IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE ABBOTT DEPAKOTE SHAREHOLDER DERIVATIVE LITIGATION	)	No. 11 C 8114
	)	Judge Virginia M. Kendall

MEMORANDUM OPINION AND ORDER

Lead Plaintiff Jacksonville Police & Fire Pension Fund, and plaintiffs Louisiana Municipal Police Employees Retirement System and Public School Retirement System of the School District of Kansas City, Missouri (collectively, the Plaintiffs) filed a consolidated shareholder derivative action on behalf of nominal defendant Abbott Laboratories ("Abbott") against the individual defendant directors of Abbott (the "Defendants") to remedy alleged breaches of their fiduciary duties. Plaintiffs assert that the breaches arise from the Defendants' knowing failure to exercise their oversight responsibility over Abbott's marketing practices with respect to its anticonvulsant drug, Depakote. Defendants moved to dismiss the Consolidated Verified Amended Shareholder Derivative Complaint (the "Complaint") for failure to adequately plead demand futility. For the reasons set forth below, this Court grants the Defendants' motion and dismisses Plaintiffs' Complaint without prejudice.

BACKGROUND

The following facts are alleged in Plaintiffs' Complaint and are presumed to be true for purposes of analyzing this motion to dismiss. *See Murphy v. Walker,* 51 F.3d 714, 717 (7th Cir. 1995).

I. Abbott and its Business

Abbott Laboratories develops, manufactures and markets a wide range of pharmaceutical products and medical devices for the diagnosis and treatment of human diseases and disorders. (Doc. 179, ¶ 22.) These products are subject to various federal laws and regulations promulgated by the Food & Drug Administration (the "FDA"). (*Id.* at ¶¶ 22, 57.) Before a prescription drug may be marketed to consumers, manufacturers such as Abbot must file a new drug application with the FDA, which includes reports of investigations, studies and other information to establish the safety and effectiveness of the drug for its intended use. (*Id.* at ¶ 58.) If the FDA approves a drug, its approved indications are listed on the drug's label. (*Id.* at ¶ 59.)

While physicians may prescribe drugs for conditions other than those approved by the FDA, a manufacturer may not market an FDA-approved drug for an "off-label" use. (*Id.* at ¶ 61.) Thus, a "drug label" - a term that includes marketing and promotional materials related to a drug - cannot describe intended uses not approved by the FDA. (*Id.* at ¶ 60.) A manufacturer who promotes a drug for unapproved uses may be subject to both civil and criminal penalties for "misbranding" under the Food, Drug and Cosmetic Act ("FDCA"). (*Id*.)

II. FDA Approvals of Depakote

In 1983, the FDA approved Depakote for the treatment of epileptic seizures in adults and children over the age of 10. (*Id.* at ¶ 2.) Subsequently, the FDA approved Depakote for: (1) manic disorders associated with bipolar disorder; and (2) the prevention of migraines. It also approved a delayed-release formulation of Depakote for these two uses. (*Id.* at ¶¶ 69-74.)

Abbott sponsored studies regarding the use of Depakote for treatment of mania and agitation in elderly patients with dementia. (*Id.* at ¶¶ 124-25, 135.) It sponsored studies regarding the use of

Depakote and Depakote DR for the treatment of schizophrenia. (*Id.* at ¶¶ 216-17.) The FDA expressed reservations about relying on these studies to approve the expanded use of Depakote. (*Id.* at ¶ 125.) These studies were terminated in 1999. (*Id.* at ¶ 129.) Depakote, like many drugs, had a number of potentially serious side effects. (*Id.* at ¶ 75.) However, physicians widely prescribed the drug. Sales of Depakote accounted for between 8-11% of Abbott's total sales between 2005 and 2008. (*Id.* at ¶ 84.)

III. The Qui Tam Complaints, the DOJ Investigation, and the Plea Agreement

Beginning in 2007, former Abbott sales representatives filed four *qui tam* complaints alleging that Abbot had engaged in a widespread, and centralized scheme to engage in off-label marketing of Depakote between 1998 and 2009.[1] (*Id.* at ¶ 88.) Those complaints were filed under seal. The *qui tam* complaints alleged that Abbott sales representatives promoted Depakote for unapproved uses, misleadingly downplayed the side effects of Depakote, and provide healthcare professions with information designed to promote their prescription of Depakote for off-label applications. (*Id.* at ¶¶ 90-94.)

On November 6, 2009, Abbott disclosed that the Department of Justice had opened an investigation into the sales and marketing of Depakote. (*Id.* at ¶ 323.) On February 4, 2011, the DOJ elected to intervene in the *qui tam* actions and unsealed a redacted version of its complaint against Abbott. (*Id.* at ¶ 327.) On November 4, 2011, Abbott announced that it had recorded a charge of $1.5 billion in connection with the probable resolution of potential civil and criminal claims arising out of the investigation. (*Id.* at ¶ 329.)

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[1] These actions were styled: (1) *U.S. ex rel. McCoyd v. Abbott Laboratories,* 1:07-cv-00081 (W.D. Va.); *U.S. ex rel. Mulcahy v. Abbott Laboratories,* 1:08-cv-0054 (W.D. Va.); *U.S. ex rel. Dietzler v. Abbott Laboratories,* 1:09-cv-00051 (W.D. Va.); *U.S. ex rel. Spetter v. Abbott Laboratories,* 1:10-cv-00006 (W.D. Va.).

On May 7, 2012, Abbott announced that it had agreed to plead guilty to a misdemeanor criminal charge and enter into a settlement with the United States and 49 state authorities to settle civil claims against the company. (*Id.* at ¶ 330.) Pursuant to this global settlement, Abbott agreed to pay $700 million in connection with the criminal plea; $800 million to resolve federal and state civil claims; and $100 million to resolve state consumer-protection claims by 46 states. (*Id.*) Abbott also agreed to enter into a Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services. (*Id.* at ¶ 334.)

As part of its plea agreement, Abbott entered into an Agreed Statement of Facts setting forth the conduct on which the plea was based. (Doc. 199-1.)[2] In that statement, Abbott conceded that it had introduced misbranded Depakote products into interstate commerce between January 1998 and December 2006, in violation of the FDCA. (*Id.*) The Agreed Statement does not include any facts relating to conduct that occurred after December 2006. (*Id.*) There is no allegation or admission in the Plea Agreement or the Statement of Facts that members of Abbott's board of directors had engaged in or approved any unlawful conduct by the company.

IV. Communications from the FDA regarding Abbott's Marketing of Depakote

Between 1997 and 2009, Abbott received thirteen Warning Letters from the FDA regarding off-label marketing practices. Two of these letters specifically related to Depakote. First, the FDA's Division of Drug Marketing, Advertising and Communications ("DDAMC") sent a warning letter to Abbott's former CEO, Duane Burnham, on June 26, 1998. (Doc. 179 at ¶ 290.) This letter

[2]The Complaint refers to and relies on the Agreed Statement of Facts. (*See, e.g.,* Doc. 179 at ¶¶ 5-6, 8, 74, 105, 124, 214, 226, 301). Accordingly, the Court may consider this exhibit in ruling on Defendants' motion. *See Wright v. Assoc. Ins. Co.,* 29 F.3d 1244, 1248 (7th Cir. 1994) ("documents attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to his claim. Such documents may be considered by a district court in ruling on the motion to dismiss.").

asserted that Abbott was promoting Depakote for unapproved purposes. (*Id.* at ¶ 291.) Second, the DDAMC sent a letter to Abbott's regulatory manager, Rick Leber, on January 22, 2009. (*Id.* at ¶ 292.) This letter notified Leber that a "Pharmacy Formulary Flashcard" used by sales representatives was misleading because it omitted material information about Depakote. (*Id.*) The DDMAC requested that Abbott "immediately cease" the dissemination of this marketing material. (*Id.*)

V. Abbot's Compliance Policies and Controls

Unfortunately, the plea agreement that Abbott entered into with the federal government in 2012 is not the first time that Abbott has pled guilty to illegal marketing charges. In July 2003, Abbott agreed to pay $600 million to settle civil and criminal charges relating to its marketing of another product.[3] As part of the settlement, Abbott entered into a five-year corporate integrity agreement. The corporate integrity agreement caused Abbott to implement a number of compliance policies and internal controls in addition to the ones that already existed. (*Id.* at ¶¶ 12, 47, 265-269.) These policies and controls include: (1) the Corporate Governance Guidelines; (2) a Code of Business Conduct; (3) an Ethics Compliance Program; and (4) a Public Policy Committee of the Board. (*Id.* at ¶ 248.) These controls are designed to prevent Abbott from violating federal and state laws in the operation of its business. (*Id.* at ¶ 277.)

VI. Abbott's Board of Directors

When the Plaintiffs filed their lawsuits in November 2011, Abbott's board of directors was composed of ten directors (the "2011 Board"). (*Id.* at ¶¶ 24-31, 37-38.) Six of these directors joined

[3] This settlement is not specifically alleged in the Complaint. However, Abbott disclosed the settlement in their 2004 Form 10-K filed with the Securities & Exchange Commission. As a result, the Court may take judicial notice of this fact. *See GE Capital Corp. v. Lease Resolution Corp.,* 128 F.3d 1074, 1080-81 (7th Cir. 1997) (stating that a district court is permitted to take judicial notice of matters of public record); *Patten v. Northern Trust Co.,* 703 F. Supp. 2d 799, 803 n. 2 (N.D. Ill. 2010) (stating that the court can take "judicial notice of matters of public record, such as...SEC filings").

the board in April 2007 or later. (*Id.*) These directors are: Samuel Scott, Glen Tilton, William Osborn, Robert Alpern, Edward Liddy and Phebe Novakovic.[4]

VII. Procedural History

The first shareholder derivative suit based on Abbott's marketing of Depakote was filed on November 8, 2011. Thereafter, seven other similar suits were filed and then consolidated in this Court. (Doc. 163.) On April 13, 2012, the Court entered an order appointing the Jacksonville Police & Fire as lead plaintiff. (Doc. 160.) Plaintiffs subsequently filed the Complaint on June 1, 2012. (Doc. 179.)

LEGAL STANDARD

The Defendants move to dismiss the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 23.1. Fed. R. Civ. P. 23.1(b)(3) requires that a plaintiff bringing a shareholder derivative action state with particularity the following:

> (A) any effort by the plaintiff to obtain the desired action from the directors or comparable authority and, if necessary, from the shareholders or members; and
>
> (B) the reasons for not obtaining the action or not making the effort.

"In contrast to a motion to dismiss pursuant to Rule 12(b)(6), a Rule 23.1 motion to dismiss for failure to make a demand is not intended to test the legal sufficiency of the plaintiffs' substantive claim. 'Rather, its purpose is to determine who is entitled, as between the corporation and its shareholders, to assert the plaintiff's underlying substantive claim on the corporation's behalf.'" *In re Veeco Instruments, Inc. Sec. Litig.,* 434 F. Supp. 2d 267, 273 (S.D.N.Y. 2006) (*quoting Levine v. Smith,* No. 8833, 1989 WL 150784, *5 (Del. Ch. Nov. 27, 1989); *Gordon v. Goodyear,* No. 12

[4]The remaining directors are Laurance Fuller, Miles White, Roxanee Austin and James Farrell.

C 369, 2012 WL 2885695, *5 (N.D. Ill. July 13, 2012); *N. Miami Beach Gen. Employees Ret. Fund v. Parkinson,* No. 10 C 6514, 2012 WL 4180566, *4 (N.D. Ill. Sept. 19, 2012). The law of the state of incorporation governs whether a demand may be excused when a shareholder files a derivative suit on behalf of a corporation. *Kamen v. Kemper Fin. Servs., Inc.,* 500 U.S. 90, 98-99 (1991); *CDX Liquidating Trust v. Venrock Assocs.,* 640 F.3d 209, 212 (7th Cir. 2011). Since Abbott is an Illinois corporation, Illinois law governs whether Plaintiffs may bring their claim. The Seventh Circuit has held that Illinois law follows Delaware law with respect to determining whether demand is futile and accordingly, "Delaware law controls" on the issue. *In re Abbott Labs. Derivative Shareholders Litig.,* 325 F.3d 795, 804 (7th Cir. 2003).[5]

Ordinarily, directors are afforded the protection of the business judgment rule. The business judgment rule is a presumption that "the directors of a corporation acted on an informed basis, in good faith, or (sic) in the honest belief that the action taken was in the best interests of the company." *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984). "Where a majority of the directors are independent or outside directors receiving no income other than usual directors' fees, the presumption of good faith is heightened." *Parnes v. Bally Entm't Corp.*, No. 15192, 2001 WL 224774, at *9, n.26 (Del. Ch. Feb. 23, 2001) (*quoting Moran v. Household Int'l, Inc.*, 490 A.2d 1059, 1074-75 (Del. Ch. 1985)). Accordingly, the Delaware Supreme Court has held that demand on a board is only futile in situations "where the facts are alleged with particularity which create a reasonable doubt that the directors' actions were entitled to the protections of the business judgment rule." *Aronson*, 473 A.2d at 808. In other words, demand is only excused if there is a substantial likelihood that a company's directors would face personal liability for the conduct complained of in the demand. *See Wood v.*

[5]The parties do not dispute that Delaware law controls here.

Baum, 953 A.2d 136, 141, n. 11 (Del. 2008) (stating that a reasonable doubt that a majority of directors is incapable of considering demand should only be found where substantial likelihood of personal liability exists) (internal citations and quotations omitted).

Delaware law recognizes two tests that may be applied to determine whether a demand on a board would be futile due to the likelihood of personal liability on the part of the directors. The first test, established by the Delaware Supreme Court in *Aronson*, applies when a plaintiff is challenging a specific decision by the board of directors. *Id.* at 814. Under this test courts must determine whether "accepting the well-pleaded facts as true, the alleged particularized facts raise a reasonable doubt that either: (1) the directors are disinterested or independent; or (2) the challenged transaction was the product of a valid exercise of the directors' business judgment." *Aronson*, 473 A.2d at 814.

The second test, established by the Delaware Supreme Court in *Rales v. Blasband*, applies when the derivative action is based on a board's inaction or a violation of the board's oversight duties. *See* 634 A. 2d 934, 937 (Del. 1993); *see also Stone v. Ritter,* 911 A.2d 362, 367 (Del. 2006). Under *Rales*, to excuse the demand element, the Court must determine whether the complaint creates a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." *Rales*, 634 A.2d at 934. To make this determination, *Rales* requires a court to analyze whether there are particularized facts that sufficiently allege that either: 1) the underlying conduct being challenged renders any of the directors 'interested' and, if so, whether other directors were compromised in their ability to act independently of the interested directors; or 2) at least half of the directors face a sufficiently substantial threat of personal liability as to the conduct alleged in the complaint to

compromise their ability to act impartially on a demand." *Desimone v. Barrow*, 924 A.2d 908, 928 (Del. Ch. 2007). The mere threat of liability is not enough, the threat must be substantial. *Rales*, 634 A.2d at 936.

These substantial pleading hurdles become even greater when a company's articles of incorporation includes an exculpatory provision that immunizes a director from liability for a breach of the duty of care. *See Bronstein v. Austin,* No. 07 C 3984, 2008 WL 4735230, at *4, n.3 (N.D. Ill. May 30, 2008) (finding that a valid exculpatory provision renders plaintiff's ability to establish a substantial threat of liability questionable). An exculpatory provision requires the plaintiff to plead particularized facts showing that a majority of the board breached their duties of loyalty or acted in bad faith. *Stone,* 911 A.2d at 367. This requires the Plaintiffs to sufficiently allege that the directors "intentionally" acted contrary to the corporation's interests, acted "with intent to violate applicable positive law," or demonstrated a "conscious disregard" for their duties. *In re Walt Disney Co. Derivative Litigation,* 906 A.2d 27, 67 (Del. 2006).

This Court has found that when a plaintiff alleges that directors knowingly failed to exercise their oversight duties, as the Plaintiffs allege here, the allegations are best analyzed under the Supreme Court of Delaware's analysis in *In re Walt Disney Co. Deriv. Litig.* and *Stone v. Ritter. See Bronstein,* 2008 WL 4735230, at *5 (analyzing allegations of a knowing failure to exercise oversight duties under *Walt Disney* and *Stone*). In *Stone*, the Delaware Supreme Court elucidated the standard set forth in *In re Caremark Int'l Inc. Deriv. Litig.* which detailed the conditions predicate for director oversight liability, namely:

> (a) the directors utterly failed to implement any reporting or information system or controls; or (b) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of

> risks or problems requiring their attention. In either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations. Where directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they breach their duty of loyalty by failing to discharge that fiduciary obligation in good faith.

Stone, 911 A.2d at 369 (citing *Guttman v. Huang*, 823 A.2d 492, 506 (Del. Ch. 2003)); *see also In re Caremark Int'l Inc. Derivative Litigation*, 698 A.2d 959, 971 (Del. Ch. 1996). In other words, a plaintiff may sufficiently allege demand futility if they allege inactivity coupled with specific "red flags" suggesting that the company's internal controls are inadequate and that these inadequacies give rise to substantial risk of illegal activity occurring. *See In re Caremark,* 698 A.2d at 971; *see also King v. Baldino,* 648 F. Supp.2d 609, 623 (D. Del. 2009). Here, Plaintiffs allege that a reporting and/or information system was in place, but that the 2011 Board consciously disregarded its fiduciary duties by choosing not to exercise its oversight responsibility and failing to address the off-label marketing practices in a timely and effective manner. *See Walt Disney*, 906 A.2d 27 (A failure to act in good faith may be shown, for instance, where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties.)

DISCUSSION

I. There Is No Basis To Excuse Demand Because A Majority of the 2011 Board Does Not Face a Substantial Threat of Personal Liability

In this case, there is no dispute that a majority of Abbott's Board is disinterested. There is no dispute that there is an exculpatory provision in Abbott's Restated Articles of Incorporation. There is no dispute that six out of the ten directors were not appointed until April 2007 or later. These six directors cannot be personally liable for conduct that occurred before they were appointed. *See, e.g., Goldberg v. Ball,* 305 Ill. App. 273, 280-81 (1st Dist. 1940); *King,* 648 F. Supp. 2d at 624;

Morrone v. Erlich, No. 09 C 1910, 2011 WL 1322085, at *6 (E.D.N.Y. Mar. 31, 2011) ("Outside directors Sloyer and Marrus, each of whom joined Arotech's Board of Directors after the Relevant Period, cannot be held liable for acts or omissions that occurred before they became affiliated with the Company.").

Accordingly, the relevant question for the Court's analysis is whether the Plaintiffs have alleged sufficient particularized facts describing conduct that occurred after April 2007 so that at least half of the directors face a substantial threat of personal liability for failing to exercise their oversight duties. In other words, have the Plaintiffs alleged with particularity a sustained or systematic failure by a majority of the 2011 Board to exercise oversight. The Court finds that they have not.

Plaintiffs contend that the following allegations demonstrate that the 2011 Board knowingly failed to exercise its oversight responsibility:

- The Board was regularly informed about Depakote sales volume and were aware that Depakote accounted for 11% of Abbott's total sales in 2007 and 9% in 2008. (Doc. 179, ¶ 199.)

- The LTC Sales Force, which was responsible for marketing Depakote for off-label uses, continued to expand until June 2007 and was not disbanded until January 1, 2009. (*Id.* at ¶ 102.)

- There was a nationwide conference call in February 2007 for the entire LTC Sales Force, Depakote marketing staff, and upper level managers where sales representatives were instruct to coach physicians on how to evade OBRA-87's restriction on "unnecessary drugs," which included Depakote. (*Id.* at ¶ 116-18.)

- Until at least June 2007, Abbott used the "Working the Wheel" tactic whereby Abbott targeted physicians and institutions that Abbott believed would produce the most off-label prescriptions of Depakote for agitation associated with dementia. (*Id.* at ¶ 104.)

- The Board never took any steps to rescind a 1998 Strategic Marketing Plan for Depakote. This plan was allegedly implemented to promote the off-label marketing of Depakote. (*Id.* at ¶¶ 96-99.)

- Until approximately July 2008, "scholarships" were provided to physicians to attend Abbott-sponsored education programs on epilepsy to reward and incentivize physicians to prescribe Depakote. (*Id.* at ¶ 199).

- The FDA's Division of Drug Marketing, Advertising and Communications sent Abbott a Warning Letter admonishing that its "Depakote ER/Depakote Continuum Care Pharmacy Formulary Flashcard" was "misleading because it omits risk information for Depakote and Depakote ER, broadens the indication of Depakote ER, omits indication information for Depakote and omits material information about Depakote ER." (*Id.* at ¶ 292.)

- In February and December 2009, Abbott's Office of Ethics Compliance made two presentations to the Board which addressed the federal government's industry-wide crackdown on illegal practices by pharmaceutical companies. These presentations specifically referenced the off-label marketing of prescription drugs and the use of illegal kickbacks in their promotion. (*Id.* at ¶¶ 314-320.)

The Plaintiffs contend that the Board was aware of this conduct because Abbot has a "highly developed network of monitoring and reporting mechanisms." (Doc. 208 at 16.) Specifically, the Plaintiffs argue that the Company's Corporate Governance Guidelines, Code of Business Conduct, Comprehensive Ethics and Compliance Program, and various Board Committees, including the Nominations and Governance Committee and Public Policy Committee, "ensured that, as a matter of affirmative obligation, key information was conveyed to Board." (*Id*.)

The Plaintiffs also argue that the Board should have been aware of the alleged conduct as a result of the *qui tam* actions filed against Abbott and the Agreed Statement of Facts entered into with the Government. (*Id.* at 21.) Other "red flags" for the Board, according to the Plaintiffs, included a 1998 FDA Warning Letter regarding promotional materials for Depakote and a subpoena issued to Abbott for e-mails of certain Abbott officers. (*Id.* at 19-21.) Finally, the Plaintiffs argue that the

Board should have been aware of the off-label marketing of Depakote because the Government had investigated Abbott before with respect to other products. (*Id.* at 22.) In particular, Plaintiffs argue that the 2001 TAP Pharmaceuticals settlement and the 2003 Ross Products Settlement were "clear red flags of potentially rampant marketing shenanigans elsewhere in the Company, which should have heightened the Board's awareness of a systemic problem." (*Id.*) As a result of these settlements, Abbott entered into a corporate integrity agreement where it agreed to reform its sales and marketing practices. (*Id.*)

A. No Sufficient Threat of Personal Liability Exists for Conduct that Occurred Prior to the Appointment of a Majority of the Board of Directors

Since it is undisputed that a majority of the Board was not appointed until after April 2007, a number of Plaintiffs' "particularized facts" and "red flags" are irrelevant for purposes of determining whether a sufficient threat of personal liability exists for a majority of the 2011 Board. For example, Plaintiffs directed the Court to the allegation in the Complaint that "there was a nationwide conference call in February 2007 for the entire LTC Sales Force, Depakote marketing staff and upper level managers where sales representatives were instructed to coach physicians on how to evade OBRA-87's restriction on 'unnecessary drugs,' which include Depakote." (Doc. 179 at 12.) However, this fact does not support Plaintiffs' position because the majority of Abbott's directors were appointed after April 2007, thus they would not be liable for any conduct that occurred in February 2007. *See, e.g., King,* 648 F. Supp. 2d at 624; *Morrone v. Erlich,* 2011 WL 1322085, at *6.

Plaintiff also argues that its allegation that "[u]ntil at least June 2007, Abbott used the 'Working the Wheel' tactic whereby Abbott targeted physicians and institutions that Abbott believed

would produce the most off-label prescriptions of Depakote for agitation associated with dementia" supports its assertion that a majority of the Board faces liability. (*Id.*) However, the cited to paragraph in the Complaint does not allege that Abbott used the "Working the Wheel" tactic until at least June 2007. It provides no time frame for this allegation. Plaintiffs cannot amend their Complaint through their brief. *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Comp.,* 631 F.3d 436, 448 (7th Cir. 2011). Accordingly, this "fact" does not support Plaintiffs' position.

Additionally, there is no reason that old red flags, such as the 1998 FDA warning, the 2001 TAP settlement and the 2003 Ross settlement, would alert the relevant Board that illegal off-label marketing practices continued after April 2007. *See, e.g., In re Intel Corp. Derivative Litigation,* 621 F. Supp. 2d 165, 175 (D. Del. 2009) (holding that because an arbitration award was made before nine of the twelve current directors joined the board, "it [was] difficult to see how this is a 'red flag' that the Directors' allegedly disregarded at their peril."). Plaintiff concedes that Abbott entered into a corporate integrity agreement in 2003 (the "2003 CIA) where it agreed to reform its sales and marketing practices. The 2011 Board was justified in relying on the 2003 CIA to believe that Abbott did indeed reform its sales and marketing practices after 2003. Accordingly, red flags that arose prior to the execution of the 2003 CIA are not red flags for the 2011 Board because they would be reasonable in concluding that Abbott cured the earlier flagged deficiencies when it entered into the 2003 CIA.

Finally, the conduct discussed in the Agreed Statement of Facts is irrelevant for purposes of determining demand futility because all of the conduct occurred between 1998 to 2006. Since a majority of the 2011 Board were not members of Abbott's Board during the period covered by the

Agreed Statement of Facts, a majority of the Board does not face a serious threat of personal liability as a result of that conduct. Moreover, the Agreed Statement of Facts is not a flag that impermissible activity continued after the covered period. The reasonable inference is the opposite. The Government investigated Abbott's conduct and concluded that the off-label marketing practices ceased in 2006. If they did not, the Government would have charged that conduct and it would have appeared in the Agreed Statement of Facts. Accordingly, the Court disregards these alleged facts and red flags in determining whether demand is excused.

B. No Sufficient Threat of Personal Liability Exists for Conduct the Board Did Not Have Notice Of

In addition to the stale allegations, there is no allegation that the Board received notice of the majority of the post-April 2007 alleged conduct. Rather, Plaintiffs contend that the Board must have learned about them because of its compliance mechanisms. Pleading the existence of compliance mechanisms is insufficient to establish knowledge or awareness. *See, e.g., Garza v. Belton,* No. 08 C 1387, 2010 WL 3324881, at *8 (N.D. Ill. Aug. 13, 2010) (holding that allegations of a corporate governance procedure, without specific allegations of notice, is insufficient to plead "conscious inaction" under *Rales)*; *In re Huron Consulting,* 971 N.E. 2d 1067 (1st Dist. 2012).

First, there is no allegation that a majority of the 2011 Board was aware that the LTC Sales Force even existed, much less that it continued to expand until June 2007. Absent specific allegations to the contrary, there is no reason for the Court to infer that the 2011 Board was ever advised of the composition of the LTC Sales Group or its mandate. *See In re Caremark,* 698 A.2d at 968 ("Most of the decisions that a corporation...makes are, of course, not the subject of director attention."); *Pfeffer v. Redstone,* No. 2317-VCL, 2008 WL 308450, *10 (Del. Ch. Feb. 1, 2008)

("[D]irectors are not as a matter of general experience presumed to know business operational information that is not of a kind routinely disclosed to boards of directors.").

Similarly, Plaintiffs' allegation that the 2011 Board never rescinded the 1998 Strategic Marketing Plan does not show that there is a substantial threat of personal liability to a majority of the 2011 Board. Obviously, the 2011 Board was not responsible for implementing the 1998 Strategic Marketing Plan. There is no allegation that the 2011 Board was aware this marketing plan existed. Even if the Board was aware of this plan, there is no specific allegation that the Board was aware that anyone in the company continued to follow it in 2007, 2008 or 2009. Indeed, the Board would have believed the opposite. To the extent the 1998 Strategic Marketing Plan promoted the off-label marketing of Depakote ,and to the extent the 2011 Board had knowledge Abbott implemented this plan, the reasonable inference is that the 2011 Board believed it was implicitly, if not explicitly, rescinded by the 2003 CIA. This is because Abbott agreed to reform its sales and marketing practices as part of the 2003 CIA.

Finally, there is no specific allegation that the Board learned of the letter the FDA sent to Abbott's regulatory manager notifying him that the Abbott's "Depakote ER/Depakote Continuum Care Pharmacy Formulary Flashcard" was misleading. *See, e.g., In re Johnson & Johnson Derivative Litigation,* No. 10-2033, 2011 WL 4526040, *25-26 (D.N.J. Sept. 29, 2011) (finding that allegations the FDA sent Johnson & Johnson warning letters were insufficient to establish oversight liability where the Plaintiff failed to allege particularized facts showing the Board was aware of these letters). Even if there were, this single letter is insufficient to create a reasonable doubt that the Board failed to exercise their oversight duties because there is no allegation that Abbott failed to remedy the concerns the FDA raised in this letter. Accordingly, these allegations fail to establish

a reasonable doubt that there is a substantial threat that a majority of the 2011 Board could be liable for the conduct alleged in the Complaint.

Plaintiffs' reliance on the *Pfizer, Allergan II and Abbott I* cases is misplaced. In *Pfizer,* the plaintiff alleged that Pfizer's board directly received "a large number of reports" about potential off-label violations. The Pfizer board also directly received "a large number of FDA violation notices and warning letters, several reports of Pfizer's compliance personnel and senior executives of continuing kickbacks and off-label marketing" and allegations of board retaliation in response to complaints of off-label marketing. *See In re Pfizer Inc. Shareholder Derivative Litigation,* 722 F. Supp. 2d 453, 456, 460 (S.D.N.Y. 2010). In contrast here, there is no evidence that a majority of the 2011 Board was aware that Abbott engaged in any off-label marketing practices during its tenure.

Allergan II and *Abbott I* are distinct because in both cases a majority of the board who would have analyzed a demand had direct knowledge of the violations at issue. In *Allergan II,* the plaintiff sought to hold the board liable for off-label marketing of Botox. The complaint in that case alleged not only that the board monitored Botox sales, but that at a majority of the relevant board of directors approved a series of annual strategic plans that "contemplated new markets for Botox that involved applications that were off-label uses," monitored sales by "different usage categories," including "how sales for off-label uses grew," and approved a plan that "explicitly linked the number of sales representatives to increased off-label sales." *Louisiana Municipal Employees' Retirement System v. Pyott,* 46 A.3d 313, 352, 355 (Del. Ch. 2012).

In *Abbott I,* which did not involve off-label marketing, the shareholder derivative complaint alleged that the FDA sent warning letters directly to a board member about continuing manufacturing problems; the FDA with representatives of the Abbott board concerning the continuing

manufacturing violations that were at issue in the FDA warning letters; The Wall Street Journal and other media outlets published articles about those same manufacturing violations; and the FDA issued a report noting deviations from good manufacturing practices. *See In re Abbott Laboratories,* 325 F.3d at 808. Furthermore, the complaint alleged that "[t]he directors who were members of the Audit Committee were aware of the violations," and under proper corporate governance procedures, would have reported the violations to the full board." *Id.* Accordingly, these cases are distinct from this instant case because unlike in those cases, there are no particularized allegations demonstrating a majority of the 2011 Board was aware of any off-label marketing practices that occurred after April 2007.

C. Plaintiffs' Remaining Allegations Are Insufficient

Plaintiffs' remaining allegations and "red flags" are insufficient to establish that a majority of the 2011 Board faces a substantial threat of personal liability. First, an allegation regarding a drug's sales volume does not lead to the conclusion that the volume was "due to the illegal activity by [Company] employees" which the Board consciously ignored. *King,* 648 F. Supp. 2d at 624; *see also In re Allergan, Inc. Shareholder Derivative Litigation,* No. 10-1352, 2011 WL 1429626, at *4 (C.D. Cal. Apr. 12, 2011) ("Plaintiffs rely solely on the assertion that the Director Defendants should have inferred the use of illegal marketing due to the high number of sales. Court have deemed such allegations insufficient for purposes of establishing demand futility."). Moreover, Depakote's sales volume appears to have been falling during the period that the majority of the Board served as directors so there would be no basis for the Board to conclude that Abbott was continuing to engage in a policy of promoting off-label marketing. (*E.g.,* Doc. 179, 84 [Showing that Abbott earned $1.5 billion from Depakote sales in 2007, which accounted for 11% of Abbott's total 2007 sales revenue

but that Abbott earned $1.3 billion from Depakote sales in 2008, which only accounted for 9% of Abbott's total 2008 sales revenue.].)

Second, Plaintiffs' allegations that the 2011 Board was aware the pharmaceutical industry has been the focus of investigations relating to off-label marketing is insufficient to establish that the Board was aware, or should have been aware, that Abbott employees were marketing Depakote for off-label uses. *See In re Citigroup Shareholder Derivative Litigation,* 964 A.2d 106, 127, 135 (Del. Ch. 2009) (problems in financial industry and losses by "Citigroup's peers such as Bear Stearns and Merrill Lynch" did not establish a "red flag."). Plaintiff has not alleged that the Office of Ethics Compliance presented any material to the Board that discussed Abbott's practices.

Indeed, in contrast to Plaintiffs' assertion that this allegation demonstrates the Board's conscious inaction, the Court finds that this allegation shows that the Board actively informed itself as to trends in the industry so that Abbott could protect itself from the missteps of its competitors. If Abbott employees were engaging in off-label marketing during this period, this bad outcome cannot be equated with bad faith on behalf of a majority of the 2011 Board. *See, e.g., In re Huron Consulting,* 971 N.E. 2d at 1084 ("Although the reporting system may have failed in this case, without more, that cannot subject the directors to personal liability for failure by Huron's 'senior management' to report the improper accounting of retention payments."); *see also Stone,* 911 A.2d at 372. Accordingly, the Court finds that this allegation does not establish a sufficient threat of personal liability to a majority of the Board so as to render demand futile.

The remainder of Plaintiffs' "red flags" are similarly deficient. These "red flags" consist of the *qui tam* actions and Judge Wilson's Order with respect to a subpoena issued by the Government to Abbott. While the *qui tam* complaints were filed years earlier, they were not made public until

they were unsealed in February 2011. Accordingly, to the extent the *qui tam* complaints qualify as a "red flag," the 2011 Board did not become aware of those "red flags" until February 2011, which is years after the complained of conduct occurred. Therefore, the existence of the *qui tam* suits does not establish a sufficient threat of personal liability to a majority of the Board so as to render demand futile.

Similarly, Judge Wilson's Order that Abbott produce deleted e-mails of top level executives in response to a government subpoena is deficient because that Order was not issued until March 10, 2010. The Complaint is devoid of any allegations that the Board allowed off-label marketing to continue after it received the subpoena or Judge Wilson's Order. Thus, regardless of whether or not this Order should have alerted the Board that off-label marketing practices had occurred at Abbott after April 2007, the Board still would not have learned of this "red flag" until after the illegal conduct occurred. Therefore, like the *qui tam* suits, this Order does not establish a sufficient threat of personal liability to a majority of the Board so as to render demand futile.[6] Accordingly, Plaintiffs have failed to sufficiently allege demand futility based on oversight liability.

II. Demand Futility under *Aronson*

Plaintiffs also claim that demand would be futile under the *Aaronson* test because the Board's decision to continually ratify the 1998 Strategic Marketing Plan is not protected by the business judgment rule. Plaintiffs contend that this decision should be analyzed under *Aronson* because it is a specific transaction. A plaintiff adequately alleges demand futility under *Aronson* if they identify

[6]It is questionable whether this Order could qualify as a red flag for the 2011 Board at all. Plaintiffs allege that Judge Wilson ordered Abbott to produce these e-mails because he "credit[ed] the government's assertion that it 'had evidence that the off-label marketing of other FDA approved drugs may have followed a similar pattern to the off-label marketing of Depakote." (Doc. 179, ¶ 299.) However, the Complaint does not provide any detail regarding the scope of the subpoena, such as the time-period from which the e-mails were sought.

a specific transaction and plead particularized facts sufficient to raise a doubt as to whether that challenged transaction was the product of a valid exercise of the directors' business judgment. *See Aronson*, 473 A.2d at 814. As described above, this allegation is insufficient to render demand futile.

There is no dispute that a majority of the 2011 Board were not members of the Board when this marketing plan was approved. There is no allegation that this marketing plan was ever subsequently reviewed by the 2011 Board. There is no allegation that this marketing plan was ever transmitted to a director who joined the Board in or after April 2007. Finally, it is reasonable to infer that this strategic marketing plan was, in fact, rescinded by Abbott's decision to enter into the 2003 CIA, in which it agreed to reform its sales and marketing practices. Accordingly, Plaintiffs failed to sufficiently allege the necessary particularized facts to show that demand would be futile under the test set forth in *Aronson.*

III. Leave to Amend

Finally, the Defendants argue that the Court should dismiss Plaintiff's complaint with prejudice for failing to allege demand futility with particularity. This would be an unduly harsh result at this stage of the litigation. Federal Rule of Civil Procedure 15(a)(2) directs a district court to grant leave to amend a complaint "when justice so requires." *See also Indep. Trust Corp. v. Stewart Info. Servs. Corp.,* 665 F.3d 930, 943 (7th Cir. 2012). In interpreting this, the Supreme Court and Seventh Circuit have held that district courts should only refuse to grant leave where there is undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to the defendants or where amendment would be futile. *See Foman v. Davis,* 371 U.S. 178, 182 (1962);

Hukic v. Aurora Loan Servs., 588 F.3d 420, 432 (7th Cir. 2009); *Arreola v. Godinez,* 546 F.3d 788, 796 (7th Cir. 2008). None of these factors are present here.

Defendants concede there is no undue delay, bad faith, dilatory motive, undue prejudice or repeated failure to cure deficiencies. Rather, they argue that amendment is futile because Plaintiffs failed to allege demand futility when they had the benefit of a books and records production, the DOJ Agreed Statement of Facts, the *qui tam* complaints and documents obtained from the FDA in drafting their Complaint. (Doc. 210 at 15.) Thus, according to Defendants, "[t]here is no reason to believe that plaintiff could further supplement its allegations of demand futility." (*Id.*)

Yet, the Court has not previously ruled on the whether the Plaintiffs adequately alleged demand futility. Plaintiffs may have knowledge of a number of other facts or details that, perhaps for strategic reasons, they did not include in this Complaint. Now that the Court has described the deficiencies in the Complaint, Plaintiffs may be able to correct those deficiencies by pleading additional facts they did not include here. Accordingly, the Court finds that the Complaint should not be dismissed with prejudice at this time.

CONCLUSION

For the reasons set forth above, the Court grants the Defendants' motion and dismisses Plaintiffs' Complaint without prejudice. Plaintiff is given leave to file an amended complaint on or before December 6, 2012.

Virginia M. Kendall
United States District Court Judge
Northern District of Illinois

Date: November 15, 2012