UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

WEST VIRGINIA PIPE TRADES HEALTH & WELFARE FUND, EMPLOYEES' RETIREMENT SYSTEM OF THE STATE OF HAWAII, and UNION ASSET MANAGEMENT HOLDING AG,

Plaintiffs,

v.

MEDTRONIC, INC., WILLIAM A. HAWKINS, GARY L. ELLIS, RICHARD E. KUNTZ, JULIE BEARCROFT, RICHARD W. TREHARNE, MARTIN YAHIRO, THOMAS A. ZDEBLICK, J. KENNETH BURKUS, and SCOTT D. BODEN,

Defendants.

Civil No. 13-1686 (JRT/FLN)

MEMORANDUM OPINION AND ORDER ON DEFENDANTS' MOTION TO DISMISS

Shawn Williams and Christopher M. Wood, **ROBBINS GELLER RUDMAN & DOWD LLP**, One Montgomery Street, Suite 1800, San Francisco, CA 94104; David P. Abel, **MOTLEY RICE LLC**, 28 Bridgeside Boulevard, Mount Pleasant, SC 29464; and Anne T. Regan, **ZIMMERMAN REED, PLLP**, 80 South Eighth Street, Suite 1100, Minneapolis, MN 55402, for plaintiffs.

Peter Carter, Kristin Zinsmaster, and Theresa Bevilacqua,, **DORSEY & WHITNEY LLP**, 50 South Sixth Street, Suite 1500, Minneapolis, MN 55402, for defendants Medtronic, Inc., Hawkins, Ellis, Kuntz, Bearcroft, Treharne, and Yahiro.

John W. Lundquist, Chelsea Brennan, and Lousene Hoppe, **FREDRIKSON & BYRON, PA**, 200 South Sixth Street, Suite 4000, Minneapolis, MN 55402, for defendants Zdeblick, Burkus, and Boden.

Investor Plaintiffs bring this consolidated class action alleging that various defendants – Medtronic, certain of its current and former officers and executives and paid consultants (collectively, "Defendants") – issued false and misleading statements and engaged in a scheme to mislead investors regarding Medtronic's financial condition, particularly with respect to the safety and efficacy of its product INFUSE. Plaintiffs allege that studies initially demonstrating the safety and efficacy of INFUSE were shown to be inaccurate by new studies published in a medical journal called The Spine Journal in May and June 2011, which revealed that the incidence of adverse events experienced with its use was between ten and fifty times the rates previously published. Plaintiffs allege that Medtronic, together with physician consultants, engaged in a scheme to defraud investors by manipulating the early studies. Plaintiffs also allege that once the new, accurate studies were published, certain Defendants made false statements defending the reliability of the early studies. Plaintiffs allege that as a result of the scheme to defraud and misleading statements, Medtronic's stock traded at artificially inflated prices during the Class Period, but then dropped almost twenty-five percent from its high point during the Class Period when the truth was revealed.

Plaintiffs bring Count I for violation of Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b) and Rule 10b-5, 17 C.F.R. § 240.10b-5(b), through false and misleading statements against Medtronic, several of its executives, and a physician consultant named Dr. Thomas Zdeblick. They also bring Count II for a scheme and course of conduct intended to mislead in violation of Section 10(b) and Rule 10b-5 against all Defendants – including two additional physician

consultants – and Count III for violation of Section 20(a) of the Exchange Act as control persons against Medtronic and the individual Medtronic executives.

Defendants move to dismiss all of Plaintiffs' claims. The Court will grant the motion in part and deny the motion in part. With respect to Count I, the Court concludes that Plaintiffs fail to allege that Defendants made materially false statements, with the exception of Defendant William Hawkins' statements regarding ongoing work with the FDA. With regard to Count II, the Court concludes that Plaintiffs' claims against the physician Consultant Defendants are barred by the statute of limitations, but will deny the motion with respect to Count II against the Medtronic Defendants. Because Count III for control person liability is derivative of other violations of the Exchange Act and the Court permits some claims to proceed against Medtronic and its officers, the Court will deny the motion with respect to Count III.

BACKGROUND

I. BRIEF BACKGROUND OF INFUSE

Before reciting Plaintiffs' specific allegations, the Court will first provide an overview of INFUSE and Plaintiffs' allegations. Medtronic developed the INFUSE bone graft as part of its spinal therapies. (Consolidated Class Action Compl. ("Compl.") ¶ 7, Nov. 4, 2013, Docket No. 28.) INFUSE is the "trade name of rhBMP-2," which is a bone morphogenetic protein ("BMP") which induces the body to develop new bone tissue. (*Id.*) INFUSE is an alternative to grafting replacement bone tissue and was the first BMP to reach the market. (*Id.*) INFUSE was approved by the FDA in July 2002 for the

treatment of degenerative disc disease, but Plaintiffs allege that its "approval indication was narrow: it was to be used **only** in single-level fusions, **only** between L4 and S1 . . . and **only** via an anterior approach." (*Id.* ¶ 8 (emphasis in original).) INFUSE was later also approved for dental surgery and for the repair of certain shin fractures, but Plaintiffs allege that it has "never been approved for any spinal fusion indication other than [the lower back] surgeries." (*Id.*) INFUSE is part of Medtronic's "spinal segment," which generated more than $3.5 billion in revenue in 2008, 2009, and 2010, which was approximately 22-23% of the company's revenue in those years. (*Id.* ¶ 20.)

Plaintiffs allege that it was Medtronic's goal to have INFUSE entirely replace iliac crest bone grafting ("ICBG") as the standard of care in spinal fusion, but that in order for that to happen it would need to have clinical studies documenting its safety and efficacy, including that INFUSE achieved better results with fewer adverse side effects for patients than traditional grafting techniques. (*Id.* ¶ 9.) Such clinical studies – their development and Medtronic's response when their validity was challenged – are at the heart of this dispute.

In addition to INFUSE, Plaintiffs allege that Medtronic also "concealed known risks" associated with a second-generation BMP called AMPLIFY. (*Id.* ¶ 22.) AMPLIFY involved the same bone-growth-inducing protein as INFUSE, but in a higher dosage – 40mg, whereas INFUSE's maximum was 12mg. (*Id.*) Some of Plaintiffs' allegations involve Medtronic's response when questions about AMPLIFY's safety were raised during its review by the FDA. AMPLIFY has not been approved by the FDA.

Plaintiffs make two substantive claims. First, Plaintiffs allege that Defendants made materially false statements during the Class Period in order to assure investors of the continued viability of INFUSE as a product and the prospect of AMPLIFY. Plaintiffs allege that these materially false statements artificially inflated Medtronic's stock price, which led investors to buy it, but that when the truth was revealed the value dropped. Second, Plaintiffs allege that before and during the Class Period, Defendants engaged in a scheme or course of conduct to manipulate the early clinical studies, which propelled INFUSE to success despite omitting many of INFUSE's adverse effects. Plaintiffs' claim for control person liability is derivative of these first two claims.

II. THE PARTIES

The lead Plaintiffs in this consolidated class action are several institutional investors: West Virginia Pipe Trades Health & Welfare Fund, Union Asset Management Holding AG, and Employees' Retirement System of the State of Hawaii, all of which allege that they purchased Medtronic common stock during the Class Period and were damaged by the conduct alleged in the complaint. (*Id.* ¶¶ 43-45.)

Plaintiffs bring this action against Medtronic and several of its officers and employees, including: William Hawkins, former Chair of the Board of Directors and CEO, (*id.* ¶ 47); Gary Ellis, Chief Financial Officer, (*id.* ¶ 48); Richard Kuntz, Chief Scientific, Clinical and Regulatory Officer, (*id.* ¶ 49); Julie Bearcroft, Director of Technology Management in Medtronic's Biologics Marketing Department, (*id.* ¶ 50); Richard Treharne, Senior Vice President of Clinical and Regulatory Affairs, (*id.* ¶ 51);

and Martin Yahiro, Medtronic Senior Director of Regulatory Affairs, (*id.* ¶ 52). The Court refers to the individual Medtronic Defendants as the "Individual Defendants" and the collection of the Individual Defendants plus Medtronic as the "Medtronic Defendants."

The complaint also alleges violations by three consultants (the "Consultant Defendants" or "physician consultants"). Dr. Thomas Zdeblick was a physician consultant for Medtronic, whom Plaintiffs allege authored some of the medical journal articles with false and misleading statements, and was the Editor-in-Chief of the *Journal of Spine Disorders*. (*Id*. ¶ 53.) Dr. Kenneth Burkus was a physician consultant for Medtronic, whom Plaintiffs allege authored some of the medical journal articles with false and misleading statements. (*Id*. ¶ 54.) Dr. Scott Boden was a physician consultant for Medtronic, whom Plaintiffs allege authored some of the medical journal articles with false and misleading statements. (*Id*. ¶ 55.)

Plaintiffs bring Count I for false and misleading statements in violation of section 10(b) and 10b-5 against only Medtronic, Hawkins, Ellis, Kuntz, and consultant Zdeblick. Plaintiffs bring Count II for scheme liability under 10(b) against all Defendants, and Count III for control person liability against only the Medtronic Defendants.

III. FALSE AND MISLEADING STATEMENTS

In Count I, Plaintiffs allege that the Medtronic Defendants and Zdeblick violated Section 10(b) and Rule 10b-5 by making statements which were knowingly or recklessly false and materially misleading.

A. The Statements

Plaintiffs point to three distinct statements or categories of statements in support of their claims under Count I for false and misleading statements.

1. Commentary on Clinical Studies in 10-Qs

First, Plaintiffs allege that the September 8, 2010[1] and December 8, 2010 10-Q forms "included substantially identical false Sarbanes Oxley certifications of both Defendants Hawkins and Ellis" which stated, among other things, that Medtronic's "clinical studies were well-planned and designed to show both the efficacy and safety of its therapies." (*Id.* ¶¶ 71-72.) Plaintiffs also point to Medtronic's March 9, 2011 filing of its third quarter 2011 ("3Q11") 10-Q, which they allege "again falsely stated that the Company's 'well-planned studies' showed the safety and efficacy of its products and therapies." (*Id.* ¶ 78.) The complaint quotes from the disclosure: "We work to improve patient access through well-planned studies which show the safety, efficacy, and cost-effectiveness of our therapies, and our alliances with patients, clinicians, regulators, and reimbursement agencies." (*Id.* (emphasis omitted).) According to Plaintiffs, this was the first time that Medtronic disclosed that it had received a non-approval letter from the FDA about AMPLIFY. (*Id.* ¶ 79.)

[1] The complaint lists the date for this 10-Q as September 28, 2010, but Plaintiffs clarify in their memorandum that the date should be September 8, 2010, which is the start of the Class Period. (Mem. in Opp'n to Mot. to Dismiss at 5, Mar. 18, 2014, Docket No. 64.) This correction is supported by the record. (*See* Decl. of Peter W. Carter, Exs. 11-12, Jan. 15, 2014, Docket No. 57.)

Plaintiffs allege that the 3Q11 10-Q "caused the Company's stock price to decline from a close of $39.80 on March 9, 2011, to a close of $38.63 on March 10, 2011." (*Id.* ¶ 82.) Plaintiffs include in their allegations commentary from various news outlets about the impact of AMPLIFY on Medtronic's stock and the viability of INFUSE, including a New York Times article from April 11, 2011. (*Id.* ¶ 83.) Later, on May 24, 2011, Medtronic issued a press release announcing its fourth quarter 2011 and fiscal year 2011 financial results and later that day held a conference call, during which Plaintiffs allege that Medtronic, "specifically, Ellis, falsely stated that [Medtronic] set high standards for quality in the industry." (*Id.* ¶ 85.)

2. Interactions and Status with the FDA

Second, Plaintiffs allege that on February 22, 2011, after releasing Medtronic's 3Q11 financial results, Medtronic hosted a conference call for analysts and investors during which Hawkins was asked about whether the FDA might delay its approval of AMPLIFY and whether any delay might negatively impact INFUSE sales. (*Id.* ¶ 73.) Plaintiffs allege that Hawkins' responses "falsely suggested that approvability had not yet been determined, and . . . that even if there were a delay, it would not impact [Medtronic]'s current business." (*Id.*) Plaintiffs point specifically to the following exchange:

> [HAWKINS:] [W]e are continuing to work with the FDA to figure out kind of where they are on this . . . . So as we learn more, we will let you know . . . . [If] there was a reason for the FDA to delay this anymore, it is not going to have a significant impact. It won't have any really impact on our current business. It is really all upside for us.

> [ANALYST:] [J]ust to clarify that, Bill. You don't feel that not having – like posterior lumbar fusion is probably the biggest off-label to use of INFUSE. And you don't think not getting AMPLIFY approved could result in a retrenchment.
>
> [HAWKINS:] No . . . . I don't see anything that would change as the result of AMPLIFY not getting approved.

(*Id.* (emphasis omitted).) Plaintiffs allege that this statement was "knowingly materially false and misleading because . . . [Medtronic] had received a letter from the FDA before January 28, 2011, stating that AMPLIFY would not be approved." (*Id.* ¶ 74.) Later in the complaint, Plaintiffs explain that in Medtronic's 3Q11 10-Q, it "disclosed for the first time that . . . it had received a non-approval letter from the FDA concerning AMPLIFY: In the third quarter of fiscal year 2011, the FDA sent Medtronic a letter advising that they were not able to approve AMPLIFY at that time without additional information from Medtronic." (*Id.* ¶ 79.)

3. Statements about Correlation with Retrograde Ejaculation

Plaintiffs allege that the truth about INFUSE began to be revealed when, on May 25, 2011, The Spine Journal published a retrospective data analysis of spinal fusion patients over a period of three years, which demonstrated that there was a 7.2% incidence of retrograde ejaculation in INFUSE patients, compared with .6% incidence in patients who did not receive INFUSE. (*Id.* ¶¶ 89-90.) Plaintiffs allege that other articles published around that time, including another published by The Spine Journal and that Bloomberg and The New York Times, also reported on these studies. (*Id.* ¶¶ 91-92.)

Plaintiffs allege that even after these reports began to surface, Defendants continued to make material misrepresentations covering up the scheme and earlier research's understatement of the link with retrograde ejaculation. They point to a May 25, 2011 New York Times article which included a response to The Spine Journal article from Zdeblick, in which he stated that the study "was of limited value because it reflected the results of a retrospective look at patients rather than a clinical trial," that "[s]uch reports 'are notorious for being misleading,'" and stating that Defendant Zdeblick had "adamantly insisted that . . . financial relationships have not affected [his] scientific judgment." (*Id.* ¶ 93 (emphasis omitted).)

Plaintiffs allege that after the May 25, 2011 articles, Medtronic's stock dropped from $40.88 on May 24, 2011 to $40.23 on May 25, 2011. (*Id.* ¶ 95.) Plaintiffs allege that at this time, "Medtronic admitted that it knew of the infertility risks in the original studies but falsely claimed they were not statistically significant," pointing to a Star Tribune article in which a Medtronic spokesperson said that the original study that supported FDA approval of INFUSE did not indicate sterility problems "common enough to be statistically linked to the product." (*Id.* ¶ 96.) The Star Tribune also reported Zdeblick's response to the reports, reporting that he stated in an email that the new study was "interesting, but a single publication in the medical literature does not constitute a truth. Retrospective trials are notorious for being misleading," and that the study has "numerous flaws" but that the study's findings were nonetheless "in line with other INFUSE studies." (*Id.* ¶ 97 (alterations and internal quotations omitted).)

Plaintiffs allege that Defendants knew that this commentary – from both Medtronic and Zdeblick – on the new study was false because a report from an investigation by the United States Senate showed that "Medtronic and Zdeblick knew as early as 2001 that retrograde ejaculation rates were higher in both investigational groups (i.e., INFUSE patients) than the control group," pointing to a 2001 PowerPoint presentation Zdeblick made to study investigators in February 2001, in which Zdeblick reported that there were rates of 10.3% and 6.3% of retrograde ejaculation in INFUSE patients as opposed to 1.5% for the control group, which Zdeblick labeled as "statistically different from control." (*Id.* ¶ 99.) Plaintiffs allege that Zdeblick later admitted that this finding "should have been mentioned in [Medtronic]'s report about the initial trial of INFUSE in the Journal of Spinal Disorders in 2002," but that he "maintained that the risk of sterility linked to INFUSE wasn't reported in journal articles because it wasn't statistically significant." (*Id.* ¶ 100.)

4. Required Financial Disclosures

In addition to these three statements, Plaintiffs also allege that Medtronic included material misstatements in its required financial disclosures. Plaintiffs allege that throughout the Class Period, Medtronic "frequently emphasized the Spine segment as an important revenue growth driver for [Medtronic] as a whole" and "knew that when the truth about INFUSE emerged, [Medtronic] would suffer material declines in sales." (*Id.* ¶¶ 130-31.) Plaintiffs allege that Defendants:

> violated SEC disclosure rules, notably Regulation S-K Item 303(a)(3)(ii) in the Management's Discussion and Analysis ("MD&A") section of

> [Medtronic]'s Class-Period financial statements by presenting a positive trend of increasing Spine segment and INFUSE (Biologics) revenue without any further disclosure that the reported results were in no way indicative of future results.

(*Id.* ¶ 132.) The parties do not focus their arguments on these allegations.

B. Allegations as to Falsity of Statements and Scienter

Plaintiffs allege that these above statements were materially and knowingly false and misleading for several reasons. First, they allege that Medtronic "did **not** 'set the standard for quality in the industry' and did **not** engage in well-planned studies showing the safety and efficacy of INFUSE or AMPLIFY," but instead that Medtronic edited and influenced the research studies which intentionally omitted and understated the adverse effects of INFUSE. (*Id.* ¶ 87(a) (emphasis original).) Plaintiffs point to one instance in which consultant Defendant Burkus admitted that for a 2002 article he authored, he "could 'take credit for only a small fraction of the work that ha[d] gone into this paper,'" because Medtronic employees had significant input. (*Id.* ¶ 87(a); *see also id.*, Ex. D.) They point to another communication in which Burkus stated that his named co-authors on the study "did not write one word," (*see id.*, Ex. E), and allege that each of the early research articles was published without any indication that Medtronic had been involved in editing or drafting the articles, (*id.* ¶ 87(a)). Plaintiffs proceed to list eleven articles which they claim Medtronic executives and employees participated in drafting or editing which failed to disclose adverse events known to or recklessly disregarded by Medtronic and the author physicians. (*Id.* ¶ 87(b).) Plaintiffs allege that Medtronic knew but failed to disclose that it had paid $210 million to physician authors who published these articles

and that "such payments, and Medtronic's involvement in the drafting and editing of these articles, were part of and/or advanced an undisclosed scheme to conceal or materially minimize adverse events" related to INFUSE. (*Id.* ¶ 87(c).) Plaintiffs further allege that the Defendants knew, but failed to disclose, Medtronic's involvement in the research even when the government and media sought to investigate the relationship between Medtronic and researchers and "while purporting to cooperate with . . . requests for information, were not in fact cooperating," but instead continued to conceal that the initial medical reports were actually "a result of the undisclosed scheme." (*Id.* ¶ 87(d).) Plaintiffs also allege that Medtronic failed to disclose that its revenue and profits in the spine unit had been driven "not by the safety and efficacy of the treatments, but by defendants' fraudulent scheme and intentional concealment of the true side effects of INFUSE" and that, further, the "potential approval and resulting sales growth of AMPLIFY was based upon the initial and continued concealment of the known adverse events and risks" associated with INFUSE. (*Id.* ¶ 87(e).)

According to Plaintiffs, Defendants also failed to disclose their knowledge that the clinical trials "were not designed to show [INFUSE]'s safety and efficacy, but to obscure and conceal known harmful side effects of INFUSE." (*Id.* ¶ 87(f).) In this regard, Plaintiffs point to an email written in 2006 by Defendant Yahiro, claiming that it shows that Medtronic's efforts to get the FDA to loosen rules governing the disclosure of adverse events were driven by a "desire to obscure adverse events associated with INFUSE and INFUSE-related products." (*Id.* ¶ 87(f).) The email states:

> Thanks for your note. I think we're all on the same page regarding the ability to determine the exact cause of an event that could possibly be related to INFUSE (or just a result of cervical surgery). We agree it would be difficult to pin it on INFUSE, which is exactly why we wrote the stopping rule that way. What we don't want is a rule that would have specific events with incidence rates, etc., that would stop the trial when it would be hard to say it WASN'T INFUSE.
>
> The way we wrote it, WE make the determination whether it was INFUSE related. This way, if a patient has an AE like severe cervical swelling, we can honestly say that it is not possible to know that the cause is definitely INFUSE and therefore the study need not be stopped.

(*Id.* ¶ 87(f) (citing *id.*, Ex. C at 17-18).) Plaintiffs claim that Yahiro is explaining that Medtronic's proposal was written the way it was so that it would be difficult to "pin" the cause of an adverse event on INFUSE. (*Id.* ¶ 87(f).) Rather than being designed to elicit information about adverse events, Plaintiffs allege that the INFUSE clinical trials were biased in favor of INFUSE. (*Id.* ¶ 87(g).) They point to two independent reviews of Medtronic's study protocols in support of this argument, which they claim point to problems in the clinical studies, including that adverse events "were generally not actively elicited" and that it was not clear "whether investigators asked about specific symptoms" that would lead to accurate diagnoses of adverse events. (*Id.* ¶¶ 87(g)-(h).) As an example of the scheme to defraud, Plaintiffs allege that Defendants were aware in June 2004 that Medtronic employee Bearcroft advised Defendant Burkus to "not include any 'significant detail' on adverse events" in one of his reports and instead that it was "appropriate to simply report the adverse events were equivalent in the two groups without the detail." (*Id.* ¶ 87(h) (citing *id.*, Ex. C).) According to Plaintiffs, it was later

revealed that a table summarizing the adverse events was therefore removed. (*Id.* ¶ 87(h).)

Plaintiffs also allege that Defendants knew and failed to disclose that future sales growth of INFUSE depended on continued concealment of this scheme, given that, as early as 2004, Medtronic was receiving complaints about severe swelling in cases where INFUSE was used in the cervical spine and that Medtronic had begun to analyze any possible causal connection between INFUSE and swelling. (*Id.* ¶ 87(i).) Plaintiffs point to an email exchange between Medtronic employee Defendant Treharne and physician consultant Boden in which Plaintiffs claim, "Treharne tried to convince Boden with an analysis that purported to show the lack of such causal relationship," but that "Boden remained unconvinced:"

> While statistically your numbers do not suggest an increased incidence, I think there is a possibility that could be a misleading conclusion.
> . . .
> At this point, the statistics do not prove anything one way or another, but I am still concerned that there could be an association between BMP-2 and edema in these cervical cases. . . . I think continued warning needs to be advised to surgeons about off-label use, especially in the cervical spine.

(*Id.* ¶ 87(i) (citing *id.*, Ex. F).) When asked by the North American Spine Society in 2004 whether doctors should be cautioned against using INFUSE in the cervical spine, Boden stated that "it may be premature for an 'official warning.'" (*Id.* ¶ 87(j).)[2]

[2] In addition to these allegations, the complaint also includes several paragraphs about various controversies involving INFUSE that occurred before the Class Period, which Plaintiffs acknowledge are "unrelated to the fraud alleged herein," but allege that they "nevertheless alerted defendants that the undisclosed scheme and continued concealment of the true facts regarding INFUSE created a risk of misleading the investing public." (*Id.* ¶¶ 62-68.)

C. Reports from The Spine Journal and Senate Committee

After The Spine Journal's May 25, 2011 article linking INFUSE with retrograde ejaculation, and media coverage in Bloomberg and the New York Times that Plaintiffs allege followed, (*see id.* ¶¶ 89-92), the United States Senate Finance Committee sent a letter request to Medtronic on June 21, 2011, in which it stated:

> We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of Infuse on behalf of Medtronic were aware that Infuse, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to Medtronic.

(*Id.* ¶ 101 (emphasis omitted).)

On June 28, 2011, The Spine Journal devoted an entire issue to the INFUSE concerns, which Plaintiffs allege, "[t]aken as a whole . . . began to inform the market, for the first time, that the research supporting the safety and efficacy of INFUSE was not reliable." (*Id.* ¶ 103.) Plaintiffs' allegations detail the articles in the June 28, 2011 issue critiquing many of the earlier studies on INFUSE. In particular, the critique pointed out that for twelve of the thirteen initial studies, Medtronic had "massive financial relationships with the doctors who authored the studies." (*Id.* ¶ 106.) The critique also reported that documents indicated that Medtronic "edited draft publications to stress the pain patients experienced from undergoing a bone graft procedure instead of receiving INFUSE." (*Id.* ¶ 107.)

Medtronic issued a press release on June 28, 2011 responding to the June edition of The Spine Journal, in which the then-CEO of Medtronic stated that The Spine Journal

"articles raise questions about researchers' conclusions in their published peer-reviewed literature, the articles do not raise questions about the data Medtronic submitted to the FDA in the approval process or the information available to physicians today through the instructions for use brochure attached to each product sold." (*Id.* ¶ 109.)

Also on June 28, 2011, Medtronic filed its FY11 Form 10-K, which was signed by the then-CEO and Defendant Ellis and included a statement about The Spine Journal articles and "conceded that the articles would have an impact on future sales." (*Id.* ¶ 112.) Plaintiffs allege that upon these disclosures, Medtronic's stock dropped $.92 to close at $38.09 on June 29, 2011, which was a one-day decline of nearly 3%. (*Id.* ¶ 113.)

Plaintiffs allege that during this time, financial news analysis of the INFUSE situation predicted that INFUSE sales would drop significantly and posed risks to Medtronic's financial health. (*Id.* ¶¶ 114-15.) Plaintiffs allege that after the publication of these reports, Medtronic's stock dropped further from $39.12 on July 1, 2011 to $37.96 on July 5, 2011. (*Id.* ¶ 116.)

D. The Yale Study and Senate Staff Report

On August 3, 2011, Medtronic announced that it was planning to publicly release INFUSE data to researchers at Yale to conduct a full review of studies of INFUSE. (*Id.* ¶ 117.) The resulting report issued in mid-2013 concluded that, compared with grafting, INFUSE did not improve pain or function and increased adverse events, possibly including cancer. (*Id.* ¶¶ 121-22.) After these reports, The Spine Journal published an article reacting to the reports and offering some final comments, including:

> In some instances, it seems investigators with strong financial ties helped design a trial, and then acted as surgeons who monitored their own complications. To complete the circuit the same surgeon/investigator would co-author the paper and then submit the manuscript for review to . . . well . . . himself as chief or section editor of the journal.
>
> . . .
>
> It is ultimately disappointing that after 15 years of largely self-congratulatory research, we have only indirectly discovered BMP-2's many potential complications. At present these 'concerns' regarding higher rates of cancer, sterility, wound problems and nerve injury remain poorly described. The suggested reason for this gap in our understanding, if true, is simply appalling: these complications were systematically 'misrepresented,' 'underreported' or just 'missing' from the first decade of publications.

(*Id.* ¶ 124.)

In addition to these reports, the U.S. Senate Finance Committee issued a staff report ("Senate Staff Report"), which made several findings, including, among others, that "Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic." (*Id.* ¶ 35.) For example, the Senate Staff Report stated that:

> An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events possibly associated with INFUSE in a 2005 *Journal of Bone & Joint Surgery* article[, and that]
>
> . . .
>
> Medtronic officials inserted language into studies that promoted INFUSE as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique.

(*Id.* ¶ 125 (citing *id.*, Ex. C at 2).) Plaintiffs characterize the report as finding that "Medtronic employees specifically crafted the content and the reporting format of the

adverse events with the specific intent to conceal or at least obscure the true adverse events' rate of incidence associated with INFUSE." (*Id.* ¶ 127.) The Senate Staff Report also stated that:

> E-mail exchanges between Dr. Burkus and Medtronic employee regarding a study of InFuse utilizing the posterior lumbar interbody fusion (PLIF) technique and published in The Spine Journal in 2004 demonstrates that Medtronic employees not only edited the draft manuscript to include comments supportive of InFuse, they also covertly participated in the peer-review process by drafting responses to peer-reviewers on behalf of the physician authors named on the paper.

(*Id.* ¶ 129 (citing *id.*, Ex. C at 15-16.)

E. Loss Causation

Plaintiffs allege that "[t]he conduct alleged herein and the materially false and misleading statements made during the Class Period caused Medtronic's common stock to trade at inflated prices as high as $43.20 per share during the Class Period – and operated as a fraud or deceit on investors in the Company's common stock" and that once "the relevant truth was disclosed" about INFUSE, "Medtronic's stock price suffered significant declines, as the artificial inflation came out of the stock price." (*Id.* ¶¶ 138-39; *see also id.* ¶ 25.) For example, Plaintiffs explain that:

> [O]n March 9, 2011, the Company filed a Form 10-Q which disclosed that the FDA had rejected its new INFUSE-related treatment AMPLIFY, and that the rejection had occurred in the third quarter of Medtronic's fiscal 2011, well before the February 22, 2011 investor conference call during which defendants were asked about the status and potential delay of approval of AMPLIFY and defendants failed to disclose the fact the Company had already been rejected. While some analysts had built in the possibility of rejection in their models, some investors hoped it would be approved. This disclosure was a substantial cause of the Company's stock

> price decline from $39.80 on March 9, 2011 to a close of $38.63 on March 10, 2011.

(*Id.* ¶ 140.) Plaintiffs also point to the events of May 25, 2011 (the initial journal reports), June 28, 2011 (the dedicated issue of The Spine Journal), July 5, 2011 (the analyst reports), and August 3, 2011 (Medtronic's public release to Yale), as events causing either continued artificially inflated prices or dropping of stock, causing economic losses to investors. (*Id.* ¶¶ 141-45.) Plaintiffs allege that after the May 25, 2011 disclosures, Medtronic's stock price dropped from a closing price of $40.88 on May 24, 2011 to $40.23 on May 25, 2011, but "remained artificially inflated due to continued misrepresentations and concealment of the true facts." (*Id.* ¶ 29.) Plaintiffs allege that after the June 28, 2011 issue, Medtronic's stock declined $.92 per share to close at $38.09, a "one-day decline of nearly 3% on volume of 10 million shares." (*Id.* ¶ 33.)

IV. SCHEME LIABILITY

In addition to their material false statements allegations, Plaintiffs also allege in Count II that Defendants engaged in a scheme and course of conduct intended to deceive the investing public and enable Medtronic to artificially inflate the price of Medtronic's stock, thus causing investors to purchase the stock at those artificially high prices. (*See id.* ¶ 163.) Plaintiffs allege that early INFUSE clinical studies "designed and sponsored by Medtronic revealed significant safety risks that would threaten Medtronic's corporate goal of replacing ICBG as the standard of care," and that because of this, Medtronic "embarked on a scheme with physician investigators and authors to conceal the significant safety risks from the public and physician community." (*Id.* ¶ 15; *see also id.*

¶ 163.) Plaintiffs allege that Medtronic did so by "forg[ing] relationships, including financial relationships, with physician authors who published research articles in respected medical journals and knowingly concealed in those original articles, or omitted altogether, known facts regarding INFUSE's adverse side effects observed in clinical trials," and that these research articles "overstated apparent disadvantages of alternate bone graft procedures . . . as opposed to treatment with INFUSE." (*Id.* ¶ 16.) Plaintiffs also allege that Medtronic and the consulting physicians (Defendants here) "knew but failed to disclose that Medtronic had paid millions of dollars to the same physician authors and that during the drafting process[] Medtronic employees heavily edited the articles and specifically excised true facts learned during clinical trials about the efficacy and side effects of INFUSE, which would have alerted the public and physicians using INFUSE about its harmful side effects." (*Id.* ¶ 17.) Many of their allegations are based on facts revealed in the Senate Staff Report and the June issue of The Spine Journal, and Plaintiffs'' allegations incorporate many of the specific examples of concerted manipulation described in the reports, discussed above.

V. CONTROL PERSON LIABILITY

Plaintiffs allege that the individual Medtronic Defendants are "officers and controlling persons of a publicly-held company" and therefore "each had a duty to promptly disseminate accurate and truthful information regarding the Company's financial condition, performance, growth, operations, financial statements, business, markets, management, earnings, present and future business prospects, and to correct any

previously-issued statements that had become materially misleading" and that the Individual Defendants' "material misrepresentations and omissions during the Class Period violated these specific requirements and obligations." (*Id.* ¶ 58.) Plaintiffs also allege that the Individual Defendants participated in drafting, preparing, and approving public shareholder reports and "were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom," because the Individual Defendants each "had access to the adverse undisclosed information." (*Id.* ¶ 59.) Plaintiffs similarly allege that the Individual Defendants each had control over the content of SEC filings and had the ability to correct misleading statements in those filings but did not, such that each of the Individual Defendants is "responsible for the accuracy of the public reports and releases" and "therefore primarily liable for the representations contained therein." (*Id.* ¶ 61.)

VI. MOTION TO DISMISS

All Defendants move to dismiss. The Medtronic Defendants and Defendant Zdeblick argue that Count I fails to state a claim because none of the relevant statements could be plausibly understood to be false or misleading, that they would not have been material to investors, and that Plaintiffs fail to allege, with the requisite specificity, scienter and the other elements of a claim under Section 10(b). The Medtronic Defendants argue that Count II for scheme liability is barred because it is based on the same underlying factual allegations as Count I, and the Consultant Defendants additionally argue that the claims against them are barred by the statute of limitations.

Finally, Defendants argue that the defects with Plaintiffs' claims under Counts I and II also doom Count III for control person liability, because such a claim is dependent upon the violations alleged in Counts I and II.

ANALYSIS

I. SECURITIES LAW AND STANDARD OF REVIEW

Section 10(b) of the Exchange Act makes it unlawful for "any person . . . [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b–5 implements the provisions of section 10(b), *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 980 (8th Cir. 2012), which makes it unlawful to (a) "employ any device, scheme, or artifice to defraud," (b) "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading," or (c) "engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person," in connection with the purchase or sale of any security, 17 C.F.R. § 240.10b-5. Count I alleges violations under subsection 10b-5(b), for untrue statements of material fact. Count II alleges violations under subsections 10b-5(a) and (c) for a fraudulent scheme, act, or course of business. *See* 17 C.F.R. § 240.10b-5.

Both types of claims are subject to a heightened pleading standard, in addition to the pleading standards applicable to all federal civil actions. *See McDonald v.*

Compellent Technologies, Inc., 805 F. Supp. 2d 725, 732 (D. Minn. 2011). A plaintiff bringing an action for false or misleading statements under Rule 10b-5(b) must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[.]" 15 U.S.C. § 78u–4(b)(1). The "circumstances of the fraud must be stated with particularity, including such matters as the time, place and contents of false representations, . . . [t]his means the who, what, when, where, and how." *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 890 (8th Cir. 2002) (internal quotations and citations omitted). "Although the heightened pleading requirements of the [Private Securities Litigation Reform Act] do not apply to claims under Rule 10b–5(a) and (c), such claims must be pleaded with specificity under" Federal Rule of Civil Procedure 9(b). *KV Pharm. Co.*, 679 F.3d at 986. Thus, a plaintiff must "specify, with particularity, what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities at issue." *Id.*; *see also* Fed. R. Civ. P. 9(b) ("a party must state with particularity the circumstances constituting fraud or mistake").

Although the Court "assumes as true all factual allegations in the pleadings, interpreting them most favorably to the nonmoving party," *Magee v. Trustees of Hamline Univ., Minn.*, 747 F.3d 532, 534-35 (8th Cir. 2014), allegations that the defendant acted with the required state of mind for a claim under Rule 10b-5(b) must, taken in their entirety, "'give rise to a strong inference of scienter,' meaning that the inference 'must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *Elam v. Neidorff*, 544 F.3d 921, 928

(8th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007)); *see also* 15 U.S.C. § 78u–4(b)(2)(A).

II. FALSE AND MISLEADING STATEMENTS

Plaintiffs' first Count alleges that certain Medtronic Defendants and researcher Zdeblick made materially false statements in violation of Section 10(b) and Rule 10b-5(b). This Count alleges, in essence, that these Defendants made several statements during the Class Period, when news outlets began to challenge the safety and efficacy of INFUSE, defending INFUSE and the early clinical studies, when they knew that those early clinical studies downplayed the adverse events associated with INFUSE and manipulated the reports on the trials in order to drive up sales. Specifically, this claim focuses on three categories of statements: (1) Statements in the 10-Q forms filed September 8, 2010, December 8, 2010, and March 9, 2011, stating that Medtronic's studies were well-planned and showed the safety and efficacy of INFUSE, (2) Defendant Hawkins' statements in the conference call with investors regarding ongoing work with the FDA on the approval of AMPLIFY that did not include mention of the non-approval letter Medtronic had recently received, and (3) statements by a Medtronic spokesperson and Defendant Zdeblick denying the statistically significant link between INFUSE and male infertility after the Spine Journal articles had come out suggesting that there was such a link. (*See* Am. Compl. ¶¶ 70-71, 78; *id.* ¶¶ 73-74, 79; *id.* ¶¶ 87, 96.)

There are six elements of a claim for material false statements under Rule10b-5(b): (1) a material misrepresentation (or omission); (2) scienter, or intent to deceive,

manipulate, or defraud; (3) a connection with the purchase or sale of a security; (4) reliance (sometimes referred to as "transaction causation");[3] (5) economic loss; and (6) "loss causation," or a causal connection between the material misrepresentation and the loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005); *see also In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006 (9th Cir. 2005).[4] Defendants challenge the first two elements – whether there was an actionable misrepresentation or omission and scienter – with regard to all of the allegedly false statements Plaintiffs raise. The Court will first outline the legal principals governing these two elements and will then consider the adequacy of Plaintiffs' allegations of both contested elements with regard to each allegedly false statement.

[3] The briefing in this case was complete before the Supreme Court issued its opinion in *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398 (2014). The parties have not attempted to argue that the Supreme Court's decision affects the application of the reliance element in this case.

[4] The Eighth Circuit typically lists the required showing for an action under Rule 10b-5(b) in four elements: "(1) misrepresentations or omissions of material fact or acts that operated as a fraud or deceit in violation of the rule; (2) causation, often analyzed in terms of materiality and reliance; (3) scienter on the part of the defendants; and (4) economic harm caused by the fraudulent activity occurring in connection with the purchase and sale of a security." *Cornelia I. Crowell GST Trust v. Possis Med., Inc.*, 519 F.3d 778, 782 (8th Cir. 2008). But as the court noted in *McDonald v. Compellent Technologies, Inc.*, 805 F. Supp. 2d 725 (D. Minn. 2011), "[s]ubstantively, it makes no difference whether a securities-fraud action's elements are arranged into a group of four (as in some Eighth Circuit cases), a group of five (as by the Court), or somewhat different groups of six (as by the Supreme Court [in *Dura*] and the Seventh Circuit)." *Id.* at 733 n.4.

A. Legal Standards

1. Material Misrepresentation or Omission

"To fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *KV Pharm. Co.*, 679 F.3d at 981; *see also Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 805 (8th Cir. 2010).

"Silence, absent a duty to disclose, is not misleading under Rule 10b–5." *KV Pharm. Co.*, 679 F.3d at 984 (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)). "A duty arises, however, if there have been inaccurate, incomplete or misleading disclosures." *Sailors v. N. States Power Co.*, 4 F.3d 610, 612 (8th Cir. 1993). Therefore, "even absent a duty to speak, a party who discloses material facts in connection with securities transactions assume[s] a duty to speak fully and truthfully on those subjects." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 561 (6th Cir. 2001) (internal quotations and citation omitted). However, the requirement is not to dump all known information with every public announcement, but the law requires "an actor to provide complete and non-misleading information with respect to the subjects on which he undertakes to speak." *In re K-tel Int'l*, 300 F.3d at 898. As the Supreme Court has recently explained, "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market," *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1322 (2011), because where there is no duty to disclose,

"[d]isclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading," *id.* (alterations and internal quotations omitted).

"[V]ague, cautionary and such obvious puffing" statements upon which "no reasonable investor would have relied" are not actionable as false statements. *In re K-tel Int'l*, 300 F.3d at 898-99. For example, the Eighth Circuit has held that a statement that "it would be 'very premature' to announce anything more," was "a cautionary note rendering the statement immaterial as a matter of law" and "not specific enough to perpetuate fraud on the market." *Id.*

2. Scienter

In the Eighth Circuit, scienter refers to either severe recklessness or intentional wrongdoing, and it can be established with evidence of "highly unreasonable omissions or misrepresentations that present a danger of misleading buyers or sellers which is either known to the defendant, or is so obvious that the defendant must have been aware of it." *Freedman v. St. Jude Med., Inc.*, --- F. Supp. 2d ---, Civ. No. 12-3070, 2014 WL 910326, at *18 (D. Minn. Mar. 10, 2014). "The inquiry . . . is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1029 (8th Cir. 2011) (quoting *Tellabs*, 551 U.S. at 322–23). "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing

inferences." *Id.* (quoting *Tellabs*, 551 U.S. at 322-23). Thus, "[a] complaint will survive . . . 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." *Tellabs*, 551 U.S. at 324.

The Eighth Circuit has observed that there are three traditional methods of establishing scienter: from facts demonstrating a mental state embracing intent to deceive, manipulate, or defraud; severe recklessness or "highly unreasonable omissions or misrepresentations involving an extreme departure from the standards of ordinary care, and presenting a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it;" and allegations of motive and opportunity, which may "support a reason to believe the defendant's misrepresentation was knowing or reckless." *In re K-tel Int'l*, 300 F.3d at 893-94 (alterations and internal quotations omitted). "[E]vidence that the individual defendants abstained from trading may undercut allegations of motive." *Id.* at 894; *see also Minneapolis Firefighters' Relief Ass'n*, 641 F.3d at 1030.

B. Allegedly False Statements

1. Validity of Clinical Studies

Plaintiffs allege that the Medtronic Defendants made materially false statements in three 10-Q forms endorsing the validity of Medtronic's clinical studies. Those three forms included similar versions of the statement that Medtronic "work[s] to improve patient access through well-planned studies which show the safety, efficacy, and cost-

effectiveness of our therapies." (Compl. ¶ 70; *see also id.* ¶¶ 71, 78.) Plaintiffs also point to Defendant Ellis' statement in a conference call that Medtronic "set[s] high standards for quality in the industry." (*Id.* ¶ 85.) Plaintiffs argue that these assertions were false because Medtronic had actually "consistently manipulated the designs and results of INFUSE clinical studies," and had "covertly scrubbed" them to avoid reporting adverse events associated with INFUSE in the studies. (Pls.' Mem. in Opp'n to Mot. to Dismiss at 5-6, Mar. 18, 2014, Docket No. 64.)

Defendants argue that these statements are not actionable as false or misleading under Rule 10b-5(b) because they are classic "puffing" statements or opinions which are not actionable. The Eighth Circuit has observed:

> [S]ome statements are so vague and such obvious hyperbole that no reasonable investor would rely upon them. The role of the materiality requirement is not to attribute to investors a childlike simplicity but rather to determine whether a reasonable investor would have considered the omitted information significant at the time . . . soft, puffing statements generally lack materiality because the market price of a share is not inflated by vague statements predicting growth. No reasonable investor would rely on these statements, and they are certainly not specific enough to perpetrate a fraud on the market.

In re Hutchinson Tech., Inc. Secs. Litig., 536 F.3d 952, 960-61 (8th Cir. 2008) (alteration and internal quotations omitted). There, the court found that a CEO's statement during an investors' conference call that "[w]e believe we are well-positioned on a number of new disk drive programs that will be transitioning into volume production in the coming months," was too vague to amount to a false statement for the purposes of a securities lawsuit. *Id.* at 960; *see also In re St. Jude Med., Inc., Sec. Litig.*, 629 F. Supp. 2d 915, 922 (D. Minn. 2009) (holding statements that company was "'well positioned' to

continue gathering market share," expected "to continue gaining market share going forward," was "competitive" heading into new year "with nothing holding back [its] program," or that it continued to "expect to see strong growth," were non-actionable puffing statements because they "would not influence investor behavior").

Plaintiffs counter that these statements are material and not puffery in light of the context in which Medtronic made them, particularly given the emphasis and weight that Medtronic had placed upon clinical studies as being the foundation of Medtronic's competitive edge in the marketplace. They point to Hawkins' statement that clinical evidence was "critical to Medtronic's . . . competitive differentiation in the marketplace" and the reason "we have gotten to where we are" to argue that such emphasis on clinical studies rendered the statements that they were "well-planned" reasonably material to investors.[5] (*See* Pls.' Mem. in Opp'n to Mot. to Dismiss at 7, 14 (citing Compl. ¶¶ 11-14); Compl. ¶ 12.) Plaintiffs are correct that "the line between mere 'puffery' and an actionable misrepresentation often depends on the context of a statement," and "even if some portions of individual statements might be too vague and general to be actionable, particular statements by Defendants must be evaluated not only in their entirety, but also in context." *In re St. Jude Med., Inc. Sec. Litig.*, 836 F. Supp. 2d 878, 888 (D. Minn. 2011) (citing *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 597–98 (7th Cir. 2006) (explaining that in context of responses to questions from analysts, statement

[5] Plaintiffs to not appear to defend the materiality of Ellis' statement that Medtronic sets "high standards for quality in the industry." (Compl. ¶ 85.) As with the statements about the validity of clinical studies, the Court concludes that this statement is not actionable because it would not be material to investors.

"went well beyond puffery: it was a direct response to an analyst's inquiry about a possible decline" in sales), *vacated in part on other grounds*, 551 U.S. 308 (2007)).

The Court is not persuaded that the context here sufficiently pushes these statements beyond the realm of immaterial puffery. First, in observing that context matters, courts have typically found otherwise vague statements to be actionable when they were made in response to a specific inquiry or question from an analyst or investor. *See Makor*, 437 F.3d at 597 (statement "went well beyond puffery" because "it was a direct response to an analyst's inquiry," and response to a frequently-asked question published in annual report was not puffery); *In re St. Jude Med., Inc. Sec. Litig.*, 836 F. Supp. 2d at 888 (determining investors would reasonably find statements to be material where "[m]any of the statements at issue were provided in direct response to questions from financial analysts at conferences held expressly to discuss STJ's earnings and guidance"). This makes sense because, if an investor or analyst has asked a specific question, the inference that they (and others) would pay attention to the response is stronger than for unsolicited statements. The statements at issue here, though, were not made in response to a question, but rather were a small part of an extensive required filing, so any inference that investors paid attention to or relied on these statements is much weaker than if they were responsive to questions. Furthermore, nearly identical language was included in three required 10-Q forms, suggesting that investors might consider them to be immaterial boilerplate language.

Second, even if Medtronic's clinical studies were responsible, in significant part, for the company's success, and assuming that investors chose to invest in Medtronic on

account of the strength of the studies, Plaintiffs have not plausibly alleged that investors' confidence in the studies depended on **these statements** in the 10-Qs. The clinical studies which Plaintiffs allege secured Medtronic's commercial success with INFUSE were published between 2005 and 2010, (*see* Compl. ¶ 10), suggesting that there were years of clinical studies upon which Medtronic hung its success before these statements were published. Without a convincing argument about how the context in which the statements were made rendered them reasonably likely to be material to investors, Medtronic's statements that its clinical studies were "well-planned" are too vague for it to be plausible that investors would have considered such statements material.

The statements here are comparable to those in *Freedman v. St. Jude Medical, Inc.*, in which the court addressed the materiality of the following statements made during an investor conference call:

> [o]ver the last few years we also have established ourselves as the industry leader for quality and reliability, with a proven track record of high quality product designs and performance. And what we are hearing back from our customers is that our ability to help them reduce risk for their patients really is becoming a key differentiator in the market place.
>
> . . . [O]ur focus on reliability is tireless. This is the single most important thing we look at when we design technology. We have strict design rules. We are always looking to improve the technology, that's the starting point, and I think the engineering team has come up with a best-in-class device here relative to all the things you want in an ICD.

--- F. Supp. 2d ---, Civ. No. 12-3070, 2014 WL 910326, at *8-9 (D. Minn. Mar. 10, 2014). The court observed that these statements were "transparently promotional and would not 'have assumed actual significance in the deliberations of the reasonable shareholder'" and that "[t]hey are the sort of 'vague, soft, puffing statements or obvious

hyperbole' on which no reasonable investor would rely in making a decision about buying or selling [the company's] stock." *Id.* at *9 (quoting *In re K-tel*, 300 F.3d at 897).

The Court finds Medtronic's statements regarding the reliability of its clinical studies to be similarly immaterial. The Court will therefore grant Defendants' motion to dismiss with regard to these statements.[6]

2. Omission of FDA Non-Approval Letter

Next, Plaintiffs allege that Defendant Hawkins' response to a question during an investor conference call about whether the FDA might delay its approval of AMPLIFY and whether any delay might negatively impact INFUSE sales was materially misleading. They argue that by responding that Medtronic "[is] continuing to work with the FDA to figure out kind of where they are on this," Hawkins omitted the fact that Medtronic had recently received a letter of non-approval from the FDA "stating that AMPLIFY would not be approved," and that the omission was material. (Compl. ¶ 74.)

There is no general duty to disclose under the securities laws. *KV Pharm. Co.*, 679 F.3d at 984 ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5." (citing *Basic*, 485 U.S. at 239 n.17)). However, some omissions can be actionable because, "even absent a duty to speak, a party who discloses material facts in connection

[6] Defendants also argue that the 10-Q statements are not false statements because "disagreements over study design and statistical analysis are insufficient to allege a materially false statement." *See In re Adolor Corp. Sec. Litig*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009); *see also In re Rigel Pharm., Inc. Sec. Litig.*, Civ. No. 09-00546, 2010 WL 8816155 (N.D. Cal. Aug. 24, 2010), *aff'd*, 697 F.3d 869 (9th Cir. 2012). The Court need not address this argument because it determines that these statements are not materially false because they are puffing statements.

with securities transactions assume[s] a duty to speak fully and truthfully **on those subjects**." *In re K-tel Int'l*, 300 F.3d at 898 (emphasis added); *see also KV Pharm. Co.*, 679 F.3d at 983 ("Having chosen to represent it was in material compliance with FDA regulations and cGMP, KV was obligated to make a full disclosure of any material facts," because "a party with no duty to speak on a particular topic must nevertheless make a full disclosure when it chooses to speak"); *see also Freedman*, 2014 WL 910326 at *11 ("where the Defendants chose to speak on the company's interactions with the FDA, they had a duty not to make inaccurate, incomplete or misleading disclosures"). Plaintiffs argue that Hawkins, having chosen to comment on Medtronic's progress with the FDA on the approval of AMPLIFY, had a duty to make a full disclosure and should have disclosed Medtronic's recent receipt of a non-approval letter.

Defendants do not dispute Plaintiffs' assertion that Hawkins' discussion of AMPLIFY's status with the FDA invoked a duty to disclose material information about that process.[7] Rather, Defendants argue that Plaintiffs "mischaracter[ized] . . . the disclosure . . . for the purpose of trying to create the impression of a misstatement," claiming that the FDA notice to which Plaintiffs point as a material omission was not an outright rejection, but rather stated only that the FDA would not approve AMPLIFY at

[7] In its opening memorandum in support of its motion to dismiss, Defendants argued only that Hawkins' statement is not actionable because it was literally true: Medtronic **was** "continuing to work with the FDA to figure out where" the FDA was on the AMPLIFY approval. This argument misunderstands the nature of Plaintiffs' allegation with regard to this statement – they argue that this statement was materially misleading because of what it did not say, not that it was facially false.

that time and requesting more information. (Medtronic Defs.' Reply ("Medtronic Reply") at 2, Apr. 18, 2014, Docket No. 69.)[8] But the import of the FDA's letter is a factual question which would be premature to resolve at this stage. Plaintiffs allege that the day Medtronic disclosed the FDA's non-approval letter in the 10-Q, investment news outlets began issuing reports suggesting that the letter could put INFUSE sales at risk. (Compl. ¶¶ 80-81.) It is plausible that the FDA's non-approval notice was enough of a negative indication of AMPLIFY's prospective approval or enough of a setback that it would have been material to investors.

Defendants also argue that an omission about a product that would add only "incremental revenues to a product segment that never amounted to more than 5% of Medtronic's overall revenues is simply not material as a matter of law." (Medtronic Reply at 2 (citing *In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 29 (1st Cir. 2012).) But this argument confuses the focus of the materiality inquiry – whether a piece of information would be material to investors is not necessarily the same as whether the revenues to which the information relates would be material in comparison to the company's overall revenue.[9] Given Plaintiffs' allegations that when Medtronic did

[8] The Court notes that the Local Rules in this district do not permit parties' reply memoranda to "raise new grounds for relief or present matters that do not relate to the opposing party's response." D. Minn. L.R. 7.1(c)(3)(B). The Court construes these arguments as adequately relating to Plaintiffs' response to Defendants' opening memorandum in support of their motion to dismiss and thus considers them.

[9] Furthermore, the only support for Medtronic's argument was a case in which the First Circuit found that an event for which there was $100 million at stake was not material enough when the company's projected revenues were more than $8 billion, observing that "an

(Footnote continued on next page.)

disclose the FDA non-approval notice, its stock dropped by more than one dollar in a day, (*see* Compl. ¶¶ 82, 140), it is plausible that negative news from the FDA regarding AMPLIFY's approval would be material to investors because it could have mistakenly led them to believe that AMPLIFY's approval (which was never obtained) was on track. (*See also id.* ¶ 80 (detailing news reports from day of third quarter 2011 10-Q noting that "AMPLIFY Non-Approvable Letter Puts InFuse Sales At Risk").) *Cf. In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 564-65 (S.D.N.Y. 2011) (holding that presentation in conference call informing investors of receipt of FDA approvable letter, in which FDA stated that "no additional trial in obesity has been requested," was material omission where investor could have interpreted statement as meaning that "the FDA had made no other requests and/or that the approval process was on track without any major concerns" when FDA had concerns and had requested an independent formal assessment on one issue). The Court thus concludes that Plaintiffs have plausibly alleged that Hawkins' statements to investors in the February 22, 2011 conference call about the status of AMPLIFY with the FDA were materially misleading such that investors would have relied upon them.

(Footnote continued.)

undisclosed speculative chance of an event that affects only a very small proportion of revenues is not material." *In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d at 29. Here, assuming Defendants' estimate that AMPLIFY's product segment amounted to less than 5% of Medtronic's sales, that percentage is significantly higher than that in *In re Boston Scientific*, which was approximately one percent, and Defendants do not argue that this circumstance involves an "undisclosed speculative chance."

The Court turns to whether Plaintiffs have adequately alleged scienter with regard to this statement. On this issue, Defendants argue only that Plaintiffs fail to allege how Hawkins' statement that Medtronic was continuing to work with the FDA was false. Defendants do not otherwise challenge the adequacy of Plaintiffs' allegations regarding Hawkins' knowledge of this material omission. Taking "all of the facts alleged . . . collectively," the Court concludes that Plaintiffs have alleged facts which "give rise to a strong inference of scienter." *Tellabs*, 551 U.S. at 323. Plaintiffs allege that Hawkins had knowledge that Medtronic had received the FDA's non-approval letter at the time he responded to the analyst's question in the conference call. (Compl. ¶¶ 73-74 ("This statement was knowingly materially false and misleading because . . . the Company had received a letter from the FDA before January 28, 2011").) Plaintiffs have also alleged that Medtronic did disclose the non-approval letter on March 9, 2011, and that investors reacted swiftly, issuing news reports suggesting that the letter might put INFUSE sales at risk and that "many investors had been clinging to the hope that an approval of Amplify would help [Medtronic] to revitalize its biologics business and its broader spine surgery franchise." (*Id.* ¶¶ 80-81.) These allegations support the inference that Hawkins knew that the non-approval would create waves among investors and that the stakes were high, such that Hawkins had an "unusual or heightened motive," *In re K-tel Int'l*, 300 F.3d at 894, to delay disclosing the non-approval as long as possible. The Court therefore concludes that Plaintiffs' allegations support a strong inference that Hawkins' alleged omission was reckless or knowing. *Cf. In re Sanofi-Aventis*, 774 F. Supp. 2d at 571 (finding allegations were "sufficient to raise a strong inference that

sanofi's alleged omission constituted recklessness" where "Plaintiffs have specifically alleged that sanofi and the individual defendants who were speakers had either knowledge of or access to the omitted facts"). The Court concludes that Plaintiffs have stated a claim for violation of Section 10(b) and Rule 10b-5(b) on the basis of Hawkins' statements regarding AMPLIFY and will thus deny Defendants' motion to dismiss in this respect.

3. Denials of Link Between INFUSE and Retrograde Ejaculation

The third set of statements Plaintiffs allege amount to violations of Rule 10b-5(b) involve statements made by a Medtronic spokesperson and by Defendant Zdeblick in response to the new studies indicating a link between INFUSE and retrograde ejaculation. After the New York Times published an article about new research suggesting a link between INFUSE and retrograde ejaculation, it published a response to the article from Zdeblick, in which he said that the new "study was of limited value because it reflected the results of a retrospective look at patients rather than a clinical trial" and that "such reports 'are notorious for being misleading.'" (Compl. ¶ 93.) The Star Tribune also quoted Zdeblick as saying in response to the study that it was "interesting, [but] a single publication in the medical literature does not constitute a 'truth.' Retrospective trials are notorious for being misleading," and that the study has "'numerous flaws'" but its "findings are nonetheless in line with other Infuse studies." (*Id.* ¶ 97 (alteration in original).) The Minneapolis Star Tribune quoted Medtronic spokeswoman Marybeth Thorsgaard as saying "that in the original study that supported FDA approval of Infuse,

infertility problems were not common enough to be statistically linked to the product." (*Id.* ¶ 96.) Plaintiffs allege that these statements were materially false because Medtronic and Zdeblick knew that there was a statistically significant link between retrograde ejaculation and INFUSE, pointing to a PowerPoint from 2001 uncovered in the Senate investigation, which listed a 10.3% incidence of retrograde ejaculation among INFUSE patients, which the PowerPoint noted was "[s]tatistically different from control." (*Id.* ¶ 99.) The Court will consider each of these statements in turn.

a. Zdeblick's Statements

Zdeblick argues that his email statements in response to the new study are not actionable because he merely expressed his disagreement with the quality and type of the new study, which he argues does not amount to a materially false statement. (Def. Zdeblick's Mem. in Supp. of Mot. to Dismiss at 15, Jan. 15, 2014, Docket No. 42 (citing *In re Rigel Pharm., Inc. Sec. Litig.*, Civ. No. 09-00546, 2010 WL 8816155, at *10 (N.D. Cal. Aug. 24, 2010), *aff'd*, 697 F.3d 869 (9th Cir. 2012)).) More fundamentally, he argues that none of his statements are actually false.[10] The Court concludes that none of his statements are plausibly considered to be false or misleading. Two of Zdeblick's statements are no more than general commentary on the value and credibility of medical studies in certain circumstances: that retrospective studies are "notorious for being

[10] Zdeblick also argues that his statement is protected by the First Amendment, and that even though Plaintiffs are private actors, their "right to bring [this] action arises from congressional statute and SEC regulation." (Zdeblick's Mem. in Supp. of Mot. to Dismiss at 22, Jan. 15, 2014, Docket No. 42.) The Court declines to reach this argument as it dismisses Count I against Zdeblick on other grounds.

misleading," and that "a single publication in the medical literature does not constitute a truth." (Compl. ¶¶ 93, 97.) Plaintiffs wisely do not explicitly allege that these statements are false, and no such inference could be drawn from them. Zdeblick's statements that the new study was of limited value on account of its methodology and that it contained numerous flaws are also not properly considered false or misleading for the purposes of securities fraud, as they merely express his disagreement over study design, methodology, and analysis. *Cf. In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) ("The fact that Variant's statistician reached a different conclusion than Adolor does not establish that Adolor's interpretation of the results were false or misleading."); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim."); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966-67 (D. Md. 1995) (statements regarding efficacy of a drug were not false or misleading, even though FDA staffers had concerns about the study design during the review process, as "[m]edical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results"). Finally, to the extent that all of his statements, taken as a whole, could be considered misleading because they have the total effect of discrediting the new study, that possibility is foreclosed by the fact that Zdeblick's final quoted statement is that the new study's findings are "in line" with results from other INFUSE studies. (Compl. ¶ 97.) This undermines any inference that his statements could be misleading to investors, and makes any inference that he had the requisite scienter to mislead less

strong than the inference that he was offering sincere, balanced commentary on a study in his field. The Court will therefore grant the motion dismiss with respect to Zdeblick's statements.

b. Medtronic Spokesperson's Statements

Medtronic argues that its spokesperson's statement was not false or misleading because, pointing to the original article, the next two sentences quote her as stating that "Medtronic disclosed these complications in its FDA submissions and on its product labeling." (Medtronic Defs.' Mem. in Supp. of Mot. to Dismiss at 20, Jan. 15, 2014, Docket No. 56 (quoting Carter Decl., Ex. 16).)[11] It also argues that it has disclosed links between INFUSE and retrograde ejaculation to the FDA since its approval in 2002, making any commentary on the link not actionable. Like Zdeblick, Medtronic argues that "it is well established that disagreements among medical professionals regarding the interpretation of data after the fact does not constitute a materially false or misleading statement for the purposes of Section 10(b)." (*Id.* (citing *In re Rigel Pharm.*, 2010 WL 8816155, at *10 ("[D]isagreements over study design and statistical analysis are insufficient to allege a materially false statement.")).) Medtronic adds in its Reply that the 2001 PowerPoint does not show a statistically significant link between INFUSE and retrograde ejaculation, but rather a link between retrograde ejaculation and one type of

[11] Like this one, some of Medtronic's arguments refer to documents that were not included in or attached to Plaintiffs' pleadings. Plaintiffs argue that the Court should not consider these documents. The Court need not resolve this issue because it does not rely on these documents in reaching the conclusions in this Order.

surgical procedure used with INFUSE as compared to a different surgical method.[12] Finally, Medtronic argues that the Yale Study undermines Plaintiffs' argument because, after reviewing all of the available literature, it found no statistically significant connection between INFUSE and retrograde ejaculation. (Medtronic Reply at 4.)

The Court concludes that Thorsgaard's statements are not false or misleading, and are therefore not actionable, for a reason not raised by Medtronic. Thorsgaard's exact words are that "**in the original study** that supported FDA approval of Infuse, infertility problems were not common enough to be statistically linked to the product." (Compl. ¶ 96 (emphasis added).) Plaintiffs' argument that this statement was false is only that a PowerPoint Zdeblick presented to Medtronic in 2001 indicated that there was a statistically significant link between retrograde ejaculation and INFUSE. But nowhere do Plaintiffs allege that the data Zdeblick presented to Medtronic in the 2001 PowerPoint is the same data or the basis of the study to which Thorsgaard was referring when she said "original study that supported FDA approval." (*Id.*) It may be the case that the 2001 PowerPoint presented data that was part of the "original study," but Plaintiffs have not so alleged. Without that connection, the Court cannot draw a plausible inference that Thorsgaard's statement is false, as she could have been referring to a different set of data or study, in which there was no statistical link between retrograde ejaculation and

[12] This argument, raised first in Medtronic's reply memorandum, would typically not be permissible under this district's Local Rules unless it was deemed to be responsive to an argument in Plaintiffs' opposition. *See* D. Minn. L.R. 7.1(c)(3)(B). Because the Court concludes that this claim must be dismissed on other grounds, the Court does not determine whether this argument is properly considered.

INFUSE. Plaintiffs may contest the **veracity** of such a study, but that would not render Thorsgaard's statement to be false.[13] Because this deficiency in Plaintiffs' allegations is one that could possibly be cured by more specific pleadings, the Court will dismiss Plaintiffs' claims without prejudice with respect to this statement.

III. SCHEME LIABILITY

In addition to their claims for material false statements under Rule 10b-5(b), Plaintiffs also bring a claim for scheme or course of conduct liability under Rule 10b-5(a) and 10b-5(c) against all Defendants. Rule 10b–5(a) prohibits "any device, scheme or artifice to defraud," and Rule 10b–5(c) prohibits "any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person," both in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b–5(a), (c). Claims brought under Rules 10b–5(a) and (c) are generally referred to as "scheme liability" claims, and are distinct from claims under Rule 10b-5(b) because they are based on deceptive conduct rather than deceptive statements. *See KV Pharm. Co.*, 679 F.3d at

[13] Plaintiffs argue that Thorsgaard's statement is, at a minimum, an actionable misstatement even if it is a statement of belief, citing to the Ninth Circuit for the proposition that "[a] statement of belief is a "'factual' misstatement actionable under Section 10(b) if (1) the statement is not actually believed, (2) there is no reasonable basis for the belief, or (3) the speaker is aware of undisclosed facts tending seriously to undermine the statement's accuracy." *Reese v. Malone*, 747 F.3d 557, 579 (9th Cir. 2014). The Court's conclusion, however, does not rest on characterizing Thorsgaard's statement as a belief, but rather on the conclusions that Thorsgaard's statement is a more precise statement than Plaintiffs make it out to be – restating the findings of an earlier study rather than contesting the truth of the new study – and that Plaintiffs have failed to allege that this specific restatement of the earlier study's findings was false because it is not clear what earlier study Thorsgaard referred to or whether it was the same study results as presented in the 2001 PowerPoint.

986. To state a claim under Rule 10b-5(a) and (c) for scheme liability, "a plaintiff must allege that the defendant (1) committed a deceptive or manipulative act (2) with scienter, (3) that the act affected the market for securities or was otherwise in connection with their purchase or sale, and (4) that defendants' actions caused the plaintiffs' injuries." *In re Parmalat Sec. Litig.*, 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006).

"Although the heightened pleading requirements of the PSLRA do not apply to claims under Rule 10b–5(a) and (c), such claims must be pleaded with specificity under Rule 9(b)." *Id.* Accordingly, a plaintiff must specify with particularity "what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities at issue." *Id.*; *see also KV Pharm Co.*, 679 F.3d at 986.

A. Plaintiffs' Allegations

Plaintiffs' scheme liability claim is based on their allegations that Medtronic, its officers, and its consulting physicians manipulated early clinical studies of INFUSE in order to conceal its significant safety risks. Plaintiffs allege that Medtronic had set a corporate goal of INFUSE becoming the standard of care in spinal fusion, but that in order to do that it needed clinical studies showing that INFUSE achieved better results with fewer adverse side effects compared to traditional bone graft procedures. (Compl. ¶ 9.) Plaintiffs allege that in order to achieve this, Medtronic, the Individual Defendants, and the Consultant Defendants designed clinical trials in a way that elicited biased results, concealed adverse side effects observed in the trials, and overstated apparent

disadvantages of other bone graft procedures. (Compl. ¶¶ 16, 108, 163.) Furthermore, Plaintiffs allege that Medtronic personnel edited journal articles published by the physician consultants and failed to disclose that it paid them millions of dollars during the drafting process. (Compl. ¶¶17, 163; *see also id.* ¶ 32 (Senate Staff Report making similar report).) Plaintiffs allege that these efforts were effective: as a result of the low indications of adverse side effects, doctors began using INFUSE for more and different types of procedures, and "'[s]ales and revenue growth was explosive,'" (*id.* ¶ 19), but that when the scheme was revealed, Medtronic's stock price declined (Pls.' Mem. in Opp'n to Mot. to Dismiss at 28 (quoting Compl. ¶ 29, 33-34, 137-145).)

B. Consultant Defendants

The Consultant Defendants each move to dismiss, each making arguments about the adequacy of Plaintiffs' pleadings, but also arguing that Plaintiffs' scheme liability claims are barred by the statute of limitations. Because the Court concludes that the statute of limitations bars Plaintiffs' claims against the Consultant Defendants, the Court addresses this issue first and does not reach the Consultant Defendants' arguments about the adequacy of Plaintiffs' allegations.

Under 28 U.S.C. § 1658, claims alleging fraud or deceit under the Exchange Act must be brought within the earlier of either two years "after the discovery of the facts constituting the violation" or five years "after such violation." 28 U.S.C. § 1658(b). Plaintiffs filed this action on June 27, 2013 (*see* Compl., June 27, 2013, Docket No. 1), so in order to be timely, Plaintiffs must not have discovered the "facts constituting the

violation" before June 27, 2011, and the last alleged violation must not have occurred before June 27, 2008. Consultant Defendants argue that the action is untimely under either measure. They argue that, at a minimum, Plaintiffs discovered the facts underlying the action on May 25, 2011, when The Spine Journal first published the new study exposing the problems with INFUSE and the media reports that followed. They also argue that Plaintiffs' scheme or course of conduct allegations include no actionable conduct by Burkus, Boden, or Zdeblick after June 27, 2008.

The Court concludes that Plaintiffs brought this action within two years of its discovery of the facts constituting the violations it alleges, because it was not until at least the June 28, 2011 issue of The Spine Journal that Medtronic's involvement in promulgating the early INFUSE studies and the physician consultants' conflicts of interest were revealed.[14] However, the five year statute of repose poses a problem for Plaintiffs' allegations against the physician consultants. In the context of a claim for scheme or course of conduct liability, "the five-year statute of repose runs from the date

[14] In *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 648 (2010), the Supreme Court interpreted "discovery" in 28 U.S.C § 1658(b) to "encompass[] . . . those facts the plaintiff actually knew [and] those facts a reasonably diligent plaintiff would have known," and held that facts supporting an inference of scienter must have been discovered in order for the two-year statute of limitations to accrue. *Id.* at 648-49. *Merck* has been interpreted to instruct also that "a fact is not deemed "discovered" until a reasonably diligent plaintiff would have sufficient information about that fact to adequately plead it in a complaint." *City of Pontiac Gen. Employees' Ret. Sys. v. MBIA, Inc.*, 637 F.3d 169, 175 (2d Cir. 2011). Plaintiffs' scheme allegations center on the concerted manipulation of studies **between** Medtronic and the physician consultants, which they do not plead was revealed until after June 27, 2011, beginning with the June 28 issue of The Spine Journal. Plaintiffs allege that the May 25, 2011 issue of The Spine Journal revealed that the frequency of adverse side effects was greater than previous INFUSE studies had indicated, but do not allege that that issue documented the relationship between Medtronic and the physician consultants which Plaintiffs allege under their scheme liability claim.

of the last fraudulent misrepresentation, and the unique role of the defendant in this particular scheme does not affect this rule." *Quaak v. Dexia S.A.*, 357 F. Supp. 2d 330, 338 (D. Mass. 2005). Plaintiffs argue that the physician consultants' involvement continued past June 2008 and through 2010, pointing to several acts by the Consultant Defendants which they argue were the last act they allege that was part of the violation:

- The physician consultants continued receiving payments from Medtronic through 2010. (Compl. ¶¶ 53-55.)
- Three studies with Defendant Burkus listed as an author, for which Plaintiffs allege that defendants "knew, but failed to disclose, that Medtronic and its executives and employees participated in drafting or editing" and included in a list of studies with regard to which Plaintiffs allege that "nearly all, if not all, failed to disclose adverse events known to or recklessly disregard by Medtronic and author physicians." (*Id.* ¶ 87(b).)
- Defendant Boden received payments from Medtronic of over $28 million "by the end of 2008." (*Id.* ¶ 87(j).)
- Zdeblick made false and misleading statements in an email response to the Star Tribune and the New York Times on May 25, 2011. (*Id.* ¶ 93-97.)

In order for any of these statements or acts to constitute the last "violation" from which five years is counted under 28 U.S.C. § 1658(b)(2), they must be adequately pled as violations under Rule 10b-5 that would actually give rise to liability. *See Asdar Grp. v. Pillsbury, Madison & Sutro*, 99 F.3d 289, 294-95 (9th Cir. 1996) (observing that pre-PSLRA three-year limitation under former 15 U.S.C. § 78i(e) statute of limitations "ordinarily begins to run under each section when a person commits the act that **gives rise to liability** under that section"). This makes sense, because otherwise a plaintiff could indefinitely extend the applicable statute of limitations under section 1658(b) by pleading frivolous, implausible violations that do not meet the heightened pleading

standards but which are recent enough to bring the rest of their alleged violations within the statute of limitations.

The Court concludes that none of these alleged violations since June 2008 meet the requisite pleading standards for the elements of a claim for scheme or course of conduct liability under Rule 10b-5(a) or (c). First, Plaintiffs fail to adequately allege that the Consultant Defendants' receipt of payments from Medtronic lasting until 2010 was done with the requisite scienter or intent to participate in a scheme to defraud. Plaintiffs' allegations that the Consultant Defendants were paid by Medtronic through 2010 do not state that they were paid in exchange for their willingness to help Medtronic conceal the dangers of INFUSE or the inadequacies of prior studies. (*See, e.g.*, Compl. ¶¶ 54 (stating only that the "Senate Report reflects that Burkus received over $6 million from Medtronic through 2010," without connection or allegation as to reason for payment).) It is a reasonable inference that medical device companies frequently engage medical researcher consultants for pay. Thus, without allegations that these fees were disproportionate to the work that the Consultant Defendants performed, Plaintiffs do not allege facts supporting an inference of scienter that is "at least as compelling as any opposing inference" of the "plausible, nonculpable explanation[]" that these payments were for valid services, not for agreement to participate in a scheme to defraud. *Tellabs*, 551 U.S. at 324; *see also In re Marsh & Mclennan Companies, Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 489 (S.D.N.Y. 2006) ("Although an auditor's receipt of consulting fees inordinately disproportionate to its auditing fees may give rise to a proper inference of motive, allegations of payment for services rendered are generally inadequate." (citing *In*

re Global Crossing, Ltd. Sec. Litig., 322 F. Supp. 2d 319, 346 (S.D.N.Y. 2004) (finding an inference of motive where an auditor received consulting fees nearly six times greater than its auditing fees))); *cf. United States v. Grimm*, 738 F.3d 498, 503 (2d Cir. 2013) ("And since the government adduced no evidence of overt acts after July 27, 2004 other than the interest payments, 'there is no evidence that any concerted activity posing the special societal dangers of conspiracy is still taking place.'").

Second, the three articles from 2009 in which Burkus was listed as an author are included in a list in the complaint regarding which Plaintiffs allege that "defendants knew, but failed to disclose, that Medtronic and its executives and employees participated in drafting or editing the following articles that **nearly all, if not all,** failed to disclose adverse events known to or recklessly disregarded by Medtronic and the author physicians." (Compl. ¶ 87(b).) This allegation does not adequately plead scienter, because, at a minimum, it does not even clearly allege that the three studies which Burkus authored actually failed to disclose adverse events, given that the allegation leaves open the possibility that not all of the articles on the list do so. Without greater specificity or certainty, the Court cannot draw a plausible inference that those three articles omitted material information, much less that Burkus intended to do so.

Third, Plaintiffs' allegations about Boden's receipt of funds in late 2008 fails for the same reasons as their allegations about the Consultant Defendants' receipt of payments through 2010 – Plaintiffs do not include allegations that make the inference that the $28 million was paid in exchange for Boden's assistance in furthering a scheme to conceal problems with INFUSE stronger than that the $28 million was payment for

valid services. *See In re Marsh & Mclennan Cos.*, 501 F. Supp. 2d at 489. Furthermore, Plaintiffs' allegations about this $28 million are inconsistent: they allege in paragraph 87(j) that his fees were "over $28 million by the end of 2008," (Compl. ¶ 87(j) (emphasis omitted)),[15] but in paragraph 55 they allege that he "received over $28 million from Medtronic through 2010," (*id.* ¶ 55). This inconsistency undermines the strength of any inference that could be drawn in favor of scienter.

Finally, Plaintiffs point to Zdeblick's May 2011 statements to the Star Tribune and the New York Times. But the Court has already concluded that these statements were not false, and thus not actionable under Rule 10(b). They therefore do not amount to a "violation" of "fraud, deceit, manipulation, or contrivance" under 28 U.S.C. § 1658(b)(2), and do not bring Plaintiffs' scheme allegations against Zdeblick within the five-year statute of repose. The Court concludes that Plaintiffs' claims for scheme and course of conduct liability against the Consultant Defendants are barred by 28 U.S.C. § 1658(b) and will therefore grant Defendants Boden, Burkus, and Zdeblick's motion to dismiss with regard to that claim. The Court will dismiss Count II against the Consultant Defendants without prejudice because the deficiencies described above are ones that could be cured by more specific allegations.

[15] Plaintiffs' allegation that Boden's payments "catapulted from $704,000 through 2004 to over $28 million by the end of 2008," (Compl. ¶ 87(j)), also does not establish a strong inference of scienter, as that increase could reflect that Boden was performing more work for Medtronic or the value of his work to Medtronic increased for other reasons.

C. Medtronic Defendants

The Medtronic Defendants do not present a statute of limitations defense, which counsel for Medtronic confirmed at oral argument. Instead, Medtronic argues that Plaintiffs' scheme allegations must fail because they are based on the same alleged falsity and deception as Plaintiffs' false and misleading statements claims under Rule 10b-5(b).

The Eighth Circuit has held that a "scheme liability claim must be based on conduct beyond misrepresentations or omissions actionable under Rule 10b–5(b)." *KV Pharm. Co.*, 679 F.3d at 987 (quoting *WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1057 (9th Cir. 2011); *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 177 (2d Cir. 2005) ("[a] defendant may only be liable as part of a fraudulent scheme based upon misrepresentations and omissions under Rules 10b–5(a) or (c) when the scheme also encompasses conduct beyond those misrepresentations or omissions")). As a result, in *KV Pharmaceutical*, the Eighth Circuit affirmed the dismissal of the plaintiffs' scheme liability claims where:

> [o]ther than incorporating the allegations regarding the misrepresentations and omissions, the investors only generally alleged Van Vliet and Bleser 'employed devices, schemes, and artifices to defraud[,] . . . engaged and participated in a continuous course of conduct to conceal adverse material information about the business [and] engaged in transactions, practices and a course of conduct that operated as a fraud and deceit upon the purchasers of KV securities.'

Id. at 986. Defendants also point to the Supreme Court's decision in *Stoneridge Investment Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148 (2008), which affirmed the Eighth Circuit's decision in *In re Charter Communications, Inc., Securities Litigation*, 443 F.3d 987, 990 (8th Cir. 2006), arguing that Plaintiffs' scheme liability claims are

"precisely the type" rejected in both cases. (Medtronic Defs.' Mem. in Supp. of Mot. to Dismiss at 34.) They point to a portion of *Stoneridge* in which the Supreme Court explains why the scheme liability claims there failed to allege reliance:

> In effect petitioner contends that in an efficient market investors rely not only upon the public statements relating to a security but also upon the transactions those statements reflect. Were this concept of reliance to be adopted, the implied cause of action would reach the whole marketplace in which the issuing company does business; and there is no authority for this rule.

Stoneridge, 552 U.S. at 160. In this quote the Supreme Court explains why **conduct**, without connection to a public statement, is not entitled to the presumption of reliance on account of the fraud on the market theory. It is not clear, nor do Defendants explain, how this observation applies to the allegations here, where Plaintiffs have alleged that Defendants' conduct – manipulating INFUSE clinical studies to overstate its efficacy and understate its risks – itself misled investors by inflating confidence in INFUSE and its sales.

It appears that Defendants' argument is that Plaintiffs' scheme liability claim must fail because it cannot be based on the same allegations as their false statement allegations under Rule 10b-5(b), but that it also cannot be disconnected from the public's awareness such that investors would not have known or made decisions on the basis of the conduct. Even if Defendants are correct that plaintiffs alleging scheme or course of conduct liability under Rule 10b-5(a) and (c) are limited to such a narrow target in order to successfully state a claim, the Court finds that Plaintiffs' allegations here adequately hit the target.

Plaintiffs' scheme and course of conduct claims are distinct from their false statement claims. Their scheme liability theory is that Defendants' **actions** in manipulating the studies (as opposed to their statements) – had the effect of artificially propping up Medtronic stock prices on account of confidence in INFUSE sales. This is distinct from their false statement claims, which allege that Defendants artificially propped up Medtronic stock prices with false statements downplaying the truth or validity of the accusations against INFUSE and Medtronic that began to unfold in 2011.

Thus, this case is distinct from *Stoneridge*, where the Supreme Court rejected scheme liability claim because it was based on conduct that was presented to the public only through a public statement, which happened to be the basis of the plaintiffs' false statement claim. *Stoneridge*, 552 U.S. at 153-55. The Supreme Court rejected this claim on the grounds that the scheme liability claim could not have influenced investor choices on its own because the public only became aware of it through the false statement, which was the basis of a separate claim. *Id.* at 160-61. Here, as explained above, the basis of the scheme liability claim is distinct from the false statements following the publications in The Spine Journal, and Plaintiffs have adequately alleged reliance for the scheme and conduct allegations, independent of the false statement allegations. In particular contrast here, the conduct alleged had another way of reaching the public – through the studies published on INFUSE (*see* ¶ 87(b)), which are not the basis of Plaintiffs' Rule 10b-5(b) claim. For the same reasons, this case is also distinct from *KV Pharmaceutical Co.*, where the Eighth Circuit affirmed dismissal of scheme liability claims for conduct that ultimately was reflected in a public statement, which was the basis of the direct false

statement claims. *See* 679 F.3d at 987 (affirming district court, which concluded "that misrepresentation claims under Rule 10b–5(b) cannot simply be recast as scheme liability claims under Rules 10b–5(a) and (c) unless a plaintiff alleges a defendant participated in a scheme that encompassed conduct beyond misrepresentation" (internal quotations omitted)).[16]

Medtronic also argues that scheme liability is "typically reserved for 'secondary violators,' such as law firms, accounting firms, or investment banks who are alleged to have participated in a scheme separate and apart from false or misleading statements made by a company or primary violator." (Medtronic Defs.' Mem. in Supp. of Mot. to Dismiss at 34.) But the cases to which it cites for this proposition indicate only that scheme liability claims **may** be brought against such secondary violators, not that they may **only** be brought against secondary violators. *See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 191 (1994) ("The absence of § 10(b)

[16] Defendants also point to *Stichting Pensioenfonds ABP v. Merck & Co., Inc.*, Civ. No. 05-5060, 2012 WL 3235783 (D.N.J. Aug. 1, 2012), in support of their position. There, plaintiffs' scheme liability claim was on the basis of allegations that a pharmaceutical company and its employees manipulated, revised, and omitted clinical trial data in order to obscure adverse effects of Vioxx. *Id.* at *8. The court rejected the claim, observing that "the complained-of fraud on investors resulting from Defendants' alleged manipulation of test data and design of studies to obscure what Plaintiff maintains was Vioxx's negative CV safety profile stems not from the performance of the studies themselves as deceptive acts but rather from Defendants' ultimate communication of materially misleading information about Vioxx to the public." *Id.* at *8-10. Beyond the fact that this unpublished opinion is not binding on the Court, (*see id.* at *1 (observing that "the Court writes only for the parties")), the Court concludes that it is not persuasive here, where the false statement claims are not the direct communication about INFUSE to the public (the court in *Stichting* declined to describe the factual background, but it appears that there the false statements were optimistic statements referencing studies which plaintiffs alleged were unreliable, *see id.* at *1, *5), but the later statements continuing to defend the earlier studies even after the earlier studies' alleged flaws had been revealed. This is a subtle, but sufficient, distinction.

aiding and abetting liability does not mean that secondary actors in the securities markets are always free from liability under the securities Acts."); *see also In re Charter Commc'ns, Inc., Sec. Litig.*, 443 F.3d 987, 991 (8th Cir. 2006) (quoting same passage from *Central Bank*), *aff'd and remanded sub nom. Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148 (2008). Medtronic has not pointed to authority indicating that a scheme liability claim may **not** be brought against the principal entity or its employees.

Finally, Medtronic argues that, "[b]ecause the adverse events are fully disclosed on the [Instructions for Use] and FDA website, Plaintiffs cannot demonstrate the essential elements of scienter, causation, or reliance." (Medtronic Defs.' Mem. in Supp. of Mot. to Dismiss at 35.) To base dismissal on this argument, the Court would need to investigate and compare the disclosures on the relevant websites with the findings of all the articles Plaintiffs cite as having been manipulated. Then, if the websites in fact disclose all of the adverse side effects Plaintiffs allege were concealed in the studies, the Court would need to determine whether investors would nevertheless have relied on the studies and not cross-checked against the websites. These inquiries are suitable for trial or summary judgment, but are too fact-dependent to be resolved at the pleading stage. The Court finds that Plaintiffs adequately allege scienter, causation, and reliance. With regard to scienter, Plaintiffs allege that the "scheme and course of conduct" was "intended to, and did, drive sales of INFUSE and with it, Medtronic's profits and share price." (Compl. ¶ 165.) In light of Medtronic's allegations that its goal was to make INFUSE the standard of care for bone growth and the need for clinical studies emphasizing its

effectiveness without side effects, these allegations give rise to a strong inference of scienter. (*See id.* ¶¶ 3-4.)[17]

With regard to causation and reliance, Plaintiffs allege that Medtronic's scheme to downplay risks in the clinical studies led to increased usage of INFUSE and "explosive" sales and revenue growth, (*id.* ¶ 19), and allege multiple examples of investor-aimed publications heeding reports on the efficacy and safety of INFUSE (*see, e.g.*, *id.* ¶¶ 12-14, 27, 32, 34.) Taken together, these pleadings adequately allege that investors would have relied on the strength of the early INFUSE studies in choosing to invest in Medtronic.

The Court thus concludes that none of Medtronic's arguments warrant dismissal of Plaintiffs' scheme liability claim, so the Court will deny the motion to dismiss with regard to Count II against the Medtronic Defendants.[18]

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[17] To the extent that Medtronic argues that Plaintiffs fail to adequately allege that the Medtronic Defendants intended to deceive **the putative class of shareholders**, Plaintiffs correctly explain that they need not allege that a defendant intended to defraud a **specific** person or group, but rather only that they intended to defraud **a** person or group. (Pls.' Mem. in Opp'n to Mot. to Dismiss at 30 (citing *United States v. O'Hagan*, 521 U.S. 642, 656 (1997) ("a fraud or deceit can be practiced on one person, with resultant harm to another person or group of persons").)

[18] In a footnote in their Reply Memorandum, Defendants argue that Plaintiffs fail to adequately plead specific violations by Defendants Kuntz, Treharne, Bearcroft, and Yahiro. Minnesota Local Rule 7.1(c)(3)(B) provides that "[a] reply memorandum must not raise new grounds for relief or present matters that do not relate to the opposing party's response." D. Minn. L.R. 7.1(c)(3)(B). Given the paucity of explanation for this argument, that it was made in a footnote, and that it is not responsive to Plaintiffs' opposition memorandum, it is not permitted by the Local Rules, and the Court declines to consider this argument. *Cf. United States v. Kerr*, 752 F.3d 206, 218 (2d Cir. 2014) ("Issues not sufficiently argued in the briefs are considered waived and normally will not be addressed . . . ." (internal quotations omitted)); *United States v. Jones*, 224 F.3d 621, 626 (7th Cir. 2000) ("Arguments that are not adequately

(Footnote continued on next page.)

IV. CONTROL PERSON LIABILITY

Section 20(a) of the Exchange Act "extends liability to those persons that control violators of Section 10(b)." *Stephenson v. Deutsche Bank AG*, 282 F. Supp. 2d 1032, 1059 (D. Minn. 2003); 15 U.S.C. § 78t(a). It states:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder 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). This section is "remedial and is to be construed liberally" and "has been interpreted as requiring only some indirect means of discipline or influence short of actual direction to hold a 'controlling person' liable." *Farley v. Henson*, 11 F.3d 827, 836 (8th Cir. 1993). Section 20(a), however, is not subject to the heightened pleading standards of either the Reform Act or Federal Rule of Civil Procedure 9(b). *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 396-97 (S.D.N.Y. 2003). Therefore, "naked allegations of control will typically suffice." *Stephenson*, 282 F. Supp. 2d at 1059-60 (alterations and internal quotations omitted).

To state a claim for control person liability, a plaintiff must prove: "(1) that a primary violator violated the federal securities laws; (2) that the alleged control person

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(Footnote continued.)

developed or supported are waived . . . ."); *Norton v. Sam's Club*, 145 F.3d 114, 117 (2d Cir. 1998) ("an argument made only in a footnote was inadequately raised").

actually exercised control over the general operations of the primary violator; and (3) that the alleged control person possessed – but did not necessarily exercise – the power to determine the specific acts or omissions upon which the underlying violation is predicated." *Lustgraaf v. Behrens*, 619 F.3d 867, 873-74 (8th Cir. 2010) (internal quotations omitted). "Culpable participation by the alleged control person in the primary violation is not part of a plaintiff's prima facie case," rather, "[i]f a plaintiff satisfies the prima facie burden, the burden shifts to the defendant to show that it 'acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.'" *Id.* (quoting 15 U.S.C. § 78t(a)); *see also Metge v. Baehler*, 762 F.2d 621, 631 (8th Cir. 1985). Section 20 claims are therefore "derivative" of "other claims under the Exchange Act, and without an underlying violation of the Exchange Act or any rule or regulation promulgated under its authority," a plaintiff cannot state a claim under Section 20." *MathStar, Inc. v. Tiberius Capital II, LLC*, 712 F. Supp. 2d 870, 882 (D. Minn. 2010).

Plaintiffs allege that each of the individual Medtronic Defendants "acted as a control person of the Company within the meaning of § 20(a)." (Compl. ¶ 167.) Defendants do not dispute this allegation, but rather argue that, because they contend that the underlying Exchange Act violations must fail, this claim too must be dismissed with prejudice. The Court has concluded, however, that at least some of Plaintiffs' claims must be permitted to proceed, including their claim for false statements based on Hawkins' statements regarding FDA progress on AMPLIFY and Plaintiffs' scheme

liability claim against the Medtronic Defendants. Thus, Plaintiffs' control person liability claim under Section 20(a) may also proceed with regard to those claims.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant Zdeblick's motion to dismiss [Docket No. 40] is **GRANTED**. Claims under Count I against Defendant Zdeblick are **DISMISSED with prejudice** and Claims under Count II against Defendant Zdeblick are **DISMISSED without prejudice**.

2. Defendant Boden's motion to dismiss [Docket No. 44] is **GRANTED**. Claims under Count II against Defendant Boden are **DISMISSED without prejudice**.

3. Defendant Burkus' motion to dismiss [Docket No. 48] is **GRANTED**. Claims under Count II against Defendant Burkus are **DISMISSED without prejudice**.

4. Defendants Medtronic, Hawkins, Ellis, Kuntz, Bearcroft, Treharne, and Yahiro's motion to dismiss [Docket No. 53] is **GRANTED in part** and **DENIED in part** as follows:

   a. The motion is **GRANTED** with respect to Count I against Defendants Ellis, Kuntz, Bearcroft, Treharne, and Yahiro. Claims under Count I against those Defendants are **DISMISSED with prejudice**.

   b. The motion is **GRANTED** with respect to Count I against Defendant Medtronic. Count I against Medtronic is **DISMISSED without prejudice.**

c. The motion is **DENIED** with respect to Count I against Defendant Hawkins.

d. The motion is **DENIED** with respect to Count II against Defendants Medtronic, Hawkins, Ellis, Kuntz, Bearcroft, Treharne, and Yahiro.

e. The motion is **DENIED** with respect to Count III.

DATED: September 29, 2014
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge