2021 WL 3604848
United States District
Court, D. Minnesota.

UNITED STATES of America and the State of California, ex rel. Steven Higgins, Plaintiffs,
v.
BOSTON SCIENTIFIC CORP., Defendant.

Case No. 11-cv-2453 (JNE/TNL)
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ORDER

JOAN N. ERICKSEN, United States District Judge

***1** On behalf of the United States and the State of California, Dr. Stephen Higgins brought this case against Boston Scientific Corporation ("BSC") under the federal False Claims Act and its California analog. Dr. Higgins argues that BSC fraudulently induced the Food and Drug Administration ("FDA") to approve of two types of implantable defibrillators when BSC failed to disclose information that revealed a design defect. He argues that by obtaining device approval through fraud, BSC caused physicians to certify that the defibrillators were medically necessary devices and to submit false claims for payment to federal health insurance programs and California Medicaid ("Medi-Cal").

BSC has moved for summary judgment and both parties have filed motions to exclude testimony from each of their opponent's

experts. Even if the Court assumes that only Relator's expert testimony is admissible, no reasonable jury could find that BSC made a false statement to the FDA that was material to its device approval decision. Therefore, as explained below, the Court will grant BSC's motion for summary judgment.

BACKGROUND

The Cognis and Teligen Devices

BSC is a medical device manufacturer that sold two types of defibrillators at issue in this case: Cognis and Teligen. DX04 at 27883. [1] Cognis devices provide cardiac resynchronization therapy defibrillation ("CRT-D") and Teligen devices are implantable cardiac defibrillators ("ICDs"). *Id.* These devices are used to prevent cardiac arrhythmias, resynchronize the heart's left and right ventricles, and provide pacemaking by delivering electrical impulses to the heart. *Id.* at 27893–95.

The Cognis and Teligen devices consist of a pulse generator that connects to heart tissue through leads. *Id.* at 27903, 27908. The leads attach to the pulse generator's header through connection ports and are held in each port with a setscrew. *Id.* at 27924–26. For these devices, BSC used a "new setscrew design referred to as the 'top-hat shaped' setscrew." *Id.* at 27926. Each setscrew cavity is sealed with plugs to protect it from contact with fluids. *Id.* at 27927. BSC created a torque wrench designed to tighten the setscrews and "protect the [pulse generator's] lead connector blocks from damage due to excessive torque forces being applied to the set screws." *Id.* at 27940.

On July 16, 2009, Version 1 Cognis and Teligen devices were recalled by BSC at the FDA's recommendation because of a design defect with the header setscrews. RX-77 at 139167; RX-79. Although the FDA found that all Version 1 Cognis and Teligen devices were affected, RX-79, it only recommended recall of devices that had not been implanted. RX-77 at 139167. Before the recall was issued, BSC had developed and obtained approval for a new version of the devices without this defect. *See* DX35 at 597120.

The Version 1 Cognis and Teligen devices were originally developed by Guidant Corporation, which was later acquired by BSC. *See* DX04 at 27883; RX-15 at 62122. In December 2007, BSC submitted a Premarket Approval Application ("PMA") Supplement to the FDA for Cognis and Teligen. DX04 at 27882. The PMA Supplement process allows for review and approval of changes to previously approved devices. *See* 21 C.F.R. § 814.39(a). The Cognis and Teligen PMA Supplement proposed modifications to two predicate devices called Renewal and Vitality. DX04 at 27883. Among several proposed modifications, BSC changed the setscrew design and modified the seal plugs to better keep fluids out. *Id.* at 27909. Included in the PMA Supplement's list of possible adverse events were "Lead migration, dislodgment," "Oversensing/undersensing," and "Incomplete lead connection with pulse generator." DX04 at 27896–97.

***2** Prior to submitting the PMA Supplement, BSC completed a Failure Mode, Effects, and Criticality Analysis to identify issues with the Cognis and Teligen devices. DX24 at

58030. It noted the predicate devices had issues related to lead connections including "stripped setscrew[s], frozen setscrew[s], excessive insertion force, high contact resistance, or leaky seal plugs." *Id.* at 58035. It explained that "[t]he high occurrence is due to the many field issues/ trends where header assembly connections (i.e. seal plugs, setscrews, & connector blocks) were either the cause or the most probable cause." *Id.* The report predicted that the new devices, Cognis and Teligen, were less likely to have the same issues because of changes made to mitigate problems with the header connections. *Id.* These changes included fewer seal plugs, a spring contact port, a new lead barrel, a top-hat setscrew design, a new torque wrench, lubricant for the seal plugs, and a design to prevent hydraulic popping of the seal plug. *Id.*

Clinical Testing

BSC did not do live clinical field testing of the new device headers before submitting the PMA Supplement but, while the application was pending, it began a clinical trial in Europe known as "COGENT." RX-22 at 17064. On the first day of the trial, the project lead for Cognis and Teligen, Sumeet Dham, noted an incident related to a shock impedance measurement. RX-25 at 5005. After the device was explanted from the patient, it was sent to the team's headquarters in St. Paul. *Id.* The next day, Dham observed a similar issue and notified his team about it. *Id.* at 5000–01. BSC's Vice President of Research and Development, Randy Nuernberg, also noted that there were five occurrences of noise during the lead impedance measurement. *Id.* at 4999–5000.

As the COGENT trial progressed, physicians continued to encounter issues in connecting the leads to the header. In a March 7, 2008 internal status report, BSC noted several issues, including issues related to the shock lead impedance test, issues related to setscrews and lead connections, noise issues, an oversensing issue, and comments about difficulty in determining whether leads were properly secured in the header. RX-34 at 115918–19. On March 13, mechanical engineer Nick Youker reported:

> Based on our testing and analysis the data suggests that under insertion of leads is the primary cause for >2000 ohm readings and loose leads in headers after tightening of setscrews. Once the field was notified to insert the torque wrench prior to lead insertion the incidence dropped off. Clearly we need to make sure that Sales training does an effective job of informing sales people of the proper lead insertion procedure prior to market launch.

RX-37 at 68724, RX-36.

On March 21, 2008, Dham requested a graph "that shows [the] frequency of set screws/lead-header connection issues as [a] function of time." RX-49 at 13127. In response, Torsten Kayser, from BSC's European team, shared a graph that showed issues declining over

time. *Id.* at 13126; RX-46. Kayser noted that he was "afraid that not all noise events get reported anymore" and "that some patients need to get re-operated." RX-49 at 13126. When Dham reported the data, indicating that issues had decreased, he attributed the decline to BSC's recent "training emphasis" in the field. *Id.* at 13125. Another BSC employee, Fred Colen questioned whether they could "really RELY on training to avoid such an issue, which apparently can happen easily and can have dramatic consequences." *Id.* at 13124. On March 25, Kayser reported 16 additional related incidents and explained that the reports "confirmed that the insertion of the leads is not always easy and that it needs special attention." RX-51 at 69485.

Pre-Approval Communications with the FDA

While the COGENT trial was ongoing, BSC met with FDA officials to "discuss the scope of a proposed amendment" to the PMA Supplement. RX-39 at 360421. At the March 17, 2008 meeting, "FDA asked for data from the OUS [Outside the U.S.] Field Following" and "BSC stated that since no follow-up data is available yet, that they would work with the lead FDA reviewer to determine what data and when to provide it." *Id.* at 360425.

***3** On March 21, 2008, the FDA sent a letter to BSC identifying deficiencies with the PMA Supplement. RX-50 at 35360. In the letter, the FDA wrote:

> You mentioned that you had OUS experience of the COGNIS/TELIGEN. In light of the OUS field findings which prompted software/firmware changes as described above in item # 1, please provide a summary of the experience, to date, which reports all adverse events (complications and observations) ....

Id. at 35361. Ronald Thompson in BSC's Regulatory Affairs division drafted the response to this letter, which he shared with Dham. RX-54; RX-55. Thompson wrote: "I think the issues related to lead insertion may get the most attention. So I will add some statement that matches what is said in the clinical report relating to the lead insertion awareness." RX-55 at 11496.

BSC responded to the deficiency letter with a memorandum, RX-57, and a clinical report with an appendix detailing device issues encountered during COGENT, RX-58. In response to the FDA's request for additional field findings, BSC wrote that it "observed 3 behaviors that BSC has decided to address prior to full market launch in any geography" and that "[n]one of these behaviors have any direct safety implications in US devices." RX-57 at 36784. One of these was "[n]oise detected during the painless Shock Impedance measurement at implant." *Id.* The memo explained: "This issue was observed in fifteen (15) devices (out of 145) of the OUS field following." *Id.* at 36785. BSC then wrote: "The noise threshold was set too low in the PG [pulse generator] hardware during shock lead impedance measurements resulting in

impedance measurement being canceled and a noise message being reported.... BSC will raise the noise threshold to the maximum level for commanded lead impedance measurements on all leads." *Id.*

The memo attached a "summary of the OUS Field Following experience, to date, including adverse events (observations and complications)." *Id.* It then noted: "There were seven (7) events associated with incomplete insertion of the IS-1 terminal pin. This has not been an issue after making the physicians more aware of the instructions provided in the current labeling." *Id.* In the memo's clinical report, BSC reported: "There have been no unanticipated adverse device effects reported in this field following to-date." RX-58 at 39708. The clinical report described noise during shock impedance measurements and incomplete lead insertion as separate issues. *Id.* at 39711–12. With respect to the incomplete lead insertion issue, the report explained that "[t]he current system guide gives instruction on how to insert the IS-1 terminal pin. Therefore no changes will be made to address this issue." *Id.* at 39712. An appendix to the report detailed clinical complications that had arisen during the COGENT trial. *Id.* at 39715–34.

After this report was submitted to the FDA, BSC representatives continued to report issues with the devices in Europe. Nick Youker had travelled to Europe on April 28, 2008 to "investigat[e] seal plug / set screw complaints" because "[a]lthough training and awareness have greatly reduced complaints, they are still there." RX-66 at 239918. In internal emails around the same time, BSC staff noted that "Hardware Design is exploring design modifications to further reduce the occurrence of pistoning." *Id.* at 239916. "Pistoning" is related to the lead connection issue and occurs when the lead is forced out of the connection port by air trapped in the seal plug. *Id.*

***4** BSC met with FDA reviewers on May 5, 2008 to discuss some software changes that would address the three issues identified in its response to the deficiency letter. *See* RX-69 at 398005. Shortly after this meeting, the FDA approved the Cognis and Teligen devices on May 8, 2008. DX09 at 35367.

Continuing Reports of Device Issues

After device approval but before the U.S. launch, BSC initiated a Real Time Review ("RTR") process to address "customer satisfaction" issues that arose during the European study. DX22 at 70704. The RTR submission sought approval for software changes and "minor associated changes to labeling." *Id.* It noted: "None of these issues have any safety implications in US devices." *Id.* BSC proposed modifying the instructions to reduce the risk of trapped air in the seal plug. *Id.* at 70728. The FDA approved the labeling changes on July 25, 2008. DX31 at 40723.

After the U.S. launch of Cognis and Teligen in August 2008, physicians continued to experience header connection issues. On August 19, 2008, Dham reported 58 device connection issues. RX-4 at 16324. Two of Dham's colleagues reported that some physicians, including a physician on BSC's Medical Advisory Board, had experienced lead connection problems. *See* RX-105 at 935. On August 21, 2008, BSC published a training document, "A Closer Look" ("ACL"),

and three videos providing additional implant instruction for the devices. RX-110. After ACL was published, BSC representatives continued to report challenges from the field. Some events required reopening a patient's chest or reoperation at a later date.

After launch, BSC submitted Medical Device Reports ("MDRs") to the FDA. FDA's Robbie Sullivan reviewed those reports on February 23, 2009 and wrote:

> A total of 181 MDRs have been received on the BSC Teligen ICD. All reports were received on November 11, 2008. The majority describe connection issues at the time of implant.... The primary device problem noted was high impedance, either pacing or shock. Some events may represent user connection issues. Several include physician complaints about the new header design, failed "tug" tests, crossthreading, and the need for air "burping" or use of mineral oil. A few events occurred after implant and required additional interventions and a return to the lab.

DX14 at 597169.

Version 2 Approval

BSC classified the lead connection issues into two separate trends: Trend 8018 ("Difficulty Securing Leads in Top Hat Setscrew & White Seal Plug Header Design"), RX-80, and Trend 8040 ("Air Bubbles in Device Header"), RX-129. BSC made design changes to address these problems and submitted a request for Real Time Review on December 17, 2008. DX34. BSC described the changes as "enhancements that will allow better setscrew performance at implant." *Id.* at 35900. BSC proposed changes that included modifying the geometry of the setscrew, pre-engaging the setscrew, changing the geometry of the seal plug, and modifying the torque wrench instructions to require the user to hold the wrench at a 90-degree angle. *Id.* at 35901–06.

On February 27, 2009, an FDA reviewer of the RTR submission noted that the issues reported "can cause serious complications" and "that the number of occurrences listed on page 2 of the meeting minutes and rates provided in the trend reports easily elevate this modification to a classification of 'corrective-fix' that should be forwarded to Office of Compliance for further analysis." RX-71. The reviewer noted: "30% of the events were discovered after the pocket was closed and 80% of those required surgical intervention. This is a serious complication." *Id.*

***5** The FDA concluded its review of the RTR submission on March 16, 2009. DX14 at 597122. It found that "[o]f the 467 observed issues, 30% (140 out of 467) of the events were discovered after the pocket was closed" and 114 of those events "required surgical intervention to resolve the issue." *Id.* at 597123. The FDA noted that the original instructions

recommended inserting the wrench at a 45-degree angle, but that the ACL training document recommended inserting the wrench at a 90-degree angle. *Id.* at 597128. The FDA approved Version 2 on March 18, 2009. DX35 at 597120.

Device Recall

The FDA completed a Health Risk Assessment of Cognis and Teligen on May 26, 2009. RX-72 at 597067. The assessment noted that the design defect affected all Cognis and Teligen devices, as well as some models of other devices, for a total of 61,895 devices worldwide. *Id.* at 597067–68. The risk assessment described the root cause of the problem: "The design of the top hat setscrew & white seal plug header in the affected devices allows for the leads to not be securely fastened to the pulse generator device as intended." *Id.* at 597068. The assessment further noted: "It can be difficult under the best of circumstances for physicians to be sure that the lead is inserted and secured into the header properly. This problem may not be spotted when it occurs for that reason." *Id.* BSC estimated that 1.91% of Cognis and Teligen devices would fail. *Id.* at 597069. The report found that adverse health consequences might occur, up to and including death. *Id.* at 597071 ("total disconnection of the lead from the header may cause loss of pacing or loss of shocks; at worst this can cause syncope or death"). When assessing the probability of risk, the FDA found a "Remote Probability" of "Serious Adverse Health Consequences or Death" and that the devices "May Cause" "Temporary or Medically Reversible Adverse Health Consequences." *Id.* at 597073.

The Health Risk Assessment was approved and signed by FDA officials on July 14, 2009. *Id.* at 597075. On July 16, 2009, FDA representatives met with BSC. RX-77 at 139166. BSC's meeting minutes noted: "FDA recommendation is to retrieve all COGNIS and TELIGEN devices with a v1 header in the United States that are currently not implanted." *Id.* at 139167. BSC agreed to initiate a "US Stop Action Notice and device retrieval" on July 17, 2009. *Id.* The FDA classified this retrieval, which affected 104 non-implanted devices in the field, as a "Class 2" recall action caused by "Device Design." RX-79 at 1–2.

Relator's Lawsuit

Dr. Steven Higgins is a California physician who specializes in cardiac electrophysiology. *See* RX-5 at 91. He served on BSC's Cardiac Rhythm Management Medical Advisory Board from 2006 to August 2009 when BSC terminated his affiliation. *Id.* at 95; DX56. He filed this action in 2011. In April 2016, the United States and California declined to intervene in the case. In August 2017, the Court granted BSC's motion to dismiss and allowed Relator to amend his complaint. BSC again moved to dismiss and the Court denied the motion.

BSC has now moved for summary judgment. Both parties moved to exclude each of their opponent's experts under *Daubert*. After these motions were filed, the magistrate judge excluded the testimony of one of Relator's experts, Dr. Lawrence Mayer. While the summary judgment and *Daubert* motions were under advisement, the Court affirmed the magistrate judge's order over Relator's objections.

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment should be entered against "a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Where there is a genuine dispute of material fact, those facts "must be viewed in the light most favorable to the nonmoving party." *Scott v. Harris*, 550 U.S. 372, 380 (2007).

DISCUSSION

***6** The False Claims Act imposes liability for submitting false claims for payment to the United States. 31 U.S.C. § 3729(a)(1). When the government declines to prosecute a False Claims Act case, a private party may bring a qui tam action on its behalf. *Id.* § 3730(b)(1), (c)(1). A liable defendant is subject to civil monetary penalties for each false claim submitted and three times the actual damages sustained by the government. *Id.* § 3729(a)(1). If successful, the relator may receive between twenty-five and thirty percent of the damages. *Id.* § 3730(d)(2).

Under the False Claims Act, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable. *Id.* § 3729(a)(1)(A)–(B). Claims under the statute include "direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (citing 31 U.S.C. § 3729(b)(2)(A)). "Knowingly" means "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). This element requires "no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B). A false statement is "material" if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

"[T]he False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions." *Escobar*, 136 S. Ct. at 1999. In cases where "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Id.*

I. Theories of Liability Raised

Dr. Higgins seeks to prove the False Claims Act's elements of falsity, causation, knowledge, and materiality by showing that third parties submitted false claims for payment to the government and that BSC caused those false

submissions. 31 U.S.C. § 3729(a)(1)(A)–(B); *see United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 741 (8th Cir. 2020) (discussing the elements of a § 3729(a)(1)(B) claim). As to the falsity element, Dr. Higgins argues that medical providers submitted claims to Medicare and Medi-Cal for Version 1 Cognis and Teligen devices, thereby falsely certifying that the devices were medically necessary when, in fact, they were defective, misbranded, and not medically necessary. To prove causation, Dr. Higgins argues that BSC caused providers to submit those claims by fraudulently inducing the FDA into approving the devices. As to the knowledge element, Dr. Higgins argues that BSC knew its representations to the FDA were false. Finally, as to materiality, Dr. Higgins argues that BSC's misrepresentations were material to FDA's approval because once the FDA learned the truth, it recalled the Version 1 devices.

Dr. Higgins argues that he raised three theories of liability in the Second Amended Complaint: "that BSC (1) caused providers to submit claims for devices and services which were not medically reasonable or necessary, (2) caused providers to submit claims for defective and misbranded devices, and (3) fraudulently induced FDA approval of the devices (and continued to defraud the FDA following the initial approval)." Relator's Mem. at 6, ECF No. 534; *see* Second Am. Compl. ¶¶ 188–220, 273–78.

***7** "The False Claims Act is not 'an all-purpose antifraud statute,' " *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)), and liability generally attaches "not to the underlying fraudulent activity, but to the claim for payment." *Benaissa*, 963 F.3d at 739. To hold BSC liable for false claims submitted by third parties, Dr. Higgins must prove that BSC caused providers to submit those false claims. He aims to satisfy the causation element by proving that BSC fraudulently induced FDA's approval of the devices. Thus, each of Dr. Higgins' theories depends upon proving causation by way of fraudulent inducement.

II. Fraudulent Inducement

Dr. Higgins seeks to prove causation in this case by showing that BSC fraudulently induced device approval and continued to defraud the FDA. This is unlike the more typical fraudulent inducement case under the False Claims Act, which involves a contractor submitting claims to the government pursuant to a fraudulently induced contract. *See, e.g.*, *In re Baycol Prods. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013). This case does not fit that mold because Dr. Higgins has not argued that BSC submitted claims pursuant to a fraudulently induced contract, but that third parties submitted claims in reliance on the FDA approval BSC fraudulently obtained. Nevertheless, fraudulent inducement may be a way to prove indirect causation in some cases. *See id.* ("[C]laims for payment subsequently submitted under a contract initially induced by fraud do not have to be false or fraudulent in and of themselves in order to state a cause of action under the FCA."); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 903 (9th Cir. 2017) ("[I]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.").

In the context of the False Claims Act, the Eighth Circuit has defined the elements of fraudulent inducement as: "(1) the defendant made a 'false record or statement'; (2) the defendant knew the statement was false; (3) the statement was material; and (4) the defendant made a 'claim' for the government to pay money or forfeit money due." *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016) (quoting *Baycol*, 732 F.3d at 875–76). Thus, for BSC to succeed on summary judgment, it must show that no reasonable jury could find that it made a knowingly false representation to the FDA that was material to the FDA's initial or continued approval of Cognis and Teligen.

A. Initial Approval

To prove that BSC fraudulently induced the FDA's approval decision for Version 1 Cognis and Teligen devices on May 8, 2008, Dr. Higgins will ultimately need to prove that BSC made misrepresentations to the FDA that were material to that decision.

1. False Statements

Dr. Higgins argues that BSC made a false statement to the FDA when, on March 17, 2008, it said that "no follow-up data is available yet" with respect to the COGENT trial. RX-39 at 360425. The meeting minutes documenting this statement also note that BSC "would work with the lead FDA reviewer to determine what data and when to provide it." *Id.* Dr. Higgins argues that this is false because BSC had already sent engineers to investigate header issues, collected data from the trial, and circulated an internal memorandum summarizing those issues on March 7, 2008. RX-34 at 115918. BSC argues that "follow-up data" was used as a term of art in this context and refers to data on how patients fare one month and three months after implant. There is a fact dispute over whether BSC's statement about follow-up data was a misrepresentation.

***8** Next, Dr. Higgins argues that certain statements BSC made in response to the FDA's March 21, 2008 deficiency letter were affirmatively false. First, BSC wrote that "[t]here were seven (7) events associated with incomplete insertion of the IS-1 terminal pin," and that "[t]his has not been an issue after making the physicians more aware of the instructions provided in the current labeling." RX-57 at 36785. Dr. Higgins argues that this statement is false because BSC had conducted training but still encountered lead connection issues. He also argues that BSC misled the FDA when it explained that it provided physician instructions on how to properly insert leads into the device header. He argues that BSC knew instructions were not effective because BSC had internally circulated a presentation slide that stated: "Training is the only viable solution because we can't rely on customers to read literature and labeling." RX-44 at 129651. Dr. Higgins points to internal emails in which BSC employees expressed concerns about relying on training, RX-31 at 13247; RX-47, although some BSC employees believed that training was reducing issue rates. *See, e.g.*, RX-46. There is a fact issue as to whether the statement about training was a misrepresentation.

Dr. Higgins next argues that BSC made a false statement when it wrote in the clinical report to the FDA: "There have been no

unanticipated adverse device effects reported in this field following to-date." RX-58 at 39708. The report defined an "unanticipated adverse device effect" as "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application." *Id.* Dr. Higgins argues that the Cognis and Teligen issues were unanticipated because they occurred at a rate that had not been reported in predicate devices. In the PMA Supplement, BSC reported incidents involving "stuck setscrews," "oversensing," and "undersensing" in the predicate devices. DX04 at 28036, 28038. Dr. Higgins calculated the rate of failures related to these issues in the predicate devices to be 0.0973%. *See id.* at 28033–40. Because the percentage of implants that had issue reports during the COGENT trial was higher than the predicate device failure rate, he argues that it is proof that BSC lied when it stated that there were no unanticipated adverse events.

This argument is based on an inaccurate reading of the PMA Supplement. The device failure rate reported in the PMA Supplement defined a failed device as a "product that was implanted (pocket closed) and subsequently failed prior to explant due to a product anomaly that was not caused by the user." *Id.* at 28034. Thus, the 0.0973% figure only accounts for predicate devices that completely failed and had to be explanted. Dr. Higgins compared the rate of total failures with the rate of all issues that were reported during the COGENT trial. But those two rates measure different things and are not directly comparable. *Compare* DX04 at 28034 (reporting complete device failures) *with* RX-31 at 13248 (describing the rate of all field issues related to the device header) *and* RX-74 at 19840–41 (describing rate of all field issues involving air bubbles in the device header). For example, one issue reported noise readings prior to implant, but the issue was resolved after the leads were secured. An issue of this variety is different from a total device failure. Again, the 0.0973% rate was the estimated rate of total device failures. Dr. Higgins compares apples to oranges. To demonstrate that the issue rate was higher than anticipated, Dr. Higgins would need to point to a representation made by BSC about the anticipated rate of total issues, not the rate of device failures. He has not identified any such representation by BSC.

There is no genuine fact issue with respect to the anticipated issue rate because Dr. Higgins has not identified record evidence that would support his claim that the rate of issues was unanticipated. However, there is a dispute over whether the nature and seriousness of the events was unanticipated. Dr. Higgins argues that the PMA Supplement did not anticipate issues related to abnormal shock impedance measurements, air bubbles in the header, or noise. The PMA Supplement does not list those types of complications. DX04 at 27896–97. This is a fact issue.

***9** Dr. Higgins next argues that the clinical report was misleading by omission. First, he argues that BSC hid adverse events from the COGENT trial in a large appendix. In the appendix, BSC described lead insertion difficulties, shock impedance failures, a setscrew redo, and an issue with a patient who flatlined as separate entries in a twenty-page

appendix. RX-58 at 39715–34. Dr. Higgins also argues that BSC classified four events improperly as "noise" when they should have been more clearly associated with the header-related issues. According to Dr. Higgins, by making these classification decisions, BSC made misrepresentations by omission.

No reasonable jury could find that the supposed misclassification or burying of these events constituted misrepresentations by omission. Dr. Higgins does not dispute that the full detail of each event was reported to the FDA in the appendix. Because the events were reported, no reasonable juror could find they were omitted. Dr. Higgins invokes the "buried facts doctrine," which applies in securities cases where "a disclosure is deemed inadequate if it is presented in a way that conceals or obscures the information sought to be disclosed." *Werner v. Werner*, 267 F.3d 288, 297 (3d Cir. 2001). The doctrine is inapplicable here because the FDA is a regulatory agency that specializes in reviewing clinical observations related to medical devices. It is thus far different from a shareholder, whom the buried facts doctrine was designed to protect. *See, e.g.*, *Kennedy v. Tallant*, 710 F.2d 711, 720 (11th Cir. 1983) (holding that piecemeal securities disclosures were inadequate where "the average person would not understand their import").

Next, he argues that the appendix to the report excluded three events. Relator has been unclear about precisely how many events were excluded. In his initial briefing, he seemed to argue that nine events went unreported. At oral argument, Relator's counsel said that there were ten separate unreported events, Summ. J. Hearing Tr. 37:20–21, and BSC's counsel disagreed, arguing that Relator had double-counted five events, *id.* 68:5–6. After the hearing, Relator's counsel submitted an additional filing [2] listing only three events. He added no detail about the unreported events but cited to an undated BSC document, RX-99, that opened a trend investigation. That trend investigation report has brief descriptions of the three unreported events: there was a high impedance reading in one, a setscrew was retightened in another, and a lead was pulled out of a header in a third. BSC argues that these events were not reportable under the COGENT protocol. Notwithstanding the lack of detail about these events, the Court must construe this dispute in the light most favorable to Dr. Higgins. Therefore, there is a fact issue about whether BSC's failure to report these three events was a misrepresentation by omission.

Dr. Higgins also argues that five events that occurred after the submission of the clinical report should have been reported to the FDA. However, he can point to no legal authority that imposed a duty on BSC to report these events to the FDA prior to device approval. FDA regulations do not impose such a requirement. Instead, an applicant must "periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e); *see id.* § 814.39(c)(1) (applying procedures for standard applications to PMA supplements). The reports must be submitted: "(1) 3 months after the filing date; (2) Following the receipt of an approvable letter; and (3) At any other time as requested by FDA." *Id.* § 814.20(e). None of these submission deadlines were triggered after BSC submitted the April 3, 2008 report but before

device approval: the three-month deadline had already passed and Dr. Higgins has presented no evidence that BSC received an approvable letter or that the FDA requested additional reports. Therefore, BSC's failure to report the five events did not violate any legal duty and could not have been a misrepresentation by omission.

***10** In short, there are fact issues with respect to four alleged misrepresentations: first, BSC's statement about the lack of follow-up data; second, BSC's statement that incomplete insertion of leads ceased to be an issue after physicians were properly trained; third, BSC's statement that no unanticipated adverse device events had occurred; finally, BSC's omission of three adverse events from the appendix to the clinical report.

2. Materiality

Under the False Claims Act, "[t]he materiality standard is demanding." *Escobar*, 136 S. Ct. at 2003. In the context of an implied false certification case, the Supreme Court has noted that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* "Such very strong evidence becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017). This reasoning is consistent with Eighth Circuit precedent on materiality under the False Claims Act. *See United States ex rel. Costner v. United States*, 317 F.3d 883, 887 (8th Cir. 2003); *Rabushka ex rel. United States v. Crane Co.*, 122 F.3d 559, 563 (8th Cir. 1997). For example, in *Costner*, the Eighth Circuit affirmed a grant of summary judgment to defendants on materiality grounds. 317 F.3d at 887. The relator had alleged that EPA contractors "concealed operational problems and numerous regulatory violations from the EPA." *Id.* at 886. It was undisputed that EPA was informed of these problems but nevertheless made payments. *Id.* at 887.

To prove materiality, Relator will need to show that the FDA would not have approved the devices had it known about any of the four misrepresentations Relator has alleged: the statement about the lack of follow-up data, the statement about training resolving header connection problems, the statement about there being no unanticipated events, and the failure to report three adverse events.

With respect to the statement about follow-up data, it is undisputed that BSC sent the FDA data from the COGENT trial on April 3, 2008. *See* RX-54, RX-57, RX-58. When the FDA made its approval decision, it knew that follow-up data was available and it had access to that data. Therefore, even if Dr. Higgins proves that BSC made a false statement when it told the FDA that there was no follow-up data available on March 17, 2008, no reasonable jury could find the statement material to the FDA's approval decision.

Next, BSC's statements about unanticipated events could not have been material because the FDA was informed of the adverse events prior to approving the devices. Relator does not dispute that BSC sent a detailed report

that contained nearly all the underlying data that Relator argues shows that the devices were defective. For example, the appendix describes numerous lead dislodgement issues discovered during and after implant. The FDA had this appendix and nevertheless approved the devices. This is strong evidence that any misrepresentation regarding unanticipated events was not material. *See Escobar*, 136 S. Ct. at 2003. To conclude otherwise would require an assumption that the FDA, "an agency armed with robust investigatory powers to protect public health and safety," did not meaningfully review the appendix. *Nargol*, 865 F.3d at 35.

***11** With respect to the statement about training, this representation could not have been material because the FDA had received the underlying data and could evaluate whether training had any effect on event rates. The data showed a significant decrease in reportable events after BSC focused on training physicians on lead insertion. RX-46. The appendix revealed that the issues had not been eliminated, which means the FDA was aware that training did not completely resolve the lead connection issue. Therefore, even if BSC's statement about training resolving the lead connection issue was false, it could not have been material to the FDA's approval decision.

That leaves the three unreported events. These three event reports describe issues identical to those already reported. One is related to a high impendence reading while two appear to simply report that a physician was able to pull the leads out when checking whether the setscrews had been adequately tightened. RX-99. The appendix reports 102 total adverse events among 57 patients, including many high impedance readings and loose connections. RX-58 at 39710. Relator has presented no evidence that would allow a jury to find that these three incidents were so critical that, if added to the report, they would have changed the FDA's approval decision. Therefore, no reasonable jury could find that the three unreported events were material to the FDA's approval decision.

Relator argues that BSC's omissions were material by relying on his FDA expert, Timothy Ulatowski, a former director of the Office of Compliance in the FDA's Center for Devices and Radiological Health. *See* RX-29, Expert Report of Timothy A. Ulatowski ("Ulatowski Report") at 8. But Mr. Ulatowski does not explain how those three events would have resulted in a different decision in light of the fact that BSC reported adverse events to the FDA in early April 2008. The undisputed facts show that the FDA was sent the underlying data and, with that data fully in hand, approved the devices.

The undisputed record demonstrates that BSC had reported nearly all known issues related to the device header before the FDA made its device approval decision. Even with that information, the FDA approved the devices. Therefore, Dr. Higgins has not produced evidence that would allow a reasonable jury to find that BSC made a misrepresentation that was material to the FDA's initial device approval decision.

B. Continued Device Approval

Dr. Higgins argues that the FDA's continued device approval was procured through fraud

because if BSC had told the FDA the truth, it would have recalled the devices sooner. Dr. Higgins primarily relies on the opinions of his expert, Mr. Ulatowski, to argue that BSC committed two regulatory violations that were fraudulent omissions under the False Claims Act. First, he argues that BSC failed to submit the supplemental training documents as a labeling change. Second, he argues that BSC failed to report device issues within five days.

FDA regulations require medical device manufacturers to report "any correction or removal of a device" that was initiated "[t]o reduce a risk to health posed by the device." 21 C.F.R. § 806.10(a)(1). In this context, a correction includes "relabeling." *Id.* § 806.2(d). Relator argues that the "A Closer Look" document published by BSC in August 2008 was a labeling change that should have been reported. He argues that BSC's failure to report that change was a misrepresentation by omission.

Even if the Court assumes that this was a misrepresentation by omission, there is no evidence it was material. An FDA employee reviewed the document in February 2009 and concluded that it "restates the instructions for operation of the set screw during surgery with detailed color diagrams and instructions." DX14 at 597167. He noted: "It does not appear that the instructions provide new information to the user but this should be confirmed by a clinician if OC [Office of Compliance] reviews the labeling in the future." *Id.* Thus, the FDA was aware of the document in February 2009 and, despite recommending further review, never noted that it should have been considered a labeling change. Relator's expert, Mr. Ulatowski, opines that this FDA staff person would not have understood the "regulatory gravity" of the change and that Office of Compliance staff would have found it to be a violation. Ulatowski Report at 69. But the undisputed evidence shows that FDA staff flagged the issue for Office of Compliance review and the FDA never found it to be a regulatory violation. This is strong evidence that even if BSC violated the labeling correction regulations it was not material because the FDA took no action despite having full knowledge of the supposed violation. *See Escobar*, 136 S. Ct. at 2003. Therefore, no reasonable jury could find that this alleged regulatory violation was material to the FDA's continued device approval.

***12** FDA regulations require a device manufacturer to submit reports of an adverse event "that requires remedial action to prevent an unreasonable risk of substantial harm to the public health" within five days. 21 C.F.R. § 803.10(c)(2)(i). Relator argues that BSC's failure to report any setscrew/header issues as five-day MDRs was a material regulatory violation. However, the parties do not dispute that BSC did submit MDR reports and that the FDA reviewed those reports by February 2009. DX14 at 597169. Despite reviewing those reports in February, the FDA did not recommend a device recall until July 2009 and never found that BSC violated the MDR regulation. Moreover, the FDA's inaction for several months after it received the reports strongly suggests that any failure to submit those reports as five-day reports was not material. Therefore, there is no evidence that would allow a jury to find that this was a material regulatory violation.

Finally, the parties do not dispute that the FDA learned the full scope of information related to the lead connection issues when BSC submitted the application for Version 2. The record shows that the FDA summarized the issues in a March 16, 2009 memorandum. *See* DX14 at 597123. Even upon learning of the issues, the FDA did not recommend a recall for about four months. The FDA's delayed action after it learned of all the relevant information, which the parties do not dispute, further supports BSC's argument that any alleged misrepresentation or omission was not material.

CONCLUSION

Dr. Higgins has failed to present evidence that would allow a reasonable jury to find that any misrepresentation or omission by BSC was material to the FDA's initial or continued approval of the devices. Because a material misrepresentation by BSC is an essential element of each of Dr. Higgins' theories of liability, no reasonable jury could find BSC liable under any of his theories. The Court declines to rule on the parties' *Daubert* motions because even if only Dr. Higgins' expert testimony were admissible, no reasonable jury could find that he met his burden to prove materiality.

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Boston Scientific Corporation's Motion for Summary Judgment [ECF No. 451] is GRANTED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

All Citations

Slip Copy, 2021 WL 3604848, Med & Med GD (CCH) P 307,108

Footnotes

1 Prefixes and leading zeros are omitted from Bates numbers throughout this opinion. "RX" citations refer to Relator's exhibits. "DX" citations refer to Defendant's exhibits.

2 At oral argument, the Court asked Relator's counsel to submit a filing clarifying "whether they are five different events or whether they are ten different events," further noting that "it shouldn't take more than a page or two." Summ. J. Hearing Tr. at 77:19–22. Relator then submitted a nine-page letter with eleven exhibits. This exceeded the scope of the Court's request and was an impermissible sur-reply. *See* LR 7.1(i). The Court will not consider the new exhibits and will only consider the letter to the extent it summarizes or cites to information already in the record.

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