United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 09-2518

Detroit General Retirement System; Stanley Kurzweil, individually and on behalf of himself and all others similarly situated,	*	
	*	Appeal from the United States
Plaintiffs – Appellants,	*	District Court for the
	*	District of Minnesota.
v.	*	
	*	
Medtronic, Inc.; Art D. Collins; William A. Hawkins; Gary L. Ellis,	*	
	*	
Defendants – Appellees.	*	

Submitted: May 12, 2010
Filed: September 16, 2010

Before BYE, MELLOY, and SHEPHERD, Circuit Judges.

BYE, Circuit Judge.

Detroit General Retirement System and Stanley Kurzweil (collectively referred to as DGRS), investor class representatives, appeal the district court's dismissal of their claims against Medtronic, Inc. and three of its officers, Art D. Collins, William A. Hawkins, and Gary L. Ellis, for failure to plead fraud with particularity as required by law. DGRS appeals the dismissal, along with a denial of its motion for leave to amend the complaint and its motion for reconsideration. We affirm.

I

Medtronic, Inc. designed, manufactured, marketed, and sold the Fidelis lead, a Food and Drug Administration (FDA)-approved medical device wire that connects an internally implanted defibrillator to a patient's heart and delivers electricity if a shock is needed. Fidelis was thinner and more flexible than earlier defibrillator leads, and therefore tolerated by a range of patients who did not do well with bulkier traditional leads. The Fidelis was considered an improvement on Medtronic's existing Quattro lead, and clinical studies in humans were not required for its approval. The Fidelis quickly became the most popular defibrillator lead on the market and by 2007 the devices had been implanted in more than 260,000 patients.

On February 15, 2007, Doctor Robert G. Hauser met with a vice president at Medtronic and informed the company he was concerned about the failure rate of the Fidelis leads at his heart clinic and he would no longer implant the device in his patients. On February 27, 2007, Hauser provided Medtronic with a study he and his colleagues had completed at the clinic, which he planned to publish in a prominent medical journal. The study found Fidelis leads had higher failure rates than the Quattro leads, concluded Fidelis leads were prone to early failure because of a tendency to fracture, and recommended against use of the device.

On March 21, 2007, Medtronic sent a letter to physicians informing them some clinics had reported higher than normal failure rates and fracturing in the Fidelis leads and informing the doctors that Medtronic was investigating the reports. The company disclosed the types of fractures reported, offered suggestions for how to prevent the fractures, and requested feedback from the doctors regarding problems with implanting the devices according to recommendation. Medtronic stated that the performance of Fidelis was "in line with other Medtronic leads" and the company's investigation "suggests that variables within the implant procedure may contribute significantly to these fractures." The letter cited a Medtronic post-market clinical

surveillance study (the longevity study) and Medtronic's analysis of returned Fidelis leads. Medtronic continued to promote and sell the Fidelis leads, and company reports indicated the market for the device was strong.

On May 5, 2007, Medtronic filed an application with the FDA to modify the design of the Fidelis lead. At a meeting with doctors at the Heart Institute on July 19, 2007, Medtronic representatives stated the company had identified a problem and was working on a possible remedy but was not going to pull the product from the market. On July 30, 2007, the Minneapolis Star Tribune published a story on the Hauser study, which was published the same month, in which a Medtronic spokesman, Rob Clark, said the study "must be taken in context as it hails from one center and does not represent the total performance experience of the Fidelis lead."

On October 15, 2007, Medtronic announced it was suspending sales of the Fidelis lead because of the potential for fractures. The company recommended that physicians stop implanting existing Fidelis leads. The press release stated the failure rate for the Fidelis lead was greater than the failure rate for the Quattro leads and while the difference was not statistically significant, it had the potential to become significant over time and the company believed pulling the leads from the market was in the best interest of patients. The release mentioned that the company had identified five deaths in which Fidelis fracture may have been a contributing factor.

Medtronic held a press conference at which representatives explained the sequence of events, starting with fracture reports early in the year which prompted the March letter, followed by a six month period of investigation into reports of device failure, and culminating with the company's decision to recall the device. Medtronic again stated the difference in the failure rate for the Fidelis compared to other models was not statistically significant but would become significant over time if it continued. Representatives disclosed the predicted impact of the recall on the business of the company, expressing particular concern for the Japanese market because Fidelis was

the only approved Medtronic lead in that market. At a subsequent conference, Medtronic representatives detailed the time line for the decision, starting with the reports of excessive fractures early in the year which prompted the March letter and caused Medtronic to examine the following six months of data from the lead analysis studies as well as data on 25,000 patients from Medtronic's CareLink database.

Medtronic's stock price dropped just over 11% from its pre-recall price of $56.33 in the days following the recall, falling to a low of $45.54 on November 7, 2007. On October 15, 2007, a products liability class action was filed against Medtronic, alleging the company knew about the failures as early as March of 2007 and failed to pull the device from the market in a timely manner. DGRS filed the instant suit, alleging Medtronic had engaged in securities fraud by misleading investors as to the seriousness of the problem with the Fidelis leads. Medtronic responded with a Rule 12(b)(6) motion to dismiss for failure to state with particularity a legitimate basis for the claims of fraud. The district court dismissed the case and this appeal followed.

II

DISMISSAL UNDER 12(b)(6)

> This court reviews de novo a dismissal for failure to state a claim. Fed.R.Civ.P. 12(b)(6); Ferris, Baker Watts, Inc. v. Ernst & Young, LLP, 395 F.3d 851, 853 (8th Cir. 2005). The court accepts as true all factual allegations, but is "not bound to accept as true a legal conclusion couched as a factual allegation." Ashcroft v. Iqbal, --- U.S. ----, 129 S.Ct. 1937, 1950, 173 L.Ed.2d 868 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 1949. The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id., quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "The court may consider,

> in addition to the pleadings, materials embraced by the pleadings and materials that are part of the public record." In re K-tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 889 (8th Cir. 2002) (quotation omitted).

McAdams v. McCord, 584 F.3d 1111, 1113 (8th Cir. 2009).

> The [Private Securities Litigation] Reform Act provides that, to survive a motion to dismiss, a securities plaintiff must satisfy two heightened pleading standards. 15 U.S.C. § 78u-4(b)(3). First, the plaintiff must plead falsity by specifying each allegedly misleading statement and the reasons why each statement is misleading. 15 U.S.C. § 78u-4(b)(1). If falsity is alleged based upon information and belief, the complaint must state with particularity all facts on which the belief is formed. Id. In addition, the plaintiff must plead scienter by "stat[ing] with particularity facts giving rise to a strong inference that the defendants acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

In re Cerner Corp. Sec. Litig., 425 F.3d 1079, 1083 (8th Cir. 2005).

False or materially misleading statements

> In order to satisfy the Reform Act's falsity pleading standard, a complaint may not rest on mere allegations that fraud has occurred. Instead the complaint must indicate why the alleged misstatements would have been false or misleading at the several points in time in which it is alleged they were made. In other words, the complaint's facts must necessarily show that the defendant's statements were misleading.

Id.

"[T]o fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as

having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988) (internal quotation marks omitted).

DGRS argues Medtronic materially misled investors when it released the March "dear doctor" letter. The text of the letter is as follows:

> Dear Doctor,
>
> Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads. While current overall Sprint Fidelis performance is consistent with other leads, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share what we know at this time.
>
> Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1) distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify a root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.
>
> For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor . . . Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.

> For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area... Medtronic recommends the lead be re-sutured and/or pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.
>
> Sprint Fidelis lead model 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September and October 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicated survival is 98.9% at two years. Sprint Fidelis 6949 performance based upon return products analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads and consistent with lead performance publicly reported by other manufacturers.

DGRS alleges the letter "falsely reassured" investors that the damage was due to doctor error and that the Fidelis model failure rate was in line with that of other leads. It is difficult to see how a letter disclosing a possible problem and an investigation into that problem was materially misleading. The letter refers to the ongoing investigation, couches the information contained in the letter itself as preliminary, and states the early investigation "suggests" that implant procedure "may" contribute significantly to the fracture reports. At no point does the letter make any unequivocal statements about the safety of the device and the language clearly indicates that doctor error is a preliminary and partial explanation for the reported fracture rates at specific clinics. Nonetheless, DGRS alleges Medtronic had a duty to disclose other information on the Fidelis fracture rates, the exclusion of which rendered the statements in the letter materially misleading.

DGRS lists a number of pieces of information which it asserts Medtronic failed to divulge. The problem with most of the information is that DGRS fails to allege facts showing Medtronic possessed the information at the time the supposedly

inconsistent statements were made. The remaining allegations fail to meet the standard for pleading under the Reform Act because, even if Medtronic was aware of the information, the information itself is not inconsistent with Medtronic's statements to the public and to investors.

DGRS alleges Medtronic's statement that "a limited number" of doctors had reported higher than expected fracture rates was misleading because at least five hospitals or clinics besides Hauser's had stopped using Fidelis leads. The complaint fails to allege that those clinics ever cited excessive fracture rates as the reason for discontinuing use of the Fidelis leads, let alone that the clinics informed Medtronic of a problem with the device at the time they discontinued use. The complaint also does not allege facts that would allow us to discern how many Fidelis leads those clinics would ordinarily have ordered or whether those leads constituted a significant enough percentage of the Fidelis business market that referring to six clinics or hospitals as a "limited number" would be materially misleading.

DGRS argues Medtronic should have disclosed the fact that the returned product analysis cited in the letter is a notoriously unreliable source of data. Even if it is true that returned product analysis is unreliable, Medtronic did not materially mislead investors because it disclosed that the data came from returned product analysis. DGRS also claims Medtronic had a duty to disclose the fact that the study sample sizes were too small to make the conclusions reliable. That argument might hold water if Medtronic had couched the results of the studies as conclusive. However, Medtronic's "dear doctor" letter indicated an investigation was ongoing because, at that point, there was no data available with a large enough data set to be conclusive. In fact, even when Medtronic pulled Fidelis from the market, both Medtronic and the FDA indicated that the statistics did not require such action, and the FDA did not require removal of the devices already implanted in patients.

Statistical Significance

The district court relied on Oran v. Stafford, 226 F.3d 275 (3d Cir. 2000), and In re Carter-Wallace, Inc., Sec. Litig., 220 F.3d 36 (2d Cir. 2000), and found Medtronic's failure to disclose statistically insignificant information could not have been misleading in light of the information disclosed in the letter. In Oran, the data presented by the defendant was characterized as inconclusive but some adverse data was omitted. Oran, 226 F.3d at 284. The court found the data was inconclusive even taking into account the adverse data, and found the omission was not material because it would not have made the data conclusive. Id. A certain number of adverse reports are expected and acceptable in medical treatments and the Oran court reasoned a company is under no obligation to divulge adverse reports unless they constitute statistically significant evidence of a problem. Id.

Medtronic disclosed the fact that there were reports of higher failure rates in its "dear doctor" letter. It omitted the actual reports and information. DGRS has failed to allege any facts proving the omitted information would have put investors on notice at that time that either doctor error was not a significant contributing factor in the device failures or the overall failure rate of the device was higher than that of other devices.

Stock Price Drop

A significant change in stock price upon disclosure of withheld information is strong evidence that the information was material. No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 949 (9th Cir. 2003). However, Medtronic's stock did not drop because the information was disclosed but because Medtronic recalled the Fidelis lead. DGRS does not allege that the information withheld would have led to a mandatory recall. DGRS admitted in its

complaint that the voluntary recall was carried out in response to an extensive investigation of data not compiled at the time the letter was written.

Other statements

DGRS also alleges all the promotional statements by the company and its earnings reports and projections describing the Fidelis leads as successful and the demand for the product as strong were materially misleading. Those arguments fail for the same reasons as above, because DGRS has not alleged facts sufficient to show there was a significant problem with the Fidelis leads at the time those statements were made. Even on the last day of the class period, the day of the recall, the data did not show a statistically significant difference in the failure numbers for the Fidelis leads compared to the Quattro. Medtronic pulled the product because analysis indicated the failure numbers would become statistically significant over time if the product continued on the market. In addition, most of the statements DGRS lists are from product advertising materials and are so vague that an investor could not reasonably rely on them for any information related to the soundness of the investment. "[S]oft, puffing statements generally lack materiality because the market price of a share is not inflated by vague statements predicting growth. No reasonable investor would rely on these statements, and they are certainly not specific enough to perpetrate a fraud on the market." Parnes v. Gateway 2000, Inc., 122 F.3d 539, 547 (8th Cir.1997).

Scienter

> Scienter can be established in three ways: (1) from facts demonstrating a mental state embracing an intent to deceive, manipulate, or defraud; (2) from conduct which rises to the level of severe recklessness; or (3) from allegations of motive and opportunity. The relevant inquiry is whether all the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any allegation, scrutinized in isolation meets that standard.

Cornelia I. Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 782 (8th Cir. 2008). DGRS cannot meet this standard for the simple reason it has not pleaded facts sufficient to show the statements were false and therefore cannot show Medtronic or its officers knew the statements to be false.

Individual Appellees

DGRS has not alleged facts to support the inference that any particular individual appellee was aware of any of the information DGRS alleges should have been released to the public. The complaint contains blanket assertions the appellees should or must have known of each of the allegedly significant facts after a review of market and other data related to Fidelis, but does not allege that any such review actually took place before the statistical analysis for the recall. The complaint does not allege that any individual appellee was a part of such review or analysis at the time the alleged materially misleading statements were made.

Medtronic

DGRS attempts to show collective scienter of Medtronic by pointing out individual pieces of information held within the company that should have (and eventually did) lead to the conclusion there was a problem with the Fidelis leads. However, the complaint fails to allege any one individual or group of individuals had, or even had access to, all those pieces of information collectively at the time the allegedly misleading statements were made. This is not a situation where the falsity was so obvious that anyone familiar with the business of the company would have known the statements to be false at the time they were made.

DGRS points to a number of "admissions" on the part of Medtronic at the time of the recall to show that Medtronic knew the Fidelis leads were failing at

unacceptable rates at the time it reassured investors. First, Medtronic's "reassurance" was qualified at best. Second, the district court is correct that these statements were all cherry-picked and taken out of context. Most of them are snippets of larger conversations and, when placed in context, it is clear the "admissions" refer to the fact Medtronic was aware of reports of a problem and was investigating during the class period, not that Medtronic knew the Fidelis leads would have to be recalled at that time.

DGRS alleges Medtronic had in its possession the data that indicated there was a problem with the Fidelis leads at the time it was still reassuring doctors that the leads were a viable product. That is true. However, mere possession of uncollected data does not indicate Medtronic was aware of the implications of that data. The complaint itself alleges Medtronic was reviewing the tracking data and does not allege the reports were conclusive any earlier than the date on which Medtronic took action with respect to the Fidelis leads. See Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 196 (2d Cir. 2008) (finding no inference of scienter where there was no allegation that raw data in possession of company had been collected into reports that would have contradicted the information released by the company during the class period).

The district court did not err in dismissing the complaint for failure to plead the element of scienter with sufficient particularity.

III

MOTION FOR LEAVE TO AMEND THE COMPLAINT[1]

"We ordinarily review the denial of leave to amend a complaint for abuse of discretion, but when the district court denies leave on the basis of futility we review the underlying legal conclusions de novo." In re NVE Corp. Sec. Litig., 527 F.3d 749, 752 (8th Cir. 2008).

DGRS argues it could have cured the problems which resulted in dismissal by amending its complaint to allege Medtronic failed to disclose that there were actually four, instead of two, ways in which the devices had been reported to fracture. However, even if this is true, multiple fracture sites in a device would not cause a recall if the overall failure rate were within normal limits. This information has no bearing on the material question, which is whether Fidelis devices were known to exceed acceptable failure rates overall. The district court did not err in denying DGRS permission to amend the complaint to add this allegation.

DGRS also requested leave to amend the complaint to include the allegation that 40% of the fractures in Medtronic's returned products data involved a hardware malfunction resulting in a break that could affect electrical performance of the lead. Again, this allegation would have absolutely no bearing on the relevant analysis. The returned products database only provides information on the devices that failed. A certain number of devices are expected to fail. The number of expected failures that result from mechanical problems is not relevant to the overall performance of the device. Even if 100% of the returned devices were mechanical failures, Fidelis would still be a viable product as long as the number of returned devices were within the

[1]DGRS also appealed the district court's denial of its motion to reconsider but did not address the issue in its brief on appeal.

acceptable failure rate. The district court did not err in refusing to allow DGRS to amend the complaint on this basis.

DGRS then attempted to add allegations that Medtronic requested permission from the FDA to modify the design of the Fidelis leads during the class period. The type of modification requested addresses one of the four fracture points discovered in the course of reviewing the physician complaints. While we do not agree with the district court's conclusion that the modification was irrelevant to the analysis, even if relevant, amendment on that basis would still be futile. Medtronic had identified a problem that was causing fractures and moved to remedy it. The other allegations in the complaint already establish Medtronic was aware of fractures due to physical failure. What is missing from the complaint is any allegation Medtronic was aware that the physical failure was causing fractures in higher than acceptable numbers across the market. This allegation would not solve the fatal defect in the complaint and the district court did not err in so determining.

IV

The district court correctly determined DGRS failed to plead with the requisite specificity facts that would show Medtronic made materially false or misleading statements. The district court did not err in refusing to allow DGRS to amend its complaint, where the allegations to be added did not cure fatal defects in the complaint.

We affirm.
