering the effect of the statements as a whole, will discuss in each grouping only those statements that were not previously discussed in prior sections.

And so I don't mean to put it aside, but it's not something that keeps me up at night. The organization here is very well aware of the importance of working with the FDA and changing as their requirements change." (*Id.* ¶ 144.)

Hospira's 2009 Form 10-K filed on February 18, 2010 contained the following statements regarding Project Fuel and Hospira's remediation efforts: (1) "Hospira is actively involved in setting quality policies and managing internal and external quality performance. Its quality assurance department provides quality leadership and supervises its quality systems."; (2) "In addition, higher production volume and cost reductions associated with Project Fuel and Facilities Optimization initiatives contributed to manufacturing efficiency gains." With regard to Hospira's receipt of FDA warning letters "alleging violations of applicable regulations and standards," the 2009 Form 10-K also acknowledged the letters and stated that, "Hospira has developed definitive action plans, implemented remedial programs and modified its practices to address these issues." The Form 10-K specified that the 2009 Warning Letter was "related to Hospira's corrective action plans with respect to the failure of certain AC power cords . . . used on certain infusion pumps and related products." (*Id.* ¶ 145.) The Form 10-K further stated that "Hospira has responded to the warning letter and is working closely with the FDA to conclude this matter." (*Id.*) Lastly, the Form 10-K stated that Hospira's "facilities and equipment are in good operating condition and are well maintained." (*Id.*) An analyst report reacted favorably to the statements, concluding that "overall positive themes are intact with Fuel driven margin expansion and underlying growth in SIP still strong." (*Id.* ¶ 148.)

In March of 2010, Werner participated in two conference calls. In the first conference call, Werner noted that Project Fuel was "adopted to drive operational excellence" and that it would "support further long-term growth," "consistent, sustainable shareholder value

performance," and "increased efficiencies." (*Id.* ¶ 149.) In response to a question from the audience, Werner further noted with respect to Project Fuel that "We've been able to exceed just about every goal we've laid out" and that it was the type of project "where sort of the more we look, the more we find. We've had -- I really can't think of any significant negative surprises." (*Id.* at 150.) In the second conference call, Werner noted that Hospira "continu[es] to be highly respected for our quality, reliability and manufacturing capabilities" and that Project Fuel "continues to have us very focused on the base business and its health." (*Id.* ¶¶ 151-52.)

B. April to June 2010

On April 16, 2010, Hospira filed with the SEC a "Form 8-K, disclosing that the Company had received a warning letter, dated April 12, 2010, from the FDA in connection with the FDA's inspection of the Company's manufacturing facilities in Rocky Mount, North Carolina and Clayton, North Carolina." (*Id.* ¶ 154.) The Form 8-K noted that the Warning Letter had "cited Current Good Manufacturing Practice deficiencies and other inadequacies at those facilities, some of which were repeat observations." (*Id.*) Hospira stated that it "t[ook] this matter seriously and intends to respond fully, and in a timely manner," and intended "a comprehensive review of its manufacturing operations to ensure compliance with applicable regulations." (*Id.*) An April 18, 2010 analyst report "had minimal reaction to disclosure of the letter" and noted that the "impact of the FDA warning letter looks manageable." (*Id.* ¶ 155.)

On April 27, 2010, Hospira "issued a press release announcing its financial results for the first quarter of 2010, which was also filed with the SEC on a Form 8-K the same day." (*Id.* ¶ 156.) The release quoted Begley as stating that Hospira's "positive performance was driven by continued momentum in our Specialty Injectable Pharmaceuticals business, as well as by additional progress on our Project Fuel optimization initiatives." (*Id.* ¶ 156.) Hospira's April

27, 2010 first-quarter 10-Q reiterated that Hospira would be taking "a comprehensive review of its manufacturing operations to ensure compliance with applicable regulations." (*Id.* ¶ 157.) On a conference call with analysts the same day, Begley and Werner made several statements addressing the April 2010 Warning Letter. Begley stated that he was confident Hospira could demonstrate its "commitment to not only implement these corrective actions, but also to ensure the global application of all improvements" and that Hospira was "raising our bar internally" and "redoubling our commitment to quality, proactively addressing certain product issues to ensure they meet our high standards." (*Id.* ¶ 159.) Werner noted Hospira was "in the process of implementing corrective actions." (*Id.*) Plaintiffs allege that Defendant Werner "attributed adjusted gross margin gains to 'improvements to manufacturing productivity, mainly as a result of Project Fuel efforts.'" (*Id.* ¶ 160.) In the question-and-answer session, Begley further stated that "It's part of the fabric of our culture, and we will do whatever it takes from a technology quality improvement standpoint to make sure that we are able to deliver the best product out there." (*Id.* ¶ 161.)

At the Bank of America Merrill Lynch Health Care Conference on May 12, 2010, Werner noted that "Project Fuel had "transformed our organization . . . driving operational excellence and freeing up capital to invest in areas for growth." (*Id.* ¶ 165.) Additionally, at the May 27, 2010 Citi Global Healthcare Conference, Werner stated that "we think that, particularly with Project Fuel, that we've positioned the Company for sustained growth." (*Id.* ¶ 166.) On a June 2, 2010 conference call, Begley commented with respect to the regulatory issues identified at the Rocky Mount and Clayton facilities that "[N]either of those are systemic issues to Hospira, and neither of those are systemic issues to the two plants either." (*Id.* ¶ 169.) He also added that "process improvements" were "taking frustration out of the organization." (*Id.* ¶ 168.) At the

June 17, 2010 Goldman Sachs Global Healthcare Conference, Werner noted that "we're tracking very well with Project Fuel and I went back four or five quarters and it just continues to notch up." (*Id.* ¶ 170.)

C. July to September 2010

On July 28, 2010, Hospira issued a press release announcing its financial results for the second quarter of 2010 that was also filed as a Form 8-K the same day with the SEC. The release quoted Begley as stating that Hospira's results were "driven . . . by continued momentum of our Project Fuel optimization initiatives." (*Id.* ¶ 172.) The release also noted that Hospira was "highly focused on executing our strategy of investing for growth" and "on driving quality improvements across our global manufacturing organization." (*Id.*)

On the same day, Hospira filed with the SEC its second-quarter 2010 Form 10-Q. The Form 10-Q reiterated that Hospira "ha[d] taken a number of actions to reduce operating costs and optimize operations," that Hospira was "working closely with the FDA to conclude th[e] matter [relating to the August 2009 Warning Letter]," and that Hospira " ha[d] begun to undertake a comprehensive review of its manufacturing operations to ensure compliance with applicable regulations." (*Id.* ¶ 173.) The Form 10-Q also acknowledged that "Hospira has responded to the April 2010 Warning Letter and is working closely with the FDA to conclude these matters." (*Id.*)

On a July 28, 2010 conference call to discuss second-quarter 2010 financial results, Begley and Werner made several statements with respect to the status of the remediation plan with the FDA. Begley stated that "[w]e believe the FDA has [accepted] the remediation plan we laid out" and that Hospira was "now dedicated to fulfilling the planned commitments, the bulk of which we expect to complete by year-end." (*Id.* ¶ 175.) Begley also noted that "[w]e

have taken our learnings from our Rocky Mount and Clayton facilities and are applying them to our manufacturing operations around the world to ensure that we meet the highest standards of quality going forward." (*Id.*) Begley and Werner further noted the success of Project Fuel in "driving improved operational performance." (*Id.*) Begley reiterated that Hospira simultaneously "remain[s] highly focused on our quality improvement efforts, working diligently to raise the standards of quality across the Company and address the concerns of the FDA." (*Id.* ¶ 175.) In the question-and-answer session following the call, Werner explained that the costs of the remediation plan "should really start to taper off as you progress through the fourth quarter [of 2010]." (*Id.* ¶ 176.) Begley noted that the FDA was "very pleased with some of the things that we are doing around creating some centralized functions here in Chicago from a quality standpoint." (*Id.* ¶ 176.) Analysts reacted positively to the statements. (*Id.* ¶ 177.) During a subsequent conference call on August 12, 2010, Werner reiterated Hospira's "very strong track record for quality and reliability" and Project Fuel's focus on "driving operational excellence." (*Id.* ¶ 178.)

On August 20, 2010, Defendants hosted a conference call with analysts regarding Hospira's CEO succession plan. (*Id.* ¶ 179.) In addressing his upcoming departure as CEO, Begley stated that "there is nothing more important for Hospira other than Project Fuel and all of our quality initiatives." (*Id.* ¶ 179.) Begley further noted Hospira's "tremendous progress on the quality front." (*Id.*) At the September 13, 2010 Morgan Stanley Global Health Conference, Werner stated that he expected a "calmer regulatory environment" for Hospira in 2011 and that "the quality issues we've seen and others have seen in the industry will be largely behind us." (*Id.* ¶ 180.)

D. October 2010 to January 2011

Hospira issued a press release on October 26, 2010 with its 2010 financial results that it filed with the SEC on a Form 8-K on the same day. The press release quoted Begley as noting "continued contributions" from Project Fuel. (*Id.* ¶ 182.) Regarding the April 2010 Warning Letter, Hospira's third quarter 10-Q filed with the SEC on October 26, 2010 noted that Hospira "had made significant progress on completing a comprehensive review of its manufacturing operations" and that "Hospira took "immediate actions to address the FDA's concerns," including recalling certain products. (*Id.* ¶ 183.) The same day, at a conference call with analysts, Begley and Werner reiterated Hospira's "progress" on "quality improvement initiatives," compliance with the Warning Letter, and Project Fuel. (*Id.*) Analysts reacted favorably to the news. (*Id.* ¶ 186.) One analyst report noted Hospira's "quality improvements" were on track. (*Id.*) Subsequently, Hospira received two "buy" ratings. (*Id.* ¶ 187.) At the January 11 JP Morgan Healthcare Conference, Werner stated with respect to remediation plans that Hospira has "essentially completed all of the activities in the Clayton and Rocky Mountain facilities that we outlined in our response to the warning letter from the FDA" and that "we think we're on a good path to bring things back to a more normal stage here in the first part of the year." (*Id.* ¶ 190.) Werner also stated "we're beginning to roll those changes out globally to all of our facilities." (*Id.*)

E. February to March 2011

On February 2, 2011, Hospira issued a press release announcing its fourth quarter and full-year financial results and filed the press release with the SEC on a Form 8-K that same day. This press release repeated substantially the same statements about Project Fuel as in the press release announcing the third quarter results, referencing the "[i]mproved manufacturing

efficiency from the company's Project Fuel optimization initiatives" and "cost savings from Project Fuel." (*Id.* ¶ 192.) On a conference call the same day, Begley stated that receipt of the warning letter "was a sizable pothole, but "we resolved to meet the FDA's expectations and raised our bar internally." (*Id.* ¶ 193.) Begley also stated that "we not only met our commitments for Project Fuel, our corporate-wide optimization initiative, but we over achieved many of our goals, allowing us to invest in key drivers of our business." (*Id.*) In addition, Begley stated that "[t]he optimized efficiencies we've achieved through Project Fuel and the focus it has instilled in the Company is driving us towards continual improvement and has enhanced our commitment to operational excellence." (*Id.*) Begley also discussed improvements to Hospira's quality-control system: "Of what is a very, very low-level complaint, we now do a thorough root cause analysis on and come up with a fix for it. Then the expectation is to incorporate that fix across the whole product line." (*Id.* ¶ 194.) Hospira's Form 10-K, filed on February 16, 2011, reiterated that "Hospira has responded to the 2010 warning letter and is working closely with the FDA to conclude the matter" and that Hospira's "facilities and equipment are in good operating condition and are well maintained." (*Id.* ¶ 195.)

F. April to June 2011

On April 26, 2011, Hospira issued a press release and filed a Form 8-K with information on its first-quarter 2011 earnings. The release quoted Begley as stating that Hospira had "made good progress in decreasing [its] level of backorders to better serve our customers" and that Hospira "remain[s] focused on driving quality enhancements throughout the organization and on improving shareholder value through strong execution and sustainable growth." (*Id.* ¶ 201.) The release also referenced "[i]mproved manufacturing efficiency from the company's Project Fuel optimization initiatives." (*Id.*) The Form 10-Q that Hospira filed with the SEC on April 26,

2011 also contained statements substantially the same as in previous filings regarding Hospira's efforts to comply with and make progress on the April 2010 Warning Letter, as well as Hospira's goal "to achieve a culture of continuous improvement." (*Id.* ¶ 202.)

As in prior quarters, on April 26, 2011, Defendants hosted a conference call with analysts to discuss first-quarter 2011 financial results. On the call, Defendants made numerous statements regarding the April 2010 Warning Letter. Significantly, Defendant Begley stated that the "next major milestone is the inspection of our Rocky Mount facility" and that Hospira "ha[d] been diligently preparing for that inspection and look[ed] forward to the FDA's response." (*Id.* ¶ 204.) Regarding Project Fuel, Werner stated, "we have very successfully concluded this two-year optimization initiative and not only consistently met our initial commitments but overachieved them." (*Id.* ¶ 204.) Regarding Hospira's relationship with the FDA, Werner noted that the FDA "ha[d] been over to the Orchid Pan Am facility," as well as to "[Hospira's] factory in Croatia" and that both had received a "clean bill of health." (*Id.* ¶ 205.) Begley further noted that "we are encouraged with the inspections that have taken place at other facilities." (*Id.* ¶ 205.) Analysts reacted positively to the statements. One report stated that "[o]perating performance was strong in 1Q with progress on the SIP and MMS quality issues." (*Id.* ¶ 206.)

On April 27, 2011, Hospira participated in the Bank of America Merrill Lynch Healthcare Conference. Begley noted that Hospira was "moving through the quality issues with the FDA" and "starting to see light at the end of the tunnel here" and that "the back orders will also improve." (*Id.* ¶ 208.) On June 6, 2011, at the Sanford C. Bernstein Strategic Decisions Conference, Begley also commented that Hospira's inventory build-up was due to a "new quality system" that "increased [Hospira's] cycle times" and resulted "in work in process and raw materials beginning to build up as it takes us longer to release product underneath those

new quality standards." (*Id.* ¶ 209.) Begley maintained that Hospira was not "capacity constrained." (*Id.*) At the June 8, 2011 Goldman Sachs Global Healthcare Conference, Werner noted Hospira's "focus . . . on the quality initiatives and working with the FDA and getting the back orders down" and that Hospira "will act like the leader and use the quality improvements, hopefully, as a strength and a differentiator." (*Id.* ¶ 210.)

G. July 2011

On July 27, 2011, Hospira issued a press release discussing its second quarter 2011 financial results and filed the press release with the SEC on a Form 8-K. The release quoted F. Michael Ball as stating that Hospira "continued to advance the business and make progress on our quality and product supply improvement initiatives." (*Id.* ¶ 212.) Hospira's second-quarter 2011 Form 10-Q filed on July 27, 2011 also contained statements substantially similar to those in prior filings regarding Hospira's "comprehensive review of its manufacturing operations," Hospira's efforts to comply with the April 2010 Warning Letter, and Project Fuel's "contribut[ion] to net manufacturing efficiency gains." (*Id.* ¶ 213.)

During a July 27, 2011 conference call with analysts to discuss second-quarter 2011 earnings and the FDA's inspection of Rocky Mount, Defendant Ball noted the following:

> During the second quarter, the FDA completed an inspection of Rocky Mount, as expected. While we received verbal feedback acknowledging that we had made progress with respect to our validation processes, the agency was not fully satisfied. We received observations and are aggressively working to address their areas of concern. We have submitted a full response with corrective and preventative actions. We continue to interact and work with the agency to resolve our warning letter and fully comply with their expectations.
>
> (*Id.* ¶ 215.)

Werner also acknowledged that "our focus on driving higher-quality manufacturing processes and products has impacted the timing of certain of our cost improvement and lean optimization

efforts in manufacturing." (*Id.*) Ball noted that Hospira "remain[ed] focused on achieving our previously-projected range given [its commitment to providing customers with high-quality products] and our expected strong sales performance, subject to product approvals and progress on our remediation and service level efforts. We believe we are on track." (*Id.*)

During the question-and-answer session, Werner explained that Hospira's focus was on "product quality and getting our supply levels built back up." (*Id.* ¶ 216.) Ball reiterated that "we need to ensure that we are making the highest quality products, the highest quality processes, we have to get things remediated." (*Id.*) Defendant Werner also discussed the return of the FDA to Hospira facilities and that Hospira had received a Form 483. Specifically, with respect to the Form 483, Werner stated that "[w]e're not expecting there to be a substantial amount of additional cost, it's just heavy lifting and working through it." (*Id.*) Werner further noted that Hospira "did receive some verbal acknowledgment that we had made some good progress, but unfortunately, it was not to the full satisfaction of the agency, and we're working very cooperatively with them to move forward." (*Id.*) Ball stated that Hospira was "taking all necessary steps in order to support Rocky Mount," noting that Hospira had deployed quality specialists and consultants to Lake Forest and "increased the number of quality people in Rocky Mount by some 20 folks going to 30 more people." (*Id.*)

ANALYSIS

On April 18, 2012, the Court appointed the Institutional Investor Group and the Laborers and Roofers Funds as Lead Plaintiffs and Motley Rice LLC and Robbins Geller Rudman & Dowd LLP as lead counsel.[3] (R. 63.) On June 25, 2012, Plaintiffs filed an Amended

[3] The Executive Committee reassigned this case from the Honorable William Hibbler to this Court on March 19, 2012. (R. 60.)

Consolidated Class Action Complaint (the "Complaint"). (R. 75.) Both counts in the Complaint are premised on securities fraud arising out of the purchase of Hospira's common stock. In count one, Plaintiffs allege that Defendants violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. Count two alleges that the Individual Defendants violated Section 20(a) of the Exchange Act. Defendants moved to dismiss the Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), for failure to plead fraud with particularity pursuant to Federal Rule of Civil Procedure 9(b), and for failure to meet the heightened pleading mandates of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), 15 U.S.C. § 78u-4. In response, Plaintiffs moved to strike Exhibits D, and O-V from Defendants' memorandum accompanying their Motion to Dismiss, as well as "all references to and assertions based upon those materials" in the memorandum. (R. 90, Pls.' Mot. to Strike.)

I. Motion to Strike

Generally, in deciding a motion to dismiss, courts look only to matters within the four corners of the complaint. *See* Fed. R. Civ. P. 12(d); *Tierney v. Vahle*, 304 F.3d 734, 738-739 (7th Cir. 2002). The Seventh Circuit, however, recognizes exceptions for "documents attached to the complaint, documents that are critical to the complaint and referred to in it," as well as "information that is subject to proper judicial notice." *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). If the court looks to documents other than the complaint and those that fall within these exceptions, the court must convert the motion to one for summary judgment under Rule 56. *See* Fed. R. Civ. P. 12(d); *Wright v. Assoc. Ins. Cos.*, 29 F.3d 1244, 1248 (7th Cir. 1994); *Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012). With respect to the "incorporation by reference" exception, "[t]he purpose . . . is to prevent parties from surviving a motion to dismiss by artful pleading or by failing to attach relevant documents." *188 LLC v.*

Trinity Indus., Inc., 300 F.3d 730, 735 (7th Cir. 2002); *Tierney*, 304 F.3d at 738 (7th Cir. 2002) ("[W]ere it not for the exception, the plaintiff could evade dismissal under Rule 12(b)(6) simply by failing to attach to his complaint a document that proved that his claim had no merit."). The classic example of a document falling within the exception is a contract in a breach of contract suit. *Tierney*, 304 F.3d at 738.

With respect to the "judicial notice" exception, a court "[t]aking judicial notice of matters of public record need not convert a motion to dismiss into a motion for summary judgment." *Ennenga*, 677 F.3d at 773. Federal Rule of Evidence 201 provides that a court may take judicial notice of "a fact that is not subject to reasonable dispute" because it (1) "is generally known within the trial court's territorial jurisdiction;" or (2) "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201; *Ennenga*, 677 F.3d at 773-74. Nevertheless, judicial notice "merits the traditional caution it is given, and courts should strictly adhere to the criteria by the Federal Rules of Evidence before taking judicial notice of pertinent facts." *Doss v. Clearwater Title Co.*, 551 F.3d 634, 640 (7th Cir. 2008).

A. Procedural Mechanism of Motion to Strike

As a threshhold matter, Defendants argue that Plaintiffs' Motion is procedurally improper because Federal Rule of Civil Procedure 12(f) only provides for motions to strike pleadings, and a motion to dismiss is not a pleading under the Federal Rules. (Defs.' Opp. Mot. to Strike 4-5.)

Federal Rule of Civil Procedure 12(f) permits a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). While Rule 12(f) does not explicitly authorize a motion to strike documents other than pleadings, courts routinely entertain such motions. *See, e.g., Ind. Ins. Co. v. Westfield Ins.*

Co., 10 C 2660, 2010 WL 3404971, at *3 (N.D. Ill. Aug. 26, 2010) (denying motion to strike portions of response to motion to dismiss); *Unytite, Inc. v. Lohr Structural Fasteners, Inc.*, 91 C 2849, 1992 WL 34143, at *6 (N.D. Ill. Feb. 13, 1992) (granting motion to strike affidavit and exhibit in plaintiff's response to motion to dismiss); *Hanover Ins. Group v. Singles Roofing Co.*, 10 C 611, 2012 WL 2368328, at *9 (N.D. Ill. June 21, 2012) (granting motion to strike unauthorized and untimely supplemental response brief to preliminary injunction motion). This authority comes from the Court's inherent power to strike impermissible filings. *Cf. Cleveland v. Porca Co.*, 38 F.3d 289, 297 (7th Cir. 1994) (upholding district court's discretion to strike filing not provided for by the Local Rules); *see also In re Bear Stearns Cos. Sec., Derivative & ERISA Litig.*, 763 F. Supp. 2d 423, 581-82 (S.D.N.Y. 2011) (noting the district court's "inherent authority to strike any filed paper which it determines to be abusive or otherwise improper under the circumstances" in deciding motion to strike exhibits from a motion to dismiss).

Regardless of whether the authority for Plaintiffs' Motion is Rule 12(f) or the Court's inherent power, the Court will address the merits of it, namely, which documents the Court may consider in deciding Defendants' Motion to Dismiss.

B. Disputed Exhibits

1. Exhibits T-V: Hospira's Proxy Statements

Defendants argue that the Court may take judicial notice of Exhibits T, U, and V, which, respectively, are Hospira's 2010, 2011, and 2012 proxy statements. (Defs.' Mem. Exs. T, U,V.) Defendants cite to these documents to "show[] the increase in Defendants Begley and Werner's Hospira stock holdings during the class period." (Defs.' Opp. Mot. to Strike 11.)

The Seventh Circuit has not addressed whether a district court on a motion to dismiss in a securities fraud action may properly take judicial notice of the truth of the statements contained

in proxy materials. Other circuits have concluded that the court may take judicial notice only of the fact that the statements as public records contain certain statements, but not the truth of the statements themselves. In *Kramer v. Time Warner Inc.*, 937 F.2d 767 (2d Cir. 1991), the Second Circuit held that a district court did not err in taking judicial notice of a joint proxy statement and an offer to purchase that were not part of the complaint in deciding a motion to dismiss a securities fraud action, when the documents at issue were "the very documents that [were] alleged to contain the various misrepresentations or omissions." *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991). The Second Circuit emphasized that the documents were "relevant not to prove the truth of their contents but only to determine what the documents stated." *Id.* Subsequently, the Fifth, Eleventh, and Third Circuits have followed *Kramer*'s approach. *See Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1278 (11th Cir. 1999) ("[W]e hold that a court, when considering a motion to dismiss in a securities fraud case, may take judicial notice (for the purpose of determining what statements the documents contain and not to prove the truth of the documents' contents) of relevant public documents required to be filed with the SEC, and actually filed."); *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1018 (5th Cir. 1996) (holding that on a motion to dismiss that SEC filings "should be considered only for the purpose of determining what statements the documents contain, not to prove the truth of the documents' contents."); *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (finding *Kramer*'s reasoning persuasive). This approach is also consistent with the holdings of courts in this District. *See, e.g.*, *George v. Kraft Foods Global, Inc.*, 674 F. Supp. 2d 1031, 1044 (N.D. Ill. 2009) ("[A] court may take judicial notice of documents filed with the SEC for the purpose of showing what statements the documents contain, but not for the proof of the facts stated therein." (internal quotation marks omitted)); *Hernandez v. Midland Credit Mgmt.*, Inc., 04 C 7844, 2006

WL 695451 (N.D. Ill. Mar. 14, 2006) (citing cases noting that "SEC filings may be considered for their content, but not for the truth of statements therein"); *Riggs Ptrs., LLC. v. Hub Group, Inc.*, 02 C 1188, 2002 WL 31415721, at *1 (N.D. Ill. Oct. 25, 2002) ("[T]he court may take judicial notice of documents filed with the SEC for the purpose of showing what statements the documents contain, but not for the proof of the facts stated therein.").

The Court agrees with the holdings of these cases. Here, in arguing that Plaintiffs have not made a sufficient showing of scienter based upon Begley's and Werner's stock sales, Defendants ask the Court to take judicial notice not only of the fact that the proxy statements contain certain sales data for Begley and Werner, but the truth of that sales data. Otherwise, such information would not be relevant to the issue of scienter. Moreover, this approach is consistent with the Seventh Circuit's decision in a related context in *Hennessy v. Penril Datacomm Networks, Inc.*, 69 F.3d 1344, 1354 (7th Cir. 1995), which upheld the district court's ruling not to take judicial notice of the number of a company's employees from a 10-K form in determining punitive damages at trial, where there was "considerable argument over the significance of the 10-K form." *Hennessy v. Penril Datacomm Networks, Inc.*, 69 F.3d 1344, 1354 (7th Cir. 1995). While citing *Kramer* in recognizing that some courts had found judicial notice of SEC filings appropriate, the Seventh Circuit nonetheless held that the "fact in question here was not capable of accurate and ready determination by resort to the 10-K." *Hennessy*, 69 F.3d at 1355.

Defendants' argument that the proxy statements merely "aggregate . . . in one place" the sales data from the Form 4s is unavailing. (Defs.' Opp. Mot. to Strike 12.) Defendants fail to specify which proxy statements or portions thereof aggregate the data from which Form 4s, which is not obvious given that the Form 4s and the proxy statements cover different time

periods. Indeed, this lack of clarity demonstrates that the facts that Defendants wish the Court to take judicial notice of are not susceptible to "accurate and ready determination."

The Court declines to take judicial notice of Exhibits T, U, and V strikes them from the record.

2. Exhibits O-S: Form 4s for Defendants' Begley and Werner

Exhibits O-S are Hospira SEC Form 4s filed in 2010 and 2011 reflecting changes in beneficial ownership of securities for Defendants Begley and Werner. (R. 87-4.) Although Plaintiffs neither cite nor reference the Form 4s in their Complaint, Defendants contend that the Complaint incorporates the Form 4s by reference because the sales data in the Complaint "match[es] the data provided in the SEC Form 4s documenting those sales." (Defs. Opp. Mot. to Strike 8.) Significantly, Defendants argue that these Forms "detail both halves of the dual-faceted transactions" and show that Werner and Begley "actually acquired more shares than they sold in all but one of their stock transactions." (*Id.* at 2, 8.) Thus, according to Defendants, "the Court may assume that Plaintiffs obtained the information in their complaint from Exhibits O-S, and so incorporated those documents by reference." (Defs.' Opp. Mot. to Strike 7.)

In support of their Motion, Plaintiffs cite the Seventh Circuit's opinion in *Wright v. Associated Ins. Cos. Inc.*, 29 F.3d 1244, 1248 (7th Cir. 1994). In *Wright*, the Seventh Circuit upheld the district court's consideration of the entirety of a health insurance risk plan administration agreement in deciding a motion to dismiss where the plaintiff failed to attach the agreement to his complaint but "repeatedly quote[d] from and refer[ed] to the Agreement in his complaint" and the agreement was "central" to the plaintiff's claims. *Wright*, 29 F.3d at 1248 (noting plaintiff's allegations that the "Agreement grant[ed] him a property interest in his employment, of which the defendants deprived him without due process of law" and that the

agreement was "the contract with which the defendants allegedly interfered").

The Seventh Circuit has not addressed, however, whether a plaintiff incorporates by reference those documents that contain the same data as the complaint but which plaintiffs neither cite to nor reference in their complaint. While Defendants argue that the Form 4s are "central" to the Plaintiffs' claim, there are notable differences between the contract in *Wright* and the Form 4s. Unlike in *Wright*, in which the plaintiff contended that the contract gave rise to the rights of which the defendant had allegedly deprived him, here, plaintiffs raise the stock sales as facts supporting but one element of their § 10(b) claim. Further, unlike the contract in *Wright*, it is not entirely clear where Plaintiffs here obtained the alleged stock information. Defendants also contend that the Court may properly consider the Form 4s on a motion to dismiss because otherwise, Plaintiffs could impermissibly evade dismissal by failing to acknowledge that Defendants not only sold but bought Hospira stock over the Class Period. Whether or not Defendants bought or sold more Hospira stock over the Class Period is not determinative of whether Plaintiffs have adequately alleged scienter, however, as *Tellabs* instructs courts to consider the allegations of scienter collectively. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326, 127 S. Ct. 2499, 2511, 168 L. Ed. 2d 179 (2007) ("*Tellabs*").

Moreover, the same reasoning in *Kramer* and *Hennessy* that weighs against considering the proxy statements also applies here. As with the proxy statements, Defendants cite to the Form 4s not to show which statements they contain, but for the purpose of demonstrating that the Defendants bought or sold a particular amount of stock during the Class Period. (Defs.' Opp. Mot. to Strike 8; Defs.' Mem. 18-19.) In other words, in challenging Plaintiffs' scienter allegations on the basis of data in the Form 4s, Defendants rely upon these documents for "the truth of their contents" as opposed to the fact of "what the documents stated." *Kramer*, 937 F.2d

at 774.

Ultimately, however, the Court need not reach this issue. Because Defendants rely upon the Form 4s to challenge Plaintiffs' scienter allegations, and the scienter inquiry turns on other allegations,[4] the Court will not decide this issue.

3. Exhibit D: FDA Report

Exhibit D is a copy of a June 15, 2012 U.S. House of Representatives Committee on Oversight and Government Reform staff report entitled "FDA's Contribution to the Drug Shortage Crisis." (Mot. to Dismiss, Ex. D.) ("FDA Report"). Plaintiffs argue that the Court may not consider the FDA report on two grounds: (1) it was neither referenced in the Complaint nor is it central to the Plaintiffs' claims; and (2) Defendants cite the FDA Report to make an impermissible "factual argument about the FDA's alleged increased enforcement against manufacturers of generic injectable pharmaceuticals." (Pls.' Mem. Mot. to Strike 4.)

Defendants cite to the FDA report in support of the allegation that "[a]t around the same time that Hospira initiated Project Fuel, the FDA began to raise its expectations for manufacturers of generic injectable pharmaceuticals through increased enforcement activity during routine inspections." (Defs.' Mem. 5.) Specifically, Defendants assert that the "number of warning letters sent by the FDA increased" by certain percentages from 2009 to 2010 and from 2010 to 2011; that these increases "clearly show a dramatic change in [sic] FDA's regulatory approach"; and that "nearly all of America's major producers of generic injectable medications were essentially required to remediate facilities at the same time." (*Id.* at 5,6.)

[4] Although the Court concludes that Plaintiffs have adequately pled scienter under the PSLRA with respect to certain statements, the stock sale allegations are not dispositive of the Court's scienter rulings.

Defendants argue that the Court may properly take judicial notice of the Report as a public record and "the facts in those exhibits on which Defendants rely." (Defs.' Opp. Mot. to Strike 8.)

The Court declines to take judicial notice of the FDA Report. Here, Defendants ask the Court to take judicial notice of the facts contained in the report, namely, that the number of warning letters sent by the FDA increased from 2009 to 2010 and from 2010 to 2011. According to Defendants, since the number of warning letters cited in the Report "can be accurately and readily determined by visiting the FDA's website and reviewing each of those letters," the Court may take judicial notice of the number of warning letters as an uncontested fact. (Defs.' Opp. Mot. to Strike 10.)

Defendants' argument is unpersuasive for several reasons. First, although Plaintiffs do not dispute the fact of whether the number of warning letters increased from 2009 to 2010 and 2010 to 2011, these facts, nonetheless, are not "readily determined from sources whose accuracy cannot reasonably be questioned." Although the FDA website does contain copies of warning letters issued in 2009, 2010, and 2010, it also designates certain warning letters in these years as "not issued," which denotes that a "close-out letter" has issued, a distinction which Defendants fail to address. *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/default.htm. Moreover, the fact of the increase in the number of letters, as one that involves a calculation–albeit a straight-forward one in theory–may, in reality, be subject to interpretation in a way that other typically judicially noticed facts are not. *See, e.g.*, *Pugh v. Tribune Co.*, 521 F.3d 686, 691 n.1 (7th Cir. 2008) (taking judicial notice of stock prices); *Deicher v. City of Evansville*, 545 F.3d 537, 541 (7th Cir. 2007) (holding district court did not abuse discretion in taking judicial notice

of filing date of complaint). Finally, the cases Defendants cite in support of their argument are distinguishable. Those cases involve courts taking judicial notice of a few warning letters, not the extrinsic fact of the total number of warning letters issued in a year, and in *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 756 (S.D. Tex. 2010), only the fact of the warning letter itself, and not the truth of its contents. *See Van Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1073 (taking judicial notice of several FDA warning letters and responses addressing the use of the term "natural"); *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 756 (S.D. Tex. 2010) ("The letter only informs St. Jude that its promotion of its surgical ablation device violated FDA regulations. The court may take judicial notice of this document without resolving whether its contents are true."); *Del Puerto Water Dist. v. U.S. Bureau of Reclamation*, 271 F. Supp. 2d 1224, 1234 (E.D. Cal. 2003) (taking judicial notice of senate and house reports while noting to the "extent their contents are in dispute, such matters of controversy are not appropriate subjects for judicial notice").

The Court declines to take judicial notice of Exhibit D and strikes those references to it in Defendants' Motion to Dismiss.

4. Stock Transaction Chart

Plaintiffs also object to Defendants' inclusion of a "stock transaction chart" in Defendants' memorandum accompanying its Motion to Dismiss on the ground that it improperly "summarizes information from Exhibits T, U, and V to assert that Defendants Begley and Werner ultimately increased their Hospira stock holdings after the class period." (Pls.' Mot. to Strike 5.); (Defs.' Mem. 19.) The chart shows the number of shares held by Begley and Werner in March 2010, March 2011, and March 2012, and the percentage change in the number of shares held from year to year. Defendants appear to have drawn the entries from Exhibits T, U,

and V, Hospira's 2010-2012 proxy statements. As the Court has already declined to take judicial notice of the contents of Exhibits T, U, V, it will not do so for the summary of such exhibits.

II. Legal Standard

In order to state a securities fraud claim under Section 10(b), Plaintiffs must allege the following elements of a fraud claim under Section 10(b): "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.[5] *Janus Capital Grp., Inc. v. First Derivative Traders*, 131 S. Ct. 2296, 2301 n.3 (2011); *see also AnchorBank FSB v. Hofer*, 649 F.3d 610, 617 (7th Cir. 2011). To succeed on a § 10(b) claim, a plaintiff must show that the defendant "made material misrepresentations or omissions." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1317, 179 L. Ed. 2d 398 (2011).

A. Rule 12(b)(6)

"A motion under Rule 12(b)(6) challenges the sufficiency of the complaint to state a claim upon which relief may be granted." *Hallinan v. Fraternal Order of Police of Chicago Lodge No. 7*, 570 F.3d 811, 820 (7th Cir. 2009). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011) (internal quotation and citation omitted). Pursuant to Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "give the defendant fair notice of what the . . . claim is and the

[5] Defendants' Motion to Dismiss does not challenge that Plaintiffs' have adequately pled the third through sixth elements of a § 10(b) claim.

grounds upon which it rests." *Bell Atl. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)). Under the federal notice pleading standards, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* Put differently, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting *Twombly*, 550 U.S. at 570); *see also McCauley v. City of Chicago*, 671 F.3d 611, 616-17 (7th Cir. 2011).

B. Rule 9(b) and the PSLRA

Under Federal Rule of Civil Procedure 9(b), Plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. Rule 9(b). Rule 9(b) requires a plaintiff to allege the "who, what, when, where, and how" of the fraud. *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 649 F.3d 436, 441-42 (7th Cir. 2011).

The Private Securities Litigation Reform Act of 1995 ("PSLRA") further increases the pleading standard in securities fraud cases. *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 594 (7th Cir. 2006) *vacated and remanded on other grounds*, 551 U.S. 308, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007) ("*Makor I*") ("The PSLRA essentially returns the class of cases it covers to a very specific version of fact pleading – one that exceeds even the particularity requirements of Federal Rule of Civil Procedure 9(b).") Congress enacted the PSLRA as a "check against abusive litigation by private parties." *Tellabs*, 551 U.S. at 313. Indeed, "[e]xacting pleading requirements are among the control measures Congress included in the PSLRA." *Id.* at 313.

The PSLRA provides that the complaint "shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4.

Under *Tellabs*,"[a] complaint will survive [a motion to dismiss] only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 756 (7th Cir. 2007) (quoting *Tellabs*, 551 U.S. at 314). Courts must also "take into account plausible opposing inferences." *Higginbotham*, 495 F.3d at 756 (quoting *Tellabs*, 551 U.S. at 323). Scienter is the "mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319. In the Seventh Circuit, "reckless disregard of the truth" qualifies as scienter.[6] *S.E.C. v. Jakubowski*, 150 F.3d 675, 681 (7th Cir. 1998). "[R]ecklessness in this context is 'an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 704 (7th Cir. 2008) ("*Makor II*"). In considering allegations of scienter, a court must ask: "When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. In describing whether an inference of scienter is "cogent" under the

[6] The Supreme Court has reserved the question of whether "recklessness" may satisfy scienter in this context. *Matrixx*, 131 S. Ct. at 1309 ("Because Matrixx does not challenge the Court of Appeals' holding that the scienter requirement may be satisfied by a showing of "deliberate recklessness," we assume, without deciding, that the standard applied by the Court of Appeals is sufficient to establish scienter.").

Tellabs inquiry, the Seventh Circuit has noted that the "plausibility of an explanation depends on the plausibility of the alternative explanations." *Makor II*, 513 F.3d at 711. "Thus, "[a]s more and more alternatives to a given explanation are ruled out, the probability of that explanation's being the correct one rises." *Id.* (citations omitted). Courts should not "scrutinize each allegation in isolation but . . . assess all the allegations holistically." *Tellabs*, 551 U.S. at 326. While "motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference . . . the absence of a motive allegation is not fatal." *Id.* at 325.

III. Information from Former Undisclosed Hospira Employees

In the Complaint, Plaintiffs allege facts based upon information from undisclosed former Hospira employees. Defendants argue that the Court should "steeply discount" allegations based upon information from these undisclosed employees. In *Makor I*, *Higginbotham*, and *Makor II*, the Seventh Circuit addressed the extent to which plaintiffs may rely on confidential sources to satisfy the heightened pleading requirements of the PSLRA. In *Makor I*, the Seventh Circuit noted that if plaintiffs support their allegations with confidential sources, they "must . . . describe their sources with sufficient particularity 'to support the probability that a person in the position occupied by the source would possess the information alleged,' or in the alternative provide other evidence to support their allegations." *Makor I*, 437 F.3d at 596 (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000) (citation omitted)). The complaint, however, need not "provide 'name, rank, and serial number' for each of these sources." *Id.* In *Higginbotham*, which followed *Makor I* and *Tellabs*, the Seventh Circuit reasoned that the *Tellabs* "competing inference" analysis requires courts to "discount allegations that the complaint attributes to . . .'confidential witnesses.'" *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 757 (7th Cir. 2007) ("To determine whether a 'strong' inference of scienter has been established, the judiciary must

evaluate what the complaint reveals and disregard what it conceals.") In *Makor II*, the Seventh Circuit clarified that a particularly troubling use of the confidential sources prompted the holding in *Higginbotham*. There, the plaintiffs described the witnesses "merely as three ex-employees of Baxter and two consultants" and sought to rely upon them exclusively to establish scienter. *Makor I*, 513 F.3d at 712.

Plaintiffs have sufficiently described their sources "to support the probability that a person in the position occupied by the source would possess the information alleged." *Makor I*, 437 F.3d at 596. For each undisclosed employee, Plaintiffs have provided the job title, duration of employment at Hospira, and a description of employee responsibilities. Unlike in *Higginbotham*, Plaintiffs rely upon the information from undisclosed sources to corroborate and particularize their allegations that Defendants' statements were misleading in light of the employees' observations and opinions regarding conditions at Hospira, rather than to allege a basis for the misleading nature of the statements that is otherwise absent from the Complaint. Thus, the Court will consider the allegations attributed to confidential witnesses and discount them as appropriate in determining whether Plaintiffs have alleged each false statement with particularity.

IV. Alleging Statements or Omissions with Particularity

Defendants argue that Plaintiffs have failed to satisfy the PSLRA requirement to plead allegedly false or misleading statements with particularity. Under the PSLRA, the complaint "shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4. With respect to whether Plaintiffs have sufficiently pled that the

statement is false or misleading, "the relevant question is 'whether the facts alleged are sufficient to support a reasonable belief as to the misleading nature of the statement or omission.'" *Makor I*, 437 F.3d at 595. Although "[m]ere silence about even material information is not fraudulent absent a duty to speak . . . If one speaks, he must speak the whole truth." *Stransky v. Cummins Engine Co., Inc.*, 51 F.3d 1329, 1331 (7th Cir. 1995). Moreover, "[t]he more important a fact would be to investors, the more likely its omission will mislead them." *Silverman v. Motorola, Inc.*, No. 07 C 4507, 2008 WL 4360648, at *10 (N.D. Ill. Sept. 23, 2008). In assessing whether a plaintiff has pled false or misleading statements with particularity, the Court must not consider allegations in "isolation," but instead must look to the complaint in its entirety. *Tellabs*, 551 U.S. at 322-23.

The Court will consider each category of alleged false or misleading statements below.

A. Failure to Disclose Rocky Mount's Facilities Were Nowhere Near "Operational Excellence"

Plaintiffs allege that throughout the Class Period that Defendants made the following statements or descriptions connecting Project Fuel with "operational excellence":[7]

(1) "We remain on track with our optimization program, which is designed to simplify our business and drive quality and operational excellence to obtain top-tier financial performance." (*Id.* ¶ 160.)

(2) Project Fuel was "[a]n aggressive enterprisewide optimization initiative we adopted

[7] Although the Court concludes that other similar-sounding statements that Project Fuel was "really serving to transform the company" constitute puffery, Plaintiffs' specific allegations that Defendants accompanied these statements with references to either "driving quality," or Hospira's "reputation of quality," "meeting the highest levels of compliance with all of our products," and "very strong track record for quality and reliability," distinguish them in context and thus require a different analysis. (*Id.* ¶¶ 160, 163, 175, 178.)

to drive operational excellence and generate top financial performance." (*Id.* ¶ 163.)

(3) "We remain on track with Project Fuel and we are pleased with our progress on this organization wide optimization program. As many of you know, Project Fuel is designed to simplify our business and drive continuous improvement and operational excellence in order to obtain top tier financial performance." (*Id.* ¶ 175.)

(4) "[I]t really was about driving operational excellence, improving margins, driving additional cash flow . . . ." (*Id.* ¶ 178.)

Plaintiffs assert that these statements omitted material facts with respect to Hospira's Rocky Mount facility because "Rocky Mount's manufacturing operations were nowhere near 'operational excellence' but in fact suffered from serious issues with regard to quality control and deterioration of its facilities and equipment." (*Id.* ¶¶ 153(a), 171(a), 181(a), 191(a), 200(a), 211(a).)

In support of this argument, Plaintiffs allege that "Project Fuel's cutbacks" resulted in "quality and equipment failures, rejected products, production delays, and re-inspection delays." (Am. Compl. ¶ 59.) Based upon information from a former Rocky Mount Quality Engineer, Plaintiffs contend that Rocky Mount was "constantly exceeding acceptable quality levels for broken glass because management 'had to make their numbers.'" (Am. Compl. ¶ 62.) A former Rocky Mount Line Coordinator also identified a problem with mixing solutions that was "attributable to the mixing team either not having been properly trained or being understaffed for the mixing portion of the production process." (*Id.* ¶ 64.) In addition, Plaintiffs allege that the Rocky Mount Quality Engineer noted that "there were 10% budget cuts 'across the board, and [q]uality was cut.'" (*Id.* ¶ 53.) Plaintiffs further contend, as supported by information from a former Rocky Mount Technician, that as a result of Project Fuel, Hospira "got rid of the quality

people," which had the effect of shifting quality control responsibilities onto the "people running the line – the production folks." (*Id.* ¶ 54.) In turn, this allegedly altered Hospira's standard operating procedures ("SOPs"), such that they "specified how production personnel were now responsible for quality control inspections and doing checks of completed products." (*Id.*) Furthermore, Plaintiffs allege that the above statements made from February to March 2010 were misleading in light of Hospira's receipt of "failure to supply" penalties. (*Id.* ¶¶ 95-99.)

Defendants argue that Plaintiffs have failed to allege with particularity that Defendants failed to disclose quality issues at Rocky Mount on two grounds: (1) Defendants disclosed the receipt of the FDA Warning Letters and Form 483s throughout the Class Period; and (2) Defendants disclosed both back orders at Rocky Mount and the receipt of "failure to supply" penalties. (Defs.' Mem. 33-34.) Plaintiffs, however, have alleged that Defendants failed to disclose in particular the effect of Project Fuel on Hospira's quality-control efforts by "reduc[ing] operating budgets and slash[ing] workforces" such that it "wreak[ed] havoc on Hospira's already declining quality control efforts, especially at Rocky Mount." (Am. Compl. ¶ 47.) Plaintiffs support these allegations with information from numerous former Rocky Mount employees connecting Project Fuel with deficiencies at Rocky Mount. (*Id.* ¶¶ 49-82.) Moreover, Plaintiffs have alleged that Rocky Mount was a significant plant for Defendants, accounting for 25% of Hospira's annual revenue. (*Id.* ¶ 38.) On the record before the Court and viewing the allegations in the light most favorable to the Plaintiffs, Plaintiffs have alleged with sufficient particularity that the alleged omissions regarding Project Fuel's impact on the Rocky Mount facility were misleading. *See Brasher v. Broadwind Energy, Inc.*, 11 CV 991, 2012 WL 1357699, at *22 (N.D. Ill. Apr. 19, 2012); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 401 (S.D.N.Y. 2005) (holding plaintiffs satisfied particularity requirement with

respect to statements "concerning the sources and significance of the revenue generated by VDM Specialists" where such statements "put the sources of VDM Specialists revenue at issue").

B. Facilities and Equipment in "Good Operating Condition" and "Well-Maintained"

Next, Plaintiffs contend that the following statement, which appeared in both Hospira's 2009 and 2010 Form 10-Ks was false or misleading:

> "Hospira believes that its facilities and equipment are in good operating condition and are well maintained." (*Id.* ¶¶ 145(b), 153(b), 195, 200(b).)

In support of this contention, Plaintiffs rely on Defendant Hardy's statements at the September 7, 2011 "Investor Day" event that Hospira's facilities were "aged" and "in need of a 'facelift,'" (*Id.* ¶ 221), as well as information from the Rocky Mount Quality Assurance Validation Engineer[8] "that Hospira failed to make necessary improvements at Rocky Mount because it was unwilling to spend the money to do so," including improvements to Rocky Mount's SOPs and its "archaic, DOS-based computer information system 'from the 80s.'" (*Id.* ¶ 84.) In addition, according to various former employees, the Rocky Mount facility had such problems as a leaking ceiling, mold in the asceptic room, defective dipsticks used to "measure mixtures of solutions in large vessels," a failed isolator used to fill glass vials used on a line that "produced roughly 115,000 to 120,000 units a day," as well as a failing depyrogenation tunnel "used to sterilize glass vials" to meet validation. (*Id.* ¶¶ 84, 86-91.) Viewing these allegations in the light most favorable to

[8] Plaintiffs allege that the former Rocky Mount Quality Assurance Validation Engineer "worked for Hospira at its Rocky Mount plant from June of 2010 to December 2011" and "was responsible for quality engineering, including evaluating and remediating deficiencies in the quality assurance practices at Rocky Mount." In addition, they allege that the "former Rocky Mount Quality Assurance Validation Engineer was tasked with bringing the plant's validation program 'more in line' with 'what was seen in the industry' at that time." (Am. Compl. 21n.13.)

Plaintiffs, Plaintiffs have alleged with the requisite specificity that Defendants made false or misleading statements regarding the condition of Hospira's facilities. *See Plumbers & Pipefitters Local Union No. 630 Pension-Annuity Trust Fund v. Allscripts-Misys Healthcare Solutions, Inc.*, 778 F. Supp. 2d 858, 879-80 (N.D. Ill. 2011); *Ross v. Career Educ. Corp.*, 12 C 276, 2012 WL 5363431, at *5 (N.D. Ill. Oct. 30, 2012) (holding allegedly false statements regarding placement rates satisfied particularity requirement where plaintiffs "clearly identify the source of each particular allegation" and "explain[] in each paragraph of the complaint exactly which [confidential witness] reported what information").

C. "Very Good Relationship" with the FDA

During the question-and-answer session of a February 4, 2010 conference call to discuss full-year 2009 financial results, Defendant Begley stated the following in response to questions as to "what extent . . . FDA policy ke[pt] [him] up at night, given all the regulatory submissions [Hospira's] got pending?" and "what's the risk?":

> First of all, we've got a very good relationship with the FDA, and we'll continue to work very closely with the FDA. . . . And so -- and I think we are on top of it. And so I don't mean to put it aside, but it's not something that keeps me up at night. The organization here is very well aware of the importance of working with the FDA and changing as their requirements change. (*Id.* ¶ 144.)

Plaintiffs allege that the statement that Hospira "has a very good relationship with the FDA" was false or misleading notwithstanding Hospira's disclosure of its receipt of the August 2009 Warning Letter from the FDA in its 2009 Form 10-K. (*Id.* ¶ 144-45, 153(d).) Plaintiffs contend that the August 2009 Warning Letter stated that the violations addressed in it "may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems" and that "[Hospira] should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance." (*Id.* ¶¶

116, 120.) Plaintiffs also maintain that the April 2010 Warning Letter, which resulted from the FDA's January 2010 inspection of Rocky Mount noted the following: "[W]e are concerned about the length of time your firm has needed to develop and implement its Validation Prioritization Plan at the Rocky Mount Facility. You have been aware of our concerns regarding process validations since 2005." (*Id.* ¶ 109.) The word "relationship" is ambiguous, however, and these other allegations do not suggest that the relationship between Hospira and the FDA was poor. Thus, Plaintiffs have failed to allege these statements were false or misleading with sufficient particularity.

D. "Systemic Issues"

On June 2, 2010, Begley participated in the Sanford C. Bernstein Strategic Decision Conference. (*Id.* ¶ 167.) With respect to the FDA and Hospira's regulatory issues, Begley stated that "[n]either of those are systemic issues to Hospira, and neither of those are systemic issues to the two plants either." (*Id.* ¶ 169.)

Plaintiffs allege that "contrary to Defendants assurances," the problems identified by the FDA were "systemic" because Project Fuel required "across the board sacrifices" throughout Hospira's manufacturing facilities. (*Id.* ¶ 171(e).) Additionally, Plaintiffs maintain that numerous quality issues "resulted in widespread production slowdowns as early as 2010." (*Id.* ¶ 95.) To support these assertions, Plaintiffs rely upon information from undisclosed former Hospira employees who worked at different locations, including the Austin Production Supervisor, based in Austin, the former Accounting Manager, based in Lake Forest, Illinois, and other former employees of the Rocky Mount facility. (*Id.* ¶¶ 49-58.) Moreover, following the Class Period, Defendant Ball noted at an October 18, 2011 conference call that issues at Rocky Mount "had implications that were greater than anticipated" and that "[r]eceiving two 483s so

close together was a clear signal that we were not making satisfactory progress to fully comply with the FDA's concerns and that we had to ramp up our remediation efforts." (*Id.* ¶ 235.) Specifically, Ball acknowledged that Hospira "did not anticipate the degree to which the production slowdown and resulting charges would impact performance through the rest of September" and lacked "visibility into the magnitude of the reversal in customer service levels." (*Id.* ¶ 234.) *Compare In re ITT Educ. Servs., Inc. Sec. & S'holder Derivatives Litig.*, 859 F. Supp. 2d 572, 578 (S.D.N.Y. 2012) ("Although the Complaint describes all of these statements . . . as 'false,' it does not allege any facts contradicting their veracity.") Accordingly, Plaintiffs have sufficiently plead with particularity under the PSLRA that the statements were false or misleading.

E. Statements Regarding Hospira's Efforts to Address the FDA Warning Letters

Defendants broadly challenge Plaintiffs' allegations that Defendants made false or misleading statements regarding Hospira's efforts to comply with the FDA Warning Letters. (Defs.' Mem. 28.) The Court will consider each category of statements below.

1. "Comprehensive Review of Manufacturing Operations," "[C]omplet[ing]" Responses to the Warning Letter, and "Roll[ing] [O]ut" Changes

Plaintiffs identify the following statements in this general category:

(1) "Hospira will be undertaking a comprehensive review of its manufacturing operations to ensure compliance with applicable regulations." (*Id.* ¶ 157).

(2) "We think we have essentially completed all of the activities in the Clayton and Rocky Mount facilities that we outlined in our response to the warning letter from [the] FDA. At some point they'll be back in the facilities. There's not an official lifting of the warning letter as of -- per se, but we fulfilled all of the things that we need to do essentially. (*Id.* ¶ 190.)

(3) "And more importantly or as important, we're beginning to roll those changes out globally to all of our facilities so that when [the] FDA shows up wherever and whenever,

> they should expect to see a very consistent approach to things across all Hospira facilities in the US and globally." (*Id.* ¶ 190.)

Plaintiffs allege that these statements were false or misleading because Hospira's Rocky Mount facility "was plagued with deficiencies that were well known within Hospira in 2010 and only increased heading into 2011" and that "Hospira had not made any concerted effort to remediate the issues identified in the April 2010 Warning Letter until after it received the June 2011 Form 483 identifying 18 more problems at Rocky Mount." (*Id.* ¶ 121.) Among other allegations, Plaintiffs point to a former Rocky Mount Batch Release Specialist's description of a consultant's visit to Rocky Mount between January and March of 2011, in which the consultant gave a powerpoint presentation entitled "something to the effect" of "10 Things in the Lab that Will Shut the Plant Down." Subsequently, Rocky Mount's management allegedly "had 'harsh words' with the consultant. (*Id.* ¶ 122.) In addition, Plaintiffs allege that according to a former Rocky Mount Quality Assurance Validation Engineer, "it was not until after the FDA had issued the Form 483 in June 2011 that 'you heard a lot of talk about timelines'" and that "corporate vice presidents [were] sent to Rocky Mount after the June 2011 Form 483 to assist in dealing with the plant's quality issues." (*Id.* ¶ 123.)

Defendants argue that Plaintiffs fail to plead these allegations with particularity because "Plaintiffs' own 'confidential' witness allegations establish that Hospira was making an effort to address the FDA's concerns." (Defs.' Mem. 28.) Plaintiffs allege facts raising contrary inferences, however, such that, according to the former Rocky Mount Quality Assurance Validation Engineer, Hospira "only began to 'dabble' in remediation efforts" after the April 2010 Warning Letter and had no "sense of urgency." (*Id.* ¶ 124.) Viewing these allegations in the light most favorable to Plaintiffs, Plaintiffs have satisfied the particularity requirement with

respect to these statements. *See Chu v. Sabratek Corp.*, 100 F. Supp. 2d 815, 821 (N.D. Ill. 2000) ("We agree with KPMG that GAAP does provide for some flexibility in the timing of revenue recognition. However, drawing all reasonable inferences in favor of the plaintiffs . . . they have sufficiently alleged that Sabratek's revenue recognition practices violated GAAP.").

2. "Tak[ing] [FDA] [M]atters [S]eriously" and "[W]orking [C]losely with the FDA"

Similarly, Plaintiffs allege the following statements are misleading:

> (1) "Hospira has responded to the April 2010 Warning Letter and is working closely with the FDA to conclude these matters. As part of Hospira's response, Hospira took immediate actions to address the FDA's concerns, including recalling the propofol and liposyn products manufactured at the Clayton facility and the fosphenytoin sodium injection products manufactured at the Rocky Mount facility." (*Id.* ¶ 183.)
>
> (2) "The FDA's Warning Letters are publicly available on the FDA's website. Hospira takes all of these matters seriously and intends to respond fully, and in a timely manner, to the FDA's Warning Letters." (*Id.* ¶ 183.)

Plaintiffs have failed to allege with particularity that these statements are false or misleading. Although these statements also concern Hospira's efforts to address the Warning Letters, the factual allegations Plaintiffs rely upon to establish that they are false or misleading are insufficient. With respect to the first statement, Plaintiffs fail to allege that Hospira did not recall products in response to the April 2010 Warning Letter. Furthermore, Plaintiffs fail to allege facts showing that Hospira did not "take[] seriously" the FDA Warning Letters. Like the statements concerning Hospira's "relationship" with the FDA, these statements are ambiguous, and Plaintiffs do not allege facts showing that Defendants did not intend to respond to the FDA's Warning Letters.

3. "Open Investigations" Trending Downward

During the question-and-answer portion of a February 2, 2011 conference call, Defendant Begley stated the following:

> Of what is a very, very low-level complaint, we now do a thorough root cause analysis on and come up with a fix for it. Then the expectation is to incorporate that fix across the whole product line. So you've seen a couple spikes like that, that have had a recent impact, but I don't see that occurring long term through the business and creating situations like we just had in Q4. And on the SIP overall, it's driven to the difficulty of us getting product out the door as efficiently as we used to, but as I talked about, we are beginning to see the light at the end of the tunnel there. And the key metric that we look at is our internal investigations and the number of open investigations we have and the aging of that. We review all of that data literally at my level weekly at the Thursday meeting, and there's people looking at the data on a daily basis, and all of those trends are downwards in each of our manufacturing plants, so that's a real positive sign. What it says is you are not opening up new investigations at all and the fact that the age is less says you're driving root cause more quickly and implementing those changes. I really believe a good piece of this is behind us as we move forward. (*Id.* ¶ 194).

Plaintiffs allege that Hospira knowingly or recklessly omitted to disclose that despite the fact that "'open investigations' were in fact trending 'downwards,'" "'open investigations' at Rocky Mount, Hospira's largest facility, were actually ballooning throughout 2011." (*Id.* ¶¶ 194, 200(d).) Plaintiffs rely upon information from the former Rocky Mount Senior Production Supervisor, who described an increase in open investigations at Rocky Mount from between 8 and 10 to 45 or 50 per month. (*Id.* ¶ 101.) Plaintiffs allege, however, that the Rocky Mount Senior Production Supervisor "worked in the flexible container group" of Hospira and then "from February 2011 until his departure in November 2011 . . . worked in the small volume unit in Rocky Mount's R2 building." (*Id.* at 33 n.21.) Given that Begley made the above statement on February 2, 2011, and Plaintiffs have alleged that the Rocky Mount Senior Production Supervisor did not join Rocky Mount until February 2011, his observations are insufficient.

Therefore, Plaintiffs have failed to satisfy the PSLRA particularity requirements for this statement.

V. Puffery

"The crux of materiality is whether, in context, an investor would reasonably rely on the defendant's statement as one reflecting a consequential fact about the company." *Makor I*, 437 F.3d at 596 (7th Cir. 2006). If "there is a substantial likelihood that disclosure of the information would have been viewed by the reasonable investor to have significantly altered the total mix of information, the statement is material." *Searls v. Glasser*, 64 F.3d 1061, 1066 (7th Cir. 1995) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32, 108 S. Ct. 978, 983, 99 L. Ed. 2d 194 (1988)). "[M]ateriality is typically an issue to be resolved by the finder of fact. *Stransky v. Cummins Engine Co.*, 51 F.3d 1329, 1333 (7th Cir. 1995) (quoting *TSC Indus., Inc.*, 426 U.S. at 450, 96 S. Ct. at 2133). Thus, "[i]f the statement amounts to vague aspiration or unspecific puffery, it is not material." *Id.* at 596; *Searls*, 64 F.3d 1061, 1066 (7th Cir. 1995) (describing puffery as a "devoid of any substantive information."). Because puffery "contains no useful information upon which a reasonable investor would base a decision" it is nonmaterial. *Id.* at 1066.

Defendants argue that "nearly all the alleged statements that Plaintiffs allege were fraudulent are immaterial puffery." (Defs.' Mem. 24.) Defendants identify the following kinds of statements as examples of puffery:

> (1) "Hospira believes that its facilities and equipment are in good operating condition and are well maintained." (Am. Compl. ¶¶ 145, 195)
>
> (2) "We believe [Project Fuel] is really serving to transform the company." (*Id.* ¶ 149.)
>
> (3) Hospira is "working across our operations to make sure that we meet the highest level of compliance and quality for both pharmaceutical and device products." (*Id.* ¶ 178.)

(4) "Hospira aims to achieve a culture of continuous improvement that will enhance its efficiency, effectiveness and competitiveness and substantially improve its cost base." (*Id.* ¶¶ 202, 213.)

(5) Hospira is "redoubling [its] commitment to quality" and "raising the bar internally." (*Id.* ¶¶ 159, 175.)

The Court will consider each of the statements that Defendants argue are puffery below.

A. *"Hospira believes that its facilities and equipment are in good operating condition and are well maintained."*

This statement appeared in the Hospira 2009 and 2010 Form 10-Ks filed with the SEC on September 18, 2010 and February 16, 2011. The Form 10-Ks also contained statements that Hospira had "developed definitive action plans" in response to "notices from regulatory authorities alleging violations of applicable regulations and standards." (*Id.* ¶¶ 145, 195.) The 2009 Form 10-K also acknowledged that Hospira had initiated voluntary recalls to address the issue. (*Id.* ¶ 145.)

Viewing the statement in the context of the "total mix" of information, it does not amount to puffery as a matter of law. First, as the statement specifically refers to the present condition of Hospira's facilities and equipment, it is different from a vague aspiration or "indefinite prediction." *Searls*, 64 F.3d at 1066-67 (noting "indefinite predictions of 'growth' are better described as puffery rather than as material statements of fact"); *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 290 (4th Cir. 1993) (distinguishing "[p]redictions of future growth" from "expressions of belief or opinion concerning current facts" "because [predictions of future growth] will almost always prove to be wrong in hindsight.") Moreover, Plaintiffs allege that the statement was made in Hospira's 10-Ks, which also mentioned Hospira's receipt of warning letters identifying quality-control issues at Hospira's facilities. Thus, notwithstanding the generality of the statement, given the context, it is not so lacking in specificity or unconnected from other

facts that the Court may conclude at this stage that the statement is entirely "devoid of any substantive information." *Searls*, 64 F.3d at 1066; *see also Novak v. Kasaks,* 216 F.3d 300, 315 (2d Cir. 2000) (noting defendants statements that "the inventory situation was 'in good shape' or 'under control' were not puffery).

B. *"We believe [Project Fuel] is really serving to transform the company."*

In context, this particular statement, which describes Project Fuel as "transforming" Hospira in terms of "support[ing] further long-term growth" and "consistent, sustainable shareholder value performance," is too vague to constitute material information. (*See* Am. Compl. ¶ 149.) Rather, the statement is the type of "rosy affirmation" that public companies regularly use to describe their initiatives. *See Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1217, *abrogated on other grounds by statute* (1st Cir. 1996) (holding statements that DEC was "basically on track," and that spokesperson was "confident that DEC was pursuing the right strategy" were immaterial puffery); *see also In re Ford Motor Co. Sec. Litig., Class Action*, 381 F.3d 563, 570 (6th Cir. 2004) ("All public companies praise their products and their objectives."); *Allscripts-Misys*, 778 F. Supp. 2d at 872 (holding statement "regarding Version 11 and its contribution to helping Allscripts become the 'Bloomberg of healthcare'" immaterial puffery). Similarly, the statements that Project Fuel has "positioned the Company for sustained growth" and "optimized [Hospira's] operations and refined [Hospira's] culture," as well as those describing the plan as a "corporate wide optimization initiative to drive long-term profitable growth and increased shareholder value" are devoid of substantive factual material and constitute puffery.[9] (*See* Am. Compl. ¶¶ 189, 166, 143.)

[9] In the alternative, Defendants argue that the PSLRA safe-harbor for forward-looking statements protects these statements. (Defs.' Mem. 35.) Because the Court concludes that these

C. Hospira is *"working across our operations to make sure that we meet the highest level of compliance and quality for both pharmaceutical and device products."*

This statement does not constitute puffery as a matter of law. Like the statement regarding the condition of Hospira's facilities, this statement, while general in nature may in context alter the total mix of information for a reasonable investor. Plaintiffs allege that Defendant Werner made the statement at a Specialty Pharmaceuticals Conference, in which he allegedly referenced Hospira's "very strong track record for quality and reliability." (*Id.* ¶ 178.) Notably, Plaintiffs allege the statement was made shortly after the release of Hospira's second-quarter 2010 financial results on July 28, 2010 and that analysts "reacted positively" to the results. (*Id.* ¶ 177.) *See Desai v. Gen. Growth Props., Inc.*, 654 F. Supp. 2d 836, 854 (N.D. Ill. 2009). Therefore, at this stage, the Court cannot conclude that the statement constitutes puffery as a matter of law. *See In re Spiegel, Inc. Sec. Litig.*, 382 F. Supp. 2d 989, 1028 (N.D. Ill. 2004).

D. *"Hospira aims to achieve a culture of continuous improvement that will enhance its efficiency, effectiveness and competitiveness and substantially improve its cost base."*

Similar to the statement regarding Project Fuel's "transformation" of Hospira, this statement is devoid of substantive factual matter. Even accounting for the context, the phrase "culture of continuous improvement" is an expression of corporate optimism that "so clearly constitut[es] the opinions of the speaker" such that a reasonable investor would not consider it material. *In re Ford Motor Co. Sec. Litig., Class Action*, 381 F.3d 563, 571 (6th Cir. 2004) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1217 (1st Cir. 1996)).

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statements are puffery, the Court need not reach this argument.

E. *"Redoubling Commitment to Quality" and "Raising the Bar Internally"*

Plaintiffs contend throughout their Complaint that various statements about Hospira "raising the bar internally" and "redoubling commitment to quality" are material. (*See* Am. Compl. ¶¶ 159, 175.) Similarly, these statements' "lack of specificity precludes [them] from being deemed material." *See Searls*, 64 F.3d at 1066; *Anderson v. Abbott Laboratories*, 140 F. Supp. 2d 894, 905 (N.D. Ill. 2001), *aff'd sub nom. Gallagher v. Abbott Laboratories*, 269 F.3d 806 (7th Cir. 2001) (noting statements about "unquantified growth are classic puffery").

VI. Scienter

Plaintiffs allege the following bases for Defendants' scienter: (1) Defendants' stock sales; (2) Defendants' alleged misleading statements themselves; and (3) Defendants' participation in meetings and receipt of reports regarding Hospira's remediation efforts. While considering the allegations in the Complaint as a whole, the Court will describe each set of allegations separately.

First, Plaintiffs allege that Begley's and Werner's stock transactions during the Class Period constitute evidence of scienter. Plaintiffs allege that Defendants "were motivated to artificially inflate Hospira's stock price during the Class Period in order to line their own pockets with the proceeds of insider stock sales." (Am. Compl. ¶ 269.) Specifically, Plaintiffs contend that Begley sold "roughly 64% of his share holdings" in June 2010 when the share price was "near its Class Period high." (*Id.* at ¶ 269.) Similarly, Plaintiffs allege that Werner, "beginning in June 2010 and continuing through early 2011" sold "over 86% of his stock holdings." (*Id.* at ¶ 270.) Because "neither Defendant Begley nor Defendant Werner sold any Hospira stock in the five years prior to the start of the Class Period . . . [these sales] were thus unusual and suspicious in both timing and amount." (*Id.* at ¶ 271.) Additionally, according to Plaintiffs, Defendants

were "motivated to hide the true scope of the Company's operational troubles and thereby keep Hospira's market value artificially inflated so that they could successfully raise $500 million in a September 2010 debt offering." (*Id.* at ¶ 272.)

Next, Plaintiffs argue that "the fact that Defendants made false and misleading statements . . . itself supports a strong inference of scienter." (Pls.' Mem. 32.) ("Simply put, an inference can be made that Defendants knew of what they spoke.")

Finally, Plaintiffs rely on their allegations regarding Defendants' monitoring of Hospira's remediation efforts through meetings and reports to support scienter. (Pls.' Mem. 33.) Specifically, Plaintiffs allege that "Defendant Begley called weekly management meetings to review Hospira's progress in its Company-wide remediation efforts." (Am. Compl. ¶ 128.) During the second-quarter 2010 earnings call on July 28, 2010, Begley explained that at such weekly meetings he would "review[] the progress on the plan, not only for Clayton and Rocky Mount, but the status of [Hospira's] initiatives across all of our manufacturing plants." (*Id*.) Defendants also "held weekly management meetings every Thursday morning that included all plant-level quality control managers." At the fourth-quarter and full-year 2010 earnings call on February 2, 2011, Begley noted at the meetings that the "senior leadership team" would discuss "inventory and related issues with "every plant manager and plant quality control manager from around world." (*Id.* ¶ 129.) Furthermore, Plaintiffs allege that Defendants held "'Town Hall meetings in which the Company's top executives discussed, among other things, ongoing issues with the FDA." (*Id.* ¶ 130.)

Plaintiffs have sufficiently alleged scienter under the PSLRA regarding Defendants' statements that Hospira's plants were "in good operating condition" and "well-maintained," statements that Hospira's regulatory issues were not "systemic," those statements regarding

Hospira's efforts to address the FDA Warning Letters that Plaintiffs have alleged with particularity, and the alleged failure to disclose Rocky Mount's facilities were "nowhere near operational excellence." Defendants' participation in various meetings on Hospira's remediation efforts support the inference that they were aware of the quality-control issues at Rocky Mount and other Hospira facilities. Although allegations that executives attended meetings or received reports on a problem do not exclusively support an inference of scienter, *see Zimmer*, 679 F.3d 952, 955 (upholding lack of scienter where plaintiffs allegations included that executives "attended meetings at which quality issues were discussed"), the circumstances allegedly surrounding these particular meetings merits pause. Plaintiffs allege that Begley called weekly management meetings "to review Hospira's progress in its Company-wide remediation efforts" and that management met with "every plant manager and plant quality control manager from around world" to discuss "inventory and related issues." (Am. Compl. ¶¶ 128, 129.) Viewing the facts as alleged in the light most favorable to Plaintiffs, these meetings were not routine, but specifically directed to addressing Hospira's remediation and quality control issues at its various facilities. Moreover, Plaintiffs allege that the August 2009 Warning Letter advised Defendants that "certain identified issues may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems." (*Id.* ¶ 127.) *See Allscripts-Misys Healthcare Solutions*, 778 F. Supp. 2d at 885 (N.D. Ill. 2011).

Plaintiffs' allegations respecting Hardy's statement at the close of the Class Period that Hospira had inherited "aged" facilities, combined with the allegations noted above, also raises an inference that Defendants' prior statements about the facilities being in "good condition," if indeed false, were made with knowledge or recklessness toward their falsity. In addition, Plaintiffs allege that between January and March of 2011, Begley "received a presentation from

a well-respected consultant that addressed the Company's quality problems" and that Begley met personally with the FDA "as part of the Company's response to the April 2010 Warning Letter." (Am. Compl. ¶¶ 133-34, 136.) These allegations raise an inference that is at least, if not more, compelling than the inference that Defendants made these statements without scienter. Indeed, if the statements as to the condition of Hospira's facilities were in fact false or misleading, it is difficult to imagine a non-culpable explanation as to how Defendants, given their monitoring of Hospira's plants in connection with Hospira's remediation efforts and quality-control problems, could have made the statements without scienter.

Nor do Defendants' disclosures on conference calls of the existence and purpose of such meetings significantly undercut the inference of scienter. While the disclosures of the meetings addressed to Hospira's quality-control issues may weigh against the conclusion that the statements were misleading, they are not dispositive of the issue as to whether, if such statements were misleading, Defendants knew or recklessly disregarded these facts.

Defendants argue that *Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 679 F.3d 952, 954 (7th Cir. 2012), which analyzed scienter in the context of similar allegations, forecloses the inference of scienter. In *Zimmer*, the plaintiff contended that Zimmer fraudulently "delayed revealing quality-control problems at its plant" and failed to use lower estimates in reflecting the impact of the suspension and recall of certain products on earnings. The Seventh Circuit rejected the plaintiff's argument that a medical-device company made a false statement and that the statement was made with scienter when the company, in taking a device temporarily off the market, attributed the device's failure rate to improper surgical technique rather than poor design quality. *See Zimmer*, 679 F.3d at 954. The Seventh Circuit noted that because "[c]orporate executives who know that one group of surgeons

experiences success, and another group failure . . . could believe that the different outcomes had been caused by differences in the way the surgeons had implanted the device," the plaintiff failed to establish an inference of scienter that is "at least as compelling as any opposing inference of nonfraudulent intent." *See Zimmer*, 679 F.3d at 955.

Zimmer, however, is distinguishable from this case given the alleged omission regarding the extent of Project Fuel's impact as a cost-cutting measure on Rocky Mount for several reasons. First, in *Zimmer*, the Seventh Circuit noted that the fact that the alleged misstatement concerned "one plant and one product that together produced less than 10% of the firm's income" undermined the inference of scienter. *See id.* at 956. Here, Plaintiffs allege that Defendants' failure to disclose the extent of Project Fuel's impact as a cost-cutting measure on Rocky Mount in particular is misleading because Rocky Mount was Hospira's largest facility and the "crown jewel" of Hospira. (Am. Compl. ¶ 38.) Because of the alleged importance of Rocky Mount to Hospira, the inference is stronger in these circumstances than in *Zimmer* that if the Defendants omitted material facts with respect to Project Fuel's impact on Rocky Mount, they did so knowingly or with reckless disregard toward this risk. *Makor II*, 513 F.3d at 711 (noting that where the alleged false statements concerned the "company's key products" it was "exceedingly unlikely" that the CEO was "unaware of the problems" in light of alternative explanations). Second, in *Zimmer*, the relationship between the gravity of the alleged problem and statements allegedly hiding it is different than in this case. There, the Seventh Circuit noted that despite the company's temporary recall of the product, ultimately "the Food and Drug Administration . . . never concluded that the Durom Cup was defectively designed or made, indeed never even issued a warning or caution concerning the Durom Cup." *Zimmer*, 679 F.3d at 955. Here, Plaintiffs allege that Project Fuel's cost-cutting over the course of the Class Period

exacerbated the problems at Rocky Mount and "left Hospira understaffed and unable to perform necessary quality control to ensure the safety of its products, plant, and equipment." (Am. Compl. ¶ 115.) In support of this allegation, Plaintiffs further point to the FDA's issuance of Form 483s in June and August of 2011 identifying failures that Plaintiffs allege "at least in part, appear to be the result of Project Fuel related cuts." (Am. Compl. ¶¶ 104-116.) Accordingly, the differences in the magnitude, timing, and nature between the alleged misstatements and the supporting allegations in *Zimmer* and those Plaintiffs identify here raise different inferences in the scienter analysis.

Viewing the allegations in the Complaint as a whole and in the light most favorable to the Plaintiffs, Plaintiffs have raised an inference of scienter that is at least as compelling as any opposing inference that, if in fact these specific statements were false or failed to disclose material facts, this risk "was either known to the defendant[s] or so obvious that the defendant[s] must have been aware of it." *Makor II*, 513 F.3d at 704.

VII. Section 20(a) Claims for Control Person Liability

Plaintiffs allege Defendants are liable under Section 20(a) of the Exchange Act. Defendants seek to dismiss the "control-person" claim on the ground that Plaintiffs have failed to allege a primary securities fraud violation. Section 20(a) of the Exchange Act provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter . . . shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . ., unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a); *see also Janus*, 131 S. Ct. at 2304. In order to state a Section 20(a) claim, Plaintiffs must allege the following: (1) a primary

securities violation; (2) each of the Defendants exercised general control over the operations of Hospira; and (3) each of the Defendants "possessed the power or ability to control the specific transaction or activity upon which the primary violation was predicated, whether or not that power was exercised." *Harrison v. Dean Witter Reynolds, Inc.*, 974 F.2d 873, 881 (7th Cir. 1992).

Because Plaintiffs have pled a primary securities violation as to those statements for which they have sufficiently alleged with particularity both that the statement is false or misleading and scienter, and Defendants have not challenged Plaintiffs' Section 20(a) claims on any other grounds, the Section 20(a) claim stands as to those statements. Conversely, with respect to the other allegedly false or misleading statements for which Plaintiffs have failed to plead a primary securities law violation, Plaintiffs' Section 20(a) claim fails. *See Pugh*, 521 F.3d at 693 ("[T]o state a claim under § 20(a), a plaintiff must first adequately plead a primary violation of securities laws.").

CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Defendants' Motion to Dismiss without prejudice and grants Plaintiffs' Motion to Strike.

Date: February 13, 2013

ENTERED

AMY J. ST. EVE
United States District Court Judge