IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

IN RE ZIMMER BIOMET HOLDINGS, INC. DERIVATIVE LITIGATION	)	CONSOLIDATED C.A. No. 2019-0455-LWW

MEMORANDUM OPINION

Date Submitted: June 15, 2021
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WILL, Vice Chancellor

This is a derivative suit brought by stockholders of Zimmer Biomet Holdings, Inc., a company that manufactures and markets various products in the highly regulated medical device industry. The plaintiffs' claims stem from a September 12, 2016 "for cause" inspection of Zimmer's North Campus site in Warsaw, Indiana by the U.S. Food & Drug Administration. The compliance problems identified during that inspection resulted in Zimmer issuing a blanket hold on shipments of products processed at the North Campus facility. Zimmer subsequently reported disappointing financial results for the third quarter of 2016, reduced its fourth quarter guidance, and saw its stock price fall 14%.

After outside analysts reported on the results of the FDA's North Campus inspection, a federal securities action and this litigation followed. In this matter, the plaintiffs seek to pursue derivative claims for breach of fiduciary duty, insider trading, unjust enrichment, and breach of contract. These claims are brought against current and former officers and directors of Zimmer and against multiple entities that sold Zimmer stock in three registered offerings in 2016. The primary theory behind the plaintiffs' claims is that Zimmer's officers and directors knew in 2015 and 2016 that Zimmer was facing serious regulatory compliance challenges but concealed them from the market while facilitating sales of Zimmer stock by private equity funds in possession of that material non-public information.

The defendants have moved to dismiss the complaint for failure to adequately plead demand futility and for failure to state a claim. I conclude that those motions must be granted. As with many derivative actions, a threshold issue in this case is whether the plaintiffs' failure to make a pre-suit demand on the Zimmer board is excused. Of the eleven-member board in place when this lawsuit was filed, the plaintiffs acknowledge that eight directors were independent, received no special benefit from the challenged trades, and had no ties to the private equity funds that traded. They argue that making a demand would nonetheless have been futile because a majority of those directors face a substantial likelihood of liability.

The plaintiffs have not alleged particularized facts to support that argument. Zimmer has an exculpation provision in its charter, meaning that the plaintiffs must plead facts suggesting a fair inference that the directors breached their duty of loyalty. The plaintiffs' complaint details a host of compliance violations—large and small—at multiple Zimmer facilities from China to Puerto Rico to Indiana, along with various remediation efforts Zimmer took throughout 2015 and 2016. But the plaintiffs point to nothing until late 2016 that would have alerted a majority of the directors to an imminent product ship hold at the North Campus and resulting financial implications. By then, the secondary offerings had been completed. In terms of disclosures, the plaintiffs cannot link what the Zimmer board knew before late 2016 to any material misstatements or omissions that the board was directly

involved in issuing. After the ship holds began in September 2016, the plaintiffs—at most—connect the four Audit Committee members to an earnings release that reduced guidance but cannot support a duty of loyalty claim against those directors.

At bottom, the plaintiffs cannot show that a majority of the board faces a substantial likelihood of liability for non-exculpated claims. There are no specific facts pleaded to support a reasonable inference that the directors acted in bad faith, intentionally concealed material information, knowingly facilitated insider trading, or deliberately ignored "red flags." Because the plaintiffs cannot demonstrate that the board's capacity for impartiality was compromised, demand is not excused as futile. This case is dismissed in its entirety under Court of Chancery Rule 23.1.

I. FACTUAL BACKGROUND

The following facts are drawn from the Verified Consolidated Stockholder Derivative Complaint (the "Complaint") and the documents it incorporates by reference.[1]

[1] Verified Consolidated S'holder Deriv. Compl. ("Compl.") (Dkt. 47). *See Winshall v. Viacom Int'l, Inc.*, 76 A.3d 808, 818 (Del. 2013) ("[A] plaintiff may not reference certain documents outside the complaint and at the same time prevent the court from considering those documents' actual terms."); *Freedman v. Adams*, 2012 WL 1345638, at *5 (Del. Ch. Mar. 30, 2012) ("When a plaintiff expressly refers to and heavily relies upon documents in her complaint, these documents are considered to be incorporated by reference into the complaint . . . ."). The parties agreed that documents produced by Zimmer pursuant to 8 *Del. C.* § 220 would be deemed incorporated into any complaint the plaintiffs filed. *See Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 797 (Del. Ch. 2016).

A. Zimmer's Business, Board, and the PE Funds

Nominal defendant Zimmer Biomet Holdings, Inc. ("Zimmer" or the "Company") designs, manufactures, and markets a variety of medical devices throughout the world.[2] Because Zimmer's products are "medical devices" under the Food, Drug, and Cosmetic Act, it is regulated by the U.S. Food & Drug Administration.[3] Zimmer's products include "Class III" medical devices (such as implantable orthopedic devices used for knee, hip, and spine treatments), which are subject to intense FDA scrutiny.[4]

The Company, as it exists today, was formed through Zimmer Holdings, Inc.'s ("Legacy Zimmer") acquisition of Biomet, Inc. ("Legacy Biomet") on June 24, 2015 for cash and stock consideration totaling nearly $15 billion.[5] Before the merger, Legacy Biomet was 97% owned[6] by funds affiliated with The Blackstone Group,[7]

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[2] Compl. ¶ 2.

[3] *Id.* ¶ 91.

[4] *See id.* ¶ 93.

[5] *Id.* ¶ 82.

[6] *Id.* ¶ 4.

[7] The defendant funds associated with The Blackstone Group are: Blackstone Capital Partners V L.P., Blackstone Capital Partners V-AC L.P., BCP V-S L.P., Blackstone Family Investment Partnership V L.P., Blackstone Family Investment Partnership V-SMD L.P., Blackstone Participation Partnership V L.P., and BCP V Co-Investors L.P. *See id.* ¶¶ 48–49. Those entities are referred to collectively as the "Blackstone Funds."

Goldman Sachs Capital Partners,[8] Kohlberg Kravis Roberts & Co. L.P.,[9] and TPG Global, LLC.[10] That group of private equity funds will be referred to as the "PE Funds." After the merger, the PE Funds held about 15% of Zimmer's publicly traded common stock.[11]

Zimmer entered into an April 14, 2014 Stockholders Agreement with Legacy Biomet's holding company (LVB Acquisition Holding, LLC) in connection with the merger.[12] The Stockholders Agreement provides that the PE Funds could require Zimmer to register its securities, enabling the PE Funds to sell their holdings in future public offerings subject to restrictions.[13]

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[8] The defendant funds associated with Goldman Sachs Capital Partners are: GS Capital Partners VI Fund, L.P., GS Capital Partners VI GmbH & Co. KG, GS Capital Partners VI Offshore Fund, L.P., GS Capital Partners VI Parallel, L.P., GS LVB Co-Invest, L.P., Goldman Sachs BMET Investors, L.P., Goldman Sachs BMET Investors Offshore Holdings, L.P., PEP Bass Holdings, LLC, Private Equity Partners 2004 Direct Investment Fund L.P., Private Equity Partners 2005 Direct L.P., and Private Equity Partners IX Direct L.P. *See id.* ¶¶ 52–53. Those entities are referred to collectively as the "Goldman Funds."

[9] Defendant KKR Biomet LLC (the "KKR Fund") is an affiliate of Kohlberg Kravis Roberts & Co L.P. *Id.* ¶¶ 56–57.

[10] The defendant funds associated with TPG Global, LLC are: TPG Partners IV, L.P., TPG Partners V, L.P., TPG FOF V-A, L.P., TPG FOF V-B, L.P., TPG LVB Co-Invest LLC, and TPG LVB Co-Invest II LLC. *See id.* ¶¶ 59–60. Those entities are referred to collectively as the "TPG Funds."

[11] *Id.* ¶¶ 4, 84.

[12] Stachel Decl. Ex. 1 ("Stockholders Agreement"), as amended March 30, 2015 (Dkt. 71); Compl. ¶ 371.

[13] Stockholders Agreement §§ 4.1, 4.3.

The Stockholders Agreement also allowed the PE Funds to nominate two directors to Zimmer's board of directors (the "Board").[14] The PE Funds nominated defendants Jeffrey K. Rhodes (an affiliate of the TPG Funds) and Michael W. Michelson (an affiliate of the KKR Fund).[15] The Stockholders Agreement permitted Michelson and Rhodes to share certain non-public information about Zimmer with the PE Funds:[16]

> Notwithstanding anything to the contrary herein, without limiting any such Principal Stockholder Director's fiduciary duties under Applicable Law, each of the parties hereto hereby consents to each Principal Stockholder Director sharing any information such Principal Stockholder Director (in his or her capacity as such) receives from the Company with the respective officers, directors, members, employees, attorneys, accountants, consultants, bankers and financial advisors of any Sponsor [PE Fund] . . . .[17]

The plaintiffs allege that defendants Rhodes and Michelson used their Board positions to engage in insider trading. Rhodes left the Board in 2017, before this litigation was filed.[18] Of the 11 directors on the Board when this suit commenced, just three—defendants Michelson and Arthur J. Higgins (an affiliate of Blackstone)

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[14] Compl. ¶ 85; Stockholders Agreement § 1.1 ("On or prior to the Closing Date, (i) the Company's board of directors (the "Board") shall take all action necessary and appropriate . . . to cause the number of directors on the Board to be increased by two (2) and (ii) the Board shall appoint two individuals selected by the [PE Funds].").

[15] Compl. ¶¶ 85, 87.

[16] *Id.* ¶ 85.

[17] Stockholders Agreement § 1.6(b); *see also id.* § 1.7.

[18] Compl. ¶ 45.

and non-party Brian Hanson (Zimmer's CEO)—purportedly lack independence.[19] The remaining eight directors on the Board at that time—Christopher B. Begley, Betsey J. Bernard, Gail K. Boudreaux, Michael J. Farrell, Larry C. Glasscock, and Robert A. Hagemann (together, the "Director Defendants"), and non-parties Syed Jafry and Maria Hilado[20]—are outside directors with no alleged ties to the PE Funds. Two other former directors—Paul M. Bisaro and Cecil B. Pickett—are also defendants but left the Board before this litigation was filed.[21]

The Complaint also names as defendants two of Zimmer's former executive officers. David C. Dvorak was Zimmer's Chief Executive Officer, President, and a member of the Board.[22] Defendant Daniel P. Florin was Zimmer's Chief Financial Officer until his resignation.[23] Dvorak and Florin left Zimmer in 2017 and 2019, respectively.[24]

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[19] Compl. ¶¶ 294 n.29, 326.

[20] *Id.* ¶¶ 35–42, 294.

[21] *Id.* ¶¶ 43–44.

[22] *Id.* ¶ 33.

[23] *Id.* ¶ 34.

[24] *Id.* ¶¶ 33–34. The Complaint also, at times, lists "Collins" as a defendant. *See, e.g., id.* ¶¶ 133, 140, 151. The plaintiffs appear to be referencing Tony W. Collins, Zimmer's Vice President, Corporate Controller, and Chief Accounting Officer during the relevant time period. He is not included in the "Parties" section of the Complaint and there are no substantive allegations about him.

B. The PE Funds Exit Their Investments in 2016.

On February 4, 2016, consistent with the Stockholders Agreement, Zimmer filed a Form S-3 shelf Registration Statement for planned public stock offerings by the PE Funds.[25] Zimmer's directors, including Michelson and Rhodes, signed the Registration Statement.[26] Three public secondary offerings pursuant to the Registration Statement followed.

First, on February 10, 2016, the Blackstone Funds sold the entirety of their Zimmer holdings and the Goldman Funds sold about half of their Zimmer investment (the "February Offering").[27] In total, the Blackstone Funds and Goldman Funds received proceeds of approximately $1.06 billion from the February Offering.[28] Zimmer issued a preliminary prospectus supplement in connection with that February Offering on February 5, 2016 and a final prospectus supplement on February 8, 2016.[29]

Then, in a June 13, 2016 public offering, the TPG Funds and KKR Fund sold about half of their remaining Zimmer shares and the Goldman Funds sold the rest of

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[25] *Id.* ¶¶ 215, 260; *see* Stockholders Agreement § 4.3.

[26] *See* Compl. ¶¶ 42, 45, 260. Specifically, Begley, Bernard, Bisaro, Boudreaux, Dvorak, Farrell, Florin, Glasscock, Hagemann, Higgins, Michelson, Pickett, and Rhodes each signed the Registration Statement. *Id.* ¶¶ 33–45, 260.

[27] *Id.* ¶ 261.

[28] *Id.* The Blackstone Funds sold 7,351,708 shares in the offering at $95.91 per share. *Id.* The Goldman Funds sold 3,675,850 shares of Zimmer stock at $96.66 per share. *Id.*

[29] *Id.* ¶ 260.

their stake (the "June Offering").[30] For that June Offering, Zimmer supplemented the Registration Statement with a preliminary prospectus supplement on June 13, 2016 and a final prospectus supplement on June 15, 2016.[31]

Finally, in a third public offering on August 9, 2016, the TPG Funds and KKR Fund each sold their remaining Zimmer shares (the "August Offering").[32] The August Offering was also conducted pursuant to the Registration Statement. Zimmer supplemented the Registration Statement with a preliminary prospectus supplement on August 9, 2016 and a final prospectus supplement on August 11, 2016.[33] As of August 9, 2016, the PE Funds were no longer invested in Zimmer.

C. The FDA's Ongoing Monitoring and Inspection of Zimmer

The plaintiffs challenge the February, June, and August Offerings because, they contend, those offerings were conducted at a time when the PE Funds had material non-public information obtained through Michelson and Rhodes.[34] They

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[30] *Id.* ¶ 262. The TPG Funds sold 3,675,855 shares—50% of its interest in the Company—at $115.31 per share, netting proceeds of roughly $424 million. *Id.* The KKR Fund sold 3,764,820 shares—50% of its interest in the Company—for $115.31 per share, netting proceeds of about $434 million. *Id.* And the Goldman Funds sold their remaining 3,675,858 Zimmer shares at $115.31 per share, also netting proceeds of approximately $424 million. *Id.*

[31] *Id.* ¶ 263.

[32] *Id.* ¶ 264. KKR Biomet sold its 3,764,820 shares at $129.00 per share, netting proceeds of roughly $486 million. *Id.* The TPG Funds sold their remaining 3,675,855 shares of Zimmer stock at $129.00 per share, netting proceeds of about $474 million. *Id.*

[33] *Id.* ¶ 265.

[34] *See, e.g.*, *id.* ¶¶ 1, 90, 250, 271.

allege that the Board, including Michelson and Rhodes—and thus the PE Funds—knew that Zimmer was facing a series of regulatory challenges that were hidden from the market at the time of the Offerings.

As a manufacturer of "Class II" and "Class III" medical devices, Zimmer is subject to biennial FDA inspections.[35] The FDA is also authorized to conduct pre-approval, compliance follow-up, and "for cause" inspections.[36] If an inspection reveals regulatory violations, FDA inspectors may identify them in a written report known as a "Form 483."[37] A company that receives a Form 483 generally responds to the FDA within fifteen days with a comprehensive plan to remedy the deficiencies.[38] If the violations are not addressed, the FDA may issue a "Warning Letter" that details the continued violations and gives the company a set amount of time to address them before further action is taken.[39] Receipt of a Warning Letter means that an offending facility can no longer obtain premarket approval on new

[35] *Id.* ¶ 93.

[36] *Id.* ¶ 94.

[37] *See FDA Form 483 Frequently Asked Questions*, U.S. Food & Drug Admin. (Jan. 9, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (explaining that a Form 483 "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the [FDCA] and related Acts"); Compl. ¶ 97.

[38] Compl. ¶ 103.

[39] *Id.*

Class III medical devices until the observations are remediated.[40] The FDA may take more drastic actions, such as issuing a "Consent Decree," where serious concerns are unremedied.[41] A "rare consequence" of an FDA inspection is a product ship hold.[42]

Both before and after the merger, various Zimmer facilities around the world were the recipients of Form 483s and Warning Letters that outlined negative observations. The Board received "detailed regular reports . . . that include[d] discussions of the risks and exposures" concerning FDA-enforced laws and regulations.[43] Board meetings often included a discussion of FDA compliance efforts and the results of both internal audits and FDA investigations.

For example, at the first Board meeting held post-merger on July 17, 2015, the Board received a presentation called "FDA and Project Trident Update."[44] The presentation described an ongoing FDA compliance remediation program called "Project Trident" in place at several Legacy Zimmer facilities.[45] The presentation

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[40] *Id.*

[41] *Id.* ¶ 104.

[42] *Id.* ¶ 19.

[43] *Id.* ¶ 8.

[44] *Id.* ¶¶ 127–28.

[45] The facilities involved in Project Trident included those located in Warsaw, Indiana; Ponce, Puerto Rico; Parsippany, New Jersey; and Winterthur, Switzerland. *Id.* ¶ 128. The plaintiffs allege that as of September 2015, Project Trident had cost Zimmer nearly $250 million. *Id.* ¶¶ 128, 138.

identified the "[s]uccessful FDA re-inspections" at Zimmer's West Campus facility in Warsaw, Indiana and the Company's Ponce, Puerto Rico facility as a top priority for 2015.[46] Both facilities had been issued Form 483s (identifying 12 deficiencies at the West Campus facility and nine deficiencies at the Ponce facility, respectively) after FDA inspections in 2014.[47] The presentation noted that Zimmer's North Campus location—the facility central to the plaintiffs' allegations given its role manufacturing crucial products—had also been inspected by the FDA in 2014 and received two negative observations.[48]

Similar presentations about compliance matters were given to the Board and Audit Committee at regular intervals during the remainder of 2015 and 2016.[49] Those presentations about "FDA and Quality Matters" would mention, among other things, FDA inspections and third-party audits at various sites, the results of those inspections, responses to prior observations, and plans for remediation.[50] The Board

[46] *Id.* ¶ 129.

[47] *Id.*

[48] *Id.* ¶ 131.

[49] The Complaint discusses Board and Audit Committee meetings and presentations in 2015 and 2016 on: July 17, 2015; September 25, 2015; December 11, 2015; February 23, 2016; May 3, 2016; July 15, 2016; August 5, 2016 (Audit Committee); September 23, 2016; October 24, 2016 (Audit Committee); and December 16, 2016. *See id.* ¶¶ 127–88.

[50] *See id.* ¶¶ 126–94.

would be told about issues at Zimmer facilities spanning the globe from Jinhua, China to Montreal, Canada.[51]

In October and November 2015, the FDA conducted a scheduled inspection of Zimmer's West Campus facility in Warsaw, Indiana and issued a Form 483 listing 10 negative observations, nine of which were repeat observations from prior FDA inspections.[52] Around the same time, the FDA was also inspecting the Company's Ponce, Puerto Rico facility.[53] That inspection resulted in four negative observations, including three repeat observations.[54] The Zimmer Board learned about the West Campus Form 483, the Ponce inspection, and other FDA inspections of Zimmer facilities during its December 11, 2015 meeting.[55]

By the time of the February Offering, the Board was aware that certain facilities were having "extensive FDA compliance problems"—including that West Campus and Ponce had received Form 483s and that Zimmer's Jinhua, China facility had received an FDA Warning Letter.[56] The plaintiffs also allege that the Board

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[51] *See id.* ¶ 11.

[52] *Id.* ¶¶ 106–07.

[53] *Id.* ¶ 109.

[54] *Id.*

[55] *Id.* ¶¶ 143–44. On December 21, 2015, Zimmer responded to the West Campus Form 483, noting that it was working to "address systemic issues." *Id.* ¶ 108. On February 12, 2016, Zimmer told the FDA that its remediation efforts at the West Campus would not be complete until June of 2017. *Id.* ¶ 110.

[56] *Id.* ¶ 268.

knew that Zimmer planned to conduct internal audits into FDA-readiness at various sites.[57]

D. Zimmer Conducts Internal Audits and the Board Receives Regular Updates on Compliance.

Various compliance matters at Zimmer facilities were identified for the Board after the February Offering. A Board presentation given at a February 23, 2016 meeting listed eight separate FDA investigations that identified one or more negative observations, including seven negative observations at Zimmer's Montreal site.[58] At that same meeting, the Board was told about the Company's plans to audit Zimmer's network of manufacturing facilities, including the North Campus.[59]

The results of those internal audits were issued in March, April, and June 2016 reports, including observations from Zimmer's North Campus facility—where "key brands" providing the Company with some of its "best competitive opportunities" were made—among others.[60] Zimmer's March 31, 2016 internal audit report titled "Corporate Complaints Process Audit" detailed six major and two minor

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[57] *Id.*; *see also* Barillare Decl. Ex. 11 (Sept. 25, 2015 Zimmer Board meeting minutes and presentation slides) (Dkt. 75).

[58] Compl. ¶¶ 111 (quoting Barillare Decl. Ex. 12 (Feb. 23, 2016 Zimmer Board meeting minutes and presentation slides)), 154.

[59] *Id.* ¶¶ 153–55; *see* Barillare Decl. Ex 12.

[60] Compl. ¶ 12.

observations at the North Campus facility.[61] The April 13, 2016 internal audit report titled "Corporate Design Controls Audit" listed four critical and 15 major observations at the North Campus.[62] And the June 7, 2016 internal audit report titled "Corporate General QMS Audit" described 15 major and five minor observations at the North Campus.[63]

The plaintiffs assert that the "audit results were provided to the Board no later than May 3, 2016 (with the third report then in draft)."[64] But the plaintiffs do not allege that the Board received a copy of the audit reports or a description of the compliance issues they addressed. The Board was given the following information in a May 3, 2016 Board presentation slide that allegedly corresponds to the three North Campus internal audits:[65]

[61] *Id.* ¶ 124; *see* Barillare Decl. Ex. 17 (Dec. 16, 2016 Zimmer Board meeting minutes and presentation slides) at 2.

[62] Compl. ¶ 124.

[63] *Id.*

[64] *Id.* ¶ 13; *see also id.* ¶ 147 & n.15.

[65] *Id.* ¶ 159 & n.18; *see* Barillare Decl. Ex. 13 (May 3, 2016 Zimmer Board meeting minutes and presentation slides).

Zimmer Biomet Establishment	Location	Audit Date	Entity	Status	Result
EtQ Complaints Enterprise Audit – Multiple Sites	N/A	Dec '15 – Mar '16	ZBQC	Reports issued 3/31/16	13 – Major 4 – Minor
Biomet Warsaw North (Design & Package)	Warsaw, IN	March 14-18	PAREXEL K&S	Report issued 4/13/16	4 – Critical 15 – Major
Corporate Audit Process	N/A	Mar 2	DLSS	Report in draft	TBD

The slide also listed similar information for 11 other audits, with varying degrees of results.[66] In total, the audits listed on the slide noted seven critical and 62 major observations.[67] The May 3, 2016 Board meeting was the last meeting before the June Offering.[68]

The Board next met on July 15, 2016. Once again, the Board received a presentation on "FDA and Quality Matters" at various Zimmer facilities.[69] The directors were updated on ongoing compliance remediation efforts at Zimmer sites.[70] They were informed, among other things, that certain remediation efforts at the

[66] *See* Compl. ¶ 159; Barillare Decl. Ex. 13.

[67] Compl. ¶¶ 159, 161.

[68] On May 27, 2016, the FDA issued a Warning Letter to Zimmer's Montreal facility. *Id.* ¶ 165. The plaintiffs do not allege that the Board was informed of that Warning Letter before the June Offering.

[69] *Id.* For example, the Board learned that a recent FDA inspection at Zimmer's Dover, Ohio facility had resulted in four negative observations. *Id.*

[70] *Id.* ¶ 167.

North Campus would not be complete until 2018[71] and that several observations from the West Campus Form 483 remained open.[72] The July 15, 2016 meeting was the last time the full Board met before the August Offering, though the Audit Committee met on August 5, 2016.[73]

E. Zimmer Lowers Guidance After the 2016 North Campus FDA Inspection and Product Ship Hold.

The FDA inspection at the core of the plaintiffs' Complaint occurred on September 12, 2016—more than a month after the August Offering.[74] That day, the FDA commenced an unannounced for cause inspection at Zimmer's North Campus facility.[75] The Board was told about the in-progress inspection during an "FDA Update" at a regularly scheduled meeting on September 23, 2016.[76]

Between the start of the inspection and September 28, 2016, the FDA identified significant issues with Zimmer's quality systems at the North Campus.[77] The inspection led to immediate disruptions to the North Campus's operations and

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[71] *Id.*

[72] *Id.* ¶ 169.

[73] The Audit Committee met to discuss the KKR Fund's and TPG Funds' planned sales of Zimmer stock in the August Offering. *Id.* ¶ 172.

[74] *Id.* ¶ 113.

[75] *Id.*

[76] *Id.* ¶ 175; Barillare Decl. Ex. 15 (Sept. 23, 2016 Zimmer Board meeting minutes and presentation slides).

[77] *See* Compl. ¶ 114.

the shipment of key products.[78] As a result, on September 29, 2016, Zimmer implemented a blanket product ship hold "to stop shipments of all final product cleaned, sterile packed, and sterilized at the Warsaw North Campus."[79] The third quarter ended the next day. A month's worth of supply shortages came after the ship hold.[80]

In the weeks that followed, the Company implemented other holds on materials and finished products at the North Campus.[81] On October 21, 2016, the blanket product ship hold began to be released in stages based on remediation efforts.[82]

On October 24, 2016, the Audit Committee—along with Zimmer's officers, its counsel, and its external auditor—met to review the Company's draft earnings release for the third quarter of 2016 and were given an "update on the ongoing FDA inspection" of the North Campus.[83] After discussion, the Audit Committee members "expressed no objections" to the contents of the draft release.[84]

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[78] *Id.*

[79] *Id.* ¶ 115 (quoting Barillare Decl. Ex. 17 at 4).

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *Id.* ¶ 181 (quoting Barillare Decl. Ex. 18 (Oct. 24, 2016 Zimmer Audit Committee meeting minutes) at 2).

[84] *Id.* (quoting Barillare Decl. Ex. 18 at 2).

Zimmer released its third quarter 2016 results on October 31, 2016.[85] It reported organic sales growth of 1.6%, which was below expectations.[86] The Company also reduced its revenue guidance for the fourth quarter of 2016.[87] The results caused Zimmer's stock price to drop nearly 14%, from a high of $122.55 the previous trading day to a closing price of $105.40 on October 31.[88] The North Campus FDA inspection and the related product ship holds were not mentioned in the earnings release or during Dvorak's earnings call with investors.[89]

On November 8, 2016, Zimmer filed its Form 10-Q for the period ending October 31, 2016.[90] The Company reported that its below guidance revenue results were attributable in part to "some temporary disruption in product supply . . . related to several factors, including implementation of operational process enhancements that have resulted in various shipment delays, and manufacturing forecasting constraints related to continued integration of our supply chain . . . ."[91] The Form 10-Q did not explicitly mention the FDA inspection at the North Campus or the related product ship holds.

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[85] *Id.* ¶ 217.

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *See id.* ¶¶ 218–19.

[90] *Id.* ¶ 221.

[91] *Id.* (alterations in original).

F. The North Campus Inspection and Product Ship Holds Are Reported.

The same day that Zimmer filed its third quarter 2016 Form 10-Q, an analyst at Northcoast Research reported on the FDA's inspection of the North Campus and the related product ship holds.[92] Northcoast reasoned that the "product supply issues" Zimmer had announced were due "at least [in] part" to the FDA inspection and shut down of certain product lines.[93] Zimmer disclosed, in response to Northcoast's report, that it was "in the process of deploying new demand planning and production planning tools" and that "enhance[ments]" to "harmonize[ ] and optimize[ ]" its processes "led to certain product shipment delays, including product manufactured at the [North Campus]."[94] Zimmer also said that it expected "to return to full shipping capacity with the impacted products over the next few weeks."[95] Zimmer's stock price continued to decline, reaching a low of $97.99 on November 14, 2016.[96]

[92] *Id.* ¶ 220.

[93] *Id.*

[94] *Id.* ¶ 222.

[95] *Id.*

[96] *Id.* ¶ 223.

G. The FDA Issues a Form 483 Related to the North Campus Inspection.

On November 22, 2016, the FDA issued a 57-page Form 483 based on the North Campus inspection.[97] The FDA identified 14 negative observations, two of which were repeat observations from the North Campus's 2014 FDA inspection.[98] Analysts obtained the Form 483 through Freedom of Information Act requests on or around December 14, 2016.[99] Morningstar Research reported it was "skeptical" that the FOIA requests would uncover any information and noted that they had "seen other medical device firms take a more proactive stance in these situations to reassure investors that management was working decisively to resolve the FDA's issues."[100] A consultant for Wells Fargo & Company commented that the 57-page Form 483 was "the longest one he remembers seeing" and that it was "quite unusual" for a Form 483 "to be so thorough in documenting a company's perceived shortcomings."[101]

On December 14, 2016, Zimmer responded to the Morningstar Research report, noting that it "ha[d] developed and [wa]s executing a remediation plan to

[97] *Id.* ¶ 116.

[98] *Id.* ¶¶ 116–17.

[99] *Id.* ¶¶ 228–29.

[100] *Id.* ¶ 229.

[101] *Id.* ¶ 230.

fully address the issues cited by the FDA."[102] Zimmer also said that it was "taking the necessary steps to address certain regulatory compliance gaps" at the North Campus site.[103] Zimmer further explained that "the anticipated full impact of all of the above-described matters was included in [its] sales and earnings guidance update issued on October 31, 2016."[104]

The Board met two days later for a regularly scheduled meeting on December 16, 2016.[105] As usual, the Board was given a presentation called "FDA and Quality Matters."[106] The directors were updated on the status of Zimmer's internal audit remediation efforts, including a site remediation plan for the North Campus.[107]

Between December 21, 2016 and April 25, 2017, Zimmer sent four written responses to the FDA about the North Campus.[108] In total, these responses to the FDA consisted of more than 22,000 pages.[109] The responses outlined the Company's internal audits and actions to address "systemic issues."[110] The Board continued to

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[102] *Id.* ¶ 231.

[103] *Id.*

[104] *Id.*

[105] *Id.* ¶ 184.

[106] *Id.*; Barillare Decl. Ex. 16 (Dec. 16, 2016 Zimmer Board meeting minutes and presentation slides).

[107] Compl. ¶ 185; Barillare Decl. Ex. 16.

[108] Compl. ¶ 190.

[109] *Id.*

[110] *Id.*; *see* Barillare Decl. Ex. 17 at 2.

receive regular updates on the North Campus inspection and Zimmer's response throughout 2017 and 2018.[111]

H. Litigation Ensues

Lawsuits began within a month of Zimmer reducing its guidance for the third quarter of 2016. On December 2, 2016, a securities class action was filed in the United District Court for the Northern District of Indiana against Zimmer and certain of its directors and officers (the "Securities Class Action").[112] The PE Funds other than the Blackstone Fund were later named as defendants in a second amended complaint filed in October 2017.[113] On September 26, 2018, the district court in Indiana denied Zimmer and the individual defendants' motion to dismiss the Securities Class Action,[114] but granted the PE Funds' motions to dismiss.[115] At the time the Complaint in this action was filed, the parties to the Securities Class Action had announced a proposed settlement of $50 million.[116]

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[111] *See* Compl. ¶¶ 189–94.

[112] *Id.* ¶ 279.

[113] *See* Second Am. Class Action Compl. for Violations of the Fed. Sec. Laws, *Shah v. Zimmer Biomet Hldgs., Inc.*, 348 F. Supp. 3d 821 (N.D. Ind. 2018) (No. 3:16-cv-00815-PPS-MGG), 2017 WL 5494812 (Dkt. 60).

[114] *See* Compl. ¶¶ 283–86; *Shah v. Zimmer Biomet Hldgs., Inc.*, 348 F. Supp. 3d 821, 851 (N.D. Ind. 2018).

[115] *Shah*, 348 F. Supp. 3d at 851.

[116] Compl. ¶ 287.

Litigation in this court began on June 14, 2019 with the filing of two separate complaints that relied upon books and records Zimmer had produced under 8 *Del. C.* § 220.[117] Those actions were consolidated on September 4, 2019.[118] The plaintiffs filed the operative Complaint on June 3, 2020.[119]

The Complaint advances six counts derivatively on behalf of Zimmer: breach of fiduciary duty against the individual defendants in Count I; insider trading against Michelson and Rhodes under *Brophy v. Cities Service Company* in Count II;[120] aiding and abetting against the PE Funds in Counts III and IV; unjust enrichment against the individual defendants and the PE Funds in Count V; and breach of contract against the PE Funds in Count VI. On September 14, 2020, each of the defendants moved to dismiss the Complaint.[121]

II. LEGAL ANALYSIS

The defendants have moved to dismiss the Complaint under Court of Chancery Rule 23.1 for failure to make a demand on the Board. All defendants except Zimmer have also moved to dismiss the Complaint under Court of Chancery

[117] *See* Dkt. 10; Compl. at 3.

[118] Dkt. 10.

[119] Dkt. 47.

[120] 70 A.2d 5 (Del. Ch. 1949).

[121] *See* Dkts. 67, 69, 72, 76. After briefing, the court heard oral argument on June 15, 2021. Dkt. 104.

Rule 12(b)(6) for failure to state a claim on which relief can be granted. The demand requirement of Rule 23.1 presents a threshold issue as to all counts in the Complaint.

A. The Legal Standard for Demand Excusal

"The decision whether to initiate or pursue a lawsuit on behalf of the corporation is generally within the power and responsibility of the board of directors."[122] A stockholder plaintiff can only pursue claims belonging to the corporation if (1) the corporation's directors wrongfully refused a demand to authorize the corporation to bring the suit or (2) a demand would have been futile because the directors were incapable of impartially considering the demand.[123] Because the plaintiffs did not make a demand on Zimmer's Board, the Complaint must plead particularized factual allegations establishing that demand was excused.[124] All of the parties agree that the standard for assessing demand excusal in this case is set forth in *Rales v. Blasband.*[125] The court applies *Rales* when "the board that would be considering the demand did not make a business decision which is being challenged in the derivative suit," such as "where directors are sued derivatively because they have failed to do something."[126]

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[122] *In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 120 (Del. Ch. 2009) (citing 8 *Del. C.* § 141(a)).

[123] *See Rales v. Blasband*, 634 A.2d 927, 932 (Del. 1993).

[124] Ct. Ch. R. 23.1; *see, e.g.*, *Guttman v. Huang*, 823 A.2d 492, 499 (Del. Ch. 2003).

[125] 634 A.2d 927 (Del. 1993).

[126] *Id.* at 933–34 & n.9.

Under *Rales*, demand is excused if the allegations in a complaint "create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand."[127] To that end, "[a] director cannot exercise . . . independent and disinterested business judgment where [the] director is 'either interested in the alleged wrongdoing or not independent of someone who is.'"[128] If "the directors face a 'substantial likelihood' of personal liability, their ability to consider a demand impartially is compromised under *Rales*, excusing demand."[129]

While engaging in this analysis, I confine myself to the well-pleaded allegations of the Complaint, the documents incorporated into the Complaint by reference, and facts subject to judicial notice.[130] All reasonable inferences from the allegations in the Complaint are drawn in favor of the plaintiffs.[131] "Rule 23.1 is not satisfied by conclusory statements or mere notice pleading."[132] Instead, "[w]hat the

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[127] *Id.* at 934.

[128] *Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *15 (Del. Ch. Aug. 24, 2020) (quoting *Hughes v. Hu*, 2020 WL 1987029, at *12 (Del. Ch. Apr. 27, 2020)).

[129] *Guttman*, 823 A.2d at 501.

[130] *See, e.g.*, *White v. Panic*, 783 A.2d 543, 546–47 (Del. 2001); *see also In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 170 (Del. 2006).

[131] *Brehm v. Eisner*, 746 A.2d 244, 255 (Del. 2000).

[132] *Id.* at 254.

pleader must set forth are particularized factual statements that are essential to the claim."[133]

B. The Demand Excusal Analysis in This Case

The court "counts heads" of the members of a board to determine whether a majority of its members are disinterested and independent for demand futility purposes.[134] The Board in place when this litigation was filed had 11 members: Higgins and Michelson; Director Defendants Begley, Bernard, Boudreux, Farrell, Glasscock, Hagemann; and non-parties Jafry, Hilado, and Hanson (together, the "Demand Board").[135] The plaintiffs concede that Jafry, Hilado, and Hanson do not face a substantial likelihood of liability.[136] And they only allege that three members of the Demand Board—Michelson, Higgins, and Hanson (as Zimmer's CEO)—lack independence or received some benefit from the PE Funds' stock sales.[137] Even if the plaintiffs could sufficiently demonstrate that those three directors lacked independence,[138] they must also impugn the disinterestedness of at least three others

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[133] *Id.*

[134] *See In re EZCORP Inc. Consulting Agreement Deriv. Litig.*, 2016 WL 301245, at *34 (Del. Ch. Jan. 25, 2016).

[135] Compl. ¶ 294.

[136] *See id.* ¶ 29.

[137] *Id.* ¶¶ 294 n.29, 311–12, 326.

[138] The plaintiffs contend only that Michelson was personally interested in the challenged stock offerings. *See id.* ¶¶ 311–12. Little is said about the interests of Higgins except that he was employed by Blackstone's healthcare group Blackstone Healthcare Partners as a "Consultant." *Id.* ¶¶ 41, 51. The plaintiff's only allegation about Hanson is that he "is not

(*i.e.*, three of Begley, Bernard, Boudreux, Farrell, Glasscock, and Hagemann) to show that a majority of the Demand Board was disabled from considering a demand.[139] The plaintiffs attempt to make that showing by arguing that the Director Defendants all face a substantial likelihood of personal liability.

"To establish a substantial likelihood of liability at the pleading stage, a plaintiff must 'make a threshold showing, through the allegation of particularized facts, that their claims have some merit.'"[140] Because Zimmer's certificate of incorporation contains an exculpation provision under 8 *Del. C.* § 102(b)(7),[141] the plaintiffs must plead with particularity facts that support a meritorious claim for breach of the duty of loyalty.[142] The Complaint primarily focuses on whether material non-public information about Zimmer's FDA compliance challenges

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independent from interested directors due to his principal occupation as Zimmer's CEO." *Id.* ¶ 294 n.29. The defendants declined to brief whether Higgins, Michelson, and Hanson could impartially consider a demand. *See* Zimmer Defs.' Opening Br. at 26 (saying the court "need not consider" the plaintiffs' allegations about the independence of those three directors). I need not reach the issue of whether Michelson, Higgins, or Hanson could impartially consider a demand because—even if they could not—the plaintiffs cannot establish demand futility.

[139] *See* Pls.' Answering Br. 7 n.2 (Dkt. 85).

[140] *In re TrueCar, Inc. S'holder Deriv. Litig.*, 2020 WL 5816761, at *12 (Del. Ch. Sept. 30, 2020) (quoting *Rales*, 634 A.2d at 934).

[141] Barillare Decl. Ex. 9 (Zimmer's Restated Certificate of Incorporation dated June 24, 2015) § 10.01.

[142] *TrueCar*, 2020 WL 5816761, at *12; *In re Goldman Sachs Gp., Inc. S'holder Litig.*, 2011 WL 4826104, at *12 (Del. Ch. Oct. 12, 2011).

played a role in the PE Funds' sales of over $3.3 billion in Zimmer stock in 2016.[143] The problem for the plaintiffs is that they failed to plead non-conclusory facts suggesting that a super-majority of directors without ties to the PE Funds knowingly facilitated insider trading. Perhaps recognizing that hurdle, they also assert that the eight members of the Demand Board named as defendants in this action face a substantial likelihood of liability for approving false and misleading disclosures, for breaching their duty of oversight, and based on the Securities Class Action. I will address each argument in turn below.

The outcome of my analysis is that none of the six Director Defendants face a substantial likelihood of liability in this action or the Securities Class Action. The plaintiffs get closest with a disclosure claim against the four Audit Committee members (Begley, Boudreaux, Glasscock, and Hagemann) but fall short of pleading a breach of the duty of loyalty. The result is that at least eight of the 11 Demand Board members are independent, had no ties to the PE Funds or disabling interests from the stock sales, and did not face a risk of liability for a non-exculpated claim.

1. The Disclosure Claim

Although the crux of the wrongdoing alleged in the Complaint is insider trading, the plaintiffs' demand futility arguments mostly focus on disclosures. The Complaint challenges numerous "SEC filings, press releases, conference calls, and

[143] *See, e.g.*, Compl. ¶ 1.

presentations to the public" Zimmer made during the relevant period,[144] including the Registration Statement and prospectuses related to the February, June, and August Offerings.[145] The gist of the plaintiffs' disclosure argument is that Zimmer was publicizing the "purported successful integration [of Legacy Zimmer and Legacy Biomet] and the Company's growing organic growth rate" at a time that Zimmer was privately facing quality and regulatory deficiencies.[146] In particular, they assert that all of Zimmer's public disclosures in 2016 were false and misleading because they "touted the purported ongoing success of the integration of [Legacy] Zimmer and [Legacy] Biomet," but "failed to disclose known systemic quality system and quality control problems," "the Company's FDA regulatory deficiencies," and "the massive remediation efforts that were necessary to bring Zimmer into compliance with FDA regulations and that would adversely impact production and distribution of key products."[147] The plaintiffs claim generally that Zimmer omitted material information from its public statements rather than challenge any specific statements by Zimmer as false or misleading.[148]

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[144] *Id.* ¶ 196; *see id.* ¶¶ 215, 221, 263, 265–66, 306, 333.

[145] *See id.* ¶¶ 215, 257, 260, 306, 315, 317, 333.

[146] *Id.* ¶ 195.

[147] *Id.* ¶¶ 211, 266.

[148] *See Citigroup*, 964 A.2d at 133 ("[T]he disclosure allegations in the complaint do not meet the stringent standard of factual particularity required under Rule 23.1. They fail to allege with particularity which disclosures were misleading, when the Company was

"Whenever directors communicate publicly or directly with shareholders about the corporation's affairs, with or without a request for shareholder action, directors have a fiduciary duty to shareholders to exercise due care, good faith and loyalty."[149] The duty of disclosure "is not an independent duty, but derives from the duties of care and loyalty."[150] The contours of that duty and what it requires of fiduciaries are context specific. Where (like here) the disclosures at issue do not concern a request for stockholder action, *Malone v. Brincat* requires that a plaintiff demonstrate scienter—*i.e.*, that the directors "deliberately misinform[ed] shareholders about the business of the corporation, either directly or by a public statement."[151] Because Zimmer's certificate of incorporation includes a Section 102(b)(7) provision, the plaintiffs "must plead particularized factual allegations that 'support the inference that the disclosure violation was made in bad faith, knowingly or intentionally'"[152] to establish demand futility.

A determination of "whether the alleged misleading statements or omissions were made with knowledge or in bad faith requires an analysis of the state of mind

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obligated to make disclosures, what specifically the Company was obligated to disclose, and how the Company failed to do so.").

[149] *Malone v. Brincat*, 722 A.2d 5, 10 (Del. 1998).

[150] *Pfeffer v. Redstone*, 965 A.2d 676, 684 (Del. 2009) (citation and internal quotation marks omitted).

[151] *Malone*, 722 A.2d at 14.

[152] *Citigroup*, 964 A.2d at 132 (quoting *O'Reilly v. Transworld Healthcare, Inc.*, 745 A.2d 902, 915 (Del. Ch. 1999)).

of the individual director defendants."[153] It is difficult to know one's state of mind at the pleadings stage, particularly for independent directors that lack any obvious motivations to act disloyally.[154] Delaware courts may infer scienter for *Malone* claims where certain types of specific factual allegations are made. A plaintiff must plead with particularly that directors "had knowledge that any disclosures or omissions were false or misleading or . . . acted in bad faith in not adequately informing themselves."[155] A plaintiff also must allege "sufficient board involvement in the preparation of the disclosures"[156] to "connect the board to the challenged statements.'"[157] Despite having access to the relevant Board minutes and materials, however, the plaintiffs cannot link what the directors learned about continuing FDA compliance challenges with any materially misleading statements they were responsible for making.

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[153] *Id.* at 134; *see also Ryan v. Armstrong*, 2017 WL 2062902, at *5 (Del. Ch. May 15, 2017) (discussing how directors' "motives, background, or relationships" factor into the demand futility analysis), *aff'd*, 176 A.3d 1274 (Del. 2017) (TABLE).

[154] *See In re GoPro, Inc.*, 2020 WL 2036602, at *11 (Del. Ch. Apr. 28, 2020) (observing a lack of pleaded facts allowing for an inference that a majority of the board was beholden to defendants who sold shares "such that [the directors] would be motivated to facilitate or cover up illegal insider trading").

[155] *Citigroup*, 964 A.2d at 134.

[156] *Id.*; *see also id.* at 133 n.91 (explaining that a plaintiff must "sufficiently allege facts showing that the director defendants were involved in preparing (or were otherwise responsible for) the alleged misleading disclosures").

[157] *TrueCar*, 2020 WL 5816761, at *13 (internal quotation marks omitted); *see also In re Dow Chem. Co. Deriv. Litig.*, 2010 WL 66769, at *11 (Del. Ch. Jan. 11, 2010).

The Complaint alleges that the Board knew about "undisclosed, serious, and 'systemic' quality control issues across many of its manufacturing facilities throughout 2015 and 2016."[158] According to the plaintiffs, the eventual temporary shutdown at the North Campus was "easily foreseeable" because of Zimmer's regulatory compliance issues.[159] But, the plaintiffs say, despite "actual knowledge of" Zimmer's FDA compliance struggles, the Director Defendants "knowingly failed" to disclose those risks and violations to the public.[160]

The operative inquiry for the court is determining when a majority of the Demand Board both learned about the potentially problematic event "and understood its significance to [the company's] financial performance."[161] This court's decision in *TrueCar* is instructive. There, the plaintiffs alleged that the board learned of a website redesign that had a materially negative effect on the company's financial performance but failed to disclose it.[162] The court found that because the board materials did not reflect any expected financial harm from the redesign, the plaintiffs "failed to allege with particularity facts sufficient to support a reasonable inference

[158] Compl. ¶ 7; *see also* Pls.' Answering Br. 35.

[159] Compl. ¶ 112.

[160] Pls.' Answering Br. 33, 35.

[161] *TrueCar*, 2020 WL 5816761, at *14.

[162] *Id.*

of *scienter*, *i.e.*, that the directors . . . knew before they signed or approved" the challenged disclosure that the company's business would subsequently "suffer."[163]

Here, the question I must consider for purposes of that analysis is when the Board understood both that the North Campus was in severe violation of FDA regulations ***and*** that the lack of compliance would have a materially negative effect on Zimmer's financial performance. The plaintiffs argue that the Board's knowledge derives from the three internal audit reports, the FDA's September 12, 2016 inspection of the North Campus, and the resulting blanket product ship hold.[164] To examine the directors' knowledge, the court will consider the plaintiffs' allegations chronologically for three time periods: (i) before May 3, 2016; (ii) from May 3, 2016, when the Board was informed about results from the internal audit reports, to September 12, 2016; and (iii) from September 12, 2016, when the FDA's for cause inspection of the North Campus began, forward.

a. Before the May 3, 2016 Board Meeting

The plaintiffs allege that the Board "already kn[ew]" about "significant violations" at the North Campus before the May 3, 2016 Board meeting where internal audit results were first discussed.[165] The Complaint explains that the Board

[163] *Id.* at *15.

[164] *See* Compl. ¶¶ 18–22, 113–19.

[165] *Id.* ¶ 18.

routinely received presentations about the Company's regulatory compliance performance during regularly scheduled meetings after the merger closed in June 2015. But the presentations the Board received at meetings between July 17, 2015 (the first Board meeting post-merger) and May 3, 2016 contain only limited and unremarkable mentions of the North Campus.[166] None of the references to "systemic" issues or negative observations at other Zimmer facilities are alleged to be related to what eventually transpired at the North Campus.

Each of the Board presentations during this time period follow a similar pattern: they list the results of FDA inspections at various Zimmer facilities, certain negative observations from those inspections, and plans for remediation. For example, on July 17, 2015, the Board was told that the North Campus (among other Legacy Biomet facilities) had been inspected in 2014, receiving two negative observations,[167] and that the North Campus was due for its biennial FDA inspection in 2016.[168] The Board was also told that outside consulting firm Parexel had performed a mock inspection of the North Campus that identified 11 major and seven minor observations leading Zimmer to open 10 "action records" to address those observations.[169] For the next three Board presentations at meetings held on

[166] *See id*. ¶¶ 127–57 (discussing Board presentations from this time period).

[167] *Id.* ¶ 131.

[168] *Id.* ¶ 268.

[169] *Id.* ¶ 131.

September 25, 2015, December 11, 2015, and February 23, 2016,[170] the only mention of North Campus that the plaintiffs identify is that the Company "planned to audit the North Campus facility in the second quarter of 2016" as part of Zimmer's 2016 corporate audit plan.[171]

These Board presentations tell a story of Zimmer's ongoing efforts to ferret out compliance issues and fix them but provide no indication that the North Campus was a "ticking time bomb."[172] That is, the portions of the presentations that the plaintiffs highlight are insufficient to demonstrate with particularity that the Director Defendants present at these meetings knew that serious compliance issues were looming at the North Campus that would ripen into negative financial consequences.[173] This pleading deficiency is enough to eliminate an inference of bad faith misconduct, especially since there is no allegation that the Director Defendants failed to adequately inform themselves. But there are several other issues that further undermine any finding that the Director Defendants face a substantial threat of personal liability for a non-exculpated disclosure claim.

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[170] *See id.* ¶¶ 135–57.

[171] *Id.* ¶ 147.

[172] *Id.* ¶ 270.

[173] *E.g.*, *TrueCar*, 2020 WL 5816761, at *14-15. Eight Demand Board members are alleged to have attended the July, September, and December 2015 Board meetings. Compl. ¶¶ 133, 140, 151. Six Demand Board members are alleged to have attended the February 2016 Board meeting. *Id.* ¶ 156.

First, the "plaintiffs fail to allege with sufficient specificity the actual misstatements or omissions that constituted a violation of the board's duty of disclosure."[174] It is entirely unclear from their scattered allegations what precisely the plaintiffs believe was material information that the Board should have disclosed during this period. Plainly, every negative observation from all of Zimmer's facilities would not have been important information to investors.[175]

The closest the plaintiffs get to the required specificity is an allegation that the Director Defendants "allow[ed]" Zimmer to "issue materially false and misleading statements and omissions about the purported successful integration and the Company's growing organic growth rate."[176] There are no particularized facts in the Complaint, however, that would support an inference that Legacy Zimmer and Legacy Biomet were not integrating as planned. As to Zimmer's organic growth rate, Zimmer reported a better-than-expected growth rate of 1.2% for the first quarter

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[174] *See Citigroup*, 964 A.2d at 133 (finding that "the disclosure allegations in the complaint do not meet the stringent standard of factual particularity required under Rule 23.1").

[175] In fact, disclosing every negative compliance violation would have cut against the goal of highlighting material information for stockholders. *See Abrons v. Maree*, 911 A.2d 805, 813 (Del. Ch. 2006) ("Delaware courts must 'guard against the fallacy that increasingly detailed disclosure is always material and beneficial disclosure.'" (quoting *Zirn v. VLI Corp.*, 1995 WL 362616, at *4 (Del. Ch. June 12, 1995) (Chancellor Allen noting that "[i]n some instances, the opposite will be true"), *aff'd*, 681 A.2d 1050 (Del.1996)); *see also In re Rouse Properties, Inc.*, 2018 WL 1226015, at *24 (Del. Ch. Mar. 9, 2018) (noting that disclosure of "insignificant detail[s]" could "dilute the value and purpose of public corporate disclosures").

[176] Compl. ¶ 195.

of 2016 and raised its revenue guidance for the remainder of the year.[177] There is nothing inherently misleading about the disclosures on these topics.

Moreover, the Complaint lacks allegations demonstrating actual Board involvement in or responsibility for disclosures. Several of the statements that the plaintiffs appear to challenge during this time period were made by Zimmer officers during earnings calls or at conferences where the Board is not alleged to have played any role.[178] The plaintiffs' arguments about Zimmer's public filings fare no better. The disclosures filed with the Securities and Exchange Commission that the plaintiffs challenge as "false and misleading" during this time period are: (1) the 2015 Form 10-K (filed with the SEC on February 29, 2016); (2) the first quarter 2016 Form 10-Q (filed with the SEC on May 10, 2016), (3) the Registration Statement (filed with the SEC on February 4, 2016); and (4) the prospectus supplements for the February Offering (filed with the SEC on February 5, 2016 and February 8, 2016).[179]

The only mentions in the Complaint of Board involvement in the 2015 Form 10-K, the Registration Statement, and the prospectus supplements are the types of allegations that this court has repeatedly found inadequate for purposes of Rule 23.1.

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[177] *Id.* ¶ 202.

[178] *See id*. ¶¶ 198–201.

[179] *See id.* ¶¶ 215, 260.

A statement that the documents were signed by the Director Defendants,[180] or that they "approved" the disclosures and "caused" or "consented to" their filing,[181] is not—without more—a particularized allegation of fact.[182] There are also no specific

[180] *See id.* ¶¶ 35–45, 306, 314; *see also* Pls.' Answering Br. 21 (asserting that "[e]ight directors reviewed, signed, approved, and issued the Registration Statement and Prospectuses used in the three offerings").

[181] Compl. ¶¶ 260, 263, 265, 328, 338.

[182] *Ellis v. Gonzalez*, 2018 WL 3360816, at *10 (Del. Ch. July 10, 2018), *aff'd*, 205 A.3d 821 (Del. 2019); *Citigroup*, 964 A.2d at 133 n.88 ("Pleading that the director defendants 'caused' or 'caused or allowed' the Company to issue certain statements is not sufficient particularized pleading to excuse demand under Rule 23.1."); *see also Brehm*, 746 A.2d at 254; *In re China Auto. Sys. Inc. Deriv. Litig.*, 2013 WL 4672059, at *8 (Del. Ch. Aug. 30, 2013) (finding the allegation "that all five directors attested to the misleading financial statements by signing one of the SEC filings at issue" insufficient to excuse demand (internal citation omitted)).

The Court of Chancery has found allegations that a defendant signed an allegedly false or misleading disclosure sufficient to state a claim for relief under the lower pleading standard of Rule 12(b)(6). *See In re Hansen Med., Inc. S'holders Litig.*, 2018 WL 3025525, at *11 (Del. Ch. June 18, 2018). That is not the case where the heightened pleading standard of Rule 23.1 applies. In addition, having reviewed the prospectuses issued in connection with the February, June, and August Offerings, none appear to bear the signature of any Director Defendant. *See* Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (Feb. 5, 2016); Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (Feb. 8, 2016); Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (June 13, 2016); Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (June 15, 2016); Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (Aug. 9, 2016); Zimmer Biomet Hldgs., Inc., Prospectus Suppl. (Form 424B7) (Aug. 11, 2016); *see also Gen. Motors (Hughes)*, 897 A.2d at 170 (permitting the court to take judicial notice of "hearsay in SEC filings" that is not subject to reasonable dispute).

The plaintiffs also note that "[t]o the extent the Director Defendants seek to limit their liability solely to public filings that they 'signed,' that argument would have little effect here, where the Registration Statement and the Offering Documents incorporated by reference other public filings at issue in this case such as the 10-K, including, specifically, the risks and uncertainties disclosed in each of those public filings." Pls.' Answering Br. 41 n.12. The plaintiffs cite no case to support this argument, and the court is aware of none.

allegations in the Complaint about the first quarter 2016 Form 10-Q. The plaintiffs only make general assertions about the role of the Audit Committee in reviewing quarterly financial statements and overseeing certain internal controls disclosures,[183] which are insufficient to demonstrate the Audit Committee's actual involvement in the statements in (or omissions from) the Form 10-Q.[184] The lack of well-pleaded allegations about the Director Defendants' involvement in the disclosures "independently preclude[s] a finding of demand futility."[185]

b. Between the May 3, 2016 Board Meeting and September 12, 2016 Inspection

The plaintiffs contend that the Board's knowledge of serious problems changed after May 3, 2016. According to the Complaint, the Board learned "no later than May 3, 2016" that Zimmer's "most important" facility—the North Campus—"was in a terrible state of FDA compliance" and a "disaster waiting to happen."[186]

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[183] Compl. ¶ 79. The Complaint describes the Audit Committee's responsibilities as including "review[ing] and discuss[ing] with management and the independent auditor the quarterly financial statements prior to their public release." *Id.*

[184] *See Wood v. Baum*, 953 A.2d 136, 142 (Del. 2008) ("Plaintiff also asserts that membership on the Audit Committee is a sufficient basis to infer the requisite scienter. That assertion is contrary to well-settled Delaware law."); *Ellis*, 2018 WL 3360816, at *11 (finding argument that audit committee members could not impartially consider a demand given their "oversight responsibility" unpersuasive because it "runs up against the well-settled rule that mere membership on a board committee is insufficient to support a reasonable inference of disloyal conduct"). Further, these allegations are not determinative as to the court's demand futility analysis because the Audit Committee members constitute a minority of the Demand Board.

[185] *Ellis*, 2018 WL 3360816, at *9.

[186] Compl. ¶ 13; *see also id.* ¶ 125.

The basis for that knowledge is alleged to be a May 3, 2016 Board presentation revealing "poor results of at least two—and potentially all three—of Zimmer's 2016 North Campus internal audits."[187]

The plaintiffs focus on a slide from that presentation that they say describes the results of the March 31, 2016 and April 13, 2016 internal audit reports that listed a total of four critical, 21 major, and two minor observations related to the North Campus.[188] That slide does not include the results of the June 7, 2016 audit report, which was "in draft" form with the result "TBD."[189] Although the plaintiffs say that copies of the internal audit reports "were provided to the Board no later than May 3, 2016," there are no particularized facts pleaded in support.[190] The plaintiffs are not even certain that the information described on the slide corresponds to the three North Campus audits in the first place.[191]

The difficulty for the plaintiffs is an absence of pleaded facts implying bad faith on the part of the Director Defendants. Even if the court accepts as true that the slide the plaintiffs highlight described the three North Campus internal audits,

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[187] *Id.* ¶ 159.

[188] *Id.* ¶¶ 85, 124, 159. The slide the plaintiffs highlight lists the March 31, 2016 internal audit report as including 13 major and four minor observations. *Id.* ¶ 159. The plaintiffs, however, allege that only six major and two minor observations from that audit report relate to the North Campus. *Id.* ¶ 124.

[189] *Id.* ¶ 159.

[190] *Id.* ¶¶ 13, 18.

[191] *Id.* ¶ 159 n.18.

there are no particularized allegations supporting a reasonable inference that the Board knew the results of the North Campus internal audits would be spell "disaster."[192] As with the prior time period, the North Campus is not singled out. The results of 11 other audits at Zimmer facilities—all with some degree of critical, major, and minor observations—are also included with the same level of detail.[193] The plaintiffs acknowledge that the May 3, 2016 presentation was largely "[l]ike other presentations before it" because it "led the Board on a global overview of all of Zimmer's FDA inspections during 2015 and 2016 to-date."[194]

The Board presentation given at the next meeting on July 15, 2016 likewise cannot support an inference of scienter. The plaintiffs again point to one slide from the July 15, 2016 Board deck that they say indicated the "severity and scope of Zimmer's manufacturing problems" at the North Campus.[195] More specifically, they focus on one line of a six-line chart on a slide that lists "Network Remediation Activities."[196] Over a dozen facilities are discussed, including "Warsaw Biomet (2016/2017/2018)" (i.e., the North Campus) with the "Driver" for remediation

[192] *Id.* ¶ 13; *see also* ¶¶ 159–161.

[193] *Id.* ¶ 159.

[194] *Id.* ¶ 158.

[195] *Id.* ¶ 167.

[196] *Id.* ¶ 166.

described as: "Corporate Audit and Zimmer Warsaw/Ponce lessons learned from Form 483 Observations."[197]

The plaintiffs make much of the fact that only the North Campus was scheduled to have remediation efforts last into 2018.[198] That may be so. But even if the court were to deduce from that detail that the North Campus' problems were "not an easy set of issues to remediate"[199] and would require a period of time to fully address, it cannot reasonably follow that the Board knew they would escalate and cause Zimmer to suffer financial harm in the future.[200] Consequently, there is no basis to infer that the Board intentionally "concealed" information about the internal audits from stockholders by creating misleading public filings.[201]

Further, the Complaint lacks allegations suggesting Board-level involvement in preparing the disclosures that satisfy the heightened pleading requirements of Rule 23.1. The only disclosures that the plaintiffs challenge during this time period are: (1) the second quarter 2016 Form 10-Q (filed with the SEC on August 8,

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[197] *Id.*; *see also id.* ¶ 187.

[198] *Id.* ¶¶ 167, 187.

[199] *Id.* ¶ 167.

[200] *See TrueCar*, 2020 WL 5816761, at *15 (finding no scienter where the plaintiffs failed to allege facts demonstrating "that the directors in attendance at the meeting knew before they signed or approved" the challenged disclosure that the company's "business . . . would suffer").

[201] Compl. ¶ 167.

2016),[202] and (2) the prospectus supplements for the June and August Offerings (filed with the SEC on June 13, 2016, June 15, 2016, August 9, 2016, and August 11, 2016, respectively).[203] Beyond the sort of contentions about "causing" or "approving" disclosures I previously found wanting,[204] the only facts pleaded that address the Board's role in these disclosures relate to an August 5, 2021 Audit Committee meeting where the August Offering was discussed.[205] But there is no allegation that the Audit Committee approved of the second quarter Form 10-Q or the prospectus supplement for the August Offering at that meeting.[206] "[F]actual details" about "how the [B]oard was actually involved in creating or approving the statements" are "crucial to determining whether demand on the [Board] would have been excused as futile."[207] Without them, I cannot conclude that the Director Defendants acted with scienter and face a substantial likelihood of liability for

[202] *Id.* ¶ 215.

[203] *Id.* ¶¶ 263, 265.

[204] *See supra* at 38–40.

[205] Compl. ¶ 172. The plaintiffs do not allege that the Audit Committee discussed any FDA compliance issues at that meeting, let alone the specific compliance issues at the North Campus.

[206] *Guttman*, 823 A.2d at 498 (dismissing complaint that was "devoid of any pleading regarding the full board's involvement in the preparation and approval of the company's financial statements" and of "particularized allegations of fact demonstrating that the outside directors had actual or constructive notice of the accounting improprieties").

[207] *Citigroup*, 964 A.2d at 133 n.88.

material omissions or misstatements in the Form 10-Q or August Offering documents.

c. After the September 12, 2016 Inspection

The primary harms alleged in this case began with the September 12, 2016 FDA inspection of the North Campus, which resulted in negative observations, product ship holds, a Form 483, and preceded reduced revenue guidance and a decline in Zimmer's stock price. All of the PE Funds had exited their investments at least a month before the inspection began. The plaintiffs' focus largely is on ordinary course SEC filings issued after the inspection, rather than filings connected to the Offerings, during this time period.

The Board first learned about the commencement of the FDA's inspection during a regularly scheduled September 23, 2016 Board meeting.[208] Zimmer management told the Board that the inspection was "'for cause' based on product complaints that had been received" and that the inspection would last for about two weeks.[209] There are no well-pleaded facts stating that the Board was told a facility shut down or product ship hold had occurred or would occur.[210] There is also no

[208] Compl. ¶ 175.

[209] *Id.*

[210] The plaintiffs allege that the FDA inspection of the North Campus had "resulted in multiple product ship holds" by the time of the September 23, 2016 meeting. *Id.* ¶ 176. The plaintiffs do not allege, however, that the Board had any knowledge of these product ship holds.

reason to believe that the Board could have foreseen the ship hold, which plaintiffs describe as a "rare consequence of an FDA inspection."[211] The Form 483 listing the results of the FDA inspection was not issued until two months after the Board meeting, on November 22, 2016.[212]

The first time that the plaintiffs allege with particularity that the full Board learned of the fallout from the North Campus inspection is at a December 16, 2016 Board meeting.[213] At oral argument, the plaintiffs clarified that they are challenging certain disclosures that were issued *before* that December 16, 2016 meeting.[214] Those disclosures appear to be: (1) Zimmer's third quarter 2016 earnings release (issued on October 31, 2016),[215] (2) Dvorak's statements to investors during an earnings call (also on October 31, 2016),[216] (3) Zimmer's third quarter 2016 Form 10-Q (filed with the SEC on November 8, 2016),[217] and (4) Zimmer's December 14,

[211] *Id.* ¶ 19. The plaintiffs do not allege that any Zimmer or Biomet facility had ever been subject to a product ship hold before September 29, 2016.

[212] *Id.* ¶ 116. The Complaint lists the date of the Form 483 as November 20, 2016 (*see id.* ¶ 9) but that appears to be an error.

[213] *Id.* ¶¶ 113, 184–88.

[214] *See* Oral Arg. Tr. 72 (June 15, 2021) (Dkt. 105) (responding to the court's question about what disclosures were challenged after September 12, 2016).

[215] *See* Compl. ¶¶ 181–82.

[216] *See id.* ¶ 218.

[217] *See id.* ¶ 221.

2016 press release in which it mentioned "certain regulatory compliance gaps at the legacy Biomet operation in Warsaw."[218]

As with disclosures from the earlier time periods, there is ambiguity around which misstatements or omissions in those disclosures the plaintiffs believe are material. There are also no particularized allegations that would suggest the Director Defendants had knowledge that the statements were materially wrong before December 16, 2016. Of course, it is not unreasonable to think that the Board would have been given updates on the North Campus inspection and the product ship holds throughout the fall of 2016. But there are no specific, factual allegations in the Complaint that would support such an inference. Even if there were, the plaintiffs still must plead facts demonstrating that the Board intentionally concealed that information from the public by causing Zimmer to issue materially misleading disclosures. They have not done so.

With the exception of the earnings release (which I will address next), the plaintiffs do not describe any Board-level involvement in these disclosures. They say nothing that could tie the directors to Dvorak's October 31, 2016 statements. There is also no allegation that the Board had any involvement in the press release, which could hardly evidence deceit in any

[218] *Id.* ¶ 231.

event since it explained that Zimmer "ha[d] developed and [wa]s executing a remediation plan to fully address the issues cited by the FDA."[219] As to the third quarter Form 10-Q, the plaintiffs' conclusory statement that Form 10-Q was "reviewed and approved by the Audit Committee and Board" does not satisfy Rule 23.1's pleading requirements.[220]

The only challenged disclosure that comes close to directly implicating any of the Demand Board members is the third quarter earnings release that was reviewed and approved by the Audit Committee. The third quarter earnings release covered the period ending September 30, 2016—just one day after the first ship hold went into effect. It is uncertain how much, if at all, the ship hold affected Zimmer's third quarter results (or what the Audit Committee knew about potential effects).[221] But based on the Complaint, there is reason to infer that the Audit Committee members

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[219] *Id.* ¶ 231. The Complaint states that this press release was only a "partial public disclosure[]." *Id.* ¶ 184. The plaintiffs do not, however, allege with particularity what material facts were omitted.

[220] *Id*. ¶ 221. *See supra* note 182 (citing cases); *see also Citigroup*, 964 A.2d at 134.

Like the earnings release discussed next, it is also not apparent that the Form 10-Q could support a finding of bad faith. That public filing announced that the company's below-guidance revenues were due to "some temporary disruption in product supply . . . related to several factors." Compl. ¶ 221. Those sorts of statements seem inconsistent with the plaintiffs' cover-up theory.

[221] On December 14, 2016, Zimmer disclosed that "the anticipated full impact of" the North Campus ship hold "was included in the Company's sales and earnings guidance update issued on October 31, 2016." *Id.* ¶ 231. The plaintiffs do not allege that this statement in particular was false or misleading.

knew that the FDA inspection of the North Campus would have an effect on Zimmer's revenue guidance when they approved the earnings release. As the Complaint points out, the Audit Committee was given an update "on the ongoing FDA inspection of [North] Campus" during its October 24, 2016 meeting.[222] "At the conclusion of [that] discussion, the Committee members expressed no objections to the contents of the draft earnings release."[223]

The earnings release cannot, however, support a finding that the Audit Committee members face a substantial likelihood of liability for a duty of loyalty claim. The plaintiffs' allegations emphasize that the earnings release *revealed* problems to the market. According to the Complaint, the earnings release "reduced [Zimmer's] revenue guidance for the fourth quarter of 2016, causing a massive decline in the share price."[224] The plaintiffs describe the third quarter 2016 disclosures as painting "a drastically different outlook" than Zimmer had previously

[222] *Id.* ¶ 181; Barillare Decl. Ex. 18.

[223] Compl. ¶ 181; Barillare Decl. Ex. 18.

[224] Compl. ¶ 23; *see also id.* ¶¶ 217, 223.

provided.[225] It is difficult to square these allegations with the plaintiffs' contention that the directors were engaging "in a scheme to defraud Zimmer investors."[226]

The plaintiffs nonetheless argue that the earning release was an attempt to "hide and obscure" information from the public because the release "contained no disclosure of the FDA inspection or manufacturing shutdown."[227] In other words, the Audit Committee did not ensure that Zimmer adequately disclosed a potential reason for its reduced guidance. That assertion might call into question the Audit Committee members' "'erroneous judgment' concerning the proper scope and content of the disclosure."[228] But that would, at best, support an exculpated claim

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[225] *Id.* ¶ 217. It is also not apparent what about the earning release was false or misleading, given the more negative outlook that it presented. The roughly 14% decline in Zimmer's stock price that the plaintiffs say demonstrates harm occurred weeks before the plaintiffs allege the market was informed about the Form 483 and ship holds at the North Campus. The plaintiffs do not allege that Zimmer's stock price fell when the market learned about the Form 483 and the product ship hold at the North Campus on December 14, 2016. The final allegation in the Complaint about the effects on Zimmer's stock price is that "[b]y November 14, 2016, Zimmer's stock price reached a low of $97.99." *Id.* ¶ 223. The dearth of allegations demonstrating any negative reaction to the disclosure of events at the North Campus further undercuts the plaintiffs' argument that those events were material ones requiring disclosure beyond the financial information Zimmer released at the end of the third quarter. Notably, the December 14, 2016 press release quoted in the Complaint states that the "full impact" of various matters including the North Campus inspection and Form 483 was "included in the Company's sales and earnings guidance update issued on October 31, 2016." *Id.* ¶ 231.

[226] *See* Pls.' Answering Br. 6.

[227] *Id.* at 17–18.

[228] *Orman v. Cullman*, 794 A.2d 5, 41 (Del. Ch. 2002) (quoting *Crescent/Mach I P'rs, L.P. v. Turner*, 846, A.2d 963, 987 (Del. Ch. 2000)); *see also Morrison v. Berry*, 2019 WL 7369431, at *18 (Del. Ch. Dec. 31, 2019) ("Bad faith, in the context of omissions, requires

for breach of the directors' duty of care.[229] An inference cannot be drawn, from the limited allegations in the Complaint, that the Audit Committee approved an earnings release reducing revenue guidance while intentionally omitting material information about a possible underlying cause.[230] The plaintiffs do not ascribe any bad faith actions or motives to the Audit Committee members that would demonstrate otherwise.

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To summarize, the Complaint lacks particularized factual allegations supporting a reasonable inference that any Director Defendant faced a substantial likelihood of liability for a disclosure claim under *Malone*. There are no particularized allegations that the directors knew that the North Campus was facing atypical compliance struggles that would have a materially negative effect on Zimmer's financial performance until late 2016. The PE Funds had already exited their investments in Zimmer by that point and, given the lack of any alleged ties between a majority of the Demand Board and the PE Funds, why the directors would

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that the omission be intentional and constitute more than an error of judgment or gross negligence.").

[229] *Id.*

[230] *See Malone*, 722 A.2d at 14 (explaining that a disclosure violation must be made "in bad faith, knowingly or intentionally"); *cf. infoUSA, Inc. S'holders Litig.*, 953 A.2d 963, 990 (Del. Ch. 2007) (explaining that directors violate their fiduciary duties "where it can be shown that the directors involved issued their communication with the knowledge that it was deceptive or incomplete").

"conceal" problems at North Campus is not apparent or alleged. The plaintiffs only sufficiently allege Board-level involvement in one disclosure after the directors gained some knowledge of the significance of the North Campus's compliance issues: the third quarter 2016 earnings release approved by the Audit Committee. That earnings release, however, could support an exculpated duty of care claim at the most. The plaintiffs' disclosure arguments are insufficient to establish a substantial likelihood of liability for a non-exculpated claim. Demand is therefore not excused for a single Demand Board member on the basis of alleged disclosure violations.

2. "Knowing Facilitation" of Insider Trading

The plaintiffs next argue that demand is futile because the Director Defendants who constitute a majority of the Demand Board face a substantial risk of liability in connection with the plaintiffs' *Brophy* claim. To state a *Brophy* claim, a plaintiff must plead that insiders (1) "possessed material, nonpublic company information" and (2) "used that information improperly by making trades because [they were] motivated, in whole or in part, by the substance of that information."[231]

The plaintiffs do not allege that any director personally sold stock in the Offerings. They do not allege that the PE Funds (or anyone else) controlled a majority of the Demand Board. The only Demand Board member who the plaintiffs

[231] *In re Oracle Corp.*, 867 A.2d 904, 934 (Del. Ch. 2004).

say "personally benefitted" from the PE Funds' stock sales is Michelson, through his affiliation with the KKR Fund.[232] Michelson is also the only member of the Demand Board named as a defendant on the plaintiffs' insider trading claim.[233]

The plaintiffs contend that the six Director Defendants face liability because they "knowingly facilitated" the PE Funds' insider trading by "approving the offerings."[234] The plaintiffs argue that "knowing facilitation" is evidenced by the directors "signing (and disseminating) the Registration Statement and related documents."[235] This is simply another iteration of the plaintiffs' disclosure claim. The plaintiffs' limited and conclusory allegations about Board-level involvement in the Registration Statement and prospectus supplements cannot support an inference of knowledge, and resulting scienter, for a *Brophy* claim just as they cannot support a non-exculpated disclosure claim.[236]

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[232] Pls.' Answering Br. 47.

[233] *See* Compl. ¶¶ 343–48.

[234] Pls.' Answering Br. 47.

[235] *Id.* at 47–48.

[236] *See supra* at 37–41; *cf. In re Fitbit Inc. S'holder Deriv. Litig.*, 2018 WL 6587159, at *13, *18 (Del. Ch. Dec. 14, 2018) (finding that a director "knowingly facilitated" insider trading where the complaint adequately alleged that a majority of the demand board knew that "the information at issue was material and nonpublic"); *In re Emerging Commc'ns, Inc. S'holders Litig.*, 2004 WL 1305745, at *39 (Del. Ch. May 3, 2004) (explaining that a director was "culpable because he voted to approve the transaction even though he knew, or at the very least had strong reasons to believe, that the . . . merger price was unfair").

The plaintiffs' other theory of "knowing facilitation" of insider trading is that the Director Defendants approved the Offerings, "including a $250 million repurchase on the February [O]ffering" and, "with respect to the August 2016 [O]ffering, grant[ed] waivers of the lock-up agreement which permitted the Private Equity Defendants to sell their shares earlier."[237] For support, the plaintiffs rely on this court's decision in *In re Fitbit Inc. Stockholder Derivative Litigation*.[238] The plaintiffs' argument fails for several reasons.

First, to show that the Director Defendants knowingly permitted insider trading by approving the Offerings, the plaintiffs must allege particularized facts supporting an inference that the directors knew that the PE Funds received material non-public information and that their sales were based on that information.[239] That the Board knew about compliance issues before the Offerings is irrelevant.[240] The plaintiffs must plead that the Board knew that the PE Funds also had that material non-public information before selling their Zimmer shares in the Offerings.

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[237] Pls.' Answering Br. 47–48.

[238] 2018 WL 658715.

[239] *See Guttman*, 823 A.2d at 505; *Stepak v. Ross*, 1985 WL 21137, at *5 (Del. Ch. Sept. 5, 1985).

[240] *See* Pls.' Answering Br. 48 (arguing that the Complaint "pleads chapter and verse about the knowledge of Zimmer's systemic manufacturing failures possessed by the Director Defendants before the Offerings and throughout the relevant period leading up to the FDA inspection").

The plaintiffs contend that Michelson and Rhodes, "as agents of their respective funds," must have shared with the PE Funds the information about Zimmer's compliance challenges that they learned during Zimmer Board meetings.[241] That is so, according to the plaintiffs, because "under the terms of the Stockholders Agreement, Michelson and Rhodes were assigned to the Board for the express purpose of representing the interests of the [PE Funds] . . . and sharing with them confidential Zimmer information."[242] These allegations are entirely conclusory. In the Securities Class Action, the federal court rejected a similar argument, finding there was no allegation in that case "that any information relating to problems at North Campus was in fact shared with the Private Equity Defendants, whether in this instance or any others."[243] Instead, the plaintiff there had alleged only that "the Private Equity Defendants had potential access to information,"[244] which is "not the same as actually possessing the specific information and knowing it."[245]

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[241] *Id.* at 71.

[242] *Id.* at 69.

[243] *Shah*, 348 F. Supp. 3d at 849.

[244] *Id.*

[245] *Id.* (quoting *Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Hldgs., Inc.*, 2011 WL 338865, at *21 (S.D. Ind. Jan. 28, 2011), *aff'd*, 679 F.3d 952 (7th Cir. 2012)).

The Complaint here has the same flaw. It discusses the *potential* for the PE Funds to access information based on the Stockholders Agreement. There are no particularized allegations that Michelson or Rhodes actually shared any information with the PE Funds. Moreover, even if the court were to infer that Michelson and Rhodes shared material non-public information with the PE Funds, the Complaint lacks any basis to infer that the rest of the Board had knowledge regarding this alleged information sharing.[246]

The plaintiffs also do not allege that the Board knew the PE Funds' sales were based on knowledge of Zimmer's compliance issues. The fact that the Board "approved" the Offerings is not enough to demonstrate scienter. The plaintiffs try to bolster their argument by arguing that the Board "grant[ed] waivers of the lock-up agreement"[247] as evidence of knowing facilitation, which was a focus of this court's decision in *Fitbit*.[248] But the Complaint mentions a lock-up agreement only once, noting that the "Defendants further facilitated the Private Equity Defendants' illegal stock sales by . . . waiving the lockup provision for the August 2016

[246] In *Fitbit*, a majority of the demand board sold stock either personally or "through their controlled funds." *Fitbit*, 2018 WL 6587159, at *14. The court in that case did not need to consider whether information shared with the board was subsequently shared with outside entities that were connected to a single member of the demand board or whether a majority of the demand board *knew* that information was shared.

[247] Pls.' Answering Br. 47.

[248] *See Fitbit*, 2018 WL 6587159, at *17–18.

offering."[249] There is nothing else pleaded about a lock-up. The Complaint does not explain what "lockup provision" the plaintiffs are referring to, when it was implemented, who implemented it, or how (when, or by whom) it was waived.[250]

The plaintiffs' allegations that the Board "approv[ed] a $250 million stock repurchase in the February 2016 offering" are equally conclusory.[251] The Complaint does not include any particularized facts regarding the Board's involvement in the stock repurchase, when the Board voted to approve the stock repurchase, or the

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[249] Compl. ¶ 318.

[250] To better understand the plaintiffs' allegations, I reviewed the publicly-filed prospectuses related to the June and August Offerings, which provide that Zimmer was subject to and lacked the power to waive a lock-up agreement. *See* Compl. ¶ 263 (referencing the June 13, 2016 and June 15, 2016 prospectus supplements). Specifically, on June 13, 2016, the Company filed a free writing prospectus which provided that Zimmer and certain officers and directors affiliated with the PE Funds would enter into a 60-day lockup after the June Offering. Zimmer Biomet Hldgs., Inc., Free Writing Prospectus (Form FWP) (June 13, 2016) ("As part of the offering, Zimmer Biomet, its chief executive officer and chief financial officer and certain of its directors and stockholders affiliated with KKR, Goldman Sachs and TPG will enter into lock-up agreements with respect to the sale of shares of common stock of Zimmer Biomet for a 60-day period following the offering, subject to customary exceptions."). Based on Zimmer's June 15, 2016 final prospectus supplement for the June Offering, it appears to me that the lock-up agreement relevant to the August Offering could only be waived by "Goldman, Sachs & Co. and J.P. Morgan Securities LLC," not the Company or the Board. Zimmer Biomet Hldgs., Inc., Prospectus Suppl. S-7 (Form 424B7) (June 15, 2016) ("Pursuant to the foregoing lock-up agreements, at any time and without notice, Goldman, Sachs & Co. and J.P. Morgan Securities LLC may release all or any portion of our common stock subject to the lock-up agreements."); *id.* at S-16 (explaining that pursuant to the lockup agreements the relevant parties could not trade "*without the prior written consent of Goldman, Sachs & Co. and J.P. Morgan Securities LLC*" (emphasis added)). These filings further cut against the plaintiffs' assertion that "granting waivers of the lock-up agreement" creates a substantial likelihood of liability for the Director Defendants.

[251] Compl. ¶ 318.

Board's composition at that time. These indefinite statements fall short of Rule 23.1's pleading requirements and provide no basis for the court to draw an inference of scienter for the Director Defendants. As a result, at least 10 members of the Demand Board cannot be found to face a substantial likelihood of liability for knowingly facilitating insider trading.

3. The *Caremark* Claim

The plaintiffs next argue that a majority of the Demand Board faces a substantial likelihood of liability under *Caremark* for failing to "[e]nsure FDA [c]ompliance."[252] Despite adopting certain phrases from *Caremark*'s progeny and asserting that the Board had "actual knowledge of 'mission critical' regulatory compliance failures,"[253] none of the counts in the Complaint are based on an oversight claim. Instead, the basis for any potential *Caremark* liability appears to be a hypothetical one raised for the first time in the plaintiffs' answering brief. At argument, counsel for the plaintiffs' stated that "the complaint *could* encompass a *Caremark* claim."[254]

Even if I were to read a loosely pleaded *Caremark* claim from the allegations in the Complaint, it would not create a substantial likelihood of liability for the

[252] Pls.' Answering Br. 50.

[253] Compl. ¶ 302.

[254] Oral Arg. Tr. 56 (emphasis added).

Director Defendants. A *Caremark* claim would have required the plaintiffs to plead particularized facts showing that either (1) "the directors utterly failed to implement any reporting or information system or controls" or that (2) "having implemented such a system or controls, [the directors] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[255] The Complaint is, on its face, inconsistent with a claim under either prong of *Caremark*.

First, rather than plead that Zimmer lacked a Board-level system of internal controls, the Complaint details the oversight systems in place to address regulatory compliance issues. For example, the plaintiffs allege that the Audit Committee was responsible for "the Company's compliance with legal and regulatory requirements, including oversight of the Company's Corporate Compliance Program."[256] The Complaint also describes the Board's oversight of regulatory compliance at multiple meetings where it received updates on FDA inspections and voluntary internal audits at Zimmer's facilities.[257]

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[255] *Reiter v. Fairbank*, 2016 WL 6081823, at *7 (Del. Ch. Oct. 18, 2016).

[256] Compl. ¶ 78.

[257] *See id.* ¶¶ 127–93 (alleging that the Zimmer Board met at least a dozen times between 2015 and 2018 and regularly received updates "giving the Board a global overview of all of the Company's FDA inspection results" and highlighting compliance related developments); *see also id.* ¶ 8.

Any argument under the second prong of *Caremark* is also contradicted by the allegations in the Complaint. The plaintiffs repeatedly allege that Zimmer actively undertook remediation efforts to resolve compliance issues such as Project Trident, "a long-running FDA compliance remediation program at several legacy Zimmer facilities."[258] They describe multiple attempts to cure ongoing FDA violations and regular updates to the Board.[259] The story the plaintiffs tell in the Complaint is a far cry from being about a board of directors ignoring "red flags."[260]

Because none of the members of the Demand Board face a substantial likelihood of liability for a *Caremark* claim, demand is not excused on that basis.

4. The Securities Class Action

The plaintiffs' final demand futility argument is that eight of the 11 Demand Board members faced "live claims" as defendants in the Securities Class Action at the time this action was filed.[261] In *Pfeiffer v. Toll*, this court found that demand was

[258] *See, e.g.*, *id.* ¶¶ 109, 123, 128, 138, 158, 177.

[259] *See, e.g.*, *supra* at 10–16, 22–23 (describing Board presentations).

[260] The plaintiffs argue in their brief that these remediation efforts were "an abject failure as the systemic problems were not being corrected, the purported remediation was repeatedly delayed and subject to massive cost overruns, and most importantly did not protect the Company from additional and ongoing FDA compliance problems for years." Pls.' Answering Br. 50 n.20. Such second-guessing also cannot form the basis of a *Caremark* claim. *See, e.g.*, *Stone v. Ritter*, 911 A.2d 362, 370 (Del. 2006); *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 971 (Del. Ch. 1996); *In re Gen. Motors Deriv. Litig.*, 2015 WL 3958724, at *1, *17 (Del. Ch. June 26, 2015); *Citigroup*, 964 A.2d at 127–29.

[261] Pls.' Answering Br. 51; *see* Compl. ¶¶ 321–25.

futile where a majority of the demand board faced a substantial likelihood of liability for alleged misconduct in a pending parallel securities action.[262] To support their argument that facts like those in *Pfeiffer* are present in this case, the plaintiffs focus on the denial of the defendants' motion to dismiss in *Shah*.[263] But in *Pfeiffer*—unlike here—the federal complaint survived "under the rigorous standards for pleading securities fraud" and raised a "powerful and cogent inference of scienter" against the director defendants.[264]

The plaintiffs here seize on language the federal court in the Securities Class Action used to characterize the federal plaintiff's allegations as telling a tale of "fraud" and describing the defendants as "knowingly sitting on a proverbial ticking time bomb of a factory known as North Campus."[265] It is not clear whether the

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[262] 989 A.2d 683 (Del. Ch. 2010), *abrogated on other grounds by Kahn v. Kohlberg Kravis Roberts & Co. L.P.*, 23 A.3d 831 (Del. 2011).

[263] *See* Compl. ¶¶ 323–25.

[264] *Pfeiffer*, 989 A.2d at 690.

[265] *Shah*, 348 F. Supp. 3d at 826–27. The "time bomb" quotation—pulled from the introduction of the opinion—does not specify whether the comments regarding fraud applied to all defendants or only to those who were subject to claims requiring a finding of fraud. Dealing with similarly vague language, the court in *TrueCar* declined to find the related securities action sufficient to impugn the board's impartiality. *See TrueCar*, 2020 WL 5816761, at *22 (finding that "it is unclear from the paragraph quoted above containing the district court's analysis in the Securities Class Action whether its comments concerning *scienter* were intended to apply to all defendants in that action or—*as would be logical—only to those who were the subject of scienter-based claims*" (emphasis added)). The court similarly expressed skepticism that strict liability claims would compromise defenses to non-exculpated duty of loyalty claims, which require evidence of bad faith. *Id.* ("As for Plaintiffs' argument, it also is unclear what 'factual defenses' a director would fear having compromised in a case that only asserts claims for strict liability

sentences from the *Shah* decision that the plaintiffs draw attention to were intended to apply to all defendants in that action. But the only claims in the Securities Class Action against the Director Defendants here were for violations of Sections 11 and 15 of the Securities Act.[266] As the plaintiffs acknowledge, "Sections 11 and 15 of the Securities Act . . . are strict liability statutes that do not require a showing of scienter."[267]

Given Zimmer's exculpation provision, the plaintiffs must demonstrate that the directors acted with scienter, "i.e., there was an 'intentional dereliction of duty' or 'a conscious disregard' for their responsibilities, amounting to bad faith."[268] Strict liability under Section 11 or Section 15 of the Securities Act alone cannot meet this high bar.[269] It has no bearing on whether the directors acted in good faith. The

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and negligence against him, for which the director would be exculpated from personal liability.").

[266] *See Shah*, 348 F. Supp. 3d at 827; Second Am. Class Action Compl. for Violations of the Federal Securities Laws, *Shah v. Zimmer Biomet Hldgs., Inc.*, 348 F. Supp. 3d 821 (N.D. Ind. 2018) (No. 3:16-cv-00815-PPS-MGG), 2017 WL 5494812, ¶¶ 454–59, 468–81, 490–97 (Dkt. 60).

[267] Pls.' Answering Br. 51.

[268] *Goldman Sachs Gp.*, 2011 WL 4826104, at *12 (quoting *In re Walt Disney Co. Deriv. Litig.*, 907 A.2d 693, 755 (Del. Ch. 2005), *aff'd*, 906 A.2d 27 (Del. 2006)).

[269] *See TrueCar*, 2020 WL 5816761, at *21 (finding that the presence of an "exculpatory charter provision and the absence of *scienter*-based claims against the Demand Board directors named in the Securities Class Action" meant that a majority of the demand board "would not face a substantial likelihood of personal liability in that action so as to compromise their ability to impartially consider a demand"); *In re LendingClub Corp. Deriv. Litig.*, 2019 WL 5678578, at *15 (Del. Ch. Oct. 31, 2019) (holding that "[l]iability

claims in the Federal Securities Action therefore cannot provide a basis to conclude that the Demand Board members named as defendants in *Shah* were unable to impartially consider a demand when this action was filed.

Relying on *Fitbit* once again, the plaintiffs argue that the *Shah* court's factual statements are probative of demand futility, even though the securities claims sustained against the directors were non-scienter based.[270] But in *Shah*, the scienter analysis only addressed the states of mind of officer defendants who faced Section 10(b) claims.[271] There were no "holistic" allegations that "suffice[d] to establish scienter" for the Director Defendants.[272] Furthermore, in *Fitbit*, the findings in the related federal action reinforced the court's conclusion that knowledge had been sufficiently pleaded against a majority of the Fitbit demand board.[273] As I previously discussed, there are no well-pleaded allegations of Board-level scienter in the Complaint that the *Shah* decision could bolster.

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under Section 11 would not, in and of itself, have gotten to the heart of whether the directors acted in bad faith concerning wrongdoing at issue in both actions").

[270] Pls.' Answering Br. 52.

[271] *Cf. Pfeiffer*, 989 A.2d at 690 (finding demand futile based, in part, on federal court decision holding that the same individual defendants acted with scienter regarding "the same trades at issue" in the Delaware action).

[272] *Fitbit*, 2018 WL 6587159, at *16.

[273] *Id.* at *16–17.

III. CONCLUSION

For the reasons described above, the plaintiffs have failed to establish that making a demand on the Zimmer Board would have been futile. At least eight members of the eleven-member Demand Board could have impartially considered a demand to pursue this action on Zimmer's behalf. As such, the defendants' motions to dismiss the Complaint pursuant to Court of Chancery Rule 23.1 are granted. The Complaint is dismissed with prejudice in its entirety.