

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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|-----------------------------|---|--------------------------------|
| JERALD KING,                | : |                                |
|                             | : |                                |
| Plaintiff,                  | : |                                |
|                             | : |                                |
| v.                          | : | Civil Action No. 08-54-GMS-MPT |
|                             | : |                                |
| FRANK BALDINO, JR., et al., | : |                                |
|                             | : |                                |
| Defendants.                 | : |                                |

**MEMORANDUM ORDER**

**INTRODUCTION**

This is a stockholder derivative suit. On January 25, 2008, Jerald King (“plaintiff”) brought this action on behalf of nominal defendant Cephalon, Inc. (“Cephalon” or “the Company”). Cephalon has an eight member board of directors (“the Cephalon Board” or “the Board”). Defendant Dr. Frank Baldino, Jr., (“Baldino”) is Cephalon’s CEO and Chairman of the Cephalon Board.<sup>1</sup> Defendants William P. Egan, Martyn D. Greenacre, Gail R. Wilensky, Vaughn M. Kailian, Charles A. Sanders, Dennis L. Winger, and Kevin E. Moley are all independent, outside directors of the Company.<sup>2</sup>

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<sup>1</sup> D.I. 1, ¶ 8 (Verified Shareholder Derivative Complaint). Plaintiff avers that he owns and has owned shares of Cephalon at all times relevant to this suit. D.I. 1, ¶ 6. On March 12, 2009, the parties consented, pursuant to 28 U.S.C. § 636(c) and Fed. R. Civ. P. 72, to the jurisdiction of United States Magistrate Judge Mary Pat Thyngne to enter a final order with respect to defendants’ motion for judgment on the pleadings. See D.I. 38.

<sup>2</sup> D.I. 1, ¶¶ 8-15. Baldino has served as Chief Executive Officer and a director since 1987, and as Chairman of the Board since 1999. Egan has served as a director of the Company since 1988. Egan is the Presiding Director of the Company and serves on the Audit Committee of the Board. Greenacre has served as a director since 1992; serves on the Stock Option and Compensation Committee; and is Chairman of the Corporate Governance and Nominating Committee of the Board. Kailian has served as a director since 2005; serves on the Stock Option and Compensation Committee; and serves on the Corporate Governance and Nominating Committee of the Board. Moley has served as a director since 2006 and serves on the Audit Committee of the Board. Sanders has served as a director since 2001 and is Chairman of the Stock Option and Compensation Committee of the Board. Wilensky has served as a director since 2002 and serves on the Corporate Governance and Nominating Committee. Winger has served as a director since 2003 and serves as Chairman of the Audit Committee of the Board.

The complaint alleges that defendants breached their fiduciary duties to the Company by failing to adequately oversee Cephalon's sales and promotions practices with respect to certain of its pharmaceutical products: Actiq, Provigil, and Gabitril. That oversight failure has allegedly resulted in large losses to the Company and the possibility of future losses.

Currently before the court is defendants' motion for judgment on the pleadings.<sup>3</sup>

## **BACKGROUND FACTS<sup>4</sup>**

Cephalon is an international biopharmaceutical company dedicated to the discovery, development, and marketing of innovative products to treat human diseases, focusing on four core therapeutic areas: central nervous system disorders, pain, oncology, and addiction. There are eight members of the Cephalon Board. Baldino is Cephalon's CEO and Chairman of the Board of Directors. The other seven defendants comprise the remainder of the Cephalon Board and are each independent, outside directors of the Company. The Company's most significant products are the drugs Provigil and Actiq, comprising approximately 48% and 23%, respectively, of the Company's consolidated net sales for the six months ended June 30, 2007.

Actiq is used to treat "breakthrough cancer pain," one of the most challenging and debilitating components of cancer pain management.<sup>5</sup> The drug is in the form of a

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<sup>3</sup> D.I. 18 (Motion of Defendants for Judgment on the Pleadings).

<sup>4</sup> Unless otherwise noted, the recited facts are contained in plaintiff's complaint. Much of plaintiff's complaint is supported by two articles, dated November 3, 2006 and November 21, 2006, published in *The Wall Street Journal*. Excerpts from those articles are included in the complaint at paragraphs 30 and 31.

<sup>5</sup> D.I. 20, Ex. A at 8 (Cephalon, Inc., Annual Report of Form 10-K for Fiscal Year Ended Dec. 31, 2007 (Filed on Feb. 28, 2007)). "Breakthrough pain is a transitory flare of moderate to severe pain that 'breaks through' the medication patients use to control their persistent pain. Breakthrough cancer pain typically develops rapidly, can reach maximum intensity in three to five minutes and typically lasts for 30 to 60 minutes. Breakthrough pain may be related to a specific activity, or may occur spontaneously and unpredictably. Cancer patients who suffer from breakthrough pain may suffer a number of episodes every

lollipop which delivers fentanyl citrate, an opioid analgesic, through the lining of the mouth thereby achieving rapid absorption of fentanyl into the bloodstream and providing pain relief that may begin within fifteen minutes. The United States Food and Drug Administration (“FDA”) approved Actiq in November 1998, and Anesta Corp. (“Anesta”) launched it in the United States in 1999. Cephalon acquired Anesta in October 2000 and relaunched Actiq in February 2001.<sup>6</sup> Actiq is sometimes prescribed by doctors for non-FDA approved, or “off-label,” uses such as headaches or back pain. Actiq is a powerful narcotic having a high potential for abuse that could prove fatal for those who do so.

Provigil was launched in the United States in February 1999 “to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.”<sup>7</sup> The active ingredient in Provigil, modafinil, “act[s] selectively in regions of the brain believed to regulate normal sleep and wakefulness.”<sup>8</sup> In January 2004, the FDA approved expansion of the Provigil label to include improving wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (“OSA/HS”) and shift work sleep disorder (“SWSD”).<sup>9</sup> Provigil is sometimes used off-

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day. Breakthrough pain can have a profound impact on an individual’s physical and psychological well-being and is often associated with a more severe and difficult to treat pain condition.” *Id.*

<sup>6</sup> *Id.*, Ex. A at 9.

<sup>7</sup> *Id.*, Ex. A at 3. “Narcolepsy is a debilitating, lifelong sleep disorder . . . . Its most common symptom is an uncontrollable propensity to fall asleep during the day.” *Id.*, Ex. A at 5.

<sup>8</sup> *Id.*, Ex. A at 3.

<sup>9</sup> *Id.* “Individuals with OSA/HS experience frequent awakenings, sometimes occurring hundreds of times during the night as a result of blockage of the airway passage, usually caused by the relaxation and collapse of the soft tissue in the back of the throat during sleep.” *Id.*, Ex. A at 5. SWSD is “a persistent or recurrent pattern of sleep disruption that leads to excessive sleepiness or insomnia due to a mismatch between the natural circadian sleep-wake pattern and the sleep-wake schedule required by a person’s environment. SWSD particularly affects those who frequently rotate shifts or work at night, which is contrary to the body’s natural circadian rhythms.” *Id.*

label by people without any illness who take the drug to stay awake.

Gabitril “is a selective GABA (gamma-aminobutyric acid) reuptake inhibitor approved for use as adjunctive therapy in the treatment of partial seizures in epileptic patients.”<sup>10</sup> Gabitril is used off-label for anxiety, pain, and other conditions. Off-label use of Gabitril has caused seizures in some who did not have epilepsy. Working with the FDA, Cephalon updated its prescription information for Gabitril, in February 2005, “to include a bolded warning describing the risk of new onset seizures in non-induced patients without epilepsy,” and thereafter “actively communicated this risk to physicians and otherwise limited [the Company’s] sales and marketing efforts” for that drug.<sup>11</sup>

Drug companies are required to apply to the FDA for approval to sell a new drug. During the approval process, the manufacturer frequently seeks approval for several different purposes, but the FDA often approves the drug for narrower uses than sought. Many times, manufacturers lobby doctors to prescribe a drug for a non-approved, off-label use and sales of a drug for off-label use frequently exceed that for FDA-approved use. Because off-label uses are not approved by the FDA, there are strict regulations regarding promotions for off-label use. The Food and Drug Administration Modernization Act of 1997 (“FDAMA”), 21 U.S.C. § 360aaa, *et seq.*, specifically authorizes a manufacturer to disseminate “written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device,” if that information complies with specific requirements listed in the act,

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<sup>10</sup> *Id.*, Ex. A at 7. “Epilepsy is a chronic disorder characterized by seizures that cause sudden, involuntary, time-limited alteration in behavior, including changes in motor activities, autonomic functions, consciousness or sensations, and accompanied by an abnormal electrical discharge in the brain.” *Id.*

<sup>11</sup> *Id.*

including the requirement that such manufacturers may only provide “authorized information” in the form of unabridged peer-reviewed articles or qualified reference publications.

In November 1998, the FDA approved Actiq for the treatment of breakthrough cancer pain, and limited marketing of the drug to oncologists and pain specialists knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.<sup>12</sup> When Cephalon acquired Actiq from Anesta in 2000, the drug had sales of \$15 million. In late 2001, Cephalon issued a new standard operating procedure “for interpreting the FDA’s risk-management program” by “expand[ing] the definition of pain specialists . . . to include anesthesiologists, physical medicine, rehabilitation medicine and palliative medicine.” This new procedure freed Cephalon from a requirement that it alert the FDA and take remedial action if any physician specialty other than oncologists or pain specialists accounted for more than 15% of Actiq prescriptions.

In 2002, pursuant to the new standard operating procedure, Cephalon “began to push the use of Actiq in patients with migraines by targeting neurologists even though its internal marketing documents for that year make clear that it didn’t expect them to prescribe the drug for cancer pain.” A document titled “Actiq in Migraine” instructed the Company’s sales representatives to pitch Actiq as “an ER on a stick.” In its Form 10-Q filed with the SEC for the period ending June 30, 2002, Cephalon attributed a sales increase of 92% for Actiq to “a dedicated sales force” and “ongoing changes in our

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<sup>12</sup> Additional limitations included that Actiq was “contraindicated in the management of acute or postoperative pain;” “must not be used in opioid non-tolerant patients;” and “is intended to be used only in the care of cancer patients.” D.I. 1, ¶ 27.

marketing approach.” Plaintiff alleges that, in reality, the change in approach was to focus on off-label marketing in violation of FDA and FDAMA mandates.

In 2003, a Cephalon compliance auditor, David Brennan, concluded that the company was failing to comply with FDA reporting requirements for Actiq. Specifically, that the Company did not report to the FDA every quarter when groups of physicians who represent potential off-label usage greater than 15% were prescribing Actiq. According to data reported in a *Wall Street Journal* article, which Cephalon did not dispute, during the first half of 2006, two specialties exceeded 15% of Actiq prescriptions: anesthesiologists at 29.5% and physical medicine and rehabilitation specialists at 16%. That data show oncologists and pain specialists accounting for less than 3% of prescriptions. After Brennan sought to have the findings of his audit published, he was terminated by Cephalon in February 2004. Cephalon purportedly offered Brennan money and job-search assistance if he agreed not to disclose the audit. Brennan refused that offer.

A *Wall Street Journal* article also reported a survey showing that between 2002 and 2005, visits by Cephalon sales representatives to non-cancer doctors to pitch Actiq increased sixfold. The doctors surveyed reported more than 300 visits by Cephalon sales representatives in both 2004 and 2005. During that time, Cephalon set high sales quotas and pushed for larger prescriptions at higher doses to expand sales of Actiq. Those higher sales quotas purportedly could not be reached without promoting the drug for off-label uses. Cephalon also flew doctors to seminars it sponsored at which speakers promoted off-label uses of Actiq.

In 2000, when Cephalon acquired Actiq, the drug had sales of \$15 million. By

2005, sales of the drug had increased to \$412 million, making it Cephalon's second highest selling drug, and in the first nine months of 2006, sales increased to \$471 million. Between June 2005 and October 2006, data suggested that more than 80% of patients using Actiq did not have cancer. In the first half of 2006, oncologists accounted for only 1% of Actiq prescriptions filled at retail pharmacies in the U.S. Also in 2006, analysts similarly estimated that approximately 80% of Provigil prescriptions, Cephalon's top selling drug, were for off-label usage. In 2005, under FDA pressure, Cephalon curtailed its marketing of Gabitril because it was causing seizures in patients without epilepsy, and sales dropped 23%.

On November 9, 2007, Cephalon filed with the SEC its Form 10-Q for its Third Quarter ended September 30, 2007. That filing reported that in September 2004, the U.S. Attorney's Office ("USAO") in Philadelphia began an investigation focusing on Cephalon's sales and promotional practices with respect to Actiq, Gabitril, and Provigil. Also in September 2004, Cephalon received a voluntary request for information from the Office of the Connecticut Attorney General that focused on the Company's sales and promotional practices with respect to those drugs.

In March 2007, Cephalon received a letter from Congressman Henry A. Waxman in his capacity as Chairman of the House Committee on Oversight and Government Reform. That letter requested information related the Company's sales and marketing practices for Actiq and Fentora, among other things. In late October 2007, Cephalon received a civil demand for information from the Office of the Massachusetts Attorney General which focused on sales and promotional practices with respect to Actiq,

Fentora,<sup>13</sup> and certain other of its products.

The Company reported that the requests for information from both the Connecticut and Massachusetts attorneys general “may involve civil penalties and/or fines.” The Company stated that it was providing documents and other information in cooperation with each of those separate inquiries, as well as the Waxman Committee. The Company also advised that, in November 2007, it was served with a “putative class action complaint filed on behalf of entities that claim to have purchased ACTIQ for use in non-cancer patients.”

Finally, Cephalon announced that in early November 2007, it had reached an agreement in principal with the Philadelphia USAO under which Cephalon was to pay \$425 million as part of a comprehensive settlement of all Federal and related state Medicaid claims. The Company also agreed to a single federal misdemeanor violation of the Federal Food, Drug and Cosmetic Act and agreed to enter into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.

Plaintiff’s complaint for breach of fiduciary duty is premised upon the defendants’ sustained and systematic failure to oversee Cephalon’s operations, including ignorance of liability creating activities within the corporation, which purportedly caused damage to the Company.

## **DISCUSSION**

Pursuant to Federal Rules of Civil Procedure 9(b), 12(c), and 23.1, defendants

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<sup>13</sup> Like Actiq, Fentora is an opioid used for the management of breakthrough pain in patients with cancer that delivers fentanyl through the lining of the mouth. D.I. 20, Ex. A at 8.

move for judgment on the pleadings dismissing the Verified Shareholder's Derivative Complaint on the grounds that plaintiff failed to make demand on Cephalon's Board of Directors or state a claim upon which relief can be granted.

Generally, judgment on the pleadings under Fed. R. Civ. P. 12(c) is appropriate when there are no material issues of fact. The moving party is required to show that it is entitled to judgment as a matter of law.<sup>14</sup> The court does not consider matters outside the pleadings, and it must accept the non-moving party's allegations as true, drawing all reasonable inferences in the non-movant's favor.<sup>15</sup> The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and the documents incorporated by reference.<sup>16</sup> A motion for judgment on the pleadings under Rule 12(c) is treated in the same manner as a Rule 12(b)(6) motion to dismiss.<sup>17</sup>

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted.<sup>18</sup> The purpose of a Rule 12(b)(6) motion to dismiss is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case.<sup>19</sup> Evaluating a motion to dismiss under Rule 12(b)(6) requires the court to accept as true all material allegations of the complaint.<sup>20</sup> "The issue is not whether a plaintiff will ultimately prevail, but whether the claimant is entitled to offer

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<sup>14</sup> *Sikirica v. Nationwide Ins. Co.*, 416 F.3d 214, 220 (3d Cir. 2005); *Inst. for Sci. Info., Inc. v. Gordon & Breach Sci. Publishers, Inc.*, 931 F.2d 1002, 1005 (3d Cir. 1991).

<sup>15</sup> *Mele v. Fed. Reserve Bank*, 359 F.3d 251, 257 (3d Cir. 2004); *Inst. for Sci. Info., Inc.*, 931 F.2d at 1005; *Taj Mahal Travel, Inc. v. Delta Airlines, Inc.*, 164 F.3d 186, 189 (3d Cir. 1998).

<sup>16</sup> Wright and Miller, *5C Fed. Prac. & Proc. Civ. 3d* § 1367 (1990).

<sup>17</sup> *Spruill v. Gillis*, 372 F.3d 218, 223 n.2 (3d Cir. 2004).

<sup>18</sup> Fed. R. Civ. P. 12(b)(6).

<sup>19</sup> *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

<sup>20</sup> *Spruill*, 372 F.3d at 223.

evidence to support the claims.”<sup>21</sup> A motion to dismiss may be granted only if, after, “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to the plaintiff, plaintiff is not entitled to relief.”<sup>22</sup>

To survive a motion to dismiss under Rule 12(b)(6), however, the factual allegations must be sufficient to “raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).”<sup>23</sup> A plaintiff is obliged “to provide the ‘grounds’ of his ‘entitle[ment] to relief’ beyond labels and conclusions.”<sup>24</sup> Although heightened fact pleading is not required, “enough facts to state a claim to relief that is plausible on its face” must be alleged.<sup>25</sup> While the court assumes that all factual allegations in the complaint are true and draws all reasonable factual inferences in the light most favorable to the plaintiff, it rejects unsupported allegations, “bald assertions,” or “legal conclusions.”<sup>26</sup> “When a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.”<sup>27</sup>

“Courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record” when reviewing a

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<sup>21</sup> *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks and citation omitted).

<sup>22</sup> *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks and citations omitted).

<sup>23</sup> *Bell Atlantic Corporation v. Twombly*, 127 S. Ct. 1955, 1965 (2007); *see also Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007).

<sup>24</sup> *Twombly*, 127 S. Ct. at 1965.

<sup>25</sup> *Id.* at 1974.

<sup>26</sup> *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations omitted); *see also Schuylkill Energy Res., Inc v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (“unsupported conclusions and unwarranted inferences” are insufficient); *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996) (allegations that are “self-evidently false” are not accepted).

<sup>27</sup> *Twombly*, 127 S. Ct. at 1969.

motion to dismiss.<sup>28</sup> A court may, however, also consider “matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders [and] items appearing in the record of the case.”<sup>29</sup> A plaintiff is entitled to notice and a fair opportunity to respond to any evidence the court might consider in its review of a motion to dismiss.

Defendants contend that they are entitled to judgment on the pleadings with respect to plaintiff’s derivative complaint on either, or both, of two grounds. First, defendants assert that plaintiff failed to make the pre-suit demand on Cephalon’s Board and has failed to allege facts demonstrating why demand would have been futile as required by Fed. R. Civ. P. 23.1. Second, defendants contend that plaintiff has not alleged any set of facts on which he can prevail on his breach of fiduciary duty claim.

According to defendants, plaintiff failed to meet the particularized pleading requirements of Fed. R. Civ. P. 23.1 which states, in relevant part, that a derivative plaintiff must “state with particularity: (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.”<sup>30</sup> The Third Circuit has held that:

Rule 23.1 requires a plaintiff to plead with particularity . . . the reasons why

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<sup>28</sup> *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 988 F.2d 1192, 1196 (3d Cir. 1993).

<sup>29</sup> *Buck v. Hampton Tp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (quoting 5B Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1357 (2004)).

<sup>30</sup> Fed. R. Civ. P. 23.1(b)(3). The demand requirement of Rule 23.1 is procedural. See *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 96 (1991). Federal courts, therefore, must combine federal procedural law with state substantive law to analyze demand futility. See *Blasband v. Rales*, 971 F.2d 1034, 1047 (3d Cir. 1992) (citations omitted) (“The substantive requirements of demand are a matter of state law. Thus, Delaware law governs the substantive requirements of [plaintiff’s] claims, including the demand component.”).

no effort was made to demand action from the board. Where a plaintiff has made no demand on the board, a court may excuse the rule's requirement if it determines that demand would have been futile. But a plaintiff is obliged to plead, with particularity, facts that establish demand futility.<sup>31</sup>

“A cardinal precept of the General Corporation Law of the State of Delaware is that directors, rather than shareholders, manage the business and affairs of the corporation.”<sup>32</sup> Therefore,

[t]he decision to bring a lawsuit or to refrain from litigating a claim on behalf of the corporation is a decision concerning the management of the corporation and consequently is the responsibility of the directors. Accordingly, because a derivative action impinges on the managerial freedom of directors, the demand requirement exists at the threshold, first to insure that a stockholder exhausts his intracorporate remedies, and then to provide a safeguard against strike suits.<sup>33</sup>

Defendants argue that plaintiff neither made the required demand on the Cephalon Board nor adequately explains why demand would have been futile. Plaintiff acknowledges that he did not make a pre-suit demand on the Cephalon Board, but argues that the complaint sets forth the reasons that demand would have been futile in this case.

Here, plaintiff does not challenge an affirmative action taken by the Cephalon Board as the basis of his allegation of breach of fiduciary duties; rather, he alleges that those breaches were a result of inaction, specifically a lack of oversight, on the part of defendants. In *Rales v. Blasband*, the Delaware Supreme court stated that to show “demand futility” when a derivative plaintiff challenges a board’s failure to fulfill its

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<sup>31</sup> *Kanter v. Barella*, 489 F.3d 170, 176 (3d Cir. 2007).

<sup>32</sup> *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984) (citing 8 *Del. C.* § 141(a)), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

<sup>33</sup> *Blasband*, 971 F.2d at 1048 (citations and internal quotation marks omitted).

fiduciary duties through inaction, as opposed to through the exercise of its business judgment, the relevant inquiry is whether the plaintiff has made “particularized factual allegations” that “create 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. If the derivative plaintiff satisfies this burden, then demand will be excused as futile.”<sup>34</sup> A court applying the *Rales* analysis first analyzes “whether the underlying conduct complained of in the complaint . . . renders any of the board members ‘interested.’”<sup>35</sup> Next, if any of the board members are interested, the court considers “whether any of the other members of the board are compromised in their ability to act independently of the directors found to be interested.”<sup>36</sup> Finally, “[i]f a majority of the board is impartial under [the] initial analysis,” the court must then “consider whether the complaint sets forth particularized facts that plead a non-exculpated claim of breach of fiduciary duty against a majority of the board, thereby stripping away their first-blush veneer of impartiality.”<sup>37</sup> Plaintiff makes several allegations purportedly demonstrating that demand is excused due to defendants’ disabling interest or lack of independence.

Plaintiff maintains that demand should be excused as a result of the alleged financial interest of the defendant directors due to benefits each receive for their service on the Board and their lack of independence based on the receipt of those benefits. The complaint alleges that “[t]he members of the Cephalon Board . . . receive

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<sup>34</sup> 634 A.2d 927, 934 (Del. 1993) (emphasis added).

<sup>35</sup> *Guttman v. Huang*, 823 A.2d 492, 501 (Del. Ch. 2003).

<sup>36</sup> *Id.* at 501-02.

<sup>37</sup> *Id.* at 502.

substantial benefits, and other emoluments by virtue of their membership on the Board and their control of Cephalon.”<sup>38</sup> Cephalon’s “non-management directors receive an annual retainer of \$35,000” and each Board member receives an additional \$3,000 for in-person attendance at Board meetings or \$2,000 for telephonic attendance. Also, Winger receives a \$12,000 retainer as Audit Committee Chair, and each Committee member receives a \$10,000 retainer. Board members also receive stock option grants of 15,000 shares when first elected or appointed to the Board and an annual grant of 10,000 shares upon the date of each annual meeting of the Board.

Based on the benefits received by the defendant directors, the complaint makes the conclusory allegation that “[t]he known principal wrongdoers are in a position to, and do, dominate and control the Cephalon Board, paying them high annual and monthly fees to assure their compliance. Thus, the Board could not exercise independent objective judgment in deciding whether to bring this action nor vigorously prosecute this action.” Similarly, the complaint alleges that, because of the receipt of those benefits, “[b]ringing an action or even adequately investigating other directors, who have the power to terminate a director’s employment, would not *likely* occur. The defendants are incapable of exercising independent objective judgment in deciding whether to bring this action.”<sup>39</sup>

The court determines that plaintiff’s allegations concerning benefits received by the director defendants does not demonstrate that they had either a disabling interest or

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<sup>38</sup> “Cephalon’s non-employee directors receive lucrative compensation for their service on the Board.”

<sup>39</sup> Emphasis added.

lacked independence. The Delaware Supreme Court has held that allegations “that directors are paid for their services as directors . . . without more, do not establish any financial interest.”<sup>40</sup> This “is not an unvarying principle that mechanically applies irrespective of the circumstances. Conceivably a situation might arise where directors’ compensation, in the form of ‘directors’ fees,’ becomes so lavish that a mechanical application of the presumption would be totally at variance with reality.”<sup>41</sup> Here, however, the court agrees with defendants that plaintiff does not allege that the benefits received by the director defendants “are unusual in kind or in degree from those received by directors of other corporations.” The benefits of membership on the Board received by defendant directors does not appear to be so lavish as to create a disabling interest.<sup>42</sup>

Similarly, those benefits do not support plaintiff’s contention that the defendant

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<sup>40</sup> *Grobow v. Perot*, 539 A.2d 180, 188 (Del. 1988), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

<sup>41</sup> *In re National Auto Credit, Inc. Shareholders Litig.*, No. Civ. A. 19028, 2003 WL 139768, at \*11 (Del. Ch. Jan. 10, 2003); *see also Orman v. Cullman*, 794 A.2d 5, 29 n.62 (Del. Ch. 2002) (“This Court’s view of the disqualifying effect of such fees might be different if the fees were shown to exceed materially what is commonly understood and accepted to be a usual and customary director’s fee.”).

<sup>42</sup> *See, e.g., In re Walt Disney Co. Deriv. Litig.*, 731 A.2d 342, 355, n.18 (Del. Ch. 1998) (“Plaintiffs also allege that many of the directors are interested because they receive director fees and stock options. For example, non-management directors receive \$30,000 a year, plus \$1,000 for each Board or committee meeting they attend. Under Delaware law, the receipt of such customary payments and benefits has been held insufficient to demonstrate . . . interest . . . .” (citing *Grobow*, 539 A.2d at 188.)) *rev’d on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000); *Amalgamated Bank v. Yost*, No. Civ. A. 04-0972, 2005 WL 226117, at \*9 (E.D. Pa. Jan. 31, 2005) (finding the allegation that the defendant directors “receive a \$50,000 per year stipend, along with stock options and fees for attending meetings” insufficient to establish director interest); *see also Poland v. Caldwell*, 89-645, 89-1255, 1990 WL 158479, at \*4 (E.D. Pa. Oct. 12, 1990) (“[C]ourts have clearly held that allegations of directors receiving the common perquisites given to a board of directors is not sufficient to show self-dealing, because if this were sufficient, all boards would be self-interested”); *cf. In re National Auto Credit*, 2003 WL 139768, at \*11 (finding that “there is nothing ‘usual and customary’ about the Directors’ Fees” where, among other additional compensation, defendant directors’ received “an increase in directors’ compensation from \$1,000 per meeting to \$55,000 annually” in connection with certain challenged transactions). The *National Auto* court made clear that “[i]t is not that the Directors’ Fees are large amounts paid on a regular basis; rather, the Directors’ Fees were the product of massive increases which reasonably can be inferred to have been granted in return for the Defendant Directors’ support of the [challenged transactions]”. *Id.*

directors lack independence.<sup>43</sup> Moreover, although the plaintiff alleges that “the known principal wrongdoers are in a position to, and do, dominate and control the Cephalon Board, paying them high annual and monthly fees to assure their compliance,” plaintiff fails to particularly identify who the “principal wrongdoers” are. In determining the question of independence, the court must determine “independent from whom and independent for what purpose.”<sup>44</sup> Other than receipt of the benefits received by membership in the Board, which by itself it not sufficient to demonstrate control, plaintiff fails to allege particular facts demonstrating that the directors were otherwise controlled by these unknown “principal wrongdoers.”<sup>45</sup>

The complaint also alleges demand would be futile because:

In order to bring this action for breach of fiduciary and common law duties, *the members of the Board would have been required to sue themselves and/or their fellow directors* and allies in the top ranks of the Company,

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<sup>43</sup> See, e.g., *White v. Panic*, 793 A.2d 356, 366 (Del. Ch.2000) (“[T]he fact that each [director] is paid an annual retainer of \$30,000 plus a fee of \$1000 for each meeting attended and annual grants of stock options does not make them beholden to [the company’s CEO.]”); *Richardson v. Ulsh*, No. 06-3934 (MLC), 2007 WL 2713050, at \*15 (D.N.J. Sept. 13, 2007) (“Under Delaware law, a shareholder plaintiff cannot show demand futility by alleging that certain directors lack independence because they receive compensation for serving on the board. Therefore, this Court finds that Plaintiff has not set forth facts sufficiently suggesting that any of the Individual Defendants were beholden to the members of the compensation committee.” (citations omitted)); see also *In re Walt Disney*, 731 A.2d at 359-60 (The fact that the salary a director defendant received from her primary occupation was low compared to her director’s fees and stock options was insufficient to demonstrate that the director lacked independence.) *rev’d on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000). The court also notes that seven of the director defendants are also independent or outside directors. See *Moran v. Household Int’l, Inc.*, 490 A.2d 1059, 1074-75 (Del. Ch. 1985) (“Where a majority of the directors are independent or outside directors receiving no income other than the usual directors’ fees the presumption of good faith is heightened.”).

<sup>44</sup> *Beam v. Stewart*, 845 A.2d 1040, 1049-50 (Del. 2004); see also *Aronson*, 473 A.2d at 815 (“There must be coupled with the allegation of control such facts as would demonstrate that through personal or other relationships the directors are beholden to the controlling person.”), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

<sup>45</sup> See *Aronson*, 473 A.2d at 816 (“[I]n the demand-futile context a plaintiff charging domination and control of one or more directors must allege particularized facts manifesting ‘a direction of corporate conduct in such a way as to comport with the wishes or interests of the corporation (or persons) doing the controlling.’ The shorthand shibboleth of ‘dominated and controlled directors’ is insufficient.”) (citation omitted), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

with whom they are well acquainted and with whom they have entangling alliances, interests, and dependencies, which they would not do. They therefore would not be able to vigorously prosecute any such actions.<sup>46</sup>

“It is no answer to say that demand is necessarily futile because . . . the directors ‘would have to sue themselves, thereby placing the conduct of the litigation in hostile hands’ . . . .”<sup>47</sup> Were demand to be found “futile merely because directors would be suing themselves . . . the demand requirement of Rule 23.1” would be eviscerated.<sup>48</sup> Plaintiff’s conclusory allegation is insufficient to demonstrate demand futility. Other than the bald assertion concerning that the directors have “entangling alliances, interests, and dependencies,” there are no particularized facts supporting that assertion. Also, the fact that the directors may be “well acquainted” with each other and that they would have to sue themselves and each other is not sufficient to excuse demand.<sup>49</sup>

The complaint further alleges that:

There was a sustained and systematic failure of the Board to exercise oversight, in that the directors knew of the violations of the law, took no steps in an effort to prevent or remedy the situation, and that failure to take any action for such an inordinate amount of time resulted in substantial corporate losses. The directors’ decision to not act was not made in good faith and was contrary to the best interests of the Company.

The defendants intentionally breached and/or recklessly and/or with gross negligence disregarded their fiduciary duties, choosing to implement a marketing scheme that completely ignored FDA mandates, including the requirement that

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<sup>46</sup> Emphasis added.

<sup>47</sup> *Brehm v. Eisner*, 746 A.2d 244, 257 n.34 (Del. 2000); *Aronson*, 473 A.2d at 815 (holding that “the mere threat of personal liability for approving a questioned transaction, standing alone, is insufficient to challenge either the independence or disinterestedness of directors . . . .”), *overruled on other grounds* by *Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

<sup>48</sup> *Jacobs v. Yang*, No. Civ. A. 206-N, 2004 WL 1728521, at \*6 n.31 (Del. Ch. 2004)

<sup>49</sup> *See, e.g., In re Walt Disney*, 731 A.2d at 355, n.18 (“Plaintiffs allege that the personal interrelationships among the directors somehow render the Director Defendants interested in the disputed transaction. Demand is not excused, however, just because directors would have to sue ‘their friends, family and business associates.’” (quoting *Abrams v. Koether*, 766 F. Supp. 237, 256 (D.N.J. 1991) (applying Delaware law)), *rev’d on other grounds* by *Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

Cephalon advise physicians that Actiq is not medically necessary for the treatment of general aches and pains and is inappropriate other than to manage persistent cancer pain in certain opioid-tolerant terminal cancer patients.

As a result of [the Board's] improper conduct, Cephalon was forced to pay a fine of over \$425 million stemming from the Federal investigations.

Under a *Rales* analysis, directors may be unable to properly consider a demand where “there are allegations that a majority of the board that must consider a demand acted wrongfully . . . [and] the directors face a ‘substantial likelihood’ of personal liability . . . .”<sup>50</sup>

The core of plaintiff’s complaint is that defendants breached their fiduciary duty of loyalty as a result of their failure to act, known as a *Caremark* claim, specifically, the board’s alleged oversight failure.<sup>51</sup> For defendants to be interested such that demand is excused, there must be a substantial likelihood of liability resulting from their alleged oversight failure.

The Delaware Supreme Court held that:

*Caremark* articulates the necessary conditions predicate for director oversight liability: (a) the directors utterly failed to implement any reporting or information systems 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

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<sup>50</sup> *Guttman*, 823 A.2d at 501; see also *Rales*, 634 A.2d at 936 (where “the potential for liability is not ‘a mere threat’ but instead . . . rise[s] to ‘a substantial likelihood’” directors have a “disqualifying financial interest that disables them from impartially considering a response to a demand . . .”). Defendants note that Cephalon has adopted a provision pursuant to 8 *Del. C.* § 102(b)(7) which protects the directors from liability for money damages resulting from the breach of certain fiduciary duties. Here, that provision is not determinative as plaintiff alleges breaches of the duty of loyalty, not only breaches of the duty of care. Section 102(b)(7) does not insulate defendants from potential liability for breaches of the duty of loyalty. See *Stone v. Ritter*, 911 A.2d 362, 367 (Del. 2006) (A section 102(b)(7) provision “can exculpate directors from monetary liability for a breach of the duty of care, but not for conduct that is not in good faith or a breach of the duty of loyalty.”).

<sup>51</sup> *In re Caremark Intern. Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996). The *Caremark* decision discusses director liability for breach of fiduciary duty due to inaction, rather than challenging an affirmative act of defendant directors.

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.<sup>52</sup>

A lack of oversight claim “is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.”<sup>53</sup> “[I]mposition of liability [on this theory] requires a showing that the directors knew that they were not discharging their fiduciary duties.”<sup>54</sup> “Only a sustained or systematic failure of oversight . . . will establish the lack of good faith that is a necessary condition to liability.”<sup>55</sup>

[I]n order to state a viable *Caremark* claim, and to predicate a substantial likelihood of director liability on it, a plaintiff must plead the existence of facts suggesting that the board knew that internal controls were inadequate, that the inadequacies could leave room for illegal or material harmful behavior, and that the board chose to do nothing about the control deficiencies that it knew existed.<sup>56</sup>

One way a plaintiff may satisfy his pleading burden is by pleading particular facts which demonstrate that the directors “ignored ‘red flags’ indicating misconduct in defiance of their duties.”<sup>57</sup>

Plaintiff alleges that defendants consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention. He contends the complaint demonstrates a “substantial likelihood” that

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<sup>52</sup> *Stone*, 911 A.2d at 370 (footnotes omitted) (emphasis in original); *id.* at 365 (“Consistent with our opinion in *In re Walt Disney Co. Deriv. Litig.*, [906 A.2d 27 (Del. 2006)] we hold that *Caremark* articulates the necessary conditions for assessing director oversight liability.”).

<sup>53</sup> *Caremark*, 698 at 967.

<sup>54</sup> *Stone*, 911 A.2d at 370 (Del. 2006) (citing *Guttman*, 823 A.2d at 506).

<sup>55</sup> *Caremark*, 698 A.2d at 971.

<sup>56</sup> *Desimone v. Barrows*, 924 A.2d 908, 940 (Del. Ch. 2007).

<sup>57</sup> *David B. Shaev Profit Sharing Account v. Armstrong*, 2006 WL 391931, at \*5 (Del. Ch. Feb. 13, 2006) (citing *Guttman*, 823 A.2d at 506).

defendants will be held liable for their fiduciary breaches, thereby establishing that the entire board has a disabling interest. Plaintiff maintains that the “substantial liability” threshold is met here, because the defendant directors exposed themselves to liability by ignoring “particularly flagrant and reprehensible wrongdoing” involving public safety. Plaintiff argues that the board’s inaction in the face of “red flags” raises a substantial likelihood of liability; that the magnitude and duration of allegedly illegal activities demonstrate the directors’ sustained or systematic failure of oversight; and that the continuing investigations demonstrate the board’s lack of disinterest.

The court first notes that plaintiff does not allege particularized facts which demonstrate what information and reporting systems exist at Cephalon, much less that there is an “utter failure to attempt to assure a reasonable information and reporting system exists . . . .”<sup>58</sup> This inadequacy is likely a result of plaintiff’s apparent failure to make use of 8 *Del. C.* § 220 to examine Cephalon’s books and records from which such particular facts might be gleaned.<sup>59</sup> The Delaware Supreme Court has made clear that:

It is no excuse for plaintiffs to argue that they are unable to allege these particularized facts because they are cut off from access to discovery at the pre-suit demand stage of a derivative suit. Plaintiffs have the opportunity to use the “tools at hand” to learn facts . . . by seeking appropriate and precisely identified corporate records in a Section 220 proceeding.<sup>60</sup>

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<sup>58</sup> *Guttman*, 823 A.2d at 506 (quoting *Caremark*, 698 A.2d at 971).

<sup>59</sup> There is no indication in the parties’ briefing on this motion nor the court’s review of the complaint that a § 220 request was made by plaintiff.

<sup>60</sup> *Brehm v. Eisner*, 746 A.2d 244, 262 n.57 (Del. 2000); see also *White v. Panic*, 783 A.2d 543, 550 n.15 (Del. 2001) (“We have emphasized on several occasions that stockholder ‘[p]laintiffs may well have the ‘tools at hand’ to develop the necessary facts for pleading purposes,’ including the inspection of the corporation’s books and records under 8 Del. C. § 220.”) (quoting *Brehm*, 746 A.2d at 266-67); *Ash v. McCall*, No. Civ. A. 17132, 2000 WL 1370341, at \*15 n.56 (Del. Ch. Sept. 15, 2000) (“I leave it to plaintiffs to adduce such facts through various pre-discovery fact-gathering methods they have at their disposal. As the Delaware Supreme Court has repeatedly exhorted, shareholders plaintiffs should use the ‘tools at hand,’ most prominently § 220 books and records actions, to obtain information necessary to sue

Indeed, the complaint specifically pleads the existence of Cephalon’s oversight mechanism in noting that Egan, Moley, and Winger serve on the Board’s Audit Committee and that the responsibilities of that committee include “ensur[ing] compliance with . . . applicable laws and regulations.” Moreover, an opinion in the wrongful termination suit brought by Brennan also demonstrates that Cephalon had an existing information and reporting system in place.<sup>61</sup> Brennan was hired as a compliance auditor and “conducted an audit of Actiq’s Risk Management Program (‘RMP’) . . . .”<sup>62</sup> Brennan and other Cephalon employees (including Cephalon’s new Director of Quality Assurance and its Vice President of Quality) also conducted an audit of a Cephalon facility located in France which manufactured the active ingredient in Provigil.<sup>63</sup> The audit by Brennan, *et al.*, “concluded that the facility was generally in compliance.”<sup>64</sup> Subsequently, Cephalon also hired an outside consultant to conduct a mock FDA inspection of the French facility in anticipation of an official FDA inspection.<sup>65</sup> That mock inspection “identified several areas where the [French] facility was in violation and needed corrective action.”<sup>66</sup> Cephalon submitted material which stated that “corrective action was taken at the [French] facility based on [the outside consultant’s] mock

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derivatively.”); *cf. Stone*, 911 A.2d at 372 (referencing bank’s “written policies and procedures designed to ensure compliance with the . . . regulations . . . [including a] policy that was produced to plaintiffs in response to their demand to inspect [the bank’s] books and records pursuant to section 220”).

<sup>61</sup> *Brennan v. Cephalon, Inc.*, No. Civ. A. 04-3241 (NLH), 2007 WL 1382801 (D.N.J. May 8, 2007). The Brennan lawsuit is incorporated by reference in the complaint and an opinion from that case is attached as an exhibit to plaintiff’s opposition brief.

<sup>62</sup> *Id.* at \*1.

<sup>63</sup> *Id.* at \*1 & \*1 n.3. The “Director of Quality Assurance,” Armando Cortez, was not a “director” on the Cephalon Board, rather, he was an employee of Cephalon. *Id.* at \*1 (listing Cortez as one of several employees that were originally named as defendants in Brennan’s suit).

<sup>64</sup> *Id.* at \*1.

<sup>65</sup> *Id.* at \*2.

<sup>66</sup> *Id.*

inspection.”<sup>67</sup> Moreover, Brennan testified that the outside consultant “had been hired *several times before* by Cephalon to conduct similar inspections at their other facilities.”<sup>68</sup>

Consequently, the court finds that the complaint fails to demonstrate an utter failure to implement any reporting or information system or controls.

Plaintiff contends that the purported red flags identified in the complaint meet the pleading requirement to show that the Board “consciously failed to monitor or oversee its operations.” To meet that requirement, plaintiff must “plead the existence of ‘red flags’—facts showing that the board ever was aware that [Cephalon’s] internal controls were inadequate, that these inadequacies would result in illegal activity, and that the board chose to do nothing about problems it allegedly knew existed.”<sup>69</sup> It is not enough “with the benefit of hindsight” that it is revealed that internal controls were inadequate and resulted in a large fine.<sup>70</sup> “The fact of those losses, however, is not alone enough for a court to conclude that a majority of the corporation’s board of directors is disqualified from considering demand that [the company] bring suit against those responsible”<sup>71</sup>

The complaint alleges that defendants, through their inaction, allowed violations of law to occur over a more than six-year period which ultimately resulted in damage to the Company. Plaintiff specifically points to allegations in the complaint that: (a) in

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<sup>67</sup> *Id.* at \*2 n.5.

<sup>68</sup> *Id.* at \*2 n.4 (emphasis added).

<sup>69</sup> *Stone*, 911 A.2d at 370 (internal quotation marks omitted).

<sup>70</sup> *Stone v. Ritter*, Civ. A. No. 1570-N, 2006 WL 302558, at \*2 (Del. Ch. Jan. 26, 2006) (failure of internal controls resulted in a \$50 million fine).

<sup>71</sup> *Id.*

2000 and 2001 new illegal “off-label” marketing and sales strategies were implemented; (b) in the first six months of 2002, the sales of Actiq increased by 92%; (c) in 2003 an intra-company audit concluded that violations of FDA mandates had taken place over the course of several years; (d) data showed that doctors other than oncologists and pain specialists were writing the vast majority of Actiq prescriptions; (e) several Federal and state regulators launched investigations in 2004; and (f) in 2005, Cephalon curtailed off label marketing of Gabitril under pressure from the FDA and sales fell 23%. Plaintiff contends that, despite those red flags, the board nevertheless allowed the illegal practices to continue. Viewed together, plaintiff argues these facts would have alerted the Board of the possibly illegal conduct had a proper oversight mechanism existed.

A significant problem with plaintiff’s complaint is the failure to identify which individual director defendants breached his or her fiduciary duties, and when those duties were breached. For instance, the complaint alleges that “defendants intentionally breached and/or recklessly and/or with gross negligence disregarded their fiduciary duties, *choosing to implement a marketing scheme* that completely ignored FDA mandates . . . .”<sup>72</sup> There are no facts supporting the conclusory statement that the *defendants* chose to implement the new marketing scheme. The complaint, quoting from a *Wall Street Journal* article, merely states that “[i]n late 2001, Cephalon issued a new ‘standard operating procedure’ internally for interpreting the FDA’s risk-management program . . . .” Nowhere does the complaint indicate *the Board*, much less which Board members, “choose to implement” that new standard operating

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<sup>72</sup> Emphasis added.

procedure. Moreover, even were to court to improperly speculate that the Board did so choose, defendants Kailian, Moley, Wilensky, and Winger could *not* have made that choice as they have served on the Board since 2005, 2006, 2002, and 2003, respectively.<sup>73</sup> Further, the complaint recites “late 2001” as the beginning of the new standard operating procedure and defendant Sanders is alleged to have served as a director “since 2001.” It is not clear, therefore, that Sanders could have participated in the speculated approval of the new procedure. The court finds, therefore, that the complaint does not set forth particularized facts supporting the allegation that the Board authorized the implementation of the new standard operating procedure.

Plaintiff also contends that the increase in the sales of Actiq in 2002 was a red flag which should have alerted the Board to wrongdoing by its employees. He also points to the document titled ‘Actiq in Migraine’ in which the *Company* instructed its sales representatives to pitch Actiq as “an ER on a stick.” There is no allegation, nor facts supporting such allegation, that the *Board* authored or approved that document. After Cephalon acquired Actiq in late 2000, it relaunched the drug in February 2001. Subsequently, sales of Actiq increased substantially. That increase does not lead to the conclusion that the increase in sales was due to illegal activity by Cephalon employees which the Board, or those actually serving on the Board at that time, consciously ignored. The complaint acknowledges that “[t]he market for off-label use often vastly exceeds the approved FDA use.” One of the *Wall Street Journal* articles quoted in the

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<sup>73</sup> The article quoted in the complaint indicates that the new standard operating procedure, at least with regard to Actiq, was implemented in 2002, but that same article is explicit that the new procedure was issued in 2001.

complaint reports that Cephalon acknowledged that Actiq was widely used off-label, but claimed it did not market the drug for unapproved uses and that it could not control how doctors prescribe the drug. That article also states that Cephalon addressed a few “wayward” sales representatives who did not follow proper sales procedures through discipline or termination. Cephalon also informs physicians of the proper use of Actiq. “When Cephalon receives a report of a doctor prescribing the drug off-label – for example, via a call or letter from a patient – it sends a letter to that doctor reminding him or her that Actiq is only for cancer pain . . . [and Cephalon] has sent more than 3,300 such letters.” The second *Wall Street Journal* article relied on by plaintiff in the complaint also reports one doctor stating that “Actiq is an effective ‘rescue’ drug for patients with bad migraines who don’t respond to other treatments.” Another neurologist stated that “48% of the drugs used to treat headaches are used off label, so using Actiq for migraines isn’t unusual.” There are also no facts plead indicating that members of the Board were privy to the data, reported in the 2006 *Wall Street Journal* articles, concerning the percentage of patients prescribed Actiq off-label or the percentage of Actiq sales that were the result of prescriptions made by oncologists. The court determines, therefore, that plaintiff has not alleged particularized facts supporting his contention that the increase in sales of Actiq raised a red flag warning the Board of illegal sales activities on the part of the Company’s employees.

Plaintiff’s allegations concerning the Brennan audit report similarly fail to plead particularized facts that the Board was made aware of that report. The Board is not named, or mentioned, in the opinion granting Cephalon’s motion for summary judgment in that action. The only defendant in this case originally named in Brennan’s suit was

Baldino, but in his capacity as a Cephalon employee, not in his capacity as a director of the Company.<sup>74</sup> There are no facts suggesting that the subject of Brennan's wrongful termination suit, which involved Brennan's audit of Actiq's Risk Management Program, was presented to, or known by the other Board members. The facts recited in the Brennan opinion reveal that, upon concluding that Cephalon was not in compliance with the FDA approval, Brennan turned in his report to his supervisor, Tim Sheehan.<sup>75</sup> Six weeks later, Brennan mentioned to a co-worker, Lisa Carle, that he had not received a response concerning his report and that he believed he should report his findings on the Actiq RMP to the FDA; but he did not have conversations with his superiors about turning over those findings directly to the FDA.<sup>76</sup> Shortly thereafter, Armando Cortez (Cephalon's new Director of Quality Assurance), met with Brennan, Sheehan, and Richard Kaplan (Cephalon's Vice President of Quality) about the Actiq RMP report and Brennan was told to set up a meeting with the other participants in the Actiq RMP audit to assure the correct information was provided. After that meeting Brennan's report was distributed internally and Carol Marchione (Cephalon Director of Quality Assurance) was to respond to the by the end of the month, which response date was later agreed to be postponed for another month. Having not received a response approximately ten days after the postponed response date, Brennan approached Sheehan and asked if he could distribute the Actiq RMP report. Sheehan informed Brennan he had to wait for

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<sup>74</sup> *Brennan v. Cephalon*, No. Civ. A. 04-3241 (NLH), 2007 WL 1382801, at \*1 (May 8, 2007) (listing Cephalon *employee* defendants as Frank Baldino, Richard Kaplan, Tim Sheehan, and Armando Cortez). All defendants except Cephalon were subsequently dismissed from the case. Cephalon's successful motion for summary judgment on Brennan's single remaining claim, for wrongful termination, was under consideration in the courts May 8, 2007 opinion. *Id.*

<sup>75</sup> *Brennan*, 2007 WL 1382801, at \*1.

<sup>76</sup> *Id.* at \*2.

approval from Cortez, whom Brennan did not contact.<sup>77</sup> The same week, Brennan was terminated for what he was told was performance related reasons with respect to an audit of the French Cephalon facility wherein he found the facility in compliance but that an outside consultant determined, in a separate inspection, was not in compliance.<sup>78</sup>

The above facts suggest that knowledge of Brennan's Actiq RMP report was limited to Cephalon employees and that Cephalon had a functioning compliance system. Any purported wrongdoing concerning Brennan's report would appear to be due to actions of Cephalon employees and there are no facts plead to support a reasonable inference that the Board was aware of that report.

Plaintiff also argues that the investigations and inquiries from the Philadelphia USAO, Connecticut and Massachusetts attorneys general, and the Waxman Committee; the settlement by the Company of certain claims and agreeing to plead guilty to a federal misdemeanor is another red flag ignored by defendants. The facts plead, however, indicate that the Board did not ignore those red flags. With regard to each instance, the Board did not ignore or evade Cephalon's obligations, but reported that it was cooperating with each investigation or inquiry by providing documents and other information. It also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services as part of its settlement of the investigation by the Philadelphia USAO. In 2005, it also curtailed certain of its Gabitril marketing practices when it learned the drug was causing seizures in patients without the disease.

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<sup>77</sup> *Id.* at \*2.

<sup>78</sup> *Id.* at \*2.

Here, the court believes plaintiff's complaint seeks to equate a bad outcome with bad faith.

With the benefit of hindsight, the plaintiffs' complaint seeks to equate a bad outcome with bad faith. The lacuna in the plaintiffs' argument is a failure to recognize that the directors' good faith exercise of oversight responsibility may not invariably prevent employees from violating criminal laws, or from causing the corporation to incur significant financial liability, or both, as occurred in . . . this very case.<sup>79</sup>

The court determines, therefore, that plaintiff fails to plead particularized facts demonstrating that the Board was aware of the actions of the alleged "principal wrongdoers" and consciously failed to act in light of that knowledge. The court finds that a majority of the Cephalon Board does not have a disabling interest due to a "substantial likelihood of liability." In light of these determinations, the court holds that plaintiff has failed to plead demand futility and his complaint is dismissed for failure to comply with Fed. R. Civ. P. 23.1.<sup>80</sup>

## **CONCLUSION**

For the reasons contained herein, IT IS ORDERED, ADJUDGED and DECREED that:

1. Defendants' Motion for Judgment on the Pleadings (D.I. 18) is

GRANTED.

August 26, 2009

/s/ Mary Pat Thyng  
UNITED STATES MAGISTRATE JUDGE

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<sup>79</sup> *Stone v. Ritter*, 911 A.2d 362, 373 (Del. 2006); *id.* at 372 ("Delaware courts have recognized that '[m]ost of the decisions that a corporation, acting through its human agents, makes are, of course, not the subject of director attention.' Consequently, a claim that directors are subject to personal liability for employee failures is 'possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.'") (footnotes and citations omitted)

<sup>80</sup> Whether or not specifically discussed, the court has considered each of plaintiff's arguments presented in opposition to defendants' motion.