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 second amended 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 Second Consolidated Verified Amended Shareholder Derivative Complaint for failure to adequately plead demand futility under Federal Rule of Civil Procedure 23.1. For the reasons set forth below, this Court denies Defendants' motion.

BACKGROUND

The following facts are alleged in Plaintiffs' Second Amended Complaint and are presumed to be true for purposes of analyzing this motion to dismiss. *See Voelker v. Porsche Cars North America, Inc.*, 353 F.3d 516, 520 (7th Cir. 2003); *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. 220, ¶ 30.) These products are subject to various federal laws and regulations promulgated by the Food & Drug Administration (the "FDA"). (*Id*.) Before a prescription drug may be marketed to consumers, manufacturers such as Abbott 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 ¶ 67.) If the FDA approves a drug, its approved indications are listed on the drug's label. (*Id.* at ¶ 68.)

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 ¶ 69.) 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 ¶ 78.) 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*.) However, Depakote was never approved by the FDA as a safe and effective treatment for the control of agitation and aggression in patients with dementia or for the treatment of schizophrenia. (*Id.* at ¶

79.) Depakote, like many drugs, had a number of potentially serious side effects. (*Id.* at ¶ 84.) 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 ¶ 93.)

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

Beginning in 2007, former Abbott sales representatives filed four *qui tam* complaints alleging that Abbott had engaged in a widespread and centralized scheme to engage in off-label marketing of Depakote between 1998 and 2009.[1] (*Id.* at ¶ 97.) . The *qui tam* complaints alleged that Abbott sales representatives promoted Depakote for unapproved uses, misleadingly downplayed the side effects of Depakote, and provided healthcare professionals with information designed to promote their prescription of Depakote for off-label applications. (*Id.* at ¶¶ 98-105.)

On November 6, 2009, Abbott disclosed that the Department of Justice had opened an investigation into the sales and marketing of Depakote. (*Id.* at ¶ 367.) 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 ¶ 371.) 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 ¶ 373.)

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 ¶ 374.) 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.

[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.).

(*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 ¶ 378.)

As part of its plea agreement, Abbott entered into an Agreed Statement of Facts setting forth the conduct on which the plea was based. (*E.g.*, Doc. 219 at 4.) In that statement, Abbott conceded that it 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.*)

However, the Civil Settlement Agreement does not limit the allegations of wrongful conduct to the same period. (Doc. 226-5.)[2] Instead, the Government alleges that Abbott marketed Depakote in an off-label manner and paid illegal kickbacks to health care professionals and long-term care pharmacy providers to induce them to promote or prescribe Depakote between January 1998 and December 31, 2008. (Doc. 220 at ¶ 374.) Abbott denies these allegations in a separate recital in the agreement. (Doc. 226-4.) Instead, Abbott contends that it did not engage in any illegal behavior during any time period not set forth in the Agreed Statement of Facts to the plea agreement. (*Id.*)

IV. Abbott'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

[2] The Complaint refers to and relies on the contents of the Civil Settlement Agreement as well as an April 17, 2008 letter sent by the Department of Justice to Lori Reiser in Abbott's Legal Department. (*See, e.g.*, Doc. 220 at ¶¶ 5, 96, 98, 166, 174, 192, 196, 208, 215, 279-81, 283, 293). Accordingly, the Court may consider these exhibits 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.").

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. (Doc. 220 at ¶ 336.) 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 ¶¶ 336-44.) These controls are designed to prevent Abbott from violating federal and state laws in the operation of its business. (*Id.* at ¶ 344.)

V. Post-2007 Red Flags Alleged by Plaintiff

Plaintiffs' Second Amended Complaint also includes allegations regarding events that occurred after a majority of the 2012 Board was appointed that Plaintiffs contend constituted "red flags" that illegal activity was occurring at Abbott. On April 17, 2008, the DOJ sent a letter to Abbott's law department stating that it was investigating the marketing and promotion of Depakote. (*Id.* at ¶ 291.) The letter directed Abbott's law department to advise the company, its employees, agents, assigns, and related or affiliated entities or persons, to preserve and not destroy any records related in any way to Depakote and/or its marketing and promotion. (*Id.* at ¶ 292; *see also* Doc. 226-4.) The letter also informed Abbott that the DOJ would be serving it with multiple subpoenas requesting documents related to various categories of information pertaining to Depakote. (Doc. 220 at ¶ 291.) Beginning on July 10, 2008, the DOJ issued the subpoenas it described in the April 17th letter. (*Id.* at ¶ 298.) The subpoenas directed Abbott to

[3]This settlement is not specifically alleged in the Second Amended 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); *see also, e.g., 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").

collect responsive documents from its "employees." (*Id.*) The subpoena defined the term "employees" to include all past and present directors. (*Id.*)

Additionally, Plaintiffs allege that the Board received reports on a regular basis from the Pharmaceutical Products Division (the "PPD"), which specifically addressed Abbott's promotional and marketing strategies for all of its primary products, including Depakote. (*Id.* at ¶¶ 286-87.) The February 2007, 2008 and 2009 reports that were presented to the Board allegedly detail Abbott's research and development plan, financial points and marketing strategies for the Company's pharmaceutical products like Depakote. (*Id.* at ¶ 289.) The Plaintiffs concede that much of the information in the reports in their possession is redacted but argue that it should be inferred that the redactions cover either direct or indirect references to the off-label marketing of Depakote.

On January 22, 2009, the FDA's Division of Drug Marketing, Advertising and Communications ("DDAMC") sent a letter to Abbott's regulatory manager Rick Leber. (*Id.* at ¶ 304.) 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.*)

Finally, the Plaintiffs contend that the content of various presentations made by Abbott's Office of Ethics Compliance to the Board during the 2009 should have been a "red flag" that illegal conduct was occurring at the company. These presentations detailed trends and risk areas for companies operating in the pharmaceutical industry. (*Id.* at ¶ 313.)

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 ¶¶ 31-39, 44-45.) Six of these directors joined 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] However, the composition of the Board has subsequently changed. Two new directors, Nancy McKinstry and Sally Blount, joined the Board and Laurence Fuller stepped down from the Board.[5] Therefore, by the date the Plaintiffs filed the Second Amended Complaint, December 6, 2012, the Board consisted of eleven members, the majority of whom did not begin serving until January 2008.

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.) The Defendants moved to dismiss the First Amended Complaint for failure to allege demand futility with the particularity required by Federal Rule of Civil Procedure 23.1. (Doc. 198.) This Court granted that motion on November 15, 2012 but gave the Plaintiffs leave to file an amended complaint. (Doc. 219.) Plaintiffs filed their Second Amended Complaint on December 6, 2012. (Doc. 220.)

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

[5] *See* Abbott Current Report filed with the Securities & Exchange Commission on Form 8-K, December 9, 2011. The Court may take judicial notice of this filing. *See GE Capital Corp.*, 128 F.3d at 1080-81; *see also, e.g.*, *Patten*, 703 F. Supp. 2d at 803 n. 2.

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)); *see also, e.g., Gordon v. Goodyear*, No. 12 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. 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).[6]

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, and 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) (internal citations omitted). "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. 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

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

determine whether "accepting the well-pleaded facts as true, the alleged particularized facts raise reasonable doubt as to whether: (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 include 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 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*); *see also In re Abbott Depakote Shareholder Derivative Litigation* ("*Depakote I*"), No. 11 C 8114, 2012 WL 5561268, at *6 (N.D. Ill. Nov. 15, 2012). Under this standard, 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. However, if a plaintiff sufficiently alleges that a majority of the directors served when the illegal conduct occurred, knew the company was committing illegal acts and did nothing to remedy the situation, demand futility should be analyzed under the standard set forth in *Aronson*. *See In re Abbott Labs.*, 325 F.3d at 806. As a result this Court must analyze: (1) whether the Plaintiffs sufficiently alleged that a majority of the 2012 Board served as directors during a period in which the alleged illegal activity occurred[7]; (2) if so, does the Plaintiff sufficiently allege that the directors had notice of

[7] In *Depakote I* this Court defined the relevant Board for purposes of determining whether demand was futile to be the Board sitting when the relevant complaint was filed. *See Depakote 1*, 2012 WL 5561268, at *7. Since a majority of these directors were not appointed until April 2007 or later, the Court assessed whether the Board faced a substantial threat of liability for conduct that occurred after April 2007. *Id.* However, the composition of the Board has changed between the time the original complaint was filed and the time the instant complaint was filed. Accordingly, the Court must now determine whether a majority of the 2012 Board faces a substantial threat of personal liability. *See Braddock v. Zimmerman*, 906 A.2d 776, 786 (Del. 2006) (holding that

the illegal activity; and (3) if the answers to the first two questions are yes, do the allegations raise a reasonable doubt that the directors' inaction was the product of valid business judgment.

DISCUSSION

In *Depakote I* this Court found the Plaintiffs failed to sufficiently allege demand futility under Rule 23.1 because they failed to allege particularized facts describing conduct that occurred after April 2007 so that at least half of the directors faced a substantial threat of personal liability for failing to exercise their oversight duties. *See Depakote I*, 2012 WL 5561268, at *6-12. The Court finds that Plaintiffs have met their burden this time because the new allegations relating to the Civil Settlement Agreement, the DOJ document preservation letter and the DOJ subpoenas are persuasive in demonstrating that a majority of the 2012 Board faces a substantial threat of personal liability.

I. Plaintiffs Sufficiently Allege that a Majority of the 2012 Board Served During a Period in which Illegal Conduct Occurred

In *Depakote I* the Court found that the majority of the relevant directors did not serve on the Board during the period in which the illegal off-label marketing scheme occurred. *See id.* at *8-9. This conclusion resulted from the fact that the vast majority of the allegations in the First Amended Complaint were tied to the Agreed Statement of Facts set forth in the criminal plea agreement entered into between the Government and Abbott. *Id.* at *9. The Court noted that the First Amended Complaint and the Agreed Statement of Fact contained a substantial number of particularized allegations regarding illegal practices that occurred at Abbott but found these allegations irrelevant for purposes of determining demand futility because the plea agreement limited the period the relevant conduct occurred to between 1998 and 2006. *See id.* at *2, 9. Since a majority of the relevant Board was not appointed until April 2007, the Court concluded

"the Rule 23.1 demand inquiry must be assessed by reference to the board in place at the time when the amended complaint is filed").

that a majority of the Board did not face a serious threat of personal liability as a result of the conduct set forth in the Statement. *See id.* at *6 (citing *Goldberg v. Ball*, 305 Ill. App. 273, 280-81 (1st Dist. 1940) (holding that directors cannot be personally liable for conduct that occurred before they were appointed); *King v. Baldino*, 648 F. Supp. 2d 609, 624 (D. Del. 2009) (same); *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.")).[8]

However, notwithstanding the turnover on the Board, these allegations sufficiently pleaded a claim for demand futility under Rule 23.1. *See In re Abbott Labs.*, 325 F.3d at 809 (holding that plaintiff sufficiently alleged demand futility where complaint alleged an illegal scheme of substantial magnitude and duration); *see also, e.g., In re Pfizer Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d 453, 460 (S.D.N.Y. 2010) ("other cases involving similar allegations that the directors knowingly or recklessly disregarded illegal activity have likewise held demand to be futile, especially when the alleged wrongdoing is of substantial magnitude and duration.") (internal citations and quotations omitted); *In re Oxford Health Plans, Inc.*, 192 F.R.D. 111, 117 (S.D.N.Y. 2000) ("where liability is based upon a failure to supervise and monitor, and to keep adequate supervisory controls in place, demand futility is ordinarily found, especially where the failure involves a scheme of significant magnitude and duration which went undiscovered by the directors").

[8] The Court also held that Plaintiffs' conclusory allegation that the Agreed Statement was a red flag that impermissible conduct continued after the covered period was not a reasonable inference. Since the Plaintiffs failed to plead any additional facts that supported this assertion, the Court concluded that the reasonable inference was the opposite. The Government investigated Abbott's conduct and concluded that the off-label marketing practices ceased in 2006. *See Depakote I*, 2012 WL 5561268, at *9.

By incorporating into the Second Amended Complaint the allegations contained in Civil Settlement Agreement entered into between the Government, the participating states and Abbott, it is now reasonable for this Court to infer that the off-label marketing scheme did not stop in 2006 as it previously found in *Depakote I*. Rather, Abbott continued to market Depakote for off-label purposes through December 31, 2008. As a result, the Plaintiff has sufficiently alleged that a majority of the 2012 Board served as directors while Abbott continued to engage in the scheme.

The Civil Settlement Agreement specifically states that "[t]he United States contends that it and the Medicaid Participating States have certain civil claims against Abbott...for engaging in the following conduct concerning the marketing, promotion and sale of Depakote between January 1998 and December 31, 2008." (Doc. 226-5 at 3.) These alleged claims include that Abbott illegally marketed Depakote in an off-label manner: (1) to healthcare providers in nursing homes for the control of agitation and aggression of dementia patients; and (2) for the treatment of schizophrenia. (Doc. 220 at ¶ 276.) The Government also alleged that Abbott violated the federal Anti-Kickback Statute by "offering and paying illegal remuneration to health care professionals and long-term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company sponsored Continuing Medical Education programs." (*Id.*)

Based on the incorporation of these allegations into the complaint, the myriad particularized allegations demonstrating that Abbott marketed Depakote for off-label uses through 2008 are plausible. For example, it is now plausible that Abbott "trained sales representatives to market Depakote for comorbidities not approved by the FDA, such as seizures combined with aggression, bipolar disorder and substance abuse, bipolar mania and dementia,

and bipolar mania and high cholesterol" (Doc. 220 at ¶ 279) through 2008, instead of until only 2006. Similarly, it is now plausible that Abbott "bribed 'key opinion leaders' with illegal kickbacks, including sports tickets, dinners, golf outings, speaker honoraria and long term consulting agreements, to provide advocacy and key market feedback in support of off-label uses of Depakote" (*Id.*) through 2008 instead of 2006. The Court can also reasonably infer that "Abbott entered into contracts with Long Term Care Pharmacy Providers . . . that included payment of rebates to the LTCPPs based on the increased use of Depakote in nursing homes for . . . the treatment of agitation and aggression in elderly dementia patients" (*Id.*) through 2008 and not just through 2006. The Second Amended Complaint is littered with these types of particularized allegations.

Defendants' arguments to the contrary are unpersuasive. First, Defendants argue that the Court should disregard the contents of the Settlement Agreement because Abbott specifically denied that illegal conduct occurred through December 31, 2008 in the Settlement Agreement. Defendants are correct that Abbott expressly denied that it engaged in any wrongful conduct with the exception of the admissions that were made in connection with the guilty plea in the criminal action. Indeed, Plaintiffs overreach in their brief when they argue that "in the Civil Settlement Agreement Abbott specifically admitted that, through December 31, 2008, it promoted Depakote off-label." (*See* Doc. 232 at pg. 6.) However, this distinction is irrelevant for purposes of deciding the motion to dismiss. At this stage the Court is required to make all reasonable inferences in favor of the non-moving party. *See, e.g., In re Veeco Instruments*, 434 F. Supp. 2d at 274 (stating that in determining whether a complaint sufficiently alleges demand futility under Rule 23.1, "plaintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged"); *In re Pfizer,* 722 F. Supp. 2d at 458 (same); *Brehm v. Eisner,* 746

A.2d 244, 255 (Del. 2000) (same). The Government's specific contentions in the Civil Settlement Agreement that Abbott continued to market Depakote in an off-label manner and continued to illegally remunerate physicians to promote Depakote through 2008 makes Plaintiffs' allegations in the Second Amended Complaint that this conduct occurred through 2008 plausible. The Court must credit those allegations as true in assessing the sufficiency of the Second Amended Complaint. Accordingly, the Court finds Plaintiffs alleged multiple particularized allegations of illegal conduct occurring through 2008. This, in turn, means they have alleged that the illegal conduct continued to occur during the period a majority of the 2012 Board served as directors.

Defendants' second argument also lacks merit. Defendants argue that the temporal scope of the release provided in the Civil Settlement Agreement does not support an inference that illegal conduct occurred through December 2008 because a release does not establish that wrongful conduct occurred throughout the period covered by the release. This argument is similarly irrelevant for purposes of deciding this motion because the Court is not deciding whether illegal conduct occurred through 2008; rather, it only decides whether Plaintiffs sufficiently allege that it did. Here the Civil Settlement Agreement supports an inference that illegal conduct occurred through December 2008 because the Government specifically contends that it did in the Settlement Agreement. Accordingly, the Court finds that the Second Amended Complaint sufficiently alleges that illegal conduct occurred during a period in which a majority of the 2012 Board served as directors so that a majority of the Board may potentially be personally liable to the corporation.

II. Plaintiffs Sufficiently Allege that a Majority of the 2012 Board Had Knowledge of the Wrongful Conduct

The second relevant question for the Court to analyze is whether the Second Amended Complaint sufficiently alleges that the Board had notice of the illegal conduct. In its prior opinion, this Court analyzed whether the 2011 Board would have had notice of certain, limited allegations of impermissible conduct that occurred after April 2007 and whether certain allegations actually constituted "red flags" to the Board. In contrast here, the Court is not limited to determining whether limited, specific allegations constituted "red flags" because the Plaintiffs have now alleged a significant scheme that continued to occur when a majority of the 2012 Board had already been appointed directors. When a derivative plaintiff alleges a particularized scheme of substantial magnitude and duration that allegedly occurred when a majority of a board served as directors, courts infer that the board had notice of the scheme for purposes of assessing demand futility. *See In re Abbott Labs.*, 325 F.3d at 808-09; *see also McCall v. Scott*, 239 F.3d 808, 823 (6th Cir. 2001) (holding that knowledge or reckless disregard of illegal conduct by a board can be inferred when the alleged wrongdoing is of substantial magnitude and duration); *In re Pfizer*, 722 F. Supp. 2d at 460 (same) (internal citations and quotations omitted); *In re Oxford Health Plans, Inc.*, 192 F.R.D. at 117 (same). Since the Plaintiffs have alleged that Abbott engaged in a scheme to illegally market Depakote in an off-label manner and to pay illegal remuneration to physicians to prescribe and promote Depakote for eleven years, including for an entire year in which a majority of the 2012 Board served as directors, Plaintiffs have alleged a scheme of magnitude and duration substantial enough to warrant the inference that the Board was aware it.

However, even without this inference, the Plaintiffs have alleged additional "red flags" in the Second Amended Complaint from which it could be reasonably inferred that a majority of

the 2012 Board had notice of the off-label marketing scheme. A court may infer that a board has notice of illegal conduct if a red flag that the conduct is occurring is waved in the board's face. *See Wood*, 953 A.2d at 143 ("Under Delaware law, red flags are only useful when they are either waved in one's face or displayed so that they are visible to the careful observer.") (internal citations and quotations omitted).

The first new red flag identified in the Second Amended Complaint is the allegation that the Department of Justice sent a letter to Abbott's law department on April 17, 2008 in which it informed Abbott that it was investigating the promotion and marketing of Depakote. The letter directed the law department to "advise the company, its employees, agents, assigns, and related or affiliated entities or persons, to preserve and not destroy any records related in any way to Depakote and/or its marketing and promotion." (Doc. 226-4.) The letter also stated that the DOJ would issue multiple subpoenas requesting documents related to the investigation. (*Id.*) Subsequently, on July 10, 2008, the DOJ began to issue subpoenas to Abbott requesting information regarding the promotion and sale of Depakote. (Doc. 220 at ¶ 298.) The subpoenas are the second new red flag identified by the Plaintiffs. These subpoenas directed Abbott to collect responsive information from its employees, including its present and former officers, directors, and representatives from January 1, 1997 through the date of service. (*Id.*) Among other things, these subpoenas requested documents pertaining to marketing, promotional, educational, or continuing medical materials based on the clinical trials/studies of Depakote. (*Id.*) They also requested all articles, reprints, abstracts, posters, monographs, and training materials provided by Abbott to sales and marketing employees regarding the use of Depakote to treat agitation, aggression, or any other condition or symptom associated with long term care residents or other elderly persons. (*Id.*) It is reasonable to infer that the receipt of the document

preservation letter and subsequent subpoenas from the DOJ put the Board on notice that the alleged off-label marketing practices were occurring in 2008.

Defendants' arguments to the contrary are unavailing. First, Defendants argue that the preservation letter and the subpoenas do not constitute "red flags" because there are no allegations that the Board was aware of them. This Court held in its prior opinion that merely pleading the existence of compliance mechanisms is insufficient to establish knowledge or awareness by a board of directors. *See Depakote I*, 2012 WL 5561268, at *9 (citing *Garza v. Belton*, No. 08 C 1387, 2010 WL 3324881, at *8 (N.D. Ill. Aug. 13, 2010; *In re Huron Consulting*, 971 N.E. 2d 1067 (Ct. App. 2012)). However, Plaintiff has alleged more than the mere existence of compliance mechanisms. The Plaintiffs allege that these documents were specifically directed to the Board. (*E.g.*, Doc. 220, ¶ 298 ["This subpoena requested documents from the Company's employees, including its present and former officers, directors, and representatives from January 1, 1997 through the date of service."].) It is reasonable to infer that the Board was aware of subpoenas issued by the DOJ that specifically directed Abbott to collect responsive documents from the Board. Any other conclusion would be preposterous.[9]

Defendants also argue that even if the Board was aware of the preservation letter and the subpoenas, no substantial risk of liability is established because there is no allegation that the Board allowed the wrongdoing to continue. In support the Defendants cite the Court's discussion in *Depakote I* that a March 2010 order by a district court that required Abbott to produce deleted e-mails did not constitute a red flag because there were no allegations that the

[9] In *In re Johnson & Johnson Derivative Litigation*, the Court found that the existence of subpoenas did not constitute a "red flag" because there were no specific allegations demonstrating the board's knowledge of the subpoenas. *See* 865 F. Supp. 2d 545, 565 (D.N.J. 2011) ("[T]here are no allegations regarding meeting dates, who was actually present at the meetings, or what subjects were discussed. Without this sort of factual detail, the Court cannot infer that a majority of the Board knew about the substance of the 2005 subpoenas, or any other subpoenas or government investigations."). However, unlike in *Johnson & Johnson*, it is reasonable to infer that the Board had knowledge of the subpoenas in this case because Plaintiffs allege that the subpoenas directed Abbott to collect responsive documents from its directors.

Board allowed off-label marketing to continue after it received the subpoena or the order. However, with some minor exceptions, the conduct alleged in *Depakote I* all occurred prior to the time the majority of the relevant Board became directors and prior to March 2010. Conversely, the Plaintiffs have now sufficiently alleged that the illegal off-label marketing of Depakote persisted until at least December 31, 2008, which is after a majority of the 2012 Board was appointed. These subpoenas were also issued while the illegal conduct continued to occur. Therefore, unlike before, Plaintiff has now sufficiently alleged that the Board allowed illegal conduct to persist after it was aware, or should have been aware, that the conduct was occurring.[10]

III. The Second Amended Complaint Adequately Raises a Reasonable Doubt that the Board Exercised Proper Business Judgment

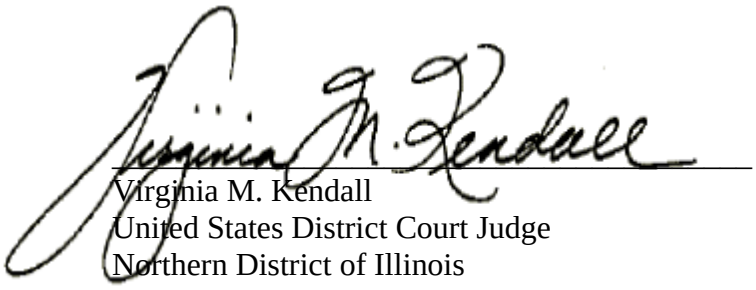
Since the Court has now found that the Second Amended Complaint sufficiently alleges that a majority of the 2012 Board had notice that Abbott's illegal scheme to market Depakote for off-label purposes was occurring while they served as directors, the Court must determine whether Plaintiffs have sufficiently raised a reasonable doubt the that the Board's decision to not act was the product of reasonable business judgment. *See In re Abbott Labs.*, 325 F.3d at 806-07 (holding that if a complaint adequately alleges that a board of directors was aware of potential problems but takes no action, demand futility should be analyzed under *Aronson*). "The business judgment rule is a presumption that in making a business decision, 'the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action was taken in the best interests of the company.'" *Id.* at 808 (quoting *Aronson*, 473 A.2d at 812). However, the

[10]Plaintiffs also argue that the redacted PPD Presentations were red flags. Plaintiffs concede that there is nothing visibly incriminating in the PPD Presentations. Instead, they ask the Court to draw the inference that the redacted material is incriminating. However, since the Court has already found that the Plaintiffs sufficiently alleged demand futility based on the Civil Settlement Agreement, the preservation letter and the subpoenas, it does not need to decide whether it is reasonable to infer that redacted material contains incriminating information. Additionally, the Court previously held that the letter sent to Leber by the FDA and the OEC presentations did not constitute red flags for the Board. *See Depakote I*, 2012 WL 5561268, at *10-12.

business judgment rule does not apply when a Board has notice of illegal conduct occurring on its watch, does nothing to remedy the situation and that inaction results in a loss to the company. *See id.* at 809 (holding that the plaintiff's allegations raised a reasonable doubt as to the application of the business judgment rule because the complaint alleged the directors knew of violations of law and took no steps to remedy the situation, ultimately resulting in substantial corporate losses). As described above, the Plaintiffs have alleged particularized facts demonstrating that a majority of the relevant Board had notice that Abbott was engaging in illegal conduct, did nothing to remedy the situation, which resulted in a $1.6 billion loss to Abbott. Therefore, Plaintiffs have sufficiently raised a reasonable doubt that the Board's inaction will not be afforded the protection of the business judgment rule.

CONCLUSION

For the reasons set forth above, the Court denies the Defendants' motion to dismiss. Ordinarily, Defendants would now have fourteen days to serve a responsive pleading. *See* Fed. R. Civ. P. 12(a)(4)(A). However, due to the complexity of the allegations and the length of the Second Amended Complaint, the Defendants shall have twenty-eight days to answer the Second Amended Complaint.



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

Date: June 5, 2013