IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

CHANNEL MEDSYSTEMS, INC., a Delaware corporation, Plaintiff and Counterclaim Defendant, v. BOSTON SCIENTIFIC CORPORATION, a Delaware corporation, and NXT MERGER CORP., a Delaware corporation, Defendants and Counterclaim Plaintiffs.	)	C.A. No. 2018-0673-AGB

MEMORANDUM OPINION

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BOUCHARD, C.

This post-trial opinion resolves claims arising from Boston Scientific Corporation s decision to terminate a merger agreement it entered into on November 1, 2017 (the Agreement) to acquire Channel Medsystems, Inc., an early stage medical device company with one product a global endometrial ablation device named Cerene. Under the Agreement, Boston Scientific could only be required to close the transaction if Cerene received FDA approval by September 30, 2019.

In late December 2017, Channel discovered that its Vice President of Quality, Dinesh Shankar, had falsified expense reports and other documents as part of a fraudulent scheme by which he stole approximately $2.6 million from the company. Unbeknownst to Channel, some of the documents Shankar falsified were contained in Channel s submissions to the FDA seeking approval of the Cerene device.

Promptly after discovering Shankar s fraud, Channel notified Boston Scientific and the FDA. Channel interacted with both of them in a fully transparent manner over the next few months as it thoroughly investigated and took actions to remediate the effects of Shankar s fraud. On April 18, 2018, the FDA accepted Channel s remediation plan, which strongly signaled that Shankar s fraud would not be the cause of any failure of the FDA to approve the Cerene device and which made the FDA s approval a distinct possibility. Despite this positive development, Boston Scientific terminated the Agreement on May 11, 2018.

On March 28, 2019, consistent with the timeframe for receiving FDA approval the parties expected when they entered into the Agreement, the FDA approved the Cerene device. Trial of this action commenced the next month.

The primary issue in this case is whether Boston Scientific was entitled to terminate the Agreement because (i) certain representations in the Agreement were inaccurate as of the date it entered into the Agreement and (ii) the failure of such representations to be true and correct has or reasonably would be expected to have a Material Adverse Effect on Channel. For the reasons discussed below, the court finds that although Shankar s fraud caused a number of representations to be inaccurate as of the date of the Agreement, Boston Scientific failed to prove that the failure of such representations to be true and accurate reasonably would be expected to have a Material Adverse Effect. The court thus concludes that Boston Scientific was not entitled to terminate the Agreement and that Channel is entitled to an order of specific performance requiring Boston Scientific to close the merger.

This decision reaches two other conclusions of note: first, that Boston Scientific breached its obligation under the Agreement to use commercially reasonable efforts to consummate the merger and, second, that Boston Scientific was not fraudulently induced to invest approximately $11 million in Channel in making a series of investments from 2015 to 2017.

I. BACKGROUND

The facts recited in this opinion are the court s findings based on the testimony and documentary evidence presented during a four-day trial held in April 2019. The record includes stipulations of fact in the Pre-Trial Stipulation and Order, over 900 trial exhibits, twenty-five depositions, and live testimony from seven fact and five expert witnesses.

A. The Parties

Plaintiff Channel MedSystems (Channel or the Company) is a Delaware corporation headquartered in Emeryville, California.[1] It is a privately held medical technology company and the developer of the Cerene device.[2]

Defendant Boston Scientific Corporation (Boston Scientific or BSC) is a Delaware corporation headquartered in Marlborough, Massachusetts.[3] It is a publicly traded medical technology company.[4] Defendant NXT Merger Corp., a wholly owned subsidiary of Boston Scientific, also is a Delaware corporation headquartered in Marlborough, Massachusetts.[5]

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[1] Pre-Trial Stipulation and Order (PTO) II.B.1 (Dkt. 170).

[2] *Id.*

[3] *Id.* ¶ II.B.2.

[4] *Id.*

[5] *Id.* ¶ II.B.3.

B. Channel Develops the Cerene Device

In 2011, Channel began to develop Cerene, a device used for global endometrial ablation, which is a procedure to treat heavy menstrual bleeding by ablating the uterine lining. Most technologies for this procedure require general anesthesia and must be performed using large pieces of equipment in a hospital operating room or ambulatory surgery center.[6]

The procedure using Cerene is less painful because it uses cryotherapy (cold temperature) rather than heat-based (burning) techniques.[7] Channel designed Cerene for use in an office setting without general anesthesia. Because Cerene is a handheld, disposable device, physicians do not need to invest capital to purchase equipment in order to use the device.[8]

C. The FDA Approval Process

As Boston Scientific has acknowledged, the FDA stringently regulates medical devices by means of a comprehensive regulatory system that is designed to ensure the safety and effectiveness of medical devices.[9] Under this system established through the Federal Food, Drug, and Cosmetic Act (FDCA) and the

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[6] JX 403.006.

[7] Tr. 6-7 (Cot). All citations to Tr. refer to the Trial Transcript Volumes I-IV from April 15-18, 2019 (Dkt. 186; Dkt. 187; Dkt. 188; Dkt. 189).

[8] JX 180.006; Tr. 7 (Coté).

[9] JX 21.020.

1976 Medical Device Amendments, 21 U.S.C. §§ 360c-360k the FDA is charged with regulating the safety and effectiveness of medical devices, and the conditions for their design, manufacture, performance, labeling, and use. [10]

The FDCA divides medical devices into three classes Class I, II, and III.[11] Class III devices, such as Cerene, are subject to the most stringent regulatory controls of all device classes. [12] According to Boston Scientific, these devices must undergo an indisputably thorough, rigorous, and costly pre-market review (some 1,200 FDA man hours at hundreds of thousands of dollars in cost) by the FDA. [13]

Before a company can market a Class III device, the FDA must review and provide a premarket approval (PMA) of the device. In order to conduct a clinical study on humans to collect data for a PMA, an applicant may obtain an Investigational Device Exemption (IDE). After conducting such a study, an applicant must submit detailed information about its device to the FDA in a PMA

[10] United States/FDA Amicus Brief, *Horn* v. *Thoratec*, 2004 WL 1143720, at *2 (FDA Brief).

[11] 21 U.S.C. § 360c.

[12] FDA Brief at *6.

[13] JX 21.021; *see* FDA Brief at *8, *20; Sullivan Dep. 38-39; Pierce Dep. 221-23.

application.[14] An applicant can apply for a PMA in a single submission or in multiple submissions known as modules.[15]

The review process for a PMA is a massive undertaking that is thorough and scientifically rigorous.[16] In reviewing a PMA, FDA scientists carefully evaluate all of the data and information submitted by the manufacturer and will often request that the manufacturer provide additional information.[17]

As part of the FDA s review, multiple experts scrutinize the applicant s compliance with the FDA s Quality System Regulation (QSR).[18] For example, the Center for Devices and Radiological Health s Office of Compliance conducts a two-tiered evaluation. It first evaluates the information in the PMA and then conducts a thorough in-person inspection, called a pre-approval inspection :

> Inspection will include an assessment of the firm s capability to design and manufacture the device as claimed in the PMA and confirm that the firm s quality system is in compliance with 21 C.F.R. 820, Quality System Regulation. The inspectional process considers the extent to which the firm has established a formal [quality system] program and has assured that the approved design is properly translated into specifications via process validation.[19]

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[14] 21 C.F.R. § 814; JX 755.007 (Ulatowski Expert Report).

[15] JX 755.007.

[16] FDA Brief at *8; *see also* Tr. 413 (Ulatowski).

[17] FDA Brief at *8 (citing 21 C.F.R. § 814.37); Tr. 413 (Ulatowski); 21 C.F.R. § 814.20(b)(14).

[18] JX 755.007-008.

[19] *Id.* .010.

As part of this process, the FDA also may conduct bioresearch monitoring inspections to ensure the quality and integrity of clinical trial data submitted in support of an application for a PMA.[20]

After completing its review, the FDA will provide a PMA only if the agency finds, among other things, that there is a reasonable assurance of safety and effectiveness of the device and that the applicant complies with the QSR.[21] The FDA s finding of a reasonable assurance of safety and effectiveness must be based on valid scientific evidence. [22]

D. Cerene s Initial FDA Approval and Clinical Study Results

On September 13, 2016, the FDA approved an IDE for CLARITY, Channel s clinical study for Cerene.[23] CLARITY involved 242 patients and satisfied its primary safety and effectiveness endpoints, as there were no serious adverse events and patients experienced successful reduction in bleeding.[24]

On July 31, 2017, Channel submitted a shell to the FDA setting forth the proposed contents of its four PMA modules, as well as a rough timeline for

[20] *See id.*; Tr. 140 (Yu); Tr. 414-15 (Ulatowski).

[21] Tr. 411, 415-16 (Ulatowski), Tr. 555-56 (Pierce), Tr. 683 (Carr).

[22] 21 C.F.R. § 860.7(c)(1).

[23] JX 85.

[24] JX 774.006-009; Tr. 112-13 (Yu).

submitting the modules.[25] Channel submitted Modules 1 and 2 on August 16, 2017 and November 21, 2017, respectively.[26]

E. Boston Scientific and Channel s Relationship

1. Boston Scientific s Initial Investments in Channel

Between 2013 and 2015, Boston Scientific invested approximately $8 million in Channel, acquiring approximately 15% of Channel s equity.[27] Before making these investments, Boston Scientific obtained information about Channel s operations and finances.[28]

Boston Scientific s initial 2013 investment entitled it to have an observer on Channel s Board of Directors.[29] This right gave Boston Scientific access to anything that was presented to the board, such as information about CLARITY, regulatory submissions, operations, and financial projections.[30]

Christopher Kaster, Boston Scientific s Vice President of Business Development and Venture Capital, held the observer position until he became a full

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[25] JX 150; JX 168.

[26] JX 171; JX 214.

[27] PTO ¶¶ II.E.2; JX 58; JX 49.002; JX 922.001.

[28] *See, e.g.*, JX 26 (BSC Presentation dated February 5, 2013 on Channel s clinical program timeline and estimated costs).

[29] JX 27.004.

[30] Tr. 12 (Coté).

Board member in late 2017.[31] As a Board observer, Kaster provided Boston Scientific senior executives, including David Pierce, Executive Vice President and President of Medical/Surgery for Boston Scientific, with updates about Channel.[32]

2. Channel Provides Boston Scientific with Periodic Updates

After Boston Scientific made its initial investment in Channel, it provided Boston Scientific with periodic updates on the status of [Channel s] business.[33] These presentations covered a variety of topics, including CLARITY, Cerene s performance, and Channel s quality system.[34] According to Ulric Coté, Channel s CEO, Channel provided these presentations to update Boston Scientific on its existing investment, not to solicit additional investments.[35] These updates included references to Shankar as part of Channel s team and as Director of Quality Assurance.[36]

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[31] Kaster Dep. 12-13, 46.

[32] *Id.* at 73; Pierce Dep. 40-43; JX 107.

[33] Tr. 13-16 (Coté).

[34] *See, e.g.*, JX 901 (Presentation titled Boston Scientific Update, dated March 25, 2016), JX 941 (same, dated Dec. 14, 2016).

[35] Tr. 13-16 (Coté).

[36] JX 36.004; JX 49.042; JX 901.043.

In June 2014, Channel stated that it would seek ISO 13485 certification, which would allow Cerene to be marketed in the European Union.[37] On March 13, 2017, Channel received its ISO 13485 certification.[38]

3. Boston Scientific Looks to Acquire Channel

Until early 2017, Boston Scientific focused on monitoring its investment in Channel, and did not pursue an acquisition of Channel s remaining equity.[39] In spring 2017, Boston Scientific learned that other suitors might seek to purchase Channel.[40] Boston Scientific then began to think about buying the company. [41]

On June 22, 2017, Boston Scientific and Channel entered into a non-binding Letter of Intent, which contemplated Boston Scientific purchasing the remaining equity of the company that it did not already own for up to $275 million, conditioned on FDA approval of Cerene.[42] Although Boston Scientific had already completed certain functional due diligence, the transaction was subject to satisfactory completion by [Boston Scientific] of additional diligence. [43]

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[37] JX 1101.026; Tr. 190-91 (Patel).

[38] PTO ¶ II.D.2.

[39] Tr. 969-71 (Morrison); Tr. 493-95 (Pierce).

[40] JX 106; JX 108.

[41] Tr. 900, 971, 972-73 (Morrison).

[42] JX 135 ¶ 1.

[43] *Id.*¶ 2.

4. Boston Scientific Engages in Due Diligence

Before and after signing the Letter of Intent, Boston Scientific conducted detailed due diligence of Channel. During this diligence, everything that was within the company [was] made available to Boston Scientific, including all regulatory, financial, and quality documents.[44] Boston Scientific had access to Channel s data room containing, among other records, extensive clinical, regulatory, quality, and financial information.[45] Channel also provided Boston Scientific with additional information as requested.[46] Terence Carr, Boston Scientific s Multisite Vice President of Quality,[47] acknowledged that Channel placed no limitations on Boston Scientific s access to its quality systems or materials. [48]

On June 5, 2017 and August 24, 2017, Boston Scientific conducted on-site visits to Channel as part of its due diligence.[49] Carr, who was Boston Scientific s corporate representative concerning its diligence and interactions with Shankar,[50]

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[44] Tr. 17 (Coté).

[45] Coté Dep. 90; Bracey Dep. 76-77, 225.

[46] Tr. 17 (Coté); Tr. 652-53 (Carr).

[47] Tr. 577 (Carr).

[48] *Id.* 653.

[49] *See* JX 121; JX 123; JX 179; JX 180.

[50] JX 722.006-007, 009-010.

attended the second on-site visit.[51] Doug Bachert, a quality manager at Boston Scientific responsible for the quality-related diligence of Channel, attended the first on-site visit and met with Shankar for approximately 45 minutes.[52]

Bachert was satisfied after his June 5 meeting that Channel was representing compliance to certain quality standards, but he had not made a determination as to whether [Channel] complied sufficiently or not.[53] On June 13, Bachert told his colleagues that Channel s system was stated as [ISO] 14971 [risk management] compliant; needs to be confirmed.[54] Boston Scientific thereafter conducted its own diligence into Channel s quality system.[55]

5. The Merger Agreement

On November 1, 2017, Channel and Boston Scientific entered into an Agreement and Plan of Merger (as defined above, the Agreement).[56] Under the Agreement, Boston Scientific agreed, subject to certain conditions, (i) to purchase immediately Series C-1 preferred stock in Channel for approximately $5.6 million, increasing its ownership to approximately 20% of the Company s equity; and (ii) to

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[51] Tr. 586 (Carr).

[52] Tr. 588-90 (Carr); *see* Bachert Dep. 55, 65, 75; Tr. 974 (Morrison).

[53] Bachert Dep. 70.

[54] JX 130.001.

[55] *See* Tr. 971 (Morrison); Bachert Dep. 73-74.

[56] JX 1 (the Agreement).

acquire Channel s remaining equity for up to $275 million pursuant to a put-call structure.[57] Under the put-call provision, Boston Scientific could exercise a call option at any time to acquire Channel and, after obtaining a PMA for Cerene from the FDA, Channel could exercise a put option to close the deal.[58]

The Agreement also permitted Boston Scientific to designate a director to Channel s Board. Boston Scientific named Kaster as its Board designee.[59] Tom Robinson, General Manager of the Boston Scientific Women s Health Division, assumed Kaster s former position as Board observer.[60]

F. Channel Discovers That Shankar Defrauded the Company

On December 29, 2017, Coté and Rhonda Bracey, Channel s Vice President of Finance, discovered certain expense reports from Shankar bearing Coté s signature that Coté had never seen before.[61] Coté and Bracey looked into the reports and discovered they were illegitimate.[62] Over the course of the New Year s weekend, Coté, Bracey, and William Malecki, Channel s Chief Operating Officer,

[57] Agreement §§ 1.1, 1.5(a), 1.6(g); PTO ¶ I.A.

[58] Agreement § 1.1.

[59] PTO ¶ II.E.4; Kaster Dep. 46.

[60] Tr. 18 (Coté); Robinson Dep. 40-41.

[61] Tr. 21-22 (Coté).

[62] *Id.* 22-23.

conducted an initial investigation into purchase orders, invoices, and expense reports submitted by Shankar.[63]

Through this investigation, Channel discovered that six of the vendors for which Shankar had been submitting purchase orders and invoices were shell companies registered to Shankar himself.[64] Most of these companies were named to imitate certain legitimate vendors, *e.g.*, Nelson Scientific Research (shell company) versus Nelson Labs (legitimate company).[65] Shankar s scheme involved paying the legitimate vendors with his personal credit card and then issuing invoices to Channel from his shell companies.[66] In some cases, Shankar submitted invoices for work that was never performed; in other cases, he submitted invoices for amounts exceeding the cost of work that was performed and pocketed the difference.[67]

Shankar laid the groundwork for his submission of fraudulent invoices during the regular budgeting process by socializing the names of his shell companies. For example, Shankar referred to just BSI rather than BSI Group (legitimate company) or BSI America (shell company).[68] Shankar also provided inflated estimates for the

[63] *Id.* 22-23; Bracey Dep. 152-56; Malecki Dep. 138-45, 148-51, 156-61.

[64] Coté Dep. 123-24; Bracey Dep. 154-56; Malecki Dep. 157-60.

[65] Tr. 30 (Coté); Malecki Dep. 160; JX 400.009; JX 576.004.

[66] JX 430.004.

[67] Tr. 23-24 (Coté); JX 355.008.

[68] Tr. 30 (Coté).

costs of services during the budget process so that, when he later issued purchase orders from his shell companies seeking approval for those services, the amounts already appeared in Channel s budget and did not arouse suspicion.[69] The subsequent invoices for payment of those same amounts thus did not arouse suspicion either.[70]

Through this part of his scheme, Shankar stole just over $2 million from Channel.[71] Separately, Shankar stole approximately $577,000 from Channel by submitting fraudulent expense reports that purported to be from various vendors, both authentic and fake.[72] Most of Shankar s fraudulent invoices and expense reports which account for about 4 or 5% of the total number submitted during his employment were for amounts below $10,000 such that, under Channel s policy at the time, CEO approval was not required for payment.[73] Shankar s deceit stunned Channel s management team. As Coté testified: To say I was shocked would be an understatement. I m still shocked. [74]

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[69] *Id.* 28.

[70] *Id.*

[71] JX 415.005; JX 922.002.

[72] JX 415.005; JX 922.002.

[73] Tr. 29-30 (Coté); JX 415.014-021.

[74] Tr. 26 (Coté).

An executive of Greenleaf Health, Inc. (Greenleaf), a healthcare regulatory and quality consulting firm that Channel retained to conduct an independent review, testified credibly that Shankar was quite adept at [his] falsifications, which were not apparent on the surface of Channel s records.[75] During diligence, Boston Scientific itself requested and received purchase orders from certain entities (BSI America, Western Packaging, and ETC Engineering Services) that Channel later discovered were shell companies that Shankar created.[76] Neither the names, the amounts, nor anything else in those documents triggered any concerns at Boston Scientific, just as they had not at Channel.[77]

On January 2, 2018, Channel confronted Shankar with the initial evidence of his wrongdoing, which Shankar eventually admitted.[78] Channel immediately placed Shankar on leave and terminated his employment shortly thereafter.[79]

G. Channel s Investigation and Remediation Efforts

1. Channel s Internal Investigation

After placing Shankar on leave, Channel continued to assess the scope and effects of his fraud. Channel retained Fenwick & West LLP to help with the

[75] Tr. 314-15 (Elder).

[76] JX 159.006.

[77] Tr. 977-78 (Morrison).

[78] Bracey Dep. 158; JX 239.003.

[79] Tr. 20-21 (Coté); JX 355.005.

investigative process.[80] In carrying out its investigation, Fenwick & West retained forensic accountants, Hemming Morse LLP, to conduct an audit of all of the financials and the expenses and invoices of the company. [81] Hemming Morse confirmed that Shankar stole approximately $2.57 million.[82]

Channel also contacted the legitimate vendors to obtain their original invoices and reports.[83] It then conducted line-by-line reviews of those documents and other records to identify information that Shankar falsified in whole or in part.[84]

Through its investigation, Channel discovered that, out of approximately 138 test reports that Channel submitted to the FDA in connection with its IDE and first two PMA modules, six reports contained information that Shankar falsified.[85] Channel also submitted four of these six reports to BSI, from which Channel was seeking a European Conformity (EC) certificate for Cerene.[86] The EC certificate allows Channel to place a CE Mark on Cerene and to market the device in the

[80] JX 403.002.

[81] Tr. 44 (Coté); JX 430.005; JX 403.002; JX 279.005.

[82] JX 430.012; JX 403.002.

[83] *See, e.g.*, JX 251; JX 241.

[84] Tr. 37-38 (Coté); Tr. 136 (Yu); Tr. 187 (Patel); *see, e.g.*, JX 533.004 (listing discrete discrepancies).

[85] Tr. 38, 50 (Coté); Tr. 119-21 (Yu); JX 658.004-007.

[86] JX 581.004-005.

European Union. Channel has yet to market Cerene in Europe and has no plans to do so.[87]

In addition to finding that Shankar falsified some records it submitted to the FDA, Channel discovered that Shankar falsified other records that were not submitted to the FDA involving (i) measurements of component parts and (ii) calibration certificates for equipment used in inspecting, manufacturing, and testing Cerene.[88] An April 2018 Board presentation, prepared while Channel was working to remediate the effects of Shankar s fraud, noted that certain other records, such as corrective and preventative action records (CAPAs) and Management Reviews, also needed additional work to become compliant with FDA regulations.[89]

On January 17, 2018, Channel referred Shankar s fraud to the Department of Justice for potential prosecution.[90] The Department of Justice pursued criminal charges against Shankar, who pled guilty and is now in prison.[91] Shankar has since repaid almost all of the $2.57 million he stole from Channel.[92]

[87] Tr. 60 (Coté).

[88] *Id.* 38-40; Tr. 178-79, 188 (Patel); JX 580; JX 652.

[89] JX 427.011; Tr. 247-48 (Patel).

[90] Tr. 44-45 (Coté); JX 269; JX 271; JX 279.

[91] Tr. 45-46 (Coté); JX 915; JX 916; JX 917.

[92] JX 917.007; Tr. 45 (Coté).

2. Greenleaf s Initial Assessment

As previously mentioned, Channel retained Greenleaf to conduct an independent assessment of (i) Channel s investigation of Shankar s fraud, and (ii) Channel s quality system related to past operations and plans for future operations. [93] Two Greenleaf executives former FDA officials David Elder and Michael Chappell visited Channel s offices from February 5-8, 2018, to review Channel s processes, procedures, regulatory submissions, and records, and to interview Channel management.[94]

According to Elder, the purpose of Greenleaf s independent assessment was [t]o bring an outside set of eyes to the work that Channel had done internally, to see if [Greenleaf] observed anything that perhaps [Channel] didn t notice, to verify that [Channel s] assessment was complete or, if [Greenleaf] found any gaps, to identify those gaps with the idea that [Channel] would review the gaps and take additional action, if needed. [95] Greenleaf documented its assessment in a report dated March 6, 2018 (the Greenleaf Report).

The Greenleaf Report concluded that (i) Channel officials were thorough and earnest[] in their investigation, open and forthcoming with information[,] and

[93] JX 355.006.

[94] Tr. 258-59 (Elder); JX 355; JX 356.

[95] Tr. 260-61 (Elder).

placed no restrictions on Greenleaf s access to information; (ii) Shankar act[ed] in isolation ; and (iii) Shankar was not directly involved in the collecting and reporting of clinical data. [96] Critically, Greenleaf did not find evidence that Shankar s conduct affected the outcome of the clinical study or impacted safety and efficacy data from the study. [97]

The Greenleaf Report commented, however, that each and every action, decision, and record with which [Shankar] was involved is suspect, particularly those with which he was solely involved, [98] such that they should be further investigated. [99] Greenleaf similarly noted that it has no confidence in [Shankar] performing his routine responsibilities as VP of Quality Assurance (QA). [100] Greenleaf recommended ways for Channel to improve its quality system in light of deficiencies it observed in order to bring the system up to compliance with FDA regulations required for the PMA.[101] For example, Greenleaf concluded that effective internal audits were not actually conducted because they had been

[96] JX 355.006-007; Tr. 262-65 (Elder).

[97] JX 355.007.

[98] *Id.* .009.

[99] Tr. 271 (Elder).

[100] JX 355.009.

[101] Tr. 55 (Coté); JX 355.021-028.

Shankar s responsibility and that Shankar, on behalf of Channel, failed to review cleanroom monitoring reports, which was required under the QSR.[102]

3. Channel s Fraud Implication Assessment Quality Plan

After conducting its initial investigation and receiving the Greenleaf Report, Channel prepared a comprehensive Fraud Implication Assessment Quality Plan to identify and remediate the effect of Shankar s misconduct on Channel s quality system, which Channel implemented over much of 2018.[103] Channel s work consisted of both top-down and bottom-up assessments.[104]

a. Top-Down Assessment

To address the potential impacts of Shankar s fraud that were identified during Channel s initial investigation, Channel opened fourteen internal audit reports (IARs), each of which addressed a distinct area, including falsified supplier test reports and regulatory submissions, calibration records, and component inspection records.[105] Channel performed a risk assessment in connection with each IAR and

[102] JX 356.009. As discussed below, the parties dispute whether all of the regulations in the QSR applied to Channel as of the Agreement Date. The court concludes that they did not and that only the QSR s design control requirements applied to Channel at that time. *See infra* Part IV.A.1.a.

[103] JX 382; JX 576.

[104] Tr. 161 (Patel); JX 382; JX 576.

[105] Tr. 48-49 (Coté); Tr. 130-31 (Yu); Tr. 159, 174-75 (Patel); JX 380; JX 383; JX 576.

identified necessary corrective actions,[106] which included re-performing certain tests affected by Shankar s fraud.[107]

Greenleaf had identified two potential concerns involving the CLARITY study. The first was that unsterile devices could have caused patient infections during the study because Shankar fabricated certain sterility records. The second was that using torque wrenches that were in an unconfirmed state of calibration could have caused some devices in the study to suffer out-of-box failures because Shankar had fabricated calibration records.[108] Channel s subsequent investigation into these potential concerns found that Shankar s actions did not affect the CLARITY study.

Sterility. To address potential sterility concerns, Channel had Tim Achuff, an expert in microbiology, review the original, authentic, sterilization test report data from Nelson Laboratories.[109] Achuff determined that Cerene met sterilization requirements and his analysis confirmed that [t]he sterility of the Cerene device was still intact.[110] In addition, Dr. Andrew Brill, Channel s medical liaison,

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[106] *See, e.g.*, JX 652.005 (listing corrective actions related to Henry Servin & Sons); JX 533.005 (listing corrective actions related to sterilization); JX 580.004 (listing corrective actions related to equipment calibration).

[107] Tr. 40 (Coté).

[108] JX 355.008.

[109] JX 533.028-034; Tr. 58 (Coté).

[110] Tr. 126 (Yu); Tr. 376 (Woodard).

reviewed infections of CLARITY patients and corroborate[d] that there is no evidence that the integrity of the Cerene device packaging nor the sterility of the Cerene device was compromised. [111]

Boston Scientific s own quality expert, Richard Reeves, observed that if you [use Cerene on] 200 patients and there s no traceable infection, that s pretty good evidence that there isn t a problem. [112] Reeves further testified that Brill s study looked pretty good and he had no reason to doubt Brill s conclusion.[113]

Out-Of-Box Failures. To address potential calibration issues, Channel sent the potentially affected equipment (*e.g.*, torque wrenches) back to the manufacturers for recalibration. The manufacturers found that the equipment measured in calibration upon arrival and satisfied their specifications.[114] Channel also obtained documentation from its suppliers confirming that the equipment does not go in and out of calibration.[115] This was important because if the equipment was properly

[111] JX 389; Tr. 57-58 (Coté); Tr. 376 (Woodard).

[112] Reeves Dep. 206.

[113] Tr. 829-31 (Reeves).

[114] Tr. 40-41 (Coté); Tr. 188-89 (Patel).

[115] Tr. 41 (Coté); Tr. 189 (Patel); Tr. 373 (Woodard); JX 580.007-008, 066-077. Contrary to Boston Scientific s assertion, Malecki did not admit that there is no way to confirm that the tools used to make the devices used in the CLARITY trial were in calibration when they were being used to make the devices. Defs. Br. 53. Malecki simply acknowledged the obvious point that it is not possible to go back in time as a general matter. *See* Malecki Dep. 261 (Q: We can t go back in time and test the tools when they were actually used

calibrated when it was retested by the suppliers, the equipment would have functioned properly when used on the CLARITY devices. Channel further determined that it already had addressed any risks posed by out-of-calibration tools satisfactorily through its risk management process.[116] Channel therefore confirmed that falsified calibration records did not affect any CLARITY devices.[117]

In addition to addressing the two issues just discussed, Channel thoroughly investigated, among other issues, falsified component inspection records from one of its suppliers.[118] Specifically, Channel re-inspected components it had on hand from the same lots used in devices manufactured for CLARITY.[119] Channel then conducted a risk assessment of its manufacturing process, which included numerous inspections and functional performance tests of every device, and evaluated the risk of nonconforming components not fitting together.[120] The re-inspection and risk assessment found that no new risks [were] introduced. [121]

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to make . . . the product, right? A: We can t go back in time, period); *see also* Malecki Dep. 260.

[116] Tr. 373 (Woodard).

[117] JX 580.005.

[118] JX 652.004-005.

[119] Tr. 180 (Patel).

[120] *Id.* 180-81; Tr. 374 (Woodard); JX 652.005, 015-068; JX 751 ¶ 131.

[121] Tr. 181 (Patel).

b. Bottom-Up Assessment

Channel also conducted a bottom-up assessment to address Greenleaf s concern that every area with which Shankar was involved was suspect. The bottom-up assessment entailed assessing all aspects of Channel s quality system, and particularly those under Shankar s control.[122]

Channel classified its various types of quality system records into fifteen categories.[123] For thirteen of these categories, which ranged in number from four to 515 records, Channel reviewed every one of its records.[124] Included within this review, Channel reviewed all of the 515 lot history records documenting Channel s manufacturing processes for the devices used in the CLARITY study, and determined that Shankar s fraud did not impact manufacturing.[125]

The remaining two categories (document change orders and incoming inspection records) contained over 1,500 records, which made it impracticable to review every record.[126] For these two categories, Channel (i) reviewed all of the records generated by Shankar and (ii) conducted a random sampling of the remaining

[122] Tr. 49 (Coté); JX 576.003.

[123] JX 732.010-011.

[124] *Id.* .014.

[125] Tr. 374-75 (Woodard); JX 732.012.

[126] *See* JX 732.014.

records,[127] using a nationally recognized sample plan similar to one that the FDA uses.[128] Ultimately, although Channel identified certain issues with its quality system unrelated to Shankar s fraud, which it fully remediated, the bottom-up assessment revealed no additional issues relating to Shankar s fraud that could affect Cerene s safety and efficacy.[129]

4. Greenleaf s Follow-up Assessment

In June 2018, Greenleaf conducted a follow-up, in-person assessment to review Channel s progress in addressing Greenleaf s prior recommendations.[130] Greenleaf s follow-up assessment is documented in a July 2018 report, which found that Channel had made an appropriate level of progress and many recommended actions were completed and others were progressing appropriately. [131]

Greenleaf also analyzed the two potential connections between Shankar s conduct and the CLARITY issues it had previously identified concerning sterility and out-of-box failures. Greenleaf provided an update describing the work Channel had done to ensure that Shankar s actions had no impact on either issue.[132]

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[127] Tr. 168-70, 205-11 (Patel); JX 732.010-011, 014.

[128] Tr. 170, 208-11 (Patel); JX 576.003.

[129] Tr. 51-52 (Coté); Tr. 170-71 (Patel); Tr. 369 (Woodard); JX 732.012.

[130] Tr. 279 (Elder).

[131] JX 634.007, 010; Tr. 282-83 (Elder).

[132] JX 634.007-008.

In addition, Greenleaf and Channel discussed Channel s classification of the IARs Channel had prepared as part of its top-down assessment.[133] Channel had classified the IARs as minor based on the definitions in its internal audit process at the time.[134] Greenleaf disagreed. It believed that Channel should have classified certain IARs as major. [135] Greenleaf also found that the impact of the questionable classifications may be minimal since in the current environment all issues have received the appropriate visibility and prioritization within the company. [136] Channel later updated its definitions of major and minor based on Greenleaf s feedback.[137]

Boston Scientific contends that Channel classified issues as minor and used IARs instead of CAPAs to reduce the likelihood that FDA would review them. [138] As noted below, however, Channel decided to provide all of the IARs (however classified) to the FDA.[139] Boston Scientific s quality expert (Reeves) acknowledged that the FDA did not raise any issues with Channel s classifications or its use of

[133] JX 592.

[134] Tr. 175-77 (Patel); JX 592.

[135] JX 592.

[136] JX 634.011; Tr. 287-88, 342-43 (Elder).

[137] Tr. 253-54 (Patel).

[138] Defs. Br. 15.

[139] Tr. 253 (Patel); Tr. 803 (Reeves); JX 380.

IARs and that the FDA is not shy when it believes that people should be doing things by way of CAPA.[140] He testified further that the classification of minor or major was not intended to prevent the FDA from learning about the issues.[141]

H. Channel Promptly Discloses Shankar s Fraud to the FDA and BSI

As Channel was investigating and remediating Shankar s misconduct, it also was communicating transparently with regulators about these issues.

1. Disclosure to the FDA

On January 11, 2018, Channel retained Greenleaf to advise it on its communications with the FDA, and in particular how best to provide the FDA with all relevant information about Shankar s misconduct.[142]

On January 22, 2018, Channel emailed the FDA s lead reviewer of its application for a PMA to request a call, which took place on January 25.[143] During that call, Channel informed the FDA of the basic facts about Shankar s fraud, and what steps Channel intended to take to remediate that fraud.[144] Channel told the FDA that Shankar falsified certain testing and other records, some of which it had

[140] Tr. 805 (Reeves).

[141] *Id.* 804.

[142] JX 262.015-024.

[143] Tr. 126-27 (Yu); JX 270.

[144] Tr. 127-28 (Yu); JX 279.

submitted to the FDA.[145] On February 1, the FDA asked Channel to withdraw and re-submit PMA Module 2 with corrected records, which Channel did.[146]

On March 16, 2018, Channel management, accompanied by Brill and Elder of Greenleaf, met with the FDA.[147] Before the meeting, Channel provided the FDA with more than 250 pages of information about Shankar s fraud, including the Greenleaf Report, Channel s Fraud Implication Assessment Quality Plan, the 14 IARs addressing Shankar s fraud, and Brill s adverse event review.[148] At the meeting, Channel delivered a presentation on Shankar s misconduct, its scope and effects, and Channel s remediation plan.[149] The FDA asked a number of questions about these and other issues, which Channel answered.[150]

At the end of the March 16 meeting, the FDA thanked the company for their transparency and for coming forward with the information quickly. [151] Elder asked the FDA if it would be interested in subsequent discussions regarding the issues

[145] Tr. 128 (Yu).

[146] *Id.* 129; JX 294; JX 494.

[147] Tr. 64 (Coté); Tr. 129, 132-33 (Yu); JX 401.

[148] JX 380; *see* Tr. 64-65 (Coté); Tr. 130-31 (Yu).

[149] Tr. 66 (Coté); Tr. 129-30 (Yu); JX 401.

[150] JX 401.002-004.

[151] *Id.* .004; Tr. 67 (Coté).

and the status and progress of the company s remediation, to which the FDA responded: follow-up would take place through the inspection process. [152]

On April 18, 2018, Channel had a follow-up call with the FDA.[153] The FDA told Channel that it ha[d] addressed all of FDA s concerns and that the agency appreciate[d] the company s transparency and timeliness. [154] Since that date, the FDA has not sought any more information about Shankar s fraud.[155]

2. Disclosure to BSI

Channel also disclosed Shankar s misconduct to BSI.[156] Channel told BSI that the fraud affected some documentation Channel had submitted to it.[157] BSI told Channel that it would address the issue during its upcoming assessments.[158]

In the fall of 2018, BSI conducted two assessments one relating to Channel s ISO 13485 quality certification and the other relating to Cerene s technical file.[159] The BSI representative who conducted the two assessments were

[152] JX 401.004; Tr. 133-34 (Yu).

[153] Tr. 138 (Yu); JX 436.

[154] JX 436.

[155] Tr. 139 (Yu).

[156] Tr. 61 (Coté); Tr. 191-93 (Patel); JX 581.

[157] JX 581.014.

[158] Tr. 61-62 (Coté); Tr. 193-95 (Patel); JX 581.037.

[159] Tr. 195-97 (Patel); JX 709; JX 685.

the same individuals whom Channel had informed of Shankar s fraud.[160] During the assessments, BSI reviewed corrected reports for tests affected by Shankar s fraud.[161] BSI s own microbiologist also reviewed the corrected sterility test reports.[162]

BSI concluded that all ISO 13485 requirements continue to be effectively implemented, that [c]ontinued certification is confirmed, and that Channel s EC certificate remains valid.[163] This meant, as Boston Scientific s quality expert (Reeves) acknowledged, that Channel at all times possessed a valid ISO 13485 and EC certificate.[164] At no point did BSI ever indicate that these certificates or Channel s CE Mark were invalid.[165]

After these assessments were completed, Channel was certified under the 2016 version of the ISO 13485 standard, which has additional [quality system] requirements and is more rigorous than the 2003 version under which Channel was previously certified.[166]

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[160] Tr. 820-21 (Reeves).

[161] Tr. 196-97 (Patel); Tr. 821-23 (Reeves); JX 685.009-010.

[162] Tr. 823-24 (Reeves); JX 685.003.

[163] Tr. 62-63 (Coté); Tr. 197-99 (Patel); JX 685.003; JX 709.004.

[164] Tr. 817-18, 825 (Reeves); *see* JX 751 ¶¶ 109-10.

[165] Tr. 63 (Coté).

[166] Tr. 197-99 (Patel); Tr. 816 (Reeves); JX 725.

I. Channel Keeps Boston Scientific Informed of Developments

The trial evidence demonstrates that Channel also was transparent with Boston Scientific. Since discovering Shankar s fraud, Channel provided Boston Scientific with frequent and thorough updates about its investigatory and remediation work, often via Kaster and Robinson.[167]

In January 2018, Coté regularly called Kaster and Robinson to update them on Channel s investigation.[168] During this period, Kaster remained very supportive and reiterated Boston s interest in Channel.[169] Robinson thanked Coté for his continued transparency,[170] and relayed the updates to senior executives of Boston Scientific, including Pierce.[171]

Robinson reported in early January, for example, that Shankar had been invoicing for new [calibration] tests that did not take place, that numerous reports were in question, that they will obviously have to redo the calibration tests (which likely would have to happen in manufacturing move and [manufacturing] module

[167] Tr. 70-71 (Coté); *see, e.g.*, JX 238; JX 247; JX 258; JX 261; JX 271; JX 275; JX 279; JX 282; JX 288; JX 295; JX 321; JX 353.

[168] Tr. 42-43, 70-71 (Coté); JX 239; Kaster Dep. 188-89.

[169] JX 271.

[170] JX 261.

[171] JX 259; JX 264; Robinson Dep. 206.

submission anyway), and that Channel was taking remedial actions.[172] Kaster commented: Bottom line is that to the best of my knowledge this will not have a material impact on the FDA timelines, an assessment with which Robinson agreed.[173] A few days later, Robinson provided another update, which noted that Channel will have to redo some tests *e.g.*, residual sterilization bioburden.[174]

On January 25, 2018, Coté, Malecki, and Yu met with Robinson and Pierce.[175] Cot updated them on Channel s work and shared Channel s plans to meet with the FDA to discuss the Greenleaf Report, which occurred in March 2018.[176] Pierce did not express any concerns about the effects of Shankar s conduct on Channel s quality system, clinical trial data, or Cerene during this meeting.[177]

After the January 25 meeting, Coté repeatedly told Pierce and others at Boston Scientific: Please do not hesitate to call me with any questions.[178] During the next three months, Boston Scientific never asked for any additional information relating

[172] JX 259.

[173] JX 264.

[174] *Id.*

[175] Tr. 75 (Coté); Tr. 468 (Pierce); JX 275.

[176] Tr. 468-69 (Pierce); JX 456.

[177] Pierce Dep. 85-87, 100-01; *see also* Pierce Dep. 82 (agreeing that [n]o one is suggesting [in January 2018] . . . that Mr. Shankar s fraud could impact the acquisition even if the FDA approves the product).

[178] *See* JX 275.

to Shankar s conduct, Channel s remediation, or its communications with the FDA.[179] Instead, teams of Boston Scientific personnel pressed forward with their work on the integration of Channel without apparent regard for Shankar s fraud.[180]

On February 21 and 22, 2018, a Boston Scientific team visited Channel s headquarters as part of its integration work.[181] At the meeting, Coté updated Boston Scientific on the results from Greenleaf s assessment.[182] Nobody from Boston Scientific expressed any potential concerns about its acquisition of Channel.[183]

On March 6, 2018, the same day Channel received the Greenleaf Report, Coté provided a copy of the report to Boston Scientific and suggest[ed] we schedule a call with the appropriate [subject matter experts] the week of the 19th to discuss the meeting with the FDA and to share updates as may be appropriate. [184] No one from Boston Scientific responded to Cot s suggestion.[185]

[179] Tr. 517, 520-24, 529 (Pierce).

[180] *Id.* 469, 517-19.

[181] JX 456.002; JX 302.

[182] Tr. 71 (Coté); JX 456; JX 366.

[183] Tr. 74 (Coté); Tr. 526-27 (Pierce).

[184] JX 353; JX 456.002; Tr. 72-73 (Coté).

[185] Tr. 516, 526-27 (Pierce).

On March 16, after meeting with the FDA, Coté reached out [to Boston Scientific] several more times offering to provide an update on our dialogue with the FDA. [186] Again, no one from Boston Scientific responded.[187]

Boston Scientific employees uniformly testified that Channel was fully transparent with Boston Scientific in the aftermath of discovering Shankar s fraud. Kaster testified that Cot kept him regularly updated as to what was going on with the company s investigation [188] and he thanked Cot for the thorough update[s] and reassured him [t]his will al[l] get resolved. [189] Robinson similarly testified he always found Mr. Coté to be transparent in [his] interactions with him, [190] and that Cot was timely, forthcoming, transparent. [191] Pierce testified he had no reason to doubt that Channel was fully transparent with Boston Scientific at all times.[192]

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[186] JX 456.002.

[187] *Id.*

[188] Kaster Dep. 191.

[189] JX 257.

[190] Robinson Dep. 99.

[191] *Id.* 219.

[192] Tr. 533 (Pierce); *see also* Tr. 474-75 (Pierce).

J. The FDA Accepts Channel s Remediation Plan

On April 18, 2018, the FDA accepted Channel s remediation plan for its PMA application. This action strongly signaled that Shankar s fraud would not impede the FDA from approving the Cerene device and made premarket approval of the device a distinct possibility. Coté emailed Pierce the next day to report the good news.[193]

Three days later, on April 22, Pierce replied and raised with Channel for the first time concerns about Shankar s fraud.[194] Pierce claimed that Boston Scientific found the Greenleaf report to be extremely troubling, requested Channel s communications with the FDA and BSI, and explained that:

> Candidly, we don t have confidence that, if all of the details set forth in the Greenleaf report (not to mention its obvious gaps) were fully disclosed to the FDA, the FDA would be acquiescing of the underlying facts or optimistic of a PMA submission based on existing study data.[195]

Despite suggesting in his April 22 email that Channel had not made full disclosure to the FDA, Pierce testified that he never meant to suggest that Channel had not been forthcoming with FDA.[196] Pierce and no one else at Boston Scientific ever identified the purported obvious gaps in the Greenleaf Report referenced in

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[193] JX 456.002.

[194] Tr. 73 (Coté); Tr. 526-27 (Pierce).

[195] JX 456.004.

[196] Tr. 530 (Pierce).

his email.[197] Pierce acknowledged that the FDA had the Greenleaf Report and thus could draw its own conclusions about any such gaps.[198]

Surprised by Pierce s April 22 email, Coté asked for an in-person meeting as soon as possible.[199] Pierce did not respond.[200] Coté reached out to Boston Scientific five times trying to schedule a call or meeting.[201] No one responded.[202]

K. Boston Scientific Terminates the Agreement

On May 11, 2018, Boston Scientific sent Channel a notice of termination. It stated in relevant part that:

> BSC hereby terminates [the Agreement] pursuant to Section 8.1(f), in light of multiple breaches of Channel s representations and warranties in Article III of the Agreement, and Section 8.1(i). The representations and warranties breached by Channel include, but are not limited to, those set forth in Sections 3.18(c), 3.22(a), 3.22(c), 3.22(f) of the Agreement. These representations and warranties were breached as of the date of the Agreement and are not curable.[203]

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[197] *Id.* 531.

[198] *Id.*

[199] Tr. 76 (Coté); JX 440; JX 456.002-003.

[200] Tr. 76 (Coté); Tr. 532-35 (Pierce).

[201] Tr. 536 (Pierce).

[202] Tr. 78-79 (Coté); Tr. 536 (Pierce).

[203] JX 475.

Pierce made the decision on behalf of Boston Scientific to terminate the Agreement. In doing so, the sole documentary evidence he relied on was the Greenleaf Report.[204]

Pierce decided to terminate the Agreement after receiving feedback about the Greenleaf Report in a March 29 meeting with Carr, Donna Gardner, Boston Scientific s Vice President of Regulatory Affairs, the Vice President of Research and Development, and Pierce s legal counsel, Mark Myhra.[205] At this meeting, no one discussed any steps Boston Scientific could take to remediate Channel s quality system.[206]

L. The FDA Reviews Channel s PMA

On August 10, 2018, Channel submitted its final PMA module to the FDA.[207] By that time, Channel had finished resubmitting the reports in earlier modules that Shankar s fraud had affected.[208]

On August 28, 2018, the FDA accepted Channel s PMA application, which the FDA formally filed on September 6, 2018.[209] The filing took place about three

[204] Tr. 484, 522-23, 537 (Pierce).

[205] Tr. 471-74 (Pierce); Tr. 620 (Carr noting Mr. Sukthankar, the Vice President of Research and Development, was also in attendance).

[206] Carr Dep. 148-49; *see also* Tr. 640 (Carr).

[207] Tr. 139 (Yu).

[208] *Id.* 138-39.

[209] *Id.* 140.

months later than planned based on Channel s initial timeline for its PMA, which was prepared before discovery of Shankar s fraud.[210]

The FDA proceeded to review Channel s PMA substantively.[211] Boston Scientific s quality expert (Reeves) testified that, because of Shankar s fraud, the FDA would review Channel s PMA application with more laser-like focus than they would if they were just reviewing this PMA as they normally do.[212] The FDA made numerous, detailed requests for additional information, none of which appeared to concern Shankar s fraud, to which Channel responded promptly.[213]

The FDA also completed four separate bioresearch monitoring inspections, one at Channel and three at separate CLARITY trial sites to evaluate, among other things, the quality and integrity of Channel s clinical trial data.[214] At the end of an FDA inspection, if inspectors observe regulatory violations, they identify them on a Notice of Inspectional Observations known as a Form 483.[215] The FDA s

[210] JX 169 (estimating date of final PMA module to be June 1, 2018).

[211] Tr. 413 (Ulatowski); Tr. 683 (Carr); JX 755.007-011, 015-017.

[212] Reeves Dep. 211.

[213] Tr. 413 (Ulatowski); JX 755.015-017.

[214] Tr. 140 (Yu); Tr. 413-14 (Ulatowski); JX 711; JX 720; JX 755.016.

[215] Tr. 141 (Yu); JX 755.016.

inspectors did not issue any Form 483 s after conducting their bioresearch monitoring inspections.[216]

From January 22 through February 1, 2019, the FDA conducted a pre-approval inspection of Channel, which lasted seven business days and included a detailed inspection of Channel s quality system.[217] The FDA inspector made two relatively minor observations (unrelated to Shankar s fraud) on a Form 483, to which Channel responded on February 22, 2019.[218]

M. The FDA Approves Channel s PMA

On March 28, 2019, the FDA approved Channel s application for premarket approval of the Cerene device.[219] Cerene therefore received FDA approval during the first quarter of 2019, as Boston Scientific originally contemplated before signing the Agreement,[220] and six months ahead of the September 30, 2019 contractual deadline in the Agreement.[221] The FDA explicitly found that there is a reasonable

[216] Tr. 141 (Yu); Tr. 414-15 (Ulatowski); JX 711; JX 720; JX 755.016.

[217] Tr. 141 (Yu); Tr. 199-201 (Patel); JX 723.002-003; JX 755.016.

[218] Tr. 141-43 (Yu); Tr. 201 (Patel); JX 740; *see also* Tr. 369-70 (Woodard).

[219] JX 2.

[220] JX 187.006.

[221] Agreement 10.2 (definition of FDA Approval).

assurance of the safety and effectiveness of [the Cerene] device.[222] The FDA also found that Channel and its contract manufacturer comply with the FDA s QSR.[223]

Reeves confirmed that the FDA s approval necessarily reflects its conclusion that Cerene is safe and effective, that Channel s quality system is compliant with the QSR, and that its clinical data is reliable, describing FDA approval as the proof in the pudding.[224] As a former FDAer, Elder of Greenleaf was pleased to see that Channel was transparent and provided FDA with information, particularly the Greenleaf Report that he worked on, before the FDA approved Cerene.[225] To Elder, this meant that the FDA had all of the information [it] needed to make an informed decision when approving Cerene.[226] Due to the FDA s approval, Channel can market Cerene in the United States immediately.[227]

II. PROCEDURAL HISTORY

On September 12, 2018, Channel filed a verified complaint asserting two claims. Its first claim asserts that Boston Scientific breached Section 6.3(b) of the Agreement by declaring its intention to cease performing its obligations thereunder

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[222] JX 757.029.

[223] *Id.* .030.

[224] Tr. 831, 844-49 (Reeves); Reeves Dep. 208.

[225] Tr. 290-91 (Elder).

[226] *Id.* 291.

[227] Tr. 560 (Pierce).

and to terminate the [Agreement] without a valid basis, and seeks the remedy of specific performance under Section 10.6 of the Agreement.[228] Its second claim seeks a declaratory judgment that (i) Boston Scientific breached its obligations under the Agreement, (ii) no Material Adverse Effect (MAE) occurred, (iii) Channel did not breach any representations or warranties that would reasonably be expected to have an MAE, and (iv) Boston Scientific had no right to terminate the Agreement.[229]

On October 3, 2018, Boston Scientific filed three counterclaims. Its first claim is for fraud in the inducement based on alleged misrepresentations and omissions about Channel s quality systems. Its second claim seeks rescission of the Agreement based on breaches of various representations and warranties. Its third claim seeks a declaratory judgment that Boston Scientific had the right to and did terminate the Agreement under Sections 8.1(f) and 8.1(i) of the Agreement.[230]

The court held a four-day trial in April 2019 and heard post-trial argument on July 26, 2019. At that hearing, the court requested supplemental briefing on an issue of contractual interpretation concerning Section 8.1(f) of the Agreement, which the parties completed on September 6, 2019.

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[228] Dkt. 1 ¶¶ 89-90.

[229] *Id.* ¶ 101.

[230] Dkt. 25 ¶¶ 41-60.

III. FRAMEWORK OF THE ANALYSIS

The parties disputes are primarily contractual. Boston Scientific contends that it terminated the Agreement in accordance with its terms. Channel contends that Boston Scientific did not validly terminate the Agreement and seeks an order of specific performance to compel Boston Scientific to close the merger.

The analysis of the parties claims focuses primarily on the following three provisions in the Agreement:

> Under Section 7.2(b), Boston Scientific s obligation to consummate the merger is subject to satisfaction of the condition that each of Channel s representations and warranties in the Agreement shall have been true and correct at the time originally made . . . except to the extent that the failure of any such representations and warranties to be true and correct does not have and would not reasonably be expected to have a Material Adverse Effect on Channel (the Representations Condition).
>
> Under Section 8.1(f)(i), Boston Scientific can terminate the Agreement at any time if any of Channel s representations and warranties in the Agreement shall be inaccurate or shall have been breached as of the Agreement Date . . . such that the condition set forth in Section 7.2(b) would not be satisfied.
>
> Under Section 6.3(b), from the Agreement Date until the Effective Time, Boston Scientific will take all further action that is necessary or desirable to carry out the purposes of this Agreement and shall use its commercially reasonable efforts to take all such action and refrain from taking any actions which would be reasonably expected to frustrate the essential purposes of the transactions contemplated by the Agreement.

Section 7.2(b) also contains a bring-down condition that requires that each of Channel s representations and warranties in the Agreement shall be true and

correct as of the Effective Time, *i.e.*, when the merger closes.[231] That aspect of Section 7.2 is not at issue here. In this case, Boston Scientific relies on Section 7.2(b) *solely* for alleged inaccuracies in or breaches of Channel s representations and warranties as of the Agreement Date, *i.e.*, November 1, 2017.

The termination right in Section 8.1(f) does not contain a cure provision for any inaccuracy in or breach of a representation and warranty as of the Agreement Date.[232] Section 8.1(f), however, incorporates the closing condition in Section 7.2(b), which has a built-in MAE requirement. Specifically, the closing condition in Section 7.2(b) shall be deemed to be satisfied unless any failures of the representations and warranties . . . to be true and correct has or would reasonably be expected to have a Material Adverse Effect on [Channel]. Thus, the Representations Condition examines the inaccuracy of specific representations and uses as its measuring stick whether the deviation between the as-represented condition and the actual condition would reasonably be expected to constitute a

[231] *See generally* Lou R. Kling & Eileen T. Nugent, *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* § 1.05[2], at 1-41 (2019 ed.) (describing the critical bringdown condition).

[232] Section 8.1(f) does contain a cure provision for an inaccuracy in or breach of any representation or warranty of [Channel] as of a date subsequent to the date of this Agreement, but that provision is irrelevant to this case. Agreement § 8.1(f).

Material Adverse Effect.[233] The reasonably be expected standard is an objective standard.[234]

In its termination notice, Boston Scientific also relied on Section 8.1(i) of the Agreement as a second ground for termination. Under Section 8.1(i), Boston Scientific can terminate the Agreement at any time if there shall have occurred any Material Adverse Effect with respect to [Channel]. The termination right in Section 8.1(i) does not depend on the existence of an inaccuracy in or breach of any representation or warranty in the Agreement but is subject to a cure provision. By the time of trial, which occurred after the FDA approved the Cerene device, Boston Scientific s reliance on Section 8.1(i) was an afterthought that depended entirely on whether or not Boston Scientific could prove an MAE for purposes of Section 8.1(f).

The analysis of the claims that follows proceeds in five parts. Section IV analyzes whether Boston Scientific was entitled to terminate the Agreement under Section 8.1(f).[235] Section V addresses Boston Scientific s reliance on Section 8.1(i).

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[233] *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *46 (Del. Ch. Oct. 1, 2018), *aff d*, 198 A.3d 724 (Del. 2018).

[234] *See id.* at *65 (citation omitted); *Frontier Oil* v. *Holly Corp.*, 2005 WL 1039027, at *33 (Del. Ch. Apr. 29, 2005) (The test would have or would reasonably be expected to have is an objective one.).

[235] When this decision refers to Boston Scientific s exercise of a right to terminate under Section 8.1(f), the court is referring to the first subsection of that provision, *i.e.*, Section 8.1(f)(i). In a footnote in its opening brief, Boston Scientific argued that the Agreement was properly terminated under Section 8.1(f)(ii) as well because Channel breached a covenant in Section 5.2 of the Agreement by manufacturing non-compliant devices that

Section VI analyzes whether Boston Scientific breached Section 6.3(b). Section VII analyzes whether Channel is entitled to the remedy of specific performance. Section VIII analyzes whether Boston Scientific is entitled to damages based on its fraudulent inducement claim.

IV. BOSTON SCIENTIFIC S TERMINATION UNDER SECTION 8.1(f)

Boston Scientific s lead argument is that it properly terminated the Agreement under Section 8.1(f) based on certain representations in the Agreement that were inaccurate as of the date of the Agreement.[236] As just discussed, Section 8.1(f) permits Boston Scientific to terminate the Agreement at any time if any of Channel s representations in the Agreement shall be inaccurate. . . such that the condition set forth in Section 7.2(b) would not be satisfied. [237] The Representations Condition in

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were used in the CLARITY study. Defs. Br. 42-43 & n.3. A covenant is a promise of future performance. *Akorn,* 2018 WL 4719347, at *8. Channel finished manufacturing the CLARITY devices more than six months before entering into the Agreement. Tr. 331-33 (Elder). Thus, Channel could not have breached the covenant in question based on this conduct.

[236] The parties frame their arguments in terms of breaches of representations. The court finds it more helpful to frame the alleged breaches of representations as inaccuracies because they are statements of fact. *See* Kenneth A. Adams, *A Manual of Style for Contract Drafting* 116 (4th ed. 2017) (One breaches an obligation, but not a statement of fact (whether you call it that or a representation). Instead, a statement of fact is accurate or inaccurate. If Abigail says that it s Monday but in fact it s Tuesday, Abigail hasn t breached anything. Instead, she s made an inaccurate statement.).

[237] Agreement § 8.1(f).

Section 7.2(b) in turn provides that Boston Scientific must consummate the merger, subject to various other conditions, if:

> Each of the representations and warranties of the Company contained in this agreement . . . shall have been true and correct at the time originally made, . . . ***except*** to the extent the failure of any such representations and warranties to be true and correct does not have and would not reasonably be expected to have a Material Adverse Effect.[238]

Boston Scientific bears the burden of proving by a preponderance of the evidence the facts supporting the exercise of its termination rights.[239] Thus, to validate its termination of the Agreement under Section 8.1(f), Boston Scientific must prove that: (i) one or more of the representations in the Agreement was inaccurate as of the Agreement Date and (ii) the failure of such representation(s) to be true and correct has or reasonably would be expected to have a Material Adverse Effect on Channel.[240] The court analyzes these two issues next.

A. Whether Any of Channel s Representations Was Inaccurate

Boston Scientific argues that Shankar s fraud rendered a number of representations in the Agreement inaccurate as of the date of the Agreement. Each of the representations Boston Scientific contends was inaccurate contains a materiality qualifier. The parties did not analyze the meaning of the term material

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[238] *Id.* § 7.2(b) (emphasis added).

[239] *Akorn*, 2018 WL 4719347, at *4.

[240] Agreement § 7.2(b).

or its variations (*e.g.*, in all material respects) for purposes of assessing the accuracy of the representations in the Agreement in their own right.

In *Frontier Oil v. Holly Corp.*,[241] this court considered the meaning of the term material as used in a warranty in a merger agreement. The court explained that, [i]n the context of the Merger Agreement, the concept of Material Adverse Effect and material are analytically distinct, even though their application may be influenced by the same factors. [242] The court then applied a disclosure-based standard of materiality for purposes of interpreting the warranty.[243]

Last year, in *Akorn, Inc. v. Fresenius Kabi AG*, Vice Chancellor Laster carefully studied the meaning of the term in all material respects in a covenant in a merger agreement.[244] There, the acquirer (Fresenius) argued, based on *Frontier Oil*, that the phrase in all material respects requires only a substantial likelihood that the . . . fact [of breach] would have been viewed by the reasonable investor as having significantly altered the total mix of information. [245] Although noting the

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[241] 2005 WL 1039027.

[242] *Id.* at *38.

[243] *Id.* (A fact is generally thought to be material if [there] is a substantial likelihood that the fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.) (quoting *TSC Indus. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)).

[244] *Akorn*, 2018 WL 4719347, at *86.

[245] *Id.*

oddity of relying on a disclosure-based standard to evaluate contractual compliance, the court endorsed using the the *Frontier Oil* test (as conceived by Fresenius). [246] The court explained that the test strives to limit the operation [of the covenants in question] to issues that are significant in the context of the parties contract, even if the breaches are not severe enough to excuse a counterparty s performance under a common law analysis. [247] Based on the analysis in *Akorn*, the court will apply here the disclosure-based standard that *Akorn* endorses in evaluating the alleged inaccuracies of representations in the Agreement.

Boston Scientific argues that Shankar s fraud rendered three categories of representations inaccurate at signing. The court considers each of these categories in the three sections that follow.

1. Compliance with Applicable Healthcare Laws

Boston Scientific s primary argument is that Channel s representation in Section 3.22(a) of the Agreement was inaccurate as of the Agreement Date because

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[246] *Id.* Vice Chancellor Laster did not apply this test when analyzing the alleged inaccuracies of various regulatory compliance representations because the merger agreement in *Akorn* included a materiality scrape provision that scrape[d] away those specific qualifiers [in the representations themselves] in favor of an aggregate MAE qualifier. *Id.* at *64. The Agreement here does not contain such a provision.

[247] *Id.* at *86.

Channel failed to design, manufacture, and test Cerene in material compliance with applicable Healthcare Laws. In Section 3.22(a), Channel represented that:

> The Company and its Subsidiaries are in material compliance with all Healthcare Laws applicable to the Company and is Subsidiaries, or the Company Business. The design, manufacture, testing, and distribution of the Products by or on behalf of the Company and its Subsidiaries is being conducted in compliance with all applicable Healthcare Laws, including, without limitation, the FDA s current good manufacturing practice regulations at 21 C.F.R. Part 820 for medical device products . . . .[248]

The good manufacturing practice regulations referenced at the end of this provision are known as the Quality System Regulation or QSR. The QSR is a system of quality regulations for medical devices that are commercially distributed [to] ensure that the product is reliable and developed correctly. [249] The QSR contains many subparts, one of which is 21 CFR 820.30, entitled Design Controls. [250]

As of the date of the Agreement, the FDA had not approved Channel to sell and distribute products in the United States but it had approved Channel to conduct its CLARITY clinical trial under an approved investigational device exemption

[248] Agreement § 3.22(a).

[249] Tr. 358-59 (Woodard).

[250] *See* 21 CFR § 820.

(IDE).[251] As a general matter, an approved IDE exempts a company from all of the quality system regulations, with the exception of design controls. [252]

The exemption afforded to an approved IDE, however, contains an important qualification. Specifically, under 21 CFR § 812.1(a), an approved IDE exempts a device from the . . . good manufacturing practice requirements under section 520(f) [of the Federal Food, Drug, and Cosmetic Act] except for the requirements found in § 820.30, if applicable (*unless the sponsor states an intention to comply with these requirements* under § 812.20(b)(3) or § 812.140(b)(4)(v)). [253] In other words, a sponsor who has obtained an approved IDE is only required to comply with the design control requirements of the QSR (Section 820.30) unless it elects to comply with other requirements of the QSR by stating an intention to do so.

Channel does not dispute that it did not comply with the entirety of the QSR as of the date of the Agreement.[254] Rather, Channel argues that it complied with the only subpart of the QSR that applied to the Cerene device when it entered into the Agreement (*i.e.*, the subpart for device controls) and that the rest of the QSR was inapplicable because Channel never stated an intention to comply with those other

[251] Tr. 359 (Woodard); *see also* JX 171 (referencing Cerene s IDE exemption # G160101).

[252] Tr. 359 (Woodard).

[253] 21 CFR § 812.1(a) (JX 782) (emphasis added).

[254] *See* Defs. Reply Br. 10-12 (listing nine sections within six subparts of the QSR that Channel did not contest it did not comply with as of the date of the Agreement) (Dkt. 196).

requirements and thus was exempt from them. Boston Scientific counters that the entire QSR did apply to the Cerene device because Channel stated an intention to comply with those requirements and that, even if Channel did not, Channel materially failed to comply with the design control requirements in any event. The preponderance of the evidence supports Channel on the first point but supports Boston Scientific on the second. The court addresses those two issues next.

a. Channel Had to Comply Only with the QSR s Design Control Requirements as of the Agreement Date

In support of its position that Channel expressed an intention to comply with all of the requirements of the QSR, Boston Scientific relies on certain statements in Channel s application for an IDE and in its quality manual. Boston Scientific first points to the following statements in Channel s IDE application:

> All products are manufactured to Channel Medsystems quality system requirements
>
> All components in the Cerene device and the collection bag are purchased to approved specifications using standard operating procedures
>
> Critical material and component specifications are . . . inspected at Incoming Inspection
>
> Suppliers of these components/materials are monitored by use of an Approved Supplier List
>
> sterilization of the Cerene device is performed by ProTech [255]

[255] Defs. Br. 36 (quoting JX 810 at CHANNEL-0016099).

Significantly, the statements quoted above appear to be ones that the FDA requires a sponsor to include in an IDE application. Specifically, 21 C.F.R. § 812.20(b)(3) provides, in relevant part, that an IDE application shall include :

> A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device. [256]

It would be illogical that statements made in an application for an IDE that the FDA requires a company to include in the application would preclude the company from obtaining the benefit of an IDE, *i.e.*, the benefit of developing a product before commercialization free of certain regulations. If that were the case, the IDE application process would preclude every company from receiving the benefit of an IDE. For this reason, the court concludes that the states an intention qualification to the exemption in Section 812.1(a) requires the sponsor to *expressly* state its intention to comply with the full QSR (or parts of it) for the exemption from the QSR (other than design controls) to not apply.

[256] 21 CFR § 812.20(b)(3) (JX 783).

Channel s FDA expert credibly testified that Channel s IDE application does not contain any affirmative statements that it intends to comply with all of the QSR,[257] and Boston Scientific has identified no such statement. Boston Scientific instead asks the court to look to the contents of Channel s quality manual for an expression of such an intention.

Specifically, Boston Scientific contends that Channel expressed an intention to comply with the entire QSR because Channel s quality system requirements which is referenced in the IDE application are defined in its quality system manual to require compliance with the entire QSR. For support, Boston Scientific points to the following statement in the quality manual: The Quality Department has full responsibility and authority for establishing, implementing and maintaining the Quality Management System in accordance with the requirements of . . . 21 CFR Part 820 Quality System Regulation. [258]

[257] Tr. 420 (Ulatowski).

[258] Defs. Br. 36-37 (quoting JX 45.003). Boston Scientific also contends that the reference in the quality manual to 21 C.F.R. Part 820 must have been intended to refer to the entire QSR because the quality manual lists as not applicable to [Channel s] products and processes one section of the QSR (21 C.F.R. 820.170) pertaining to installation activities. *Id.* at 37-38. As the quality manual itself makes clear, this regulation would never apply to Channel because there are no installation activities for the Cerene device. *See* JX 45.004. Thus, one cannot infer from the reference to Section 820.170 in the quality manual that Channel was attempting to make an affirmative statement of a present intention to comply with all of the other requirements of the QSR.

The statement in the quality manual quoted above, however, does not reflect a *present* intention to comply with all of the QSR requirements. Rather the statement implies that the full QSR was not in effect at the time, thus the reason the Quality Department was responsible for establishing and implementing such a system. Lori-Ann Woodard, Channel s quality expert, testified knowledgeably and credibly that a single-device start-up company like Channel would begin by complying with the design control requirements in Section 820.30 and then ramp up to full compliance by the time it applies for premarket approval (PMA) and begins marketing its product.[259] The statement of the Quality Department s responsibility and authority in the manual is consistent with this approach.

Apart from the lack of any affirmative statement of a present intention to comply with the QSR in Channel s quality manual, Boston Scientific s reliance on the manual fails for a separate reason. Inherent in the states an intention exception to the exemption in Section 812.1(a), the sponsor must make the statement to the FDA. Boston Scientific concedes that Channel did not submit its quality manual to the FDA in its IDE application but maintains that the manual was still subject to

[259] Tr. 360-61 (Woodard).

inspection by the FDA.[260] The FDA, however, only engages in such inspections for the PMA application process, not the IDE application process.[261]

Finally, Boston Scientific elicited expert testimony that Section 812.1 only exempts the *device* receiving the IDE from the QSR and not the *company*, and therefore, Channel was still required to comply with the rest of the QSR.[262] FDA guidance, however, specifically and clearly states the contrary: Sponsors of IDE s are also exempt from the Quality System (QS) Regulation except for the requirements for design controls. [263] The court credits the agency s guidance over the proffered testimony.[264] For this and the other reasons discussed above, the court concludes that Channel only needed to comply with the design controls section of the QSR (21 C.F.R. § 820.30) when it entered into the Agreement.

b. Channel s Representation in Section 3.22(a) was Inaccurate as of the Agreement Date

The court turns next to whether Channel s representation under Section 3.22(a) of the Agreement was inaccurate because it was not in material compliance with 21 C.F.R. § 820.30, the design control requirements. Under those requirements,

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[260] Defs. Reply Br. 15.

[261] JX 736 ¶ 25; *compare* 21 C.F.R. § 814 (PMA), *with* 21 C.F.R. § 812 (IDE).

[262] Tr. 706-07 (Reeves).

[263] JX 791.001.

[264] Tr. 700 (Reeves).

Channel must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.[265] Specifically, Channel was required to establish and maintain procedures for, among other things, design verification, design validation, and the documentation and approval of design changes before their implementation.[266] The results of design verification and validation had to be included in a design history file, which each manufacturer shall establish and maintain . . . for each type of device.[267]

Boston Scientific focuses on two issues:

> According to the Greenleaf Report, the rationale and the internal discussions that resulted in the decision to institute [changes to Cerene] in the design history file were not always detailed,[268] despite such detail being required under Section 820.30.[269]
>
> Shankar s falsified test records impacted verification and validation testing, which is done under the design control requirements of Section 820.30.[270]

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[265] 21 C.F.R. § 820.30(a)(1).

[266] 21 C.F.R. § 820.30(f)-(g), (i).

[267] 21 C.F.R. § 820.30(f)-(g), (j).

[268] JX 356.010; *see* JX 356.024 (noting there were only a few incidents where there was a record of the elements of the findings that resulted in the decision to make changes in the device and documentation of the reason for the change was commonly not available).

[269] JX 736.030 (Reeves Expert Report); JX 356.023.

[270] Tr. 396 (Woodard); Tr. 306 (Elder).

As to the first issue, Boston Scientific argues that the lack of documentation on the reasons for implementing changes to the device is contrary to Section 820.30 s requirement that manufacturers adhere to procedures for identification, documentation, validation, . . . review, and approval of design changes before their implementation. [271] Channel counters that even if that is the case, it is not material because the Greenleaf Report further states that Channel maintains a robust design control program with detailed device evolutional changes well documented in change control documentation and detailed engineering drawings. [272] Considered alone, the lack of detail in the design history file noted in the Greenleaf Report would not be significant to the parties in the context of the Agreement. Combined with the presence of falsified records in the design history file, however, the court finds that Channel s noncompliance with the design control requirements was material.

The parties focus on the fact that Shankar falsified seven records on sterilization validation and package seal integrity that appeared in six reports.[273] As Elder explained and as documented in the Greenleaf Report, these falsified

[271] 21 C.F.R. § 820.30(i).

[272] JX 356.010.

[273] *See* JX 356.014-016 (documenting false records submitted in regulatory filings to FDA); JX 658.004-007 (listing altered . . . reports that were submitted to FDA). The record also reflects that Shankar falsified records concerning (i) measurements of at least four component parts and (ii) instrument and equipment calibration, which Channel did not submit to the FDA. JX 356.016-019.

documents were used in verification and validation testing[274] and, by Channel s own admission six of these documents were included in the design history file as of the date the Agreement was signed.[275] Elder further testified that Channel s quality system had significant issues that resulted in fraudulent documents being created, [276] and Channel s own quality expert acknowledged that a design history file that contains false test reports cannot comply with Section 820.30.[277]

Channel counters that because the design history file included numerous other records, the presence of only six test reports containing falsified documents was not material.[278] For materiality purposes, however, the small percentage of affected test reports is not determinative. Depending on the circumstances, a single test report generated from falsified content may be significant enough to establish material non-compliance with Section 820.30.

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[274] Tr. 305-06 (Elder) (confirming that Shankar had falsified records of dimensional inspections conducted [of] components used in the production of medical devices . . . used in verification and validation testing.); *see also* JX 356.016-017.

[275] Pl. s Resp. Br. 73 (Of the numerous records contained in the [design history file] as of November 1, 2017, six were inauthentic.) (Dkt. 193).

[276] Tr. 320 (Elder); JX 637.001-002.

[277] Tr. 396 (Woodard).

[278] Tr. 50 (Coté); Tr. 119-20 (Yu). In January 2018, Channel had approximately 170 quality records in its quality system, 138 of which were submitted to the FDA in connection with Channel s IDE and first two PMA modules. Tr. 119-20 (Yu). The second PMA module was filed with the FDA after the Agreement was entered into on November 1, 2017, and thus it is unclear how many of these records were in the design history file as of the Agreement Date.

Focusing on the contents of the reports, Channel asks the court to consider as part of the total mix of information the results of its internal investigation, which validated the conclusions in the six affected test reports and found after a really deep dive that Shankar had no impact.[279] The fact that Channel s investigation determined that the falsified documents did not alter the conclusions of the affected test reports, however, does not mean that the presence of falsified quality records could not be significant to a reasonable acquirer for other reasons for example, as presenting a potential obstacle to obtaining FDA approval for the Cerene device.

Although a close call, having carefully considered the evidence of record, the preponderance of the evidence demonstrates that a reasonable investor/acquirer would view the manner in which Channel failed to comply with the design control requirements of Section 820.30 as having significantly altered the total mix of information.[280] In particular, the lack of compliance with a portion of the quality system regulation due to the creation of false records concerning equipment calibration, sterility, and device packaging used in verification and validation testing of the device likely would be significant to a reasonable acquirer. Even if the falsified records did not impact the integrity of the design history file, the very fact that there were falsified records in the design history file would call into question

[279] Tr. 405-06 (Woodard).

[280] *Akorn*, 2018 WL 4719347, at *86.

Channel s ability to secure FDA approval. Accordingly, the court finds that the representation in Section 3.22(a) was inaccurate as of the date of the Agreement.

2. Clinical Study Device Compliance

In its second category, Boston Scientific argues that Channel breached Sections 3.22(f), 3.32(b), and 3.32(c) as of the date of the Agreement, because all of the devices used in the CLARITY clinical trial were manufactured under a noncompliant quality system, when Shankar was the sole quality assurance employee. [281] In Section 3.22(f), Channel represented and warranted that all of its clinical trials complied in all material respects with applicable healthcare laws:

> All preclinical and clinical trials . . . that have been or are being conducted by or on behalf of, or sponsored by, [Channel] . . . have been conducted in compliance in all material respects with standard medical and scientific research procedures and the experimental protocols, procedures, and controls pursuant to applicable Healthcare Laws . . . .[282]

In Section 3.32(b), Channel represented and warranted that the goods and services Channel supplied complied in all material respects with applicable laws:

> The goods and services supplied by [Channel] have complied, in all material respects, with all Laws and with all government, trade association and other mandatory and voluntary requirements, specifications and other forms of guidance.[283]

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[281] Defs. Br. 42-43.

[282] Agreement § 3.22(f).

[283] *Id.* § 3.32(b).

In Section 3.32(c), Channel represented and warranted that its products did not contain any material defect:

> None of the Products developed, used, manufactured or sold by [Channel] prior to the Closing contained any material quality, design, engineering, manufacturing or safety defect.[284]

With respect to Sections 3.22(f) and 3.32(b), Boston Scientific has not identified any applicable laws or requirements that Channel failed to comply with, other than design control requirements of the QSR. Boston Scientific also has not identified any evidence relevant to these representations other than the records Shankar falsified concerning components used in the production of medical devices used in the human clinical study.[285] In other words, Boston Scientific s argument concerning the inaccuracy of Sections 3.22(f) and 3.32(b) duplicates the argument it made concerning Section 3.22(a), discussed in the previous section. Thus, for the same reasons that the representation in Section 3.22(a) was inaccurate, Boston Scientific has proven by a preponderance of the evidence that Sections 3.22(f) and 3.32(b) also were inaccurate as of the date of the Agreement.

With respect to Section 3.32(c), which focuses on whether device itself was defective, Boston Scientific argues in essence that because the Greenleaf Report

[284] *Id.* § 3.32(c).

[285] Tr. 305-06, 309 (Elder); JX 356.016-018.

said, all of the devices in the [CLARITY clinical] study had been manufactured under a noncompliant quality system, those devices must have been materially defective.[286] Noncompliance with certain validation and verification testing requirements, however, does not mean that the Cerene device necessarily was defective and, critically, Boston Scientific has failed to identify any evidence of an actual material defect. For this reason, the court finds that Boston Scientific failed to prove by a preponderance of the evidence that the representation in Section 3.32(c) was inaccurate as of the date of the Agreement.

3. Statements to the FDA

Boston Scientific s final category of alleged inaccurate representations focuses on the veracity of Channel s communications with and submissions to the FDA, which implicates Sections 3.18(c), 3.22(c), and 3.22(h) of the Agreement. Section 3.22(c) provides that Channel s regulatory filings were true and correct:

> All applications, notifications, submissions, information, . . . and filings . . . , when submitted to the FDA or any other Governmental Authority, were true, accurate and complete in all material respects as of the date of submission.[287]

In Section 3.22(h), Channel represented and warranted that Channel had not made an untrue statement of material fact to the FDA or any other Governmental

[286] Defs. Br. 19; *see also id.* 42-46.

[287] Agreement § 3.22(c).

Authority or done anything that would reasonably be expected to provide a basis for the FDA to invoke its Fraud Policy. [288] Section 3.18(c) addresses more generally applications and submissions in support of Permits and requires them to be true, complete and correct in all material respects. [289] The term permits is defined as permits, licenses, franchises, approvals, authorizations, registrations, clearances, and exemptions . . . necessary for [Channel] to . . . carry on its business. [290]

As of the date of the Agreement, Channel had made submissions to the FDA for its IDE and Module 1 of its PMA application, which included three of the six test reports that contained information that Shankar falsified.[291] These three test reports included the sterilization validation and package seal integrity records discussed above.[292] Boston Scientific argues that the false records in Channel s IDE and Module 1 submissions were material because, as Channel s own expert (Timothy Ulatowski) testified, [w]hen submitted, [Channel s submissions] were significant

[288] *Id.* § 3.22(h).

[289] *Id.* § 3.18(c).

[290] *Id.* § 3.18(b)(i).

[291] Tr. 114, 119-21 (Yu); Tr. 38 (Coté); JX 356.014 (Greenleaf report confirming that Shankar caused false information to be submitted in regulatory filings to FDA). Channel submitted Module 2 for the PMA to the FDA on November 21, 2017, after signing the Agreement, and withdrew it later. Tr. 129 (Yu).

[292] JX 658.004-006.

in regard to, for example, approval of the IDE.[293] Boston Scientific also contends that the severe consequences for filing any false statement with the government such as criminal liability under 18 U.S.C. § 1001, an injunction, or invocation of the FDA s Fraud Policy undermines any contention that filing false information with the FDA would be insignificant to a reasonable acquirer.[294]

Channel counters, once again, that the results of its investigation negate the materiality of these test reports. As discussed above, however, a reasonable acquirer would find the fact that falsified reports were submitted to the FDA to alter the total mix of information for other purposes, namely to call into question Channel s ability to secure FDA Approval. For this reason, Boston Scientific has proven by a preponderance of the evidence that the false information submitted to the FDA before the Agreement Date was material. Thus, Sections 3.18(c), 3.22(c), and 3.22(h) were inaccurate as of the date of the Agreement.[295]

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[293] Tr. 437-38 (Ulatowski).

[294] Defs. Br. 48.

[295] With respect to Sections 3.22(c) and 3.22(h), Boston Scientific asserts that Channel also provided falsified information to BSI because the technical information submitted by [Shankar] through upload . . . to BSI s website portal for review included some of the same false information that had been submitted to FDA. Defs. Br. 41-42 (quoting JX 356.019). In making this argument, Boston Scientific did not identify which specific laws or legal requirements govern submissions to BSI, which is necessary to determine if Channel committed a violation. Regardless, for the reasons explained above, Boston Scientific has proven that the representations in Sections 3.22(c) and 3.22(h) were inaccurate based on Channel s submissions to the FDA, making any further violations of those provisions based on its submissions to BSI cumulative.

* * * * *

In sum, for the reasons discussed above, Boston Scientific has proven by a preponderance of the evidence that Channel s representations in Sections 3.18(c), 3.22(a), (c), (f), (h), and 3.32(b) of the Agreement were inaccurate at signing but failed to prove the inaccuracy of Section 3.32(c).

B. Whether Channel s Inaccurate Representations in the Agreement Would Reasonably Be Expected to Result in an MAE

Having determined that a number of the representations in the Agreement were inaccurate as of the Agreement Date, the next question is whether Boston Scientific has proven that the failure of those representations to be true and correct has or would reasonably be expected to have a Material Adverse Effect on Channel.[296] Before turning to consider the evidence on this question, the court addresses several legal issues relevant to how the termination provision in Section 8.1(f) operates.

[296] Agreement § 7.2(b).

1. Legal Framework of Section 8.1(f)

The Agreement defines "Material Adverse Effect" in relevant part, as follows:

> "Material Adverse Effect" means with respect to [Channel], any change or effect occurring after the Agreement Date that, when taken individually or together with all other adverse changes or effects occurring after the Agreement Date, is materially adverse to the business, results of operations, assets or financial condition of [Channel].[297]

The definition in the Agreement goes on to enumerate a series of carve-outs, but none of them are relevant to this case.

As is typical with MAE clauses, the Agreement does not define what "material" means for purposes of an MAE.[298] In the absence of such a definition, Delaware courts applying MAE clauses—including, most recently, in *Akorn*—have held that the effect should "substantially threaten the overall earnings potential of the target in a durationally-significant manner."[299]

Seizing on a different part of the *Akorn* decision, discussed above, where the court considered the standard for a covenant that used "in all material respects" language, Boston Scientific suggests that the court should apply a disclosure-based standard of materiality in determining whether there has been a Material Adverse

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[297] *Id.* § 10.2.

[298] *See Akorn*, 2018 WL 4719347, at *48 (citations omitted).

[299] *Id.* at *53 (quoting *In re IBP, Inc. S holders Litig.*, 789 A.2d 14, 68 (Del. Ch. 2001)); *see also Hexion*, 965 A.2d at 738; *Frontier Oil*, 2005 WL 1039027, at *34.

Effect.[300] According to Boston Scientific, the operative question should be whether the fraud would have been important to BSC s decision to enter into the Agreement. [301] This position is devoid of merit. The concept of Material Adverse Effect and material are analytically distinct. [302] And, as just mentioned, *Akorn* itself applied the significantly higher standard of materiality that Delaware courts have used in the past in the absence of a contractual definition of materiality when applying MAE clauses.

In *Akorn*, based on a thorough review, Vice Chancellor Laster summarized other teachings from our law relevant to applying an MAE clause, as follows:

> A buyer faces a heavy burden when it attempts to invoke a material adverse effect clause in order to avoid its obligation to close. A short-term hiccup in earnings should not suffice; rather the Material Adverse Effect should be material when viewed from the longer-term perspective of a reasonable acquirer. In the absence of evidence to the contrary, a corporate acquirer may be assumed to be purchasing the target as part of a long-term strategy. The important consideration therefore is whether there has been an adverse change in the target s business that is consequential to the company s long-term earnings power over a reasonable period, which one would expect to be measured in years rather than months.[303]

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[300] Defs. Br. 83-84.

[301] *Id.* 83.

[302] *Frontier Oil*, 2005 WL 1039027, at *38.

[303] *Akorn*, 2018 WL 4719347, at *53 (citations omitted).

The reasonably be expected to standard is an objective one.[304] Future occurrences qualify as material adverse effects and an MAE can have occurred without the effect on the target s business being felt yet.[305] But a mere risk of an MAE cannot be enough.[306] There must be some showing that there is a basis in law and in fact for the serious adverse consequences prophesied by the party claiming the MAE.[307] When determining if something would reasonably be expected to result in an MAE, the court considers quantitative and qualitative aspects.[308]

During post-trial argument, the parties disagreed on how the termination provision in Section 8.1(f) interacts with the Representations Condition in Section 7.2(b), which contains the forward-looking would reasonably be expected MAE requirement. The court requested supplemental briefing on that dispute, which

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[304] *Id.* at *46 (internal quotation marks omitted).

[305] *Id.*

[306] *Id.* at *65; *see also* Kling & Nugent, *supra* note 231, § 11.04[9], at 11-60 n.102 (discussing the reasonably be expected to standard).

[307] *Akorn*, 2018 WL 4719347, at *65 (quoting *Frontier Oil*, 2005 WL 1039027, at *36 n.224). Vice Chancellor Laster noted that one commentator argues that the would reasonably be expected formulation is best thought of as meaning likely to happen, with the likely, in turn, meaning a degree of probably greater than five on a scale of ten, which the Vice Chancellor equated to more likely than not. *Id.* at *65 n.646 (citations omitted).

[308] *Id.* at *65 (citing *Frontier Oil*, 2005 WL 1039027, at *37).

highlighted two temporal issues concerning the interplay of those provisions. The court addresses these temporal issues next.

To repeat, under Section 8.1(f), Boston Scientific may terminate the Agreement at any time prior to the Effective Time if any representation or warranty of [Channel] contained in this Agreement shall be inaccurate or shall have been breached as of the Agreement Date . . . such that the [Representations Condition] would not be satisfied. [309] The Representations Condition in Section 7.2(b), including the preface, states in relevant part:

> 7.2 Conditions to the Obligation of [Boston Scientific] and Merger Sub. The obligations of [Boston Scientific] to consummate the Merger after delivery of . . . a Put Option Election Notice by [Channel] are subject to the satisfaction of the following further conditions . . . :
>
> * * *
>
> (b)(i) Each of the representations and warranties of [Channel] contained in this Agreement . . . shall have been true and correct at the time originally made . . . except to the extent the failure of any such representations and warranties to be true and correct does not have and would not reasonably be expected to have a Material Adverse Effect on [Channel]. . . . For clarity, it is agreed that the condition set forth in clause (b)(i) of this paragraph shall be deemed to be satisfied unless any failures of the representations and warranties identified in clause (b)(i) to be true and correct has or would reasonably be expected to have a Material Adverse Effect on Channel.[310]

[309] Agreement § 8.1(f).

[310] *Id.* § 7.2.

The first temporal issue arising from reading these two provisions together is determining what date the court should look to in assessing whether there was a reasonable expectation that an MAE would occur at some point in the future. The second issue is at what point in time, as of that date, an MAE would reasonably be expected to occur.

With respect to the *first* issue, Channel contends that Section 8.1(f) requires the court to evaluate whether there was a reasonable expectation of an MAE as of the date Boston Scientific provided its notice of termination, *i.e.*, on May 11, 2018.[311] Boston Scientific agreed during post-trial argument that the termination date was the relevant date,[312] but then changed its position. It now asserts that the relevant date is shortly after March 6, 2018 because that is when Boston Scientific read the Greenleaf Report and formed the expectations that led to termination. [313] This flip of position is odd given Boston Scientific s stance at post-trial argument that the two-month difference between March and May of 2018 is immaterial to whether it was entitled to terminate the Agreement under Section 8.1(f).[314] In any event, the court finds that the appropriate date to use is the termination date.

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[311] Pl. s Supp. Answering Br. 1, 18 (Dkt. 207).

[312] *See* Post-Trial Tr. 25, 43 (July 26, 2019) (Dkt. 203).

[313] Defs. Supp. Opening Br. 13 (Dkt. 206).

[314] Post-Trial Tr. 43 (So what the logical way to read the contract is at the time you terminate because you can terminate at any time was there a reasonable expectation of

The critical language of the MAE provision in Section 7.2(b) is that an MAE must reasonably be expected an objective standard. As a matter of common sense, the logical time to test whether a party had an objective right to terminate under Section 8.1(f) is to examine the facts and circumstances when the party actually took action to terminate. This approach is not only logical, it provides precision by fixing a specific date to apply the terms of the contract, whereas using an earlier date invites guesswork and imprecision on what date to use. Boston Scientific advances no persuasive reason for using an earlier date and the court can conceive of none. To the contrary, Boston Scientific s change of position appears to be a pretext to try to elide evidence unhelpful to its case (*i.e.*, the FDA s approval of Channel remediation plan in April 2018) even though Boston Scientific did not have the strength of its convictions to terminate the Agreement before Channel received that approval. Based on the foregoing, the court finds that the most sensible way to read the Agreement is to consider, as of the termination date, whether there was a reasonable expectation of an MAE.

With respect to the *second* issue, Channel contends that Section 8.1(f) requires Boston Scientific to prove, as of termination, that any inaccuracies in Channel s representations were such that an MAE would reasonably be expected as of the time

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an MAE. So May-March, I mean, it doesn t matter because there was nothing happened materially between).

of the anticipated closing.[315] Boston Scientific agrees that the reasonably be expected language in Section 7.2(b) is an inherently forward-looking concept, [316] but it is silent on what time frame the court should consider in applying Section 8.1(f), which means the inquiry would be open-ended.[317] For the reasons explained below, the court agrees with and adopts Channel s interpretation.

A key difference between the parties interpretations is their treatment of the preface to Section 7.2(b), quoted above, as it relates to Section 8.1(f). Before considering where the parties disagree about the preface, it is useful to review what is not in dispute. The Agreement makes clear that: (i) Channel could only exercise its put-right if Cerene received FDA approval on or before September 30, 2019; (ii) upon receipt of FDA approval, Channel had twenty-one days to deliver a Put Option Election Notice; and (iii) upon delivery of the Put Option Election Notice, Boston Scientific would be obligated to close within 15 days.[318] The record also shows that, when the parties entered into the Agreement, they expected that FDA would approve Cerene in the first quarter of 2019.[319] All of this means that the parties expected the transaction to close in April or May of 2019.

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[315] Pl. s Supp. Answering Br. 1.

[316] Defs. Supp. Reply Br. 9 (Dkt. 209).

[317] *Id.* 6.

[318] Agreement 1.1(b), (d), 10.2 (definitions of FDA Approval and Put Period).

[319] JX 437; JX 438; JX 297.004-005, 011-012.

Turning to the parties areas of disagreement, Channel contends that because Section 7.2(b) is a closing condition . . . whether it would not be satisfied . . . therefore must be assessed at the expected time of closing. [320] For the reasons just explained, the way the preface operates supports this timing.

As an interpretative matter, Channel argues that the preface is a necessary and indispensable part of the section both grammatically and logically because they are both part of the same sentence and without the preface, Section 7.2(b) contains nothing more than an abstract statement. [321] The court agrees. Indeed, the ability to terminate at any time prior to the Effective Time language upon which Boston Scientific relies heavily itself appears in the preface of Section 8.1(f).[322] It would be illogical to construe one of the two provisions at issue (Section 8.1(f)) in tandem with its preface while disregarding the preface for the other (Section 7.2(b)).

Boston Scientific makes essentially two other arguments opposing Channel s interpretation. Both are without merit.

First, Boston Scientific argues that Channel s interpretation would require it to delay the exercise of its termination rights until the issuance of a Put Option Election Notice and thus render meaningless the language in the preamble of

[320] Pl. s Supp. Answering Br. 1.

[321] *Id.* 6.

[322] The preface of Section 8.1 is quoted in full in Part V below.

Section 8.1 allowing it to terminate at any time.[323] This is incorrect. Requiring Boston Scientific to prove, as of termination, that any inaccuracies in Channel s representations would reasonably be expected to have a Material Adverse Effect as of an *anticipated* closing date, does not mean that Boston Scientific would have to wait to terminate until after the issuance of a Put Election Option. Boston Scientific *can* terminate at any time prior to the Effective Time whether or not Channel has delivered a Put Option Election Notice. To do so under Section 8.1(f) without violating the other terms of the Agreement simply means that Boston Scientific must show there was an inaccurate representation that, as of termination, would reasonably be expected to have a Material Adverse Effect as of when the parties anticipated the merger would close. Interpreting the Agreement in this manner gives meaning to all parts of Sections 7.2(b) and 8.1(f).

Second, Boston Scientific argues that Channel s interpretation would render meaningless the cure provision in Section 8.1(f),[324] which is limited to an inaccuracy in or breach of any representation . . . of [Channel] as of a date subsequent to the date of this Agreement.[325] This is a *non sequitur*. The fact that Boston Scientific could not validly terminate the Agreement under Section 8.1(f) unless the

[323] Defs. Br. 1-5; Defs. Supp. Reply Br. 9.

[324] Defs. Supp. Reply Br. 10.

[325] Agreement § 8.1(f).

alleged breach of representation reasonably would be expected to have a Material Adverse Effect has nothing to do with the cure provision in Section 8.1(f). Indeed, Channel does not dispute that it has no contractual right to cure a representation that was inaccurate as of the Agreement Date, which is logical because one cannot go back in time to fix a representation made as of a date in the past.[326] But that does not mean that Boston Scientific is exempted from having to establish that such an inaccuracy would reasonably be expected to have a Material Adverse Effect in order to terminate under Section 8.1(f). Nor does it mean that Boston Scientific may not have other recourse, such as indemnification rights, for inaccurate representations that would not reasonably be expected to rise to the level of a Material Adverse Effect.[327]

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For the reasons explained above, the court concludes that Boston Scientific has the burden to prove that, as of the termination date, the inaccurate representations in the Agreement would reasonably be expected to have a Material Adverse Effect

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[326] Post-Trial Tr. 77 ([Y]ou can t cure a breach of rep at signing because you can t go back and make it true at signing).

[327] *See* Agreement 9.2(a) (Channel shall . . . indemnify, defend and hold harmless [Boston Scientific] . . . from and against . . . any breach by [Channel] of any representation [or] warranty . . . made by [Channel] in this Agreement.); *see also* Kling & Nugent *supra* note 231, § 1.05[2] at 1-41 (If a representation is false when made, that is, when the agreement is executed, the representing party may be liable for damages whether or not the transaction closes.).

on Channel around the time the parties expected the merger to close. As it turns out, the precise timeframe in the future for examining whether an MAE would reasonably be expected ends up being of little consequence in this case. That is because, as discussed in the next section, the court finds that Boston Scientific has not proven that, as of the termination date, the inaccurate representations would reasonably be expected to have a Material Adverse Effect at any future point in time.

2. Boston Scientific s Evidence of an MAE

On June 19, 2018, about one month after terminating the Agreement, Boston Scientific asserted in a letter to Channel that its submission of false information to regulators has placed the approval of Cerene in jeopardy, thereby substantially threatening Channel s overall earnings potential. [328] This assertion flew in the face of many facts known to Boston Scientific when it terminated the Agreement several weeks earlier, on May 11, 2018 most significantly, the FDA s acceptance of Channel s remediation plan for premarket approval on April 18, 2018.[329] That action was the culmination of the following series of events:

> In late January 2018, Channel met with the FDA and made it aware of Shankar s fraud, including the six falsified reports submitted to the FDA.[330]

[328] JX 514.006.

[329] JX 456.005.

[330] Tr. 126-28 (Yu); JX 270; JX 279.

In February 1, 2018, the FDA asked Channel to withdraw and re-submit PMA Module 2 with corrected records, which Channel did.[331]

In March 16, 2018, Channel and representatives of Greenleaf met with the FDA.[332] One week before that meeting, Channel provided the FDA with more than 250 pages of information about Shankar s fraud, including: (i) the Greenleaf Report, (ii) Channel s Fraud Implication Assessment Quality Plan, (iii) the fourteen IARs addressing Shankar s fraud, (iv) Brill s adverse event review, and (v) a lengthy report summarizing Channel s investigation and remediation efforts related to its IDE and PMA Module 1.[333]

After receiving this information, the FDA thanked the company for their transparency and for coming forward with the information quickly. [334] When asked if the FDA would be interested in subsequent discussions regarding the issues and the status and progress of the company s remediation, the FDA responded that follow-up would take place through the inspection process. [335]

On April 18, 2018, the FDA told Channel that it ha[d] addressed all of FDA s concerns and that the agency appreciate[d] the company s transparency and timeliness. [336] Since that date, the FDA did not seek any more information about Shankar s fraud.[337]

Also on April 18, 2018, the FDA and Channel discussed the schedule for continuing to submit the remaining modules of the PMA and to complete the process by July only one month later than the originally forecasted submission date of June.[338]

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[331] Tr. 129 (Yu); JX 294; JX 494.

[332] Tr. 64 (Coté), 129, 132-33 (Yu); JX 401.

[333] JX 380; *see* Tr. 64-65 (Coté); Tr. 130-31 (Yu).

[334] JX 401.004; Tr. 67 (Coté).

[335] JX 401.004; Tr. 133-34 (Yu).

[336] JX 436.001.

[337] Tr. 139 (Yu).

[338] *Id.* 138; JX 436.

The FDA s acceptance of Channel s remediation plan on April 18, 2018 strongly signaled that Shankar s fraud would not be the cause of any failure of the FDA to provide premarket approval of the Cerene device and made receipt of premarket approval the triggering event for Channel to exercise its put-right under the Agreement to close the merger a distinct possibility. Indeed, the FDA approved Channel s PMA application on March 28, 2019, consistent with the timeframe Boston Scientific expected before it signed the Agreement. That approval occurred a few weeks before trial. The court considers next the qualitative and quantitative aspects of the evidence of an MAE that Boston Scientific offered at trial.

a. Qualitative Significance

Presumably because Channel received FDA approval for Cerene, Boston Scientific did not press at trial its initial explanation for a reasonably expected MAE, *i.e.*, that Shankar s fraud substantially threatened Channel s overall earnings potential *by jeopardizing its chances of obtaining FDA approval*. Rather, Boston Scientific shifted its strategy to argue that Shankar s fraud was reasonably expected to have a Material Adverse Effect *notwithstanding Channel s receipt of FDA approval* on the theory that Boston Scientific would still need to remediate and retest the product before placing Cerene on the market.

Pierce, who read the Greenleaf Report in early March 2018, testified he made the decision on behalf of Boston Scientific to terminate the Agreement after

receiving feedback about the Greenleaf Report from several Boston Scientific executives during a March 29 meeting.[339] The Greenleaf Report was the sole documentary evidence Pierce relied on in deciding to terminate the Agreement.[340] According to Pierce, the report made it clear to him that Boston Scientific could only market [Cerene] in good faith by going all the way back to the beginning and redoing the entire design history file, redoing the IDE submission, reconducting the clinical trial, and ultimately resubmitting the PMA.[341] This stated belief is not credible, however, given the circumstances surrounding Pierce s decision to terminate the Agreement.

To start, Pierce already had received the information contained in the Greenleaf Report through the periodic updates Channel was providing Kaster and Robinson.[342] Pierce also oddly purported to rely on the Greenleaf Report in deciding to terminate the Agreement while ignoring Greenleaf s fundamental conclusion

[339] Tr. 471-73, 478-79 (Pierce).

[340] *Id.* 537.

[341] *Id.* 472-73, 537; *see also id.* 485-86. Carr testified that he and other executives at the meeting shared Pierce s view, but Pierce was the one who made the decision and the other executives to which Carr referred (Gardner and Sukthankar) did not testify at trial. Tr. 620-21 (Carr).

[342] *See supra* Part I.I.

that it did not find evidence that Shankar s activities had any impact on Channel s clinical data.[343]

Significantly, Pierce decided to terminate the Agreement without taking any number of actions one reasonably would have expected him to take before making such a consequential decision. For example, before Pierce terminated the Agreement, no one at Boston Scientific: (i) spoke with Greenleaf or Channel about the findings in the Greenleaf Report;[344] (ii) used an outside consultant to examine the effect of Shankar s fraud;[345] (iii) quantified the costs of remediating Channel s quality systems;[346] or (iv) made any effort to understand what Channel had done to improve its quality systems since discovering Shankar s fraud.[347]

Pierce also did not confer with a number of executives whose perspectives on Channel and terminating the Agreement would seem highly relevant. Pierce did not consult with Boston Scientific s Head of Quality or its Chief Medical Officer, whose major responsibility is the clinical work associated with Boston Scientific s products and also understanding the clinical risks and benefits of Boston Scientific s

[343] JX 355.006-007.

[344] Tr. 516 (Pierce).

[345] *Id.* 522-23.

[346] Tr. 640 (Carr).

[347] *Id.* 642.

products. [348] He also did not consult with Kaster, Boston Scientific s designee to Channel s Board and long-time Board observer, whom Pierce acknowledged knew more about Channel than he did.[349] At the time, Kaster believed, based on the regular Board updates he was receiving, that Shankar s fraud was more or less a non-issue :

> Q. So your reaction initially upon learning this was you thought this was all a non-issue unless any of his actions impacted the data, and by data, in your mind, when you conveyed that you were talking about human patient data?
> A. Yes.
> Q. Okay. And you know today, or at least based on what you know today, none of his actions impacted human patient data?
> A. Correct.
> Q. And I think it s fair to say based on this you still feel this is all a non-issue; correct?
> A. More or less, yeah.[350]

Nor did Pierce consult with Robinson, Channel s Board observer.[351]

Boston Scientific has no written record of the March 29 meeting and, incredibly, it did not generate a single scrap of paper assessing the impact of Shankar s fraud on Channel s quality system after it received the Greenleaf

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[348] Pierce Dep. 46; Tr. 541 (Pierce).

[349] Tr. 538-39 (Pierce).

[350] Kaster Dep. 214 (objections omitted); Tr. 539-40 (video of Kaster deposition testimony); *see also* Kaster Dep. 85 (Kaster did not have doubts that Channel fix[ed] whatever problems there were arising from Shankar s fraudulent activities on Channel and its quality systems.).

[351] Tr. 516 (Pierce).

Report.[352] The lack of any such documentation not only casts doubt on the bona fides of the termination decision, it belies Pierce s representation to Coté in an April 22 email that Boston Scientific was thoroughly assessing the entire impact of Dinesh Shankar s actions on your quality systems, pre-clinical and clinical data as well as the putative product. [353]

When asked how he could justify scrapping all the work Channel had done on the Cerene device and essentially starting from scratch even after the FDA approved the device, Pierce testified that it was based upon Boston Scientific s expectations of quality and not an action another company necessarily would take under the same circumstances.[354] The weight of the evidence before the court, however, shows that Pierce s explanation is inconsistent with how Boston Scientific itself has acted in the past and that Boston Scientific s litigation position of the need to start from scratch to remediate Cerene is not objectively reasonable.

The record demonstrates, and the court finds, that FDA approval of Cerene, which appeared likely when Boston Scientific terminated the Agreement, undercuts Boston Scientific s assertion that it would need to keep Cerene off the market while it engages in its own remediation efforts and potentially conducts an additional

[352] *Id.* 528.

[353] JX 456.004.

[354] Tr. 476-77, 478 (Pierce).

clinical trial. Channel s receipt of FDA approval meant that the FDA a highly respected neutral third party had meticulously examined Channel s PMA submission and found that there is reasonable assurance that Cerene is safe and effective. [355]

Testimony from Boston Scientific s own employees confirm the importance of FDA approval. For example, Carr, a senior member of Boston Scientific s quality staff who participated in the March 29 meeting with Pierce,[356] testified:

> Q. The PMA approval progress is rigorous. Correct?
> A. That s correct.
> Q. And approval of a PMA indicates that FDA believes a product is safe and effective. Correct?
> A. Correct.
> Q. FDA would not approve a product that doesn t meet its high standards. Correct?
> A. I would believe that to be true, yes.[357]

Boston Scientific s corporate representative Lisa Sullivan similarly endorsed the significance of FDA approval. She testified that Boston Scientific has repeatedly contended in thousands of product liability cases that FDA approval demonstrates that products are safe and effective and that Boston Scientific has always been willing to rely on the FDA s statements.[358] In 2018, for example, in response to a

[355] JX 757.029-030.

[356] Tr. 578-79, 620-21 (Carr).

[357] *Id.* 683.

[358] Sullivan Dep. 46.

60 Minutes investigatory piece about Boston Scientific s transvaginal mesh products, Boston Scientific stated that [a]ny allegations [that] continu[e] to question the integrity or legitimacy of [the] resin [used in these products] are false and irresponsible because the FDA had determined that a change in the resin supplier did not raise any new safety or effectiveness concerns. [359]

Boston Scientific s quality expert (Reeves) could not identify any instance where Boston Scientific or any other company voluntarily rebuilt a quality system for a device from scratch and redid its clinical testing after receiving FDA approval.[360] To the contrary, Reeves acknowledged that even after one of his clients had received multiple warning letters from the FDA and had been advised to rebuild its quality system, the client continued to market the product during remediation.[361]

Boston Scientific offered no fact testimony of any instance where it voluntarily rebuilt a quality system from scratch and/or redid clinical testing for an FDA-approved device without prompting from the FDA, and evidence of its own past practices belies that this would be necessary before marketing Cerene. In 2015, Boston Scientific acquired American Medical Systems (AMS), a men s health products company, which had recently received a warning letter from the FDA

[359] JX 327.004.

[360] Tr. 837-38 (Reeves).

[361] *Id.* 836-37.

concerning validation issues.[362] As discussed below, Boston Scientific identifies AMS as its best comparable to Channel for the cost of remediation. Yet Boston Scientific kept AMS s products on the market throughout the AMS remediation process, despite having received an FDA warning letter something Channel has never received.[363]

Boston Scientific argues that even with FDA approval, Shankar s fraud would reasonably be expected to have a Material Adverse Effect because completion of the merger would expose Boston Scientific to products liability litigation, competitive harm, and future regulatory action.[364] Each of these concerns is a risk that a businessperson legitimately would consider, although to repeat there is not a single scrap of paper that Boston Scientific actually analyzed any of these risks when Pierce made the termination decision.[365] Rather, the evidence about these concerns consists of seemingly after-the-fact rationalizations, is highly speculative and does not come close to proving that, as of the termination, Boston Scientific reasonably expected that these concerns would rise to the level of a Material Adverse Effect.

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[362] Tr. 611 (Carr); JX 738.013.

[363] Tr. 675-78 (Carr).

[364] Defs. Br. 58-62.

[365] Tr. 528-29 (Pierce).

With respect to product liability claims, Boston Scientific elicited testimony that details about Shankar s fraud and Channel s remediation likely would be significant fodder for plaintiff s attorneys in a hypothetical product liability case.[366] Boston Scientific, however, failed to identify any defect or substantive problem with Cerene that could form the basis of a products liability claim and it made no effort to quantify the increased risk of such hypothetical claims.

In *Frontier Oil*, this court declined to find that a *pending* toxic tort litigation that could be catastrophic for the company caused an MAE where the buyer had not demonstrated (or even seriously tried to demonstrate) the likelihood of an MAE resulting from the litigation or to give the court the basis to make a reasonable and an informed judgment of the probability of an outcome on the merits. [367] The court noted that the mere existence of a lawsuit cannot be determinative of an MAE but rather [t]here must be some showing that there is a basis in law and in fact for the serious adverse consequences prophesied by the party claiming the MAE. [368]

Here, Boston Scientific s product liability concerns are far weaker than the concerns that were found deficient in *Frontier Oil* because there is no pending

[366] Tr. 434-35 (Ulatowski); Tr. 480-81 (Pierce).

[367] *Frontier Oil*, 2005 WL 1039027, at *12, *36.

[368] *Id.* at *36 n.224.

litigation, there is no identified product defect or articulated basis for a product liability claim, and no showing has been made about the likelihood of any exposure or the costs involved. In short, there is no basis here in law and in fact for the serious consequences about which Boston Scientific is now professing concern.

With respect to competitive harm, Pierce testified that the idea of fraud could and would be used by competitors to try to establish doubt around Cerene.[369] Competitors undoubtedly will seize upon whatever debating points they think will help them gain market share but it is not self-evident that focusing on Shankar s fraud would have a material impact on Cerene sales given the imprimatur of FDA approval. Apart from simply identifying the risk of competitive harm, Boston Scientific did not present any evidence showing how Cerene s projected sales would be reduced because of Shankar s fraud if it proceeded to sell the product upon receiving FDA approval, let alone reduced so significantly as to cause a Material Adverse Effect.[370]

Finally, Boston Scientific argues that if the deal closes, Boston Scientific would be susceptible to future regulatory action on Cerene because Channel failed

[369] Tr. 481 (Pierce).

[370] The only impact on sales for which Boston Scientific provided evidence was an analysis by its valuation expert. He analyzed the projected impact of delaying sales of Cerene for two to four years to re-remediate the product and, potentially, to conduct a new clinical trial. This analysis is discussed in Part IV.B.2.b.

to submit two documents to the FDA that were created after the FDA accepted Channel s remediation plan: the second Greenleaf report, prepared in June 2018, and an internal audit of Channel s quality management system conducted by a consultant (Linda Lovett) in September 2018.[371] It stands to reason that the introduction of any new healthcare product inherently carries a risk of future regulatory action, thus Boston Scientific must show that Shankar s fraud would reasonably be expected to significantly increase this risk. It has not done so.

Channel s FDA expert (Ulatowski) credibly testified that the FDA would not have expected Channel to produce either of these documents unsolicited.[372] Ulatowski explained (and the record confirms) that the FDA stated at its March 2018 meeting with Channel that the FDA inspector would follow up at the premarket approval inspection about anything the inspector thought was important to review, which is the FDA s usual procedure.[373] The contents of the two documents in question also do not raise any red flags concerning Shankar s fraud.

As to the second Greenleaf report, Boston Scientific focuses on its reference to a new data integrity issue concerning a vendor, Henry Servin & Sons, which inspected certain components. The cited data integrity issue, however, concerned

[371] Defs. Br. 15, 61.

[372] Tr. 423-24 (Ulatowski).

[373] *Id.* 423-25; JX 401.004.

the vendor s own computer server and was completely unrelated to Shankar s fraud.[374] Boston Scientific also draws attention to Greenleaf s recommendation in its second report that Channel ensure that its classification of the IARs it opened to investigate Shankar s fraud as minor is supportable. Each of these IARs was provided to the FDA and, importantly, the second Greenleaf report specifically found that the impact of the questionable classifications may be minimal since in the current environment, all issues have received the appropriate visibility and prioritization within the company. [375]

As to the Lovett audit, which was a regularly scheduled internal audit that the FDA normally would not receive,[376] Boston Scientific does not contend that any of its observations or concerns pertained to Shankar s fraud. The audit, furthermore, provided an overall positive assessment of Channel s quality system: continued

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[374] When investigating Shankar s fraud, Channel discovered that Henry Servin & Sons had sold its server, which housed all of the raw data for not only Channel, but for some other clients as well. Tr. 179 (Patel). In response, Channel (i) informed the FDA about the issue in an IAR it provided to the FDA, (ii) opened a CAPA, (iii) terminated the vendor, (iv) re-inspected components that the vendor inspected, and (v) conducted a risk assessment that did not identify any additional risks. *Id.* 179-85; JX 380.073; JX 652.004-005.

[375] JX 634.011.

[376] *See* JX 595.076 (The audit was completed to identify gaps and/ or opportunities in the company s quality management system according to the internal audit schedule[].); Tr. 281-82 (Elder) (explaining that the FDA normally permits a company to maintain confidentiality of internal audits to make sure it s done well so the company can identify their deficiencies and take corrective action to address them outside of an FDA inspection.).

enhancement and implementation is encouraged to assure the associated [Quality System] controls and procedures *continue to demonstrate* full compliance to applicable regulations [and] standards. [377]

In sum, the weight of the evidence demonstrates convincingly that Boston Scientific s professed need notwithstanding FDA approval of the Cerene device to remediate and retest Cerene before placing it on the market is not objectively reasonable, and that Boston Scientific s concerns about potential products liability litigation, competitive harm, and future regulatory action are based on little more than unsubstantiated speculation. The court next turns to the quantitative aspects of the evidence of an MAE that Boston Scientific presented at trial.

b. Quantitative Significance

Boston Scientific asserts that Shankar s fraud and the related inaccurate representations in the Agreement made it reasonable to expect that the value of Channel had been substantially impaired. [378] There is no bright-line test for determining an MAE based on quantitative considerations. As discussed in *Akorn*, one influential treatise observes that most courts which have considered decreases in the 40% or higher range found a material adverse effect to have occurred. [379] The

[377] JX 595.077 (emphasis added).

[378] Defs. Br. 13.

[379] *Akorn*, 2018 WL 4719347, at *53 (citing Kling & Nugent, *supra* note 231, §11.04[9], at 11-66).

Akorn decision itself found that remediation costs that equated to approximately 21% of the target s standalone equity value implied by the merger agreement would be material when viewed from the longer-term perspective of a reasonable acquiror. [380] For the reasons explained below, Boston Scientific failed to demonstrate any material decline in Channel s value.

Boston Scientific based its quantitative case for proving an MAE on testimony from its expert, Tim Cummins, a managing director of Stout Risius Ross, LLC.[381] Cummins assessed the impact of Shankar s fraudulent activities on the value to [Boston Scientific] of Channel . . . as of November 1, 2017. [382] To do so, Cummins estimated the value of Channel to Boston Scientific based on the information available at signing. He then compared this value to his estimate of the value of Channel to [Boston Scientific] had [Boston Scientific] been aware of Mr. Shankar s actions and been able to incorporate the expected costs and time delays necessary to remediate Channel s quality assurance system and perform new clinical trials for Channel s only product, the Cerene Cryotherapy Device. [383]

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[380] *Id.* at *74 (quoting *IBP*, 789 A.2d at 68).

[381] Tr. 994 (Cummins).

[382] JX 738.004; Tr. 998 (Cummins).

[383] JX 738.006.

Starting with Boston Scientific s pre-agreement deal model, Cummins adjusted (i) the time and cost required to remediate Channel s quality system and, potentially, to conduct a new clinical trial and (ii) the discount rate.[384] Cummins analyzed three potential scenarios, which forecasted delays in realizing cash flows of two, three, four years, respectively: (i) a two-year remediation process with no new clinical trial, (ii) one year of remediation followed by a new two-year clinical trial, and (iii) two years of remediation followed by a new two-year clinical trial.[385] He applied two different discount rates to these three scenarios: the 13% discount rate used by Boston Scientific in its pre-Agreement deal model and a 15% discount rate to incorporate a scenario that included . . . some additional assumption of risk in those cash flows.[386] As depicted below, Cummins estimated that Channel s value to Boston Scientific decreased by 24% to 54% under these six scenarios from the value of $488 million that Boston Scientific s initial deal model placed on Channel:[387]

[384] Tr. 998-99 (Cummins).

[385] *Id.* 1019, 1030.

[386] *Id.* 1025-26.

[387] *Id.* 1001, 1010, 1029-30.

	13% Discount Rate	15% Discount Rate
2-Year Delay	**-24%** ($115 million decline)	**-37%** ($180 million decline)
3-Year Delay	**-33%** ($163 million decline)	**-46%** ($225 million decline)
4-Year Delay	**-42%** ($203 million decline)	**-54%** ($262 million decline)

The court does not credit this analysis for numerous reasons discussed next.

First, and foremost, Cummins premised his analysis on the assumption that Boston Scientific would need to shelve Cerene for two to four years while it rebuilt Channel s quality systems and possibly undertakes a new clinical trial. This assumption came from perspectives that Boston Scientific employees provided in the midst of litigation that Cummins did not attempt to validate independently.[388] As discussed above, Boston Scientific failed to offer any persuasive evidence to establish that this assumption is objectively reasonable. Indeed, as discussed above, Boston Scientific s own track record and the testimony of its own witnesses belie the contention that it was necessary to remediate and retest Cerene before placing it on the market given the FDA s approval of the device.[389]

The valuation impact of shelving Cerene for two to four years is massive. Channel s valuation expert, Kenneth Lehn, a finance professor at the University of

[388] *Id.* 1042-43.

[389] *See* Part IV.B.2.a.

Pittsburgh, testified credibly and without contradiction that, depending on the scenario, between 91% and 95% of the reduction in Channel s value modeled by Cummins analysis is attributable to delaying Channel s cash flows into the future by two to four years.[390] Cummins failure to provide a reliable basis for putting these cash flow delays into his model undermines the soundness of the key driver of his model.[391]

Second, Cummins model analyzed the putative change in Channel s value to Boston Scientific, which incorporated merger synergies,[392] instead of analyzing any reduction in the standalone value of Channel. This decision flies in the face of this court s uniform approach to valuing a target on a standalone basis in determining whether an MAE has occurred.[393] Boston Scientific also has not argued nor could

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[390] Tr. 1075, 1090-93, 1097 (Lehn); JX 749 ¶¶ 40-42, 47.

[391] *See* Tr. 1096 (Lehn) (stating that to say that in perpetuity all those free cash flows get pushed out, to me, requires some reliable basis. And Mr. Cummins has provided none.).

[392] Tr. 1064 (Cummins); *see also* Morrison Dep., February 26, 2019, 66-69 (discussing synergies included in BSC s pre-agreement deal model); Morrison Dep., March 13, 2019, 39-40, 45-46, 48, 53, 62 (same).

[393] *Akorn*, 2018 WL 4719347, at *56 ([E]very prior decision has looked at changes in value relative to the seller as a standalone company.). Boston Scientific argues that using synergies would be beneficial *to Channel* because, as the court in *Akorn* noted, it increases the denominator for purposes of any percentage-based comparison. Defs. Reply Br. 24 (quoting *Akorn*, 2018 WL 4719347, at *56). The point here, however, is that the refusal to use a standard methodology again calls in to question the reliability of Cummins work. *See Akorn*, 2018 WL 4719347, at *56 (Akorn s desire to include synergies is understandable . . . but it is not supported by the Merger Agreement or the law.).

it that the text of the Agreement compels use of a different approach here.[394] More broadly, Cummins adopted the rest of Boston Scientific s model without considering whether the inputs were appropriate and did not alter its base model even when he believed it made assumptions that didn t seem likely. [395]

Third, Cummins uncritically accepted an assumption for remediation costs that Boston Scientific provided to him. Specifically, Cummins used a $17 million estimate for remediation costs he received from Carr based on Boston Scientific s purchase of AMS.[396] But Cummins made no effort to consider if this comparison was valid. He just took the word of Boston Scientific employees about AMS being an appropriate example without attempting to independently validate that. [397]

Had Cummins inquired, he might (and should) have questioned whether AMS was a relevant comparable. Carr testified that he didn t do any specific research

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[394] *See* Agreement 10.2 (defining Material Adverse Effect to refer, in relevant part, to any change or effect occurring after the Agreement Date that . . . is materially adverse to the business, results or operations, or assets or financial condition *of the Company*, *i.e.*, Channel.).

[395] Cummins Dep. 108 (Q: So even if the BSC s model was incorrect, you were still going to use that? A: As the baseline, yes.), 112-13 (A: [T]hey had no working capital investment assumption in year 1 of their model, which didn t seem likely. Q: And did you go back and ask why they had no working capital and investment assumption? A: I did. Q: What was the response? A: They didn t have a great answer to that.); Tr. 1082-89 (Lehn); Tr. 1051-52 (Cummins); JX 749 ¶¶ 44-46 (Lehn Expert Report).

[396] JX 766; Tr. 610-13 (Carr); Tr. 1014-17 (Cummins).

[397] Tr. 1051 (Cummins); *see also* Tr. 1050 (Cummins) (Q: So aside from what BSC employees told you, you have no reason to think Channel s quality system remediation work would be similar to AMS s quality system remediation. Correct? A: Correct.).

as to what comparable would be the best for Cummins to use and he admitted that AMS which had four product families with multiple products in each was the most expensive remediation he ever oversaw at Boston Scientific.[398] On the eve of trial, Boston Scientific was compelled to produce remediation costs for four recent remediation efforts of single-device start-up companies, which ranged from $1.88 million to $3.52 million.[399] Yet Cummins never reviewed any of them in performing his analysis to see if they were more suitable for making a comparison.[400]

Fourth, in three of the six scenarios in his model, Cummins increased the discount rate by two percentage points to account for increased competition once Boston Scientific introduced the product after performing two to four years of remediation and, potentially, a new clinical trial.[401] Cummins testified he would have preferred another approach to address the increased risk profile, essentially admitting that the increase to the discount rate was little more than a non-rigorous fudge factor. [402]

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[398] Tr. 673, 675 (Carr).

[399] JX 925; JX 926.

[400] Tr. 1054-55 (Cummins).

[401] *Id.* 1034-35.

[402] *Id.*; *see also* Tr. 1086 (Lehn testifying that this discount rate manipulation becomes a fudge factor. There s no empirical basis for increasing the base discount rate of 13 percent by 2 percentage points).

Boston Scientific takes Channel s valuation expert (Lehn) to task for criticizing Cummins analysis without providing his own opinion on valuation. It is Boston Scientific, however, not Channel, who bears the burden to prove an MAE. Boston Scientific also relies on Lehn s testimony that it is reasonable to believe, at least directionally that the fraud reduced Channel s value compared to its value as represented in the Agreement.[403] Lehn testified, credibly, that this belief was reasonable but he did not opine on how significant any reduction would be.[404] Lehn s acknowledgement of a directional reduction in value of unknown significance does not satisfy Boston Scientific s significant burden to prove an MAE.

The only expert who provided an opinion that an MAE would reasonably be expected was Cummins. For the reasons explained above, the court finds that Cummins analysis is not reliable and does not credit it. As such, Boston Scientific failed to provide any quantitative evidence of a reasonably expected MAE.

* * * * *

For the reasons explained above, Boston Scientific failed to prove based on both qualitative and quantitative factors that it was entitled to terminate the Agreement under Section 8.1(f).

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[403] Tr. 1107-08 (Lehn).

[404] *Id.*

V. BOSTON SCIENTIFIC S TERMINATION UNDER SECTION 8.1(i)

Boston Scientific s notice of termination invoked Section 8.1(i) as a second ground for terminating the Agreement in addition to Section 8.1(f).[405] Under Section 8.1(i), Boston Scientific can terminate the Agreement at any time, subject to a cure provision, if an MAE with respect to Channel shall have occurred:

> 8.1 Termination of Agreement. This Agreement may be terminated and the Merger may be abandoned at any time prior to the Effective Time, notwithstanding the delivery of a Put Option Election Notice or Call Option Election Notice or any requisite approval and adoption of this Agreement and the transactions contemplated hereby by the Company Stockholders:
>
> (i) by [Boston Scientific], if there shall have occurred any Material Adverse Effect with respect to [Channel] . . . provided, however, that if the circumstances giving rise to such Material Adverse Event are capable of being ameliorated or cured prior to the Termination Date, then for so long as the party that has experienced a Material Adverse Event continues to exercise commercially reasonable efforts to ameliorate or cure the circumstances giving rise to such Material Adverse Event, this Agreement may not be terminated pursuant to this Section 8.1(i) prior to the Termination Date . . . .[406]

The termination right in Section 8.1(i) does not depend on the existence of any inaccuracy in or breach of any representation in the Agreement.

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[405] JX 475.

[406] Agreement § 8.1(i) (emphasis added). The Termination Date is 90 calendar days after the date of delivery of an option election notice, which may be extended up to 30 days if the parties are still seeking any other governmental approvals or authorizations as may be reasonably necessary in connection with the closing of the merger. *Id.* § 8.1(b).

By the time of trial, which occurred after FDA approval of Cerene, Boston Scientific s reliance on Section 8.1(i) became an afterthought. Apart from quoting the provision, Boston Scientific devoted literally one sentence of its opening post-trial brief to the issue, which simply refers back to its argument for proving an MAE under Section 8.1(f).[407] Accordingly, for all the reasons discussed previously for why Boston Scientific failed to prove an MAE for purposes of terminating the Agreement under Section 8.1(f), it also failed to do so under Section 8.1(i).

VI. CHANNEL S CLAIM FOR BREACH OF SECTION 6.3

Channel asserts that, apart from failing to prove an MAE under Sections 8.1(f) or 8.1(i), Boston Scientific could not terminate the Agreement for the independent reason that it breached its obligation to use commercially reasonable efforts to consummate the merger. In Section 6.3(b) of the Agreement, Boston Scientific covenanted to:

> Take all further action that is necessary or desirable to carry out the purposes of this Agreement, and . . . use its commercially reasonable efforts to take all such actions and . . . refrain from taking any actions which would be reasonably expected to frustrate the essential purposes of the transactions contemplated by this Agreement, if [Boston Scientific] were to deliver a Call Option Election Notice or [Channel] were to deliver a Put Option Election Notice.[408]

[407] Defs. Br. 87.

[408] Agreement § 6.3(b).

Our Supreme Court interpreted a similar covenant to impose obligations to take all reasonable steps to solve problems and consummate the transaction. [409] When evaluating whether a merger partner has used reasonable best efforts, this court has looked to whether the party subject to the clause (i) had reasonable grounds to take the action it did and (ii) sought to address problems with its counter party. [410] Channel bears the burden of proving by the preponderance of the evidence that Boston Scientific breached Section 6.3(b) of the Agreement.[411]

Channel asserts that Boston Scientific violated the obligations it owed under Section 6.3(b) through its cursory, careless and unreasonable actions in purporting to terminate the Agreement for no valid basis with no meaningful consideration. [412] The court agrees. For the reasons discussed above, Boston Scientific did not have reasonable grounds to terminate the Agreement when it did, particularly given that

[409] *Williams Cos. v. Energy Transfer Equity, L.P.*, 159 A3d 264, 272 (Del. 2017).

[410] *Akorn*, 2018 WL 4719347, at *91. Although the Agreement here refers to the use of commercially reasonable efforts while the provision in *Akorn* referred to the use of reasonable best efforts, Delaware case law [contains] little support for . . . distinctions between these two clauses. *Id.* at *87 & n.796.

[411] *See id.* at *4 (the party alleging improper exercise of termination by a counterparty because that party was in material breach of its own obligations bears the burden of proving by a preponderance of the evidence the facts necessary to establish its claim that the exercising party could not exercise those rights).

[412] Pl. s Resp. Br. 88.

the FDA already had accepted Channel s remediation plan, which made it likely Channel would receive premarket approval for the Cerene device.[413]

Boston Scientific claims its receipt of the Greenleaf Report in early March was the pivotal moment that made it realize the need to terminate the Agreement, but the record shows that Boston Scientific made no reasonable efforts to engage with Channel or to take other appropriate actions to attempt to keep the deal on track after that point. Specifically:

> After receiving the Greenleaf Report on March 6, Boston Scientific did not exercise its right under the Agreement to obtain additional information from Channel and did not raise any concerns with Channel for six weeks.[414]
>
> On April 22 after learning three days earlier that the FDA had accepted Channel s remediation plan Boston Scientific emailed Channel claiming there were obvious gaps in the Greenleaf Report but Boston Scientific did not identify what they were.[415]
>
> After receiving Pierce s April 22 email, Channel provided the information Boston Scientific had requested in the email, and Coté reached out to Pierce or other Boston Scientific representatives five times trying to schedule a call or meeting but no one from Boston Scientific responded to his requests.[416]
>
> On May 11, Boston Scientific terminated the Agreement without ever (i) raising any concerns, or seeking to communicate with

[413] *See supra* Part IV.B.2.

[414] Tr. 516-17, 526-27 (Pierce).

[415] JX 456.004.

[416] Tr. 74 (Coté); Tr. 531-37 (Pierce).

> Greenleaf or (ii) engaging any outside experts to analyze Channel s clinical data, its quality system, or Cerene.[417]

To borrow the words of a similar case, Boston Scientific s utter failure to make any [meaningful] attempt to confer with [Channel] when [Boston Scientific] first became concerned with [the Greenleaf Report], both constitutes a failure to use reasonable best efforts to consummate the merger and shows a lack of good faith. [418] The lack of good faith here is corroborated by contemporaneous evidence that Boston Scientific was looking for a way out of its deal with Channel due to growing concerns that Cerene would be difficult to market and that the proposed transaction was complicating a potential divestment of part of Boston Scientific s business.

In December 2017, for example, Boston Scientific s Director of Marketing, Jenny Lee, and Vice President of Sales, Scott Sanders, were openly discussing how to terminate the transaction because of Cerene s low rates of amenorrhea (the complete cessation of menstrual bleeding). In one email, Sanders posited: [W]hy would we want to sell a technology with the worst [amenorrhea] data. [419] Lee replied: Only way to get out of deal is if FDA doesn t approve the device. [420]

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[417] Tr. 516, 522-23 (Pierce).

[418] *Hexion*, 965 A.2d at 755-56 (finding breach of provision requiring reasonable best efforts to obtain financing where Hexion failed to confer with its counterparty when it first became concerned about the potential issue of insolvency).

[419] JX 231.

[420] *Id.* .002.

On January 26, 2018, Sanders brought his concerns to his manager, Kristin LaRocca, Boston Scientific s Vice President of Sales for Urology and Pelvic Health.[421] Three days later, LaRocca emailed Pierce with a summary of the Pro s and Con s of the Channel deal.[422] The Con s included low amenorrhea rates and a crowded competitive landscape, but did not mention Shankar s fraud.[423] LaRocca concluded that Cerene will be a very heavy lift to commercialize and urged Pierce to not move forward [with the deal] based on the material adverse changes in the business due to the degradation in the data [on amenorrhea rates] reported. [424]

Also in early 2018, Boston Scientific was considering a sale of its entire Surg-Gyn business, which covered products like Cerene.[425] But Boston Scientific

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[421] JX 276.

[422] JX 280.

[423] *Id.*

[424] *Id.* Boston Scientific asserts that it knew of Channel s amenorrhea rates before entering into the Agreement, and that the rates were only one factor in evaluating the benefits of the device. Defs. Br. 68; *see* Tr. 453-54, 547 (Pierce). As discussed above, however, the evidence of record shows that even if Boston Scientific was aware of the amenorrhea rates before entering into the Agreement, there was growing concern among Boston Scientific employees about the data. In an apparent attempt to distance these concerns from termination of the Agreement, Pierce testified that LaRocca was not involved in the decision to terminate. Tr. 575 (Pierce). This testimony flies in the face of Boston Scientific s designation of LaRocca as a Court of Chancery Rule 30(b)(6) representative on its decision to terminate the Merger Agreement. JX 722.008.

[425] JX 323; JX 338; JX 395.

recognized that the Channel deal was complicating it from coming to an agreement.[426] Charlie Attlan, Boston Scientific s Senior Vice President for Corporate Strategy and Business Development, warned Pierce at the end of February 2018 that it was too complicated to be discussing sale of Surg Gyn . . . while at the same time . . . finalizing option exercise on Channel. [427] By March 13, 2018, Pierce indicated that he wanted to sell it all, leading Attlan to ask: Dealing with the Channel put would not be trivial here . . . you d want to divest that as well? [428] Pierce replied: Yes. Realize the complexity of this. [429]

Boston Scientific argues that motive to avoid a deal does not demonstrate the lack of a contractual right to do so. [430] That is true but beside the point. The evidence of Boston Scientific s motives simply adds credence to and corroborates other robust facts demonstrating that Boston Scientific did not fulfill its obligations to engage with Channel in a commercially reasonable manner to vet any concerns it may have had about the findings in the Greenleaf Report and to keep the transaction on track thereafter. To the contrary, Boston Scientific simply pulled the ripcord.

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[426] JX 323; Pierce Dep. 184.

[427] JX 338.

[428] JX 395.

[429] *Id.*

[430] Defs. Br. 86 (citing *William Cos., Inc. v. Energy Transfer Equity, L.P.*, 2016 WL 3576682, at *2 (Del. Ch. June 24, 2016), *aff d*, 159 A.3d 164 (Del. 2017)).

VII. CHANNEL S REQUEST FOR SPECIFIC PERFORMANCE

Channel requests that the court grant the remedy of specific performance to require Boston Scientific to close the merger in light of its wrongful termination of the Agreement. As a general matter, specific performance is appropriate if the requesting party establishes that (1) a valid contract exits, (2) it is ready, willing, and able to perform, and (3) that the balance of equities tips in favor of the party seeking performance. [431] Channel bears the burden of proving that it is entitled to specific performance by clear and convincing evidence.[432] The only one of the three elements in dispute is the balance of the equities, which clearly weighs in Channel s favor for two reasons.[433]

First, the parties expressly agreed that a failure to perform under the Agreement would cause irreparable harm for which the remedy of specific performance would be available: The parties hereto agree that irreparable damage may occur in the event that any provision of this Agreement was not performed in

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[431] *CC Fin. LLC v. Wireless Prop, s, LLC*, 2012 WL 4862337, at *8 (Del. Ch. Oct. 1, 2012).

[432] *Akorn*, 2018 WL 4719347, at *4.

[433] Boston Scientific contends in a footnote that Channel waived the right to seek specific performance because its response brief omitted any serious or substantive argument. Defs. Reply Br. 42 n.7. This argument fails. Boston Scientific has been on notice since the outset of the case that the primary relief Channel was seeking is an order of specific performance. Channel s verified complaint expressly sought specific performance (Dkt. 1 ¶ 90, Prayer for Relief ¶ b) and its initial brief did address the issue, albeit briefly. *See* Pl. s Resp. Br. 91-92.

accordance with the terms hereof and that the parties may be entitled to seek specific performance of the terms hereof.[434] Although this provision does not tie the court s hands in fashioning appropriate equitable relief, it reflects the parties understanding that specific performance would be available in this circumstance, which is entirely consistent with past Delaware cases granting specific performance for failure to perform under a merger agreement.[435]

Second, clear and convincing evidence demonstrates that the equities weigh in Channel s favor. Channel itself was a victim of Shankar s fraud. Promptly upon discovering the fraud, Channel acted in good faith by fully investigating and remediating the fraud with the assistance of expert advisors and doing so while being fully transparent with its regulators (FDA and BSI) and its counterparty (Boston Scientific). Boston Scientific, on the other hand, will obtain the essence of what it bargained for by closing the transaction an FDA-approved Cerene device. Although several of Channel s representations were inaccurate as of the date of the Agreement, Shankar s fraud did not compromise Channel s quality system or its clinical study in such a manner that would warrant termination of the Agreement under the bargain the parties struck in the Agreement. Finally, Boston Scientific

[434] Agreement § 10.6.

[435] *See IBP*, 789 A.2d at 84 (granting specific performance of the merger agreement after finding party improperly terminated the merger agreement); *Hexion*, 965 A.2d at 762 (requiring Hexion to specifically perform its obligations consistent with the merger agreement after finding it breached certain provisions of the agreement).

breached its obligation to use commercially reasonable efforts to consummate the transaction.

VIII. BOSTON SCIENTIFIC S FRAUDULENT INDUCEMENT CLAIM

Apart from its claims arising under the Agreement, Boston Scientific asserts that Channel fraudulently induced it to invest approximately $11 million in Channel from 2015 to 2017, for which Boston Scientific seeks damages.[436] The elements of a fraudulent inducement claim, for which Boston Scientific bears the burden of proof,[437] are as follows:

> 1) a false representation, usually one of fact, made by the defendant; 2) the defendant s knowledge or belief that the representation was false, or was made with reckless indifference to the truth; 3) an intent to induce the plaintiff to act or to refrain from acting; 4) the plaintiff s action or inaction taken in justifiable reliance upon the representation; and 5) damage to the plaintiff as a result of such reliance.[438]

For the reasons discussed next, Boston Scientific failed to carry its burden of proof on its fraud claim. The court focuses on the evidence concerning the first two elements, which is dispositive.

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[436] Defs. Br. 70. As initially pled, Boston Scientific s fraud claim also sought rescission of the Agreement. *See* Counterclaim ¶ 46 (Dkt. 25). Boston Scientific did not address this request for relief during post-trial briefing and thus waived the issue.

[437] *See Ross Hldg. & Mgmt. Co. v. Advance Realty Gp.*, 2014 WL 4374261, at *37 (Del. Ch. Sept. 4, 2014) (placing the burden of proof on the plaintiff to prove its fraudulent inducement claim against the defendants).

[438] *Stephenson v. Capano Dev. Inc.*, 462 A.2d 1069, 1074 (Del. 1983).

A. Boston Scientific Failed to Prove that Channel Made a False Representation

Boston Scientific contends that Channel made essentially two false representations to induce it to invest in Channel: [i] that Shankar was a bona fide Director of Quality and [ii] that Channel would, and did receive, certification for the ISO 13485 quality standard. [439] For support, Boston Scientific points to written statements from documents Channel provided to Boston Scientific during the 2013 to 2017 period.[440]

With respect to Shankar s role at Channel, Boston Scientific points to statements in the following documents: (i) an April 2013 email from Coté describing Shankar as Channel s Director of Quality [441] and (ii) two presentations in February 2014 and May 2016 identifying Shankar as part of Channel s Highly Experienced Team and describing his qualifications as follows:

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[439] Defs. Br. 70.

[440] Boston Scientific attempted to elicit testimony from each of its own fact witnesses concerning oral statements Channel made that allegedly were false, but their testimony strained credibility and collapsed into admissions that they were relying only on written documents. *See* Tr. 493 (Pierce); Tr. 651 (Carr); Tr. 953-54, 967-68 (Morrison). Boston Scientific thereafter abandoned its reliance on purported oral statements for its fraud claim. *See* Defs. Reply Br. 36 (BSC made clear that the false statements on which it relies were made in ***documents***.).

[441] JX 33.

> 15 years experience in the areas of operational management, quality assurance and regulatory affairs. Prior leadership roles at Intrapace, C8 Medisensors and Flextronics. MSEE from Drexel.[442]

A fundamental problem with Boston Scientific s fraud claim is that these statements were true. Indeed, Boston Scientific concedes that Shankar held the title of Director of Quality, and it does not challenge the factual accuracy of any specific statement in the description of his qualifications.[443]

Instead of challenging the literal truth of any of these statements, Boston Scientific argues they show that Channel held out Shankar as a Director of Quality who would *adequately* perform his duties. [444] According to Boston Scientific, [t]he omission of the fact that Shankar failed to discharge those duties is sufficiently misleading to support a claim of fraud. [445] For support, Boston Scientific cites *Metro Communication Corp. BVI v. Advanced Mobilecomm Technologies Inc.*[446]

In *Metro,* a telecommunications venture provided to a prospective investor management reports that included specific statements regarding applications for digging permits [that] were submitted to . . . municipality authorities, and reported that [w]e are making efforts to obtain the permit [in Sao Paolo] by the end of

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[442] JX 36.004 (February 2014 presentation); JX 49.042 (May 2016 presentation).

[443] *See* Defs. Reply Br. 35.

[444] Defs. Br. 88 (emphasis added).

[445] Defs. Reply Br. 35.

[446] 854 A.2d 121, 144-46 (Del. Ch. 2004).

July. [447] In the context of deciding a motion to dismiss under Court of Chancery Rule 9(b) for failure to plead fraud with particularity, the court found that [a]ssuming the truth of the allegations in the complaint, those statements were misleading because they described the permitting process without indicating that some of the permits were obtained through bribery. [448] Unlike in *Metro*, the statements Boston Scientific identifies here consist of straightforward biographical facts and do not speak to how Shankar performed his job at Channel in any qualitative sense such that omitting his asserted failure to do so adequately would render the statements that Channel actually made misleading.

With respect to Channel s ISO 13485 certification, Boston Scientific points to statements in the following documents: (i) a 2014 presentation stating that Channel would seek ISO 13485 certification;[449] (ii) a November 2016 email from Coté stating that Channel had passed the 13485 certification audit, [450] and (iii) a May 2017 board presentation stating that Channel [r]eceived certificate for ISO 13485. [451] Once again, each of these statements was true. Channel did seek an ISO

[447] *Metro*, 854 A.2d at 145.

[448] *Id.* at 146.

[449] JX 1101.026.

[450] JX 99.

[451] JX 117.023; *see also* Bachert Dep. 73 (recalling that Shankar stated Channel is 13485-certified by BSI.).

13485 certification; BSI issued a report in November 2016 stating that Channel met the requirements of ISO 13485:2003 ; and Channel received its ISO 13485 certification in March 2017.[452]

Relying again on *Metro*, Boston Scientific argues that these statements were misleading because Channel failed to disclose that it had submitted some fraudulent documents to obtain the certification from BSI. Boston Scientific, however, failed to prove that the documents in question were necessary to obtain the certification or that Channel was in possession of an unlawful certification. In fact, after Channel disclosed Shankar s fraud to BSI, BSI reported that Channel s *[c]ontinued* certification is confirmed and the EC certificate *remains* valid. [453] Given the absence of any evidence that Channel violated a legal requirement in connection with obtaining its ISO 13485 certification from BSI, the statements in Channel s documents referenced above were not false or misleading.

B. Boston Scientific Failed to Prove Channel s Knowledge of Falsity or Recklessness

Even if any of the statements discussed above constituted a misrepresentation, Boston Scientific s fraud claim would still fail because it has not proven (i) that

[452] PTO ¶ II.D.1-2.

[453] JX 684.003 (October 2018 BSI report) (emphasis added); Tr. 62-63 (Coté); *see also* JX 709 (September 2018 BSI report stating that Channel continued to effectively implement ISO 13485:2003 and had fully implemented the new ISO 13485:2016 standards).

Channel knew that any of the statements discussed above were false or (ii) that it acted with reckless indifference to the truth. The court addresses these issues, in turn, next.

Beginning with the issue of knowledge, the general rule under Delaware law is that a corporation is liable for the acts and knowledge of its agents even when the agent acts fraudulently or causes injury to third persons through illegal conduct. [454] There is an important exception to this rule where the employee abandons the [employer s] interests and act[s] solely to advance his own personal financial interest, rather than that of the corporation itself. [455] This exception is limited, but it covers the unusual case where the employee s actions show the type of total abandonment of the corporation s interests that is characteristic of, for example, outright stealing from the corporation. [456] Even stealing may not be enough to trigger this exception if the company still receives a benefit from its employee s actions.[457]

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[454] *Stewart v. Wilmington Tr. SP Servs., Inc.*, 112 A.3d 271, 303 (Del. Ch. 2015).

[455] *Id.*

[456] *Id.*

[457] *Id.* at 310 (declining to apply the adverse interest exception to an employees alleged theft where a complaint was replete with allegations that the employees fraud allowed the company to be authorized as Delaware-domiciled captive insurers); *see also In re Am. Int l Grp. Inc., Consol. Deriv. Litig.*, 976 A.2d 872 (Del. Ch. 2009), *aff d sub nom. Teachers Ret. Sys. of La. v. Gen. Re Corp.*, 11 A.3d 228 (Del. 2010) (declining to extend the adverse interest exception where the Complaint plainly pleads that AIG s participation

This case provides a classic example for when the adverse interest exception should apply. The evidence shows that Shankar s fraud was for his own benefit, and to the detriment of Channel. He stole a large sum of money from Channel and falsified its records, which put Channel at risk of not receiving FDA approval and jeopardized its merger with Boston Scientific. Shankar s theft, pure and simple, represented a total abandonment of [Channel s] interests. [458]

Boston Scientific argues that Shankar s fraud was not ***solely*** intended to advance his personal interest [because] it also advanced the company in that he helped Channel obtain IDE approval, ISO 13485 certification, and CE mark based on documents he falsified to conceal Channel s quality system deficiencies. [459] This assertion lacks factual support. Boston Scientific provided no evidence that Shankar *intended* to help Channel obtain any of these approvals through his fraudulent actions. Indeed, his fraud and the falsified documents he submitted to regulators had the potential to endanger these approvals, and there is no evidence that Channel would not have received these approvals absent Shankar s fraud.

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in each of the schemes resulted in tangible (if eventually short-lived) benefits to the corporation).

[458] *Stewart,* 112 A.3d at 303.

[459] Defs. Reply Br. 37.

This case is markedly different from *In re American International Group, Inc., Consolidated Derivative Litigation*,[460] on which Boston Scientific relies. In that case, the court imputed knowledge to a corporation at the motion to dismiss stage where it was clear, on the face of the complaint, that the top-ranking employees engaging in fraud benefitted both the company (by increasing its stock price) and themselves (by increasing their own compensation and chances for promotion).[461] Here, Shankar s fraud provided no benefit to Channel, only detriment. For this reason, the court will not impute his knowledge of the fraud to Channel. Thus, even if any of the representations discussed previously were false, Boston Scientific has failed to prove that Channel knew they were false.

Nor did Boston Scientific prove that Channel was reckless in making any of the allegedly false representations. To establish recklessness, Boston Scientific must prove that Channel, through its employees, consciously ignored specific warning signs that illicit activities were occurring. [462] [O]rdinary negligence is insufficient to support a claim of common law fraud, and it is not sufficient for the facts to show that the managers should have known about the fraud.[463]

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[460] 976 A.3d 872.

[461] *Id.* at 892.

[462] *Metro*, 854 A.2d at 147.

[463] *Id.* at 148.

Boston Scientific asserts that evidence of the following warning signs is sufficient to prove that Channel acted with reckless indifference to the truth:

> failure to perform due diligence in hiring Shankar;
>
> failure to enact sufficient checks and balances necessary for strong cash control despite warnings from its financial auditor;
>
> discovery of the fraud only by happenstance;
>
> failure to properly verify, monitor, or audit its vendors;
>
> failure to keep minutes of Management Review meetings or review internal audit reports, some of which had no findings;
>
> failure to detect Shankar s theft of more than $2.5 million, despite Channel s cash reserves rarely being over $10 million in any quarter.[464]

This evidence demonstrates, at most, negligence on the part of Channel and its employees and is not sufficient to prove recklessness because the evidence does not establish that anyone at Channel *consciously* ignored any warning signs of Shankar s fraud.

Contrary to Boston Scientific s assertions, for example, William Malecki, Channel s Chief Operating Officer, vetted Shankar by speaking to someone Malecki knew at a previous employer identified on Shankar s resume and confirming that Shankar had worked there for eight years.[465] Although one could argue it was

[464] Defs. Reply Br. 38-39.

[465] Malecki Dep. 85-86.

negligent not to do more, there is no evidence that any warning signs (*e.g.*, a previous termination due to theft or fraud, or poor performance reviews) materialized from Malecki s vetting that Channel consciously disregarded.

The cited evidence concerning Channel s financial auditor concerned a recommendation for handling cash disbursements.[466] Coté credibly testified without contradiction, that the auditor never identified anything related to Shankar s fraud and that the fraud had nothing to do with the auditor s recommendation.[467]

Boston Scientific does not explain how the fraud s accidental discovery shows recklessness if anything that fact cuts against the notion that Channel consciously disregarded warning signs. Boston Scientific also does not cite evidence that anyone at Channel knew that it was failing to audit its suppliers or that its internal audit reports were being forged.

As to the amount of Shankar s fraud, although $2.57 million represented a significant percentage of Channel s cash reserves in any given quarter, $2.57 million was the *total* amount that Shankar stole over almost five years and not at one time.[468] In total, Shankar s fraudulent invoices and expense reports accounted for about 4 or 5% of the total number of invoices and expense reports submitted during his

[466] JX 80; Tr. 32 (Coté).

[467] Tr. 32-33 (Coté).

[468] *See* JX 916 (Shankar s Plea Agreement).

employment at Channel,[469] most of which were for amounts below the threshold that required Cot s approval to avoid detection.[470]

Boston Scientific suggests Channel was reckless because [i]t was in Channel s best interest for its management to turn a blind eye before an agreement to sell the company was signed.[471] This is speculation not evidence. What the record shows is that Channel was transparent with the FDA and Boston Scientific upon discovering Shankar s fraud, and acted with dispatch to address it.[472] This type of responsible conduct is hardly what one would expect from someone intent on turning a blind eye.

In sum, the court finds based on the preponderance of evidence that there is no legal basis to impute Shankar s knowledge to Channel and that Channel did not act with reckless indifference to the truth. This conclusion provides an independent basis for entry of judgment in Channel s favor on Boston Scientific s fraud claim apart from the failure to prove the existence of a false statement.[473]

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[469] Tr. 29-30 (Coté).

[470] *See id.* 29.

[471] Defs. Reply Br. 39.

[472] *See supra* Part I.F-I.

[473] Channel advances several other arguments for why the fraud claim should fail. The court need not address these issues in view of its findings on the lack of a false statement and the failure to prove Channel s knowledge of falsity or recklessness.

IX. CONCLUSION

For the reasons explained above, Boston Scientific was not entitled to terminate the Agreement and breached its obligation to use commercially reasonable efforts to consummate the merger; Channel is entitled to an order of specific performance requiring Boston Scientific to close the merger; and Boston Scientific failed to prove its claim for fraudulent inducement. The parties are directed to confer and to submit an implementing order consistent with this decision within five business days.