IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Barbara Forman, individually and on behalf of others similarly situated,	:	
	:	Case No. 1:17-cv-774
Plaintiff,	:	
	:	Judge Susan J. Dlott
v.	:	
	:	Order Granting Motion to Dismiss
Meridian Bioscience, Inc., *et al.*,	:	
	:	
Defendants.	:	

This matter is before the Court on Defendants' Motion to Dismiss (Doc. 32) this securities fraud case. Defendants move to dismiss on the grounds that Plaintiff cannot state a claim for relief under the Private Securities Litigation Reform Act ("PSLRA"). For the reasons that follow, the Court will **GRANT** the Motion to Dismiss.

I. FACTUAL ALLEGATIONS

A. Introduction

The well-pleaded facts in the Amended Complaint (Doc. 29) are considered to be true for purposes of this Motion to Dismiss. Court-appointed Lead Plaintiff Barbara Forman alleges claims on behalf of herself and a proposed class of persons and entities who purchased or acquired securities of Defendant Meridian Bioscience, Inc. between March 4, 2016 and October 23, 2017 ("the Class Period"). (Doc. 29 at PageID 178.) Meridian is a life sciences company which, among other things, develops, manufactures, sells, and distributes clinical diagnostic test kits. (*Id.*) It is a publicly-held company and its securities are registered with the SEC and traded on NASDAQ. (*Id.* at PageID 178–179.) Defendant John A. Kraeutler is the former CEO and Chairman of the Board of Directors of Meridian. Defendant Melissa A. Lueke has served as Meridian's Vice President, CFO, and Secretary since 2001, and she was appointed Executive

Vice President in 2009. (*Id.* at PageID 178.)

Plaintiff alleges generally that Meridian made misstatements about blood lead level testing systems manufactured by Magellan Biosciences, Inc., a company which Meridian acquired in March 2016. Plaintiff alleges that Meridian misstated the efficacy of the blood lead level testing systems and concealed known regulatory problems.

B. Meridian Business Difficulties in the Period Prior to March 24, 2016

In the period prior to the acquisition of Magellan, Plaintiff alleges that Meridian was facing a host of difficulties with its existing product lines. Plaintiff alleges that those difficulties, which are summarized in this subsection, created pressure for Meridian to secure future growth by acquiring a third-party company with an existing product line.

Meridian's business lines are split into two reporting segments, diagnostics and life sciences. (*Id.* at PageID 181.) Diagnostics provided 75% of Meridian's consolidated net revenues for fiscal year 2015. (*Id.* at PageID 182.) Meridian's diagnostics business was focused on non-molecular diagnostic products prior to March 24, 2016. Meridian had launched a molecular testing platform called illumigene in 2011, but it did not perform as well as expected due to market competition. (*Id.* at PageID 182–184.)

Also, in early 2016, Meridian acknowledged the upcoming expiration of its patents for its *H. pylori* products in May 2016. (*Id.* at PageID 187.) Meridian stated in its quarterly Form 10-Q report on February 9, 2016 that it "expect[ed] competition with respect to our *H. pylori* products to increase" and that the increased competition could lead to an adverse impact on prices, on the ability to maintain business at current prices, and on future revenues and gross profits. (*Id.*) Meridian made similar statements about the effect of the expiration of the *H. pylori* products in the 2016 Form 10-K it filed with the SEC on November 29, 2016. (*Id.* at PageID 188.)

Finally, Meridian had a low research and development budget, and a high dividend payout policy of 75% to 85%, that stunted its ability for organic growth. (*Id.*)

In early 2016, industry analysts were criticizing Meridian's performance, its narrow product field, and its high prices relative to competitors. (*Id.* at PageID 185–187.) Industry analysts suggested that Meridian make an acquisition to compel growth. (*Id.* at PageID 183–189.) Meridian, in fact, did acquire an outside company, Magellan, in March 2016. However, Plaintiff alleges that Meridian knew or learned, but did not reveal to the investing public, that Magellan's blood level testing systems did not work as intended with venous blood samples.

C. Magellan Biosciences, Inc. and Its LeadCare Products

Magellan Biosciences, Inc. and its wholly-owned subsidiary, Magellan Diagnostics, Inc. (jointly, "Magellan"), a company headquartered in Billerica, Massachusetts, manufacture systems to test lead levels in blood under the LeadCare name. (*Id.* at PageID 180, 190.) Amy Winslow was the President and CEO of Magellan starting in 2011. (*Id.* at PageID 264.) Magellan launched the LeadCare system in 1997, LeadCare II in 2006, LeadCare Ultra in August 2013, and LeadCare Plus in July 2015. (*Id.* at PageID 192–193.) LeadCare products were intended to provide quick diagnoses at the point of care, such as a physician's office, without having to send a blood sample to a laboratory. (*Id.* at PageID 194, 196.)

LeadCare systems were designed to test blood samples drawn either from a vein or from a capillary in the finger or heel. The blood samples are mixed with testing reagents and placed in the LeadCare testing device. The blood lead level results are displayed by the testing device. (*Id.* at PageID 196.) The tests are used for screening purposes only. No further testing is required for low lead blood level results, but patients are advised to take a confirmatory test if lead blood level results are high. (*Id.* at PageID 196–197.) LeadCare II, LeadCare Ultra, and

LeadCare Plus are subject to FDA regulation as Class II medical devices. They require FDA clearance through a premarket 510(k) notification. (*Id.* at PageID 198.)[1]

Magellan learned in a September 2013 study entitled "Blood Treatment in Reagent Stability Study" ("Reagent Study") that the accuracy of the LeadCare Ultra system improved when the reagent was allowed an incubation period. However, LeadCare Ultra's original instructions or labeling called for immediate test analysis, not for the use of an incubation period. (*Id.* at PageID 199–200.) Magellan received two customer complaints in August 2014 that LeadCare Ultra had underestimated lead blood levels, and it received another complaint in October 2014 that LeadCare Ultra had underestimated lead blood levels for eight different patients. However, Magellan did not follow its own policy to report the issue to the FDA in a medical device report ("MDR") within 30 days. (*Id.* at PageID 200–201.) Instead, it submitted one MDR to the FDA in April 2015 for the August 2014 complaints. (*Id.* at PageID 200.)

In November 2014, Magellan opened an internal corrective action request ("CAR") 108 to investigate underestimation issues in the LeadCare II, LeadCare Ultra, and LeadCare Plus systems. (*Id.* at PageID 201.) Magellan also issued a notice to customers instructing them to incubate the reagent mixture for twenty-four hours prior to testing in the LeadCare Ultra system, but it did not validate the twenty-four-hour incubation period, nor timely inform the FDA about the corrective action. It did send a copy of the notice to customers with the April 2015 MDR to the FDA. (*Id.* at PageID 201–202.) FDA regulations required that CEO Winslow be appraised

[1] Plaintiff alleges that a 510(k) notification is a "premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 C.F.R. § 807.92(a)(3)) that is not subject to Premarket Approval." (Doc. 29 at PageID 198.) The Sixth Circuit has described the 510(k) process as "a streamlined process" that is focused on equivalence to another product on the market, and that "does not comment on safety." *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 573–74 (6th Cir. 2012).

of any quality problems and corrective actions undertaken by Magellan in regard to FDA-regulated products. (*Id.* at PageID 267.)

In mid-2015, Magellan opened engineering change orders to change the labeling for LeadCare Plus and LeadCare Ultra to include a twenty-four-hour incubation period, but it did not report the changes to the FDA. (*Id.* at PageID 202–204.) Plaintiff asserts that the customer complaints and internal reports concerning the underestimation issue were required by federal regulation to be reported to Magellan management. (*Id.* at PageID 203–204.)

D. Meridian Acquires Magellan

On March 24, 2016, Meridian announced the acquisition of Magellan for $66 million. (*Id.* at PageID 180.) Meridian recorded more than $42 million in goodwill on its financial statements following the acquisition which it said represented the amount of consideration paid exceeding Magellan's fair market value. (*Id.* at PageID 191.) It described the goodwill as consisting of Magellan's customer base, distribution channels, industry reputation, and management and workforce talent. (*Id*.) Winslow became the executive vice-president, president and CEO of the Magellan business unit when the acquisition was completed. (*Id.* at PageID 266.) As the head of the Magellan business unit within Meridian, Winslow was responsible for providing a powerpoint presentation regarding Magellan's sale performance, forecast, and marketing program for a monthly business review meeting held at Meridian's headquarters. Winslow also participated in business review meetings called "flash calls" the first Thursday of every month to discuss Magellan's performance and outlook. (*Id.* at PageID 207.)

Meridian issued a press release in conjunction with the acquisition, which it attached to its March 2016 Form 8-K filed with the SEC, in which it described Magellan as "the leading provider of point-of-care lead testing systems with placements in more than 6,500 physician

offices and clinics nationwide." (*Id.* at PageID 190, 211.) It stated that Magellan "pioneered the engineering, development, and manufacturing of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults." (*Id.*) It stated that from a "strategic perspective, the acquisition of Magellan provided" both "point-of-care capability" and "a new growth driver." (*Id.*) It further stated that "Magellan [had] maintained a clear focus on developing and marketing test systems that are well recognized for their accuracy and ease-of-use." (*Id.* at PageID 191.) Meridian concluded that "there is excellent growth potential in Magellan Diagnostics on its own, both with the existing products and the pending new product pipeline." (*Id.*)

Meridian attached a copy of the Merger Agreement between Meridian and Magellan to its May 2016 Form 10-Q filed with the SEC. (*Id.* at PageID 212.) Kraeutler signed the Merger Agreement on behalf of Meridian as its CEO, and Peter Glick signed it on behalf of Magellan as its executive chairman and president. (*Id.* at PageID 212; Meridian May 2016 Form 10-Q, Ex. 10.1 at 79–80.)[2] Magellan made the following representations and warranties in the Merger Agreement:

> (g) The Company has made available to Parent all material reports, documents, claims, notices, filings, minutes, transcripts, recordings and other material correspondence between the Target Company Group, on the one hand, and any Healthcare Regulatory Authority, on the other hand, since January 1, 2013.
>
> (h) All material reports, documents, claims, applicable registration files and dossiers, notices and similar filings required to be filed, maintained, or furnished to any Healthcare Regulatory Authority by the Target Company Group since January 1, 2010 have been so filed, maintained or furnished and, to the

[2] Plaintiff relied upon and quoted from SEC filings in its Complaint, but did not attach the filings as exhibits to the Complaint. Meridian, likewise, cites to additional information in certain SEC filings without attaching those SEC filings. The SEC filings all are publicly available. Meridian can cite to SEC filings as public records to rebut purported misstatements in a complaint without converting the dismissal motion into a summary judgment motion. *In re Omnicare, Inc. Sec. Lit.*, 769 F.3d 455, 466–67 (6th Cir. 2014); *In re Keithley Instruments, Inc. Sec. Litig.*, 268 F. Supp. 2d 887, 893 (N.D. Ohio 2002).

> Company's Knowledge, were complete and correct in all material respects on the date filed (or were corrected in or supplemented by a subsequent filing).
>
> (i) All clinical testing conducted by or on behalf of the Target Company Group is being conducted in accordance with the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a et seq.

(Doc. 29 at PageID 204.)

Meridian acknowledged in the Merger Agreement that it had undertaken a due diligence investigation of such Magellan documents and information that it deemed necessary. (*Id.*) Meridian had sent its executive vice president for global and regulatory affairs and quality assurance, Susan Rolih, onsite to Magellan to conduct due diligence regarding regulatory compliance. (*Id.* at PageID 205.) Plaintiff alleges that Magellan's customer complaints and FDA correspondence concerning the underestimation issue were the type of documents required to be made available to Meridian during the due diligence process when Meridian acquired Magellan. (*Id.* at PageID 203–204, 255.)

E. Magellan's Post-Acquisition Performance and Continued Problems

After Meridian acquired Magellan, Meridian expressed confidence in the Magellan business unit, despite the fact that problems continued to arise with the use of venous blood samples in the LeadCare systems.

Kraeutler stated at a healthcare conference in September 2016 that Magellan was beating its monthly expectations. (*Id.* at PageID 192, 208.) Magellan constituted 31.4% of Meridian's total assets and 5.1% of its total net revenues for the fiscal year ending September 30, 2016. (*Id.* at PageID 219.)

On October 20, 2016, Meridian issued a press release, attached to a Form 8-K filed with the SEC, in which it noted that "Magellan performed above revenue expectations." (*Id.* at PageID 215.) Meridian stated that it was "expecting low double-digit revenue growth on a

normalized annual basis from continued success in placing the LeadCare II platform in the domestic market." (*Id.* at PageID 215–216.)

On November 4, 2016, Magellan, a subsidiary of Meridian by this time, sent a notice to customers letter informing them to implement a 4-hour incubation period for venous blood samples on the LeadCare II system. (*Id.* at PageID 261.) This notice to customers identified a rubber stopper for test tubes manufactured by non-party Becton Dickinson as causing the lead underestimation issue in the LeadCare II system. (*Id.* at PageID 205.) Approximately one week later, on November 11, 2016, Magellan issued a product bulletin again blaming the rubber stoppers made by Becton Dickinson for the inaccurate test results. (*Id.* at PageID 261.) On November 17, 2016, Meridian opened an engineering change order to revise the label for LeadCare II to include the four-hour incubation period. (*Id.* at PageID 206.) Meridian did not report this label change to the FDA. Magellan tried to send an MDR to the FDA regarding underestimation issue in the LeadCare II system in November 2016, but it was returned by the FDA for being submitted in the wrong format. Magellan did not re-submit the MDR to the FDA until May 8, 2017. (*Id.* at PageID 224, 261.)

On November 10, 2016, Meridian issued a press release, attached to its November 2016 Form 8-K, giving guidance for the company's prospects in 2017. (*Id.* at PageID 216.) The company stated that "[f]or the fiscal year ending September 30, 2017, management expects net revenues to be in the range of $205 million to $210 million and per share diluted earnings to be between $0.81 and $0.85." (Meridian November 2016 Form 8-K, at Ex. 99.1 at 8.) Meridian stated that it "believe[d] these projections are reasonable, and will continue to be realistic, with quarter-to-quarter results supporting our expectations." (*Id.*, Ex. 99.1 at 7; *see also* Doc. 29 at PageID 216.) It also stated that the acquisition of Magellan had "exceeded [its] expectations in

satisfying the demand for testing children for elevated blood lead levels." (Doc. 29 at PageID 216.) It forecast that the Magellan business unit was "expected to report low-double-digit organic growth in fiscal 2017 with the potential for upside performance." (*Id.*)

The November 10, 2016 press release included an express disclaimer for forward-looking statements: "All statements that address operating performance or events or developments that Meridian expects or anticipates will occur in the future, including but not limited to, statements relating to per share diluted earnings and revenue, are forward-looking statements." (Meridian November 2016 Form 8-K, at Ex. 99.1 at at 10.) It also specifically stated that "[c]osts and difficulties in complying with [FDA] laws and regulations" and the "uncertainty of regulatory approvals and the regulatory process" could lead to "unanticipated expenses and delays and interruptions to the sale of new and existing products . . . ." (*Id.*, Ex. 99.1 at 11.)

On December 14, 2016, Meridian filed a Definitive Proxy Statement with the SEC stating that Kraeutler had received 15,000 stock options valued at $53,300 and Lueke had received 12,500 stock options valued at $44,416 in connection with the Magellan acquisition. (Doc. 29 at PageID 272.)

On January 13, 2017, Magellan received a customer complaint that the LeadCare Ultra system underestimated the lead level for five different patients despite using the twenty-four-hour incubation period. (*Id.* at PageID 206.) Meridian did not report this to the FDA. (*Id.* at PageID 206, 231.)

On January 25, 2017, Meridian issued a press release, attached to its January 2017 Form 8-K, revising its 2017 guidance downward and reducing its regular cash dividend. (*Id.* at PageID 222–223.) It reduced its expected net revenues from $205 million–$210 million to $193 million–$199 million, and it reduced its per share diluted earnings from $0.81–$0.85 to $0.64–

$0.69. (*Id.*) The press release explained that the reason for the downward adjustment was due to revenue declines in its Americas diagnostics business. (Meridian January 2017 Form 8-K, Ex. 99.1.) Meridian specifically contrasted the difficulties in the Americas diagnostic business with the positive trends in the life sciences and Magellan diagnostic business units. (*Id.*) Meridian's stock price fell from $16.45 on January 24, 2017 to $12.80 on January 25, 2018. (Doc. 29 at PageID 224.) Meridian would report later in the year that the Americas diagnostic business unit, including Magellan, constituted 71% of its revenues for 2017. (Meridian November 2017 Form 10-K at 33.)

F. FDA Inspection, Recall, and Warning Letter

The problems with Magellan's LeadCare systems became more widely known starting in mid-2017 and, Plaintiff alleges, caused Meridian's stock price to drop. Plaintiff alleges that two relevant events occurred on May 10, 2017. First, the FDA began a fifteen-day inspection of Magellan's Billerica, Massachusetts facility. (Doc. 29 at PageID 174, 209.) Seven days later, the FDA issued a press release warning that certain Magellan lead tests provided inaccurate results when performed on blood drawn from a vein. (*Id.* at PageID 225–227.) The FDA warned that the lead tests, when conducted with a venous draw, "may provide results that are lower than the actual level of lead in the blood." (*Id.* at PageID 226.) It warned that the issue possibly dated back to 2014 and that the Magellan LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra were all covered by the warning. The FDA warning did not allege that the lead tests results were inaccurate when blood was drawn from a finger or heel stick. The price per share of Meridian's stock fell from $14.75 on May 16, 2017 to $13.45 on May 17, 2017. (*Id.* at PageID 227.)

Second, on May 10, 2017, Meridian announced that Kraeutler would retire. Kraeutler had signed an employment agreement the previous October which had contemplated him remaining employed by the company through September 30, 2018. (*Id.* at PageID 210, 263.)

The FDA began a Class I recall of all LeadCare Ultra and LeadCare Plus products on May 18, 2017 recommending the removal of venous blood samples as an allowable sample type. The recall was later expanded to include LeadCare and LeadCare II products. (*Id.* at PageID 175, 227–228, 263.)

On June 29, 2017, the FDA issued to Magellan a Form-483 inspection report—later released to the public on July 13, 2017—in which the FDA concluded that Magellan had concealed regulatory violations and defects in the LeadCare products. (*Id.* at PageID 199, 229.) Plaintiff summarized the FDA observations to Meridian as follows:

> Defendants: (1) did not ensure the design validation for devices conformed to defined user needs and intended uses; (2) used an inadequate risk analysis with respect to falsely low lead results across the LeadCare product line; (3) did not maintain adequate procedures for receiving, reviewing and evaluating customer complaints which led to customer complaints going improperly addressed or not addressed at all; (4) failed to implement proper investigation or the institution of a Medical Device Report per FDA requirements; (5) failed to maintain procedures for corrective and preventative action with respect to inbound complaints, including several that were left indefinitely open or closed without verifying any corrective instruction remediated the issue; (6) failed to inform the FDA of several of its notices to customers that included incubation instructions to correct lead level underestimation; (7) failed to adequately establish procedures for design change, including their failure to report changes to labeling to include incubation periods; (8) expanded original acceptance criteria to fit results observed in validation studies rather than establishing these criteria prior to the study; (9) failed to report multiple MDRs upon learning of a marketed device malfunction that was likely to cause death or contribute to a death or serious injury if the malfunction were to recur related to the LeadCare Ultra system's underestimation of lead levels; and (10) failed to establish a control product that conformed to specific requirements.

(*Id.* at PageID 229, 233–248.)

On October 23, 2017, the FDA issued a warning letter stating that the LeadCare II and LeadCare Ultra systems were adulterated and misbranded under federal law based on the unapproved labeling and design changes. (*Id.* at PageID 233–244.) Meridian's stock price dropped from $15.80 on October 20, 2017, to $15.20 on October 23, 2017, to $14.50 on October 24, 2017. (*Id.* at PageID 176, 245.)

In January 11, 2018, the FDA issued a press release addressing the role that Becton Dickinson's vacutainer tubes played in the causing inaccurate venous draw testing results. The FDA stated that it did not "have evidence showing that other blood tests are adversely affected when [Becton Dickinson] blood collection tubes are used." (*Id.* at PageID 252.) In March 2018, the FDA issued a press release crediting Becton Dickinson's conclusion that the Anodic Stripping Voltammetry technology used in the LeadCare testing systems, and not in other products known to Becton Dickinson, is incompatible with thiuram, a material found in the rubber stoppers. (*Id.* at PageID 254.)

Meridian reported its first quarter 2018 results on January 28, 2018. (*Id.* at PageID 253.) It announced a 20% decrease in operating income for the entire company and a 20% decrease year-over-year for Magellan lead testing business unit revenues. (*Id.*) Meridian also reported that it experienced $500,000 in remedial costs with more expected to be incurred. (*Id.*)[3]

G. Relevant Statements in Meridian's SEC Filings

Meridian made its regular SEC filings throughout the Class Period. Plaintiff highlights the following statement about the efficacy of Magellan products Meridian made in the May 2016

[3] Plaintiff also makes allegations concerning importance of accurate lead blood level testing in light of the lead contamination crises experienced in Flint, Michigan and Sebring, Ohio during the past five years. The Court is troubled by the serious public health implications raised by Plaintiff's allegations against Magellan and Meridian, but the Court will focus in this Order only on those allegations relevant to the securities fraud claim.

Form 10-Q, the August 2016 Form 10-Q, the November 2016 Form 10-K, the February 2017 Form 10-Q, and the May 2017 Form 10-Q:

> Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

(*Id.* at PageID 211–212.)

Meridian made other relevant statements in the November 2016 Form 10-K. Meridian stated that "[e]ach of the diagnostic products currently marketed by us in the United States has been cleared by the FDA pursuant to the 510(k) clearance process or is exempt from such requirements." (Meridian November 2016 Form 10-K at 12; Doc. 29 at PageID 213.) It stated that its diagnostic products provided "accuracy, simplicity, and speed." (Meridian November 2016 Form 10-K at 6–7; Doc. 29 at PageID 214.) Meridian noted that Magellan constituted 31.4% of its total assets and 5.1% of its total net revenues. (*Id.* at PageID 219.)

In November 2017, after the FDA recall, warning letter, and inspection report, Meridian issued its 2017 Form 10-K in which it changed its description of Magellan to emphasize its use with capillary blood samples: "Magellan is a leading manufacturer of products cleared by the Food & Drug Administration ("FDA") for the point-of-care *testing of capillary blood* to diagnose lead poisoning in children and adults." (*Id.* at PageID 246 (emphasis changed).)

Meridian also made statements about its internal controls in these SEC filings. The May 2016 Form 10-Q and the August 2016 Form 10-Q both included language about the effectiveness of Meridian's internal controls related to financial reporting. (*Id.* at PageID 217–222.) Meridian used the following language:

> As of [effective date], an evaluation was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended. Based on

> that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of [effective date]. There have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the [ ] fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control . . . .

(*Id.* at PageID 217–218.) Meridian owned Magellan for the quarter preceding the August 2016 Form 10-Q, but it did not address whether it had reviewed Magellan's internal controls before issuing the form. (*Id.*)

In the November 2016 Form 10-K, Meridian for the first time disclaimed that it had reviewed Magellan's internal controls: "The Company's assessment of and conclusion on the effectiveness of its internal control over financial reporting did not include the internal controls of Magellan Biosciences, Inc. . . . ." (*Id.* at PageID 219.) Meridian again disclaimed that it had reviewed Magellan's internal controls related to financial disclosures in its February 2017 Form 10-Q. (*Id.* at PageID 220.) However, in the May 2017 Form 10-Q and the August 2017 Form 10-Q, Meridian reverted to using the disclaimer-less language it had used in the August 2016 Form 10-Q. (*Id.*)

Finally, in the November 2017 Form 10-K Meridian stated that it had "identified a material weakness in our internal control over financial reporting that, if not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements." (*Id.* at PageID 222.) It further stated, "deficiencies related to Information Technology General Controls ('ITGC') intended to restrict access to certain data and applications . . . impacting financial reporting functions and controls." (*Id.*)

II. PROCEDURAL POSTURE

On November 15, 2017, Forman filed a Class Action Complaint asserting claims under the Securities Exchange Act of 1934 ("Exchange Act") on behalf of a class defined as "all

persons or entities, other than Defendants and their affiliates, who purchased or otherwise acquired Meridian securities from March 25, 2016 through July 13, 2017, both dates inclusive." (Doc. 1 at PageID 1–2.) Three months later, the Court appointed Forman as lead plaintiff and Levi & Korsinsky, LLP as lead counsel. (Doc. 20.)

On April 16, 2018, Forman filed an Amended Complaint against Defendants Meridian, John Kraeutler, and Melissa Lueke "on behalf of herself and all other persons or entities who purchased or otherwise acquired securities of [Meridian] between March 24, 2016 and October 23, 2017." (Doc. 29.) She asserted two claims for relief:

> Count I: Violations of § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against all Defendants; and
>
> Count II: Violations of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against all Defendants.

(*Id.* at PageID 278–282.)

III. LEGAL STANDARD ON MOTION TO DISMISS

Federal Rule of Civil Procedure 12(b)(6) allows a party to move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To withstand a dismissal motion, a complaint must contain "more than labels and conclusions [or] a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In most cases, courts do not require "heightened fact pleading of specifics, but only enough facts to state a claim for relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A district court examining the sufficiency of a complaint must accept

the well-pleaded allegations of the complaint as true. *Id.*; *DiGeronimo Aggregates, LLC v. Zemla*, 763 F.3d 506, 509 (6th Cir. 2014).

In a securities fraud case, the complaint also must satisfy the heightened standard for pleading fraud set forth in Federal Rule of Civil Procedure 9(b). *Dougherty v. Esperion Therapuetics, Inc.*, 905 F.3d 971, 978 (6th Cir. 2018). "The complaint must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* The PSLRA, 15 U.S.C. § 78u-4(b), imposes two further pleading requirements: (1) the complaint must identify each statement alleged to be misleading and explain the reason it is misleading, and (2) it must state facts with particularity that give rise to a strong inference that the defendant acted with the required state of mind. *Id.*

IV. ANALYSIS

Section 10(b) of the Exchange Act generally makes it unlawful for any person using mails or instrumentalities of interstate commerce to use a "manipulative or deceptive device" in connection with the purchase or sale of a security. 15 U.S.C. § 78j(b). SEC Rule 10b-5 generally makes it unlawful for a person using mails or instrumentalities of interstate commerce to commit fraud in connection with the purchase or sale of a security. 17 C.F.R. § 240.10b-5.

A plaintiff must prove six elements to establish a claim for violation of § 10(b) of the Exchange Act or SEC Rule 10b-5: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Dougherty*, 905 F.3d at 979 (citation omitted).

Section 20(a) of the Exchange Act, 15 U.S.C. § 78t, provides for joint and several liability for controlling persons for violations of the Exchange Act.

A. Material Misrepresentation

The Sixth Circuit has explained that the analysis for when a misrepresentation has been made is different depending upon whether a misstatement or omission is alleged, and whether it concerns hard information or soft information. The Sixth Circuit stated the following standard for affirmative misstatements:

> A misrepresentation is an affirmative statement that is misleading or false. When an alleged misrepresentation concerns "hard information"—"typically historical information or other factual information that is objectively verifiable"—it is actionable if a plaintiff pleads facts showing that the statement concerned a material fact and that it was objectively false or misleading. When an alleged misrepresentation concerns "soft information," which "includes predictions and matters of opinion," a plaintiff must additionally plead facts showing that the statement was "made with knowledge of its falsity[.]"

In re Omnicare, Inc. Sec. Litig., 769 F.3d 455, 470 (6th Cir. 2014) (citations omitted). The subjective aspect of the affirmative misstatement test requires plaintiffs "to allege particular facts demonstrating that defendants had actual knowledge that their statements concerning soft information were false or misleading at the time that they were made," but it can be examined with the scienter prong. *Id.* at 471.[4]

[4] The Sixth Circuit set forth different standards for misrepresentations by omission:

In lieu of targeting a defendant's misleading or false statements, a plaintiff may focus on a defendant's omission—its failure to disclose information when it had a duty to do so. "A duty to affirmatively disclose 'may arise when there is insider trading, a statute requiring disclosure,' or, as relevant in this case, 'an inaccurate, incomplete[,] or misleading prior disclosure.'" To complicate matters further, when a person or corporation comes into possession of information that makes a prior statement "inaccurate, incomplete, or misleading," different duties to disclose the new information arise, perhaps unsurprisingly, depending on whether the new information is hard or soft. If the new information is hard, then a person or corporation has a duty to disclose it if it renders a prior disclosure objectively inaccurate, incomplete, or misleading. If the new information is soft, then a person or corporation has a duty to disclose it "'only if [it is] virtually as certain as hard facts'" and contradicts the prior statement. In other words, the new information must be so concrete that the defendant must have actually known that the new information renders the prior statement misleading or false and still did not disclose it. Whether newly acquired soft information is sufficiently concrete to trigger a duty to disclose will undoubtedly depend upon the facts in a given case, and the

The "materiality requirement is satisfied when there is 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." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (internal quotation and citation omitted). Context matters when determining materiality. *In re Omnicare*, 769 F.3d at 478.

1. Statements Concerning LeadCare's Efficacy

Plaintiff alleges that several categories of statements were misleading. First, Plaintiff contends that Meridian made material misstatements when it asserted during the Class Period in press releases and SEC filings that the LeadCare testing systems were FDA-cleared, accurate, and provided point-of-care capability. Plaintiff argues that the LeadCare systems failed to meet all of those standards. She alleges that when a venous blood sample was used, the LeadCare systems required a lengthy incubation period of up to twenty-four hours, and therefore did not provide immediate, accurate, point-of-care results. Although Plaintiff addresses all of Meridian's statements regarding the efficacy of the LeadCare systems with a broad brush stroke, the Court will provide a closer examination of the purportedly misleading statements.

To begin, Meridian's repeated statement in several Forms 10-Q and the November 2016 Form 10-K that Magellan was "a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults" and "the leading provider of point-of-care lead testing systems" is not actionable. (Doc. 29 at PageID 211–212.) Plaintiff has not pleaded facts suggesting that this statement is false or gives a false impression. Even after the LeadCare products recall, it remained true that Magellan manufactured LeadCare systems that

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nature of both the prior disclosure and the new information will determine whether new information makes a prior disclosure false or misleading.

Id.

were FDA-cleared and point-of-care accurate for use with capillary blood samples to diagnose lead poisoning in children and adults. Plaintiff has not identified any other company who manufactured lead testing systems which were FDA-cleared and point-of-care accurate. Therefore, Meridian did not mislead when it stated that Magellan was a leading manufacturer or provider of such systems.

However, Meridian stated in the November 2016 Form 10-K that all of its diagnostic products, including the Magellan LeadCare systems, were FDA cleared. (Doc. 29 at PageID 213.) Plaintiff does not dispute that this statement was literally true, but she alleges that the statement gave a materially false impression. Plaintiff alleges that Meridian did not timely provide the FDA with its notices to customers to use incubations periods for venous blood samples, about changes to its package labeling to instruct about the incubation period, or about customer complaints. As such, Plaintiff alleges that the LeadCare systems were not FDA-cleared to use with an incubation period for venous blood samples. The Court agrees that the particular statement that all Magellan products were FDA cleared is actionable on the theory that it gave a materially false impression. *See Bondali v. YumA Brands, Inc.*, 620 F. App'x 483, 491–92 (6th Cir. 2015).[5]

2. Statements in the Merger Agreement

Plaintiff next alleges that Meridian made false statements when it adopted and executed the Merger Agreement. In the Merger Agreement, Magellan made the statements that (1) it had filed all material reports with the FDA and that all reports were complete and accurate, and (2) it

[5] To the extent that Plaintiff alleges that Meridian wrongly stated that the LeadCare systems provided accurate results with venous blood samples if an incubation period was utilized (as opposed to point-of-care accurate), this is not actionable. Plaintiff alleges that Meridian received complaints in January 2017 that the LeadCare Ultra tests gave inaccurate results even when the incubation period was used, but Plaintiff does not assert that Meridian made any particular statements about the accuracy of LeadCare tests after that date.

had conducted all clinical testing in accordance with FDA regulations. (Doc. 29 at PageID 204.) The representations at issue were part of the warranties made by Magellan to Meridian in Article III of Merger Agreement. (Meridian May 2016 Form 10-Q, Exhibit 10.1 at 29, 50.) The statements are not actionable because they were made by Magellan, not Meridian. The Supreme Court has held that only the person or entity with control of the content of a statement is the maker of the statement who can be liable for a misrepresentation under Rule 10b-5. *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142–43 (2011). The Merger Agreement was signed by Kraeutler on behalf of Meridian and by Peter Glick on behalf of Magellan. Meridian cannot be held liable for the warranty representations made to it by the opposing party in an arms-length business transaction before the merger took effect. Plaintiff has not alleged that after the acquisition Meridian vouched for, adopted, or re-stated Magellan's warranties to it. The Court will dismiss the Amended Complaint to the extent that Plaintiff asserts claims based on representations made by Magellan in the Merger Agreement.

3. Statements about Meridian's Expectations for Magellan

Next, Plaintiff asserts that three statements made by Meridian in the November 10, 2016 press release attached as an exhibit to November 2016 Form 8-K are actionable misrepresentations. The first statement is that Meridian expected its projections for fiscal year 2017—specifically the expectation that Meridian's net revenues would be in the range of $205 million to $210 million with diluted earnings in the range of $0.81 to $0.85 per share—to be "reasonable, and [would] prove to be realistic, with quarter-to-quarter results supporting our expectations." (Meridian November 2016 Form 8-K, Ex. 99.1 at 8; Doc. 29 at PageID 216.) Plaintiff asserts that statement was false because Meridian had no basis to believe that *Magellan* would meets quarter-to-quarter projections. (Doc. 29 at PageID 216.) Plaintiff has mixed up

apples and oranges, so to speak. The statement that *Meridian* would meet its fiscal 2017 expectations is not disproven by a general allegation one business unit, *Magellan*, would not meet its quarterly expectations.

Additionally, this is a forward-looking statement.[6] The PSLRA contains a safe harbor for forward-looking statements. Forward looking statements are defined to include statements of revenue and earnings. 15 U.S.C. § 78u-5(c)(i)(1)(A). A forward-looking statement is one whose veracity cannot be determined at the time the statement is made. *Dougherty*, 905 F.3d at 983. Subject to limitations, a defendant will not be liable for a material forward-looking statement if either (1) the statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) "the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(A)–(B). This Meridian press release contained cautionary language, including that the costs and difficulties of complying with FDA regulations could impact future growth. (Meridian November 2016 Form 8-K, Ex. 99.1 at 10–11.)

Plaintiff argues that boilerplate cautionary language is not sufficient. However, the cautionary language here is analogous to the cautionary language found to be substantive and effective by a sister court in this District. *See Willis v. Big Lots, Inc.*, No. 2:12-cv-604, 2016 WL

[6] Plaintiff argues that this is a not purely forward looking because it is a mixed statement accompanied by present fact. The Court disagrees. Meridian's guidance for its future revenues and earnings per share are distinguishable from the statements in the case cited by Plaintiff, *In re EveryWare Global, Inc. Securities Litigation*, 175 F. Supp. 3d 837 (S.D. Ohio 2016), *aff'd IBEW Loc. No. 58 Annuity Fund v. Everyware Global, Inc.*, 849 F.3d 325 (6th Cir. 2017). The statement in the case was that the company was "on track" to meet its revenue projections. *Id.* at 855. The Court stated that the PSLRA safe harbor provisions did not apply because the statements were related to the company's "then-current conditions." *Id.* Here, conversely, Meridian stated that it believed its projections to be reasonable and that they would be proven in the future to be realistic.

8199124, at *15 (S.D. Ohio Jan. 21, 2016). The cautionary language in *Willis* stated that the following factors could influence future performance: the economic and credit crisis, the cost of goods, competitive pressures, economic pressures on the company and its customers, the availability of brand name closeout goods, and freight costs. *Id.* The language used by Meridian is different as it is tailored to a different industry, but it warns of similarly broad risks: the inability to protect its intellectual property, consolidation of hospitals and laboratories, economic recessionary pressures, difficulties in complying with FDA regulations, and economic conditions in foreign countries. (Meridian November 2016 Form 8-K, Ex. 99.1 at 10–11.) This Court finds that Meridian's cautionary language is sufficiently meaningful.

Plaintiff also contends that the cautionary language is not meaningful because Meridian knew about, but did not disclose, specific problems with the LeadCare products likely to trigger FDA oversight. Some courts have concluded that cautionary language is not "meaningful" under § 78u-5(c)(1)(A)(i) when a company knows that the potential risks they have identified have occurred already. *See, e.g.*, *In re Nash Finch Co.*, 502 F. Supp. 2d 861, 873 (D. Minn. 2007) ("[C]autionary language can not be 'meaningful' when defendants know that the potential risks they have identified have in fact already occurred, and that the positive statements they are making are false."); *In re SeeBeyond Techs. Corp. Sec. Litig.*, 266 F. Supp. 2d 1150, 1165 (C.D. Cal. 2003) (stating that § 78u-5(c)(1)(A)(i)'s requirement "that *meaningful* cautionary language accompany the forward-looking statement severely limits the possibility that false or misleading statements could be made with actual knowledge and yet be protected under the safe harbor provision").

However, the Sixth Circuit has concluded that the speaker's state of mind is irrelevant when the forward-looking statement is accompanied by objectively meaningful cautionary

language. "In other words, if the statement qualifies as 'forward-looking' and is accompanied by sufficient cautionary language, a defendant's statement is protected regardless of the actual state of mind." *Miller v. Champion Enters. Inc.*, 346 F.3d 660, 672 (6th Cir. 2003); *see also Beaver Cnty. Retirement Bd. v. LCA-Vision, Inc.*, No. 1:07-cv-750, 2009 WL 806714, at *14 (S.D. Ohio Mar. 25, 2009) ("Plaintiff's allegation that Defendants had actual knowledge that consumer demand was slipping . . . does not save the claim because the existence of the meaningful cautionary statement renders the issuer's state of mind irrelevant."). In one case, the Sixth Circuit found that a memory-foam mattress company that had warned generally about risks from mattress competitors entering the market for memory-foam mattresses was protected under the safe harbor provision, even though the company did not disclose an internal analysis of the risks posed by a particular competitor. *Pension Fund Grp. v. Tempur-Pedic Int'l, Inc.*, 614 F. App'x 237, 244 (6th Cir. 2015). Here, Meridian warned about risks inherent in complying with FDA regulations. That is sufficient to make the cautionary language meaningful.

The second alleged misrepresentation in the November 2016 press release was that Magellan "exceeded [Meridian's] expectations in satisfying the demand for testing children for elevated blood lead levels." (Doc. 29 at PageID 216.) Plaintiff did not plead what expectations Meridian had for Magellan or how those expectations had not been exceeded as of November 2016. Plaintiff has not pleaded facts to make this an actionable misrepresentation.

The third and final statement Meridian made in the November 10, 2016 press release was that it believed the Magellan business unit would report "low-double-digit organic growth in fiscal 2017 with the potential for upside performance." (*Id.*) This is also a forward-looking statement under the PSLRA. The Court has concluded that Meridian used meaningful cautionary language when it warned about the potential impact of complying with the FDA regulatory

process that provides a safe harbor for the statements about future Magellan growth. The Court concludes that none of Meridian's statements about its expectations for Magellan in the November 2016 press release are actionable misrepresentations under the PSLRA. The Court will dismiss the Amended Complaint to the extent the claims are based on these alleged misrepresentations about Magellan's future performance.

4. Meridian's Statements about the Effectiveness of Its Internal Controls

Finally, Plaintiff alleges that Meridian misrepresented the effectiveness of its internal controls following the acquisition of Magellan. (Doc. 29 at PageID 217–222.) As the Court understands the allegations, Plaintiff alleges that Meridian made a series of disclosures about its internal controls related to financial reporting in its Forms 10-Q and 10-K issued between May 2016 and November 2017. Meridian disclaimed that it had reviewed Magellan's internal controls in some of those Forms 10-Q and 10-K, but it did not disclaim that it had reviewed Magellan's controls in other Forms 10-Q and 10-K. Most relevantly, Meridian stated for the first time in the November 2017 Form 10-K that it had identified deficiencies in its internal controls that could result in material misstatements in its financial statements. (*Id.* at PageID 222.) Plaintiff interprets this to be an admission that Meridian knowingly or recklessly disregarded that Magellan lacked sufficient internal controls when it acquired Magellan. (*Id.*)

Defendants point out the inadequacy of these allegations. Meridian did not disclose any deficiencies related to internal controls until the November 2017 Form 10-K. The mere fact that Meridian disclosed a known deficiency in November 2017 does not, without more, suggest that it knew about the deficiency prior to that disclosure. Plaintiff fails to plead facts suggesting that Meridian knew prior to November 2017 about the internal control deficiencies. The Court will

dismiss the Amended Complaint to the extent the claims are based on these alleged misrepresentations about internal controls.

B. Scienter

"In the securities-fraud context, scienter includes a knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." *Dougherty*, 905 F.3d at 979 (citation omitted). Recklessness is defined in this context as a "highly unreasonable conduct which is an extreme departure from the standards of ordinary care ... akin to conscious disregard." *Id.* at 980 (citation omitted).

A court examining whether a plaintiff has adequately pleaded scienter must (1) accept all factual allegations as true, (2) consider the complaint, and the documents incorporated in the complaint, in their entirety, and (3) "take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007); *see also Dougherty*, 905 F.3d at 979 (quoting *Tellabs*). This requires the Court to look at the allegations holistically and collectively, not on an allegation-by-allegation basis. *Frank v. Dana Corp.*, 646 F.3d 954, 961 (6th Cir. 2011). The third factor requires a court to "consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 324. "A complaint will survive, we hold, 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." *Id.*

The Sixth Circuit examines scienter with reference to nine non-exhaustive factors:

> (1) insider trading at a suspicious time or in an unusual amount;
>
> (2) divergence between internal reports and external statements on the same subject;
>
> (3) closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information;

> (4) evidence of bribery by a top company official;
>
> (5) existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit;
>
> (6) disregard of the most current factual information before making statements;
>
> (7) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication;
>
> (8) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and
>
> (9) the self-interested motivation of defendants in the form of saving their salaries or jobs.

Helwig v. Vencor, Inc., 251 F.3d 540, 552 (6th Cir. 2001); *see also Dougherty*, 905 F.3d at 979 (quoting *Helwig*).

The Court must examine whether scienter exists only as to the November 2016 form 10-K statement that all of the Meridian diagnostics products, including the Magellan LeadCare products, were FDA cleared. Plaintiff argues that four *Helwig* factors, plus several non-*Helwig* factors, support a finding of scienter. Specifically, Plaintiff argues that the alleged facts show the following *Helwig* factors support a finding of scienter here: (2) a divergence between internal reports and external statements, (3) closeness in time between an alleged fraudulent statement and the later inconsistent disclosure, (6) disregard of the most current factual information before making statements, and (9) the self-interested motivation in terms of salary or jobs.

The second and sixth factors are related and will be addressed together. The Court concluded above that Plaintiff adequately has pleaded that Meridian made actionable false representations that all of the Magellan products were FDA cleared in the November 2016 Form 10-K. Plaintiff pleaded that in doing so Magellan and Meridian disregarded internal documents demonstrating problems with the LeadCare systems when using venous samples such as the

September 2013 Reagent Study, CAR 108 opened in November 2014, the labeling changes to include an incubation period, the November 2016 notice to customers and product bulletin, and the customer complaints over several years. These internal documents suggest that an incubation period was required to achieve accurate results, but the FDA had not cleared LeadCare systems with the use of an incubation period.

To the extent that these Magellan documents were created or received prior to the acquisition by Meridian, Plaintiff has pleaded that the documents would have been made available to Meridian during the due diligence process. Plaintiff also pleaded that Winslow, the former Magellan president and CEO who became an executive vice-president and the head of the Magellan business unit for Meridian, participated in monthly "flash calls" with other Meridian executives to discuss monthly performance and outlook. Plaintiff specifically pleaded that customer complaints would have been discussed in these conference calls. The Court finds that the allegations are specific enough to withstand a Rule 12(b)(6) challenge. The second and sixth *Helwig* factors favor a finding that scienter exists. Such divergence between internal documents and public reports can be a "key factor" to finding scienter. *Dougherty*, 905 F.3d at 981.

However, the third *Helwig* factor does not support a finding of scienter. Meridian stated in the November 2017 Form 10-K that all of its products were FDA cleared. The FDA did not issue the recall of the LeadCare products until May 2017. A six-month distance in time between the false representation and the public disclosure of contrary facts is too remote to be suggestive of scienter. *See Doshi v. Gen. Cable Corp.*, 823 F.3d 1032, 1042 (6th Cir. 2016) (stating that an 86-day gap did not allow a scienter inference); *City of Monroe Emps. Retirement Sys. v. Bridgestone Corp.*, 399 F.3d 651, 687–88 (6th Cir. 2005) (finding a four-month period to not be probative of scienter).

Plaintiff makes only a bare-bones argument that the ninth *Helwig* factor weighs in favor of scienter. "[G]eneral allegations of an executive's desire to protect his position within a company or increase his compensation do not comprise a motive for fraud, because such a desire is shared by all corporate officers." *Dougherty*, 905 F.3d at 981–82 (internal quotation and citation omitted). Rather, "a plaintiff must show concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 690 (6th Cir. 2004). Plaintiff does not plead facts to meet that standard here.

None of the other *Helwig* factors apply in this case. Instead, Plaintiff seeks to boost her scienter analysis with non-*Helwig* factors. For example, Plaintiff alleges that the fact that John Kraeutler announced his retirement as the CEO of Meridian in May 2017 on the same day the FDA began its fifteen-day inspection of Magellan's facility in Massachusetts is evidence of scienter. *See Willis*, 2016 WL 8199124, at *34 (finding that resignation of a merchandising executive on the same day that the company announced it had not met earnings expectations was evidence of scienter). Kraeutler's retirement was unexpected because he had an employment contract through September 2018. However, Meridian points out that the retirement announcement stated that Kraeutler would continue to serve as CEO until his successor was chosen and that he would remain as the executive chairman of the company's board of directors. (May 2017 Form 8-K at Ex. 99.1.) Moreover, Kraeutler's retirement was announced before the FDA issued the recall, its inspection report, or the warning letter. This factor weighs slightly in favor of a finding of scienter.

Next, Plaintiff asserts that the FDA recall, inspection report findings, and warning letter are themselves evidence of scienter. However, the case she cites in support of the proposition

that FDA violations can be indicative of scienter is distinguishable in material respect. In *Guam v. Invacare Corp.*, No. 1:13cv1165, 2014 WL 4062456, at *5–7 (N.D. Ohio Aug. 18, 2014), the court found scienter where the company issued public statements to investors mischaracterizing the violations found by the FDA *after* the FDA issued its warning letters. Here, in contrast, Plaintiff does not allege that Meridian made any misstatements to the investing public after the FDA issued its product recall, findings, or warning letter. To the extent Plaintiff alleges that Meridian had prior knowledge of the underlying problems confirmed by the FDA findings and warning letter, those allegations have been addressed in the analysis of the second and sixth *Helwig* factors. The purported factor does not weigh in favor of a finding of scienter.

Finally, Plaintiff asserts that the Meridian's January 2017 downward guidance adjustment is evidence of scienter. Meridian stated that it adjusted its guidance downward and reduced its dividend because it was experiencing continuing difficulty in its Americas diagnostic business unit. It stated in the same SEC filing that the Magellan business unit performance was strong. However, Plaintiff alleges that the real reasons for the downward adjustment were the problems with Magellan's LeadCare systems which came to light in November 2016, including Meridian's issuance of the public bulletin blaming the Becton Dickinson rubber stoppers for inaccurate test results, its decision to revise the labeling for LeadCare II to include a four-hour incubation period, and its failed attempt to send an MDR to the FDA concerning the LeadCare II labeling change.

Meridian responds that Plaintiff's theory is facially implausible. Magellan products constituted only 5.1% of Meridian's overall revenues for fiscal year 2016. It was only a fraction of the overall Americas diagnostic business unit. Moreover, the LeadCare Plus and LeadCare Ultra testing systems, which were primarily used with venous blood samples, constituted only

10% of Magellan's annual revenues. The LeadCare and LeadCare II systems were used primarily with capillary blood samples. (Meridian November 2017 Form 10-Q at 30.) Meridian contends that it would not have reduced its 2017 projected earnings and cut its dividend—blaming the decision on weakness in the larger portion of the Americas diagnostics business unit—to conceal a weakness in the smaller Magellan diagnostics business unit. That is, Meridian contends that it would not have adjusted its guidance downward—an action likely to cause a stock price drop—to conceal problems with a smaller business unit.

Also, Meridian points out that it made voluntary disclosures to the public about the need for an incubation period for the LeadCare systems when venous blood samples were used. Magellan issued notices to customers in November 2014 and November 2016 instructing them to use incubation periods for venous blood samples for certain LeadCare systems. It sent a medical device report to the FDA in April 2015 which includes the November 2014 notice to customers. The Court does not discount Plaintiff's allegations that Meridian's and Magellan's disclosures to the FDA were untimely and insufficient, but their voluntary public disclosure of information about the need for incubation periods undercuts an inference of an intent to deceive or conceal.

Finally, it is useful to examine Plaintiff's overarching theory of liability and Meridian's response thereto. Plaintiff alleges that Meridian knowingly acquired a company facing serious regulatory problems, including a likely FDA product recall, to ameliorate its weakening financial position. Specifically, Plaintiff alleges that Meridian faced difficulties in its core diagnostic 2016 business unit because (1) its illumigene product was not performing as well as expected, (2) it was going to lose the patents for its *H. pylori* products in May 2016, and (3) it had a small research and development budget. Therefore, Plaintiff alleges, Meridian acquired Magellan to provide it with new diagnostic products and new growth driver. However, Plaintiff also alleges

that Meridian knew that Magellan was facing serious regulatory problems, including a likely FDA product recall, because Magellan fraudulently was concealing the fact that its LeadCare products could not provide point-of-care accuracy without the use of an incubation period for venous blood samples.

Meridian contends this overall theory is nonsensical. Meridian asks why it would seek to boost it revenues and stock prices by acquiring a company with regulatory liabilities that would imperil its future prospects. Meridian asserts that it is more likely that Meridian believed that the acquisition of Magellan in fact would bolster its bottom line. Meridian does not dispute that it faced business difficulties prior to the acquisition of Magellan in early 2016. Meridian knew that Magellan's LeadCare products had been FDA cleared for use with capillary and venous blood samples and that the use of the products with capillary blood samples accounted for the majority of Magellan's revenues. Additionally, while Plaintiff has alleged that Meridian knew or should have known that Magellan had made changes to LeadCare's labeling and instructions without timely informing the FDA, there is no allegation that Meridian would have known that the use of an incubation period did not ameliorate the underestimation problem for venous blood samples. Meridian did not receive customer complaints about problems with incubated samples until January 2017. Therefore, Meridian's purportedly misleading, but literally true, statement in November 2016 that all of Magellan's LeadCare systems were FDA cleared likely was not made with knowing, deliberate, or reckless intent to deceive investors.

Plaintiff's theory of liability is not as compelling as Meridian's non-culpable explanation. As such, the Court concludes that Meridian's specific statement in November 2016 that all of its products were FDA cleared does not rise to the level of "a knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." *Dougherty*, 905 F.3d at 878 (citation

omitted). Because Plaintiff has not met the scienter requirement, the Court need not consider the remaining element of a securities fraud claim. The Court will dismiss the Exchange Act claims against Defendants.

V. CONCLUSION

For the foregoing reasons, the Motion to Dismiss (Doc. 32) is **GRANTED**.

IT IS SO ORDERED.

Dated this 13th day of February, 2019.

BY THE COURT:

S/Susan J. Dlott
Susan J. Dlott
United States District Judge