IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

LOUISIANA MUNICIPAL POLICE EMPLOYEES' RETIREMENT SYSTEM, and U.F.C.W. LOCAL 1776 & PARTICIPATING EMPLOYERS PENSION FUND,	)	
Plaintiffs,	)	
v.	)	C.A. No. 5795-VCL
DAVID PYOTT, HERBERT W. BOYER, LOUIS J. LAVINGNE, GAVIN S. HERBERT, STEPHEN J. RYAN, LEONARD D. SCHAEFFER, MICHAEL R. GALLAGHER, ROBERT ALEXANDER INGRAM, TREVOR M. JONES, DAWN E. HUDSON, RUSSELL T. RAY, and DEBORAH DUNSIRE,	)	
Defendants,	)	
and	)	
ALLERGAN, INC.,	)	
Nominal Defendant.	)	

NOMINAL DEFENDANT ALLERGAN, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE VERIFIED SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

This action began with a derivative claim brought by Louisiana Municipal Police Employees Retirement System ("LMPERS"), a shareholder of Allergan, Inc. ("Allergan" or the "Company"), on September 3, 2010, just two days after Allergan announced that it had reached a resolution with the United States Government (the "Government") regarding the Government's investigation into certain therapeutic uses of BOTOX® (onabotulinumtoxinA). LMPERS has now been joined by U.F.C.W. Local 1776 & Participating Employers Pension Fund ("UFCW") (collectively the "Plaintiffs"), and together they seek on Allergan's behalf "disgorgement" of more than $600 million from Allergan's twelve directors, though (i) there is no allegation that the directors profited personally from the settlement, and (ii) a § 102(b)(7) charter provision exculpates the directors from personal liability. Plaintiffs have failed to make a pre-suit demand upon Allergan's board of directors (the "Board") to pursue those claims. Yet, despite receiving extensive copies of books and records from Allergan, including its Board materials and communications with directors, Plaintiffs have failed to plead demand futility by any measure, let alone the stringent pleading requirements of Court of Chancery Rule 23.1. Accordingly, Plaintiffs' Verified Second Amended Derivative Complaint (the "Complaint") should be dismissed.

This action has now been pending for nearly a year, during which time a new plaintiff has been added, two new complaints have been filed, and voluminous Allergan books and records have been provided to Plaintiffs in response to UFCW's eight page, 39 paragraph demand under Delaware General Corporation Law ("DGCL") Section 220 (the "220 Documents"). Nonetheless, despite having ample opportunity to integrate any new evidence into their new Complaint, the problem with Plaintiffs' pleadings remains the same today as it was one year ago: Plaintiffs plead no facts showing that the Board ever directed, approved, or otherwise condoned

the off-label marketing of BOTOX®, and, thus, cannot meet the demand futility requirement under Rule 23.1 for usurping Allergan's control over its own claims.

Rather than pleading any facts actually connecting the Board to off-label marketing, Plaintiffs try instead to show that the Board "must have" known that Allergan was engaged in off-label marketing. That tactic takes two forms. First, Plaintiffs claim that because the Board approved strategic plans including sales goals for BOTOX®—an unremarkable fact—the Board must have known that a large portion of BOTOX® sales were off-label. That conclusion, even if accurate, ignores the uncontested fact that off-label sales are legal, and thus the Board's knowledge or ignorance of those sales is irrelevant. Second, Plaintiffs offer up assertions of alleged off-label marketing by unnamed others within the Company and then, taking a logical leap, arrive at the conclusion that the Board was therefore involved in off-label marketing. That conflation of Board action and employee action ignores the longstanding principle that a board of directors, no matter how diligent and no matter how earnest, cannot always prevent wrongdoing by company employees.

If there are any claims for Allergan to pursue, Plaintiffs have alleged no particularized facts that cast any doubt on the ability of Allergan's Board to act in good faith in considering them. Plaintiffs' pleadings are insufficient to justify their usurpation of the Board's proper role in deciding whether a lawsuit should be initiated on behalf of the Company, and their Complaint must be dismissed.

STATEMENT OF FACTS[1]

A. The Parties

Allergan is a global, multi-specialty health care company focused on discovering, developing and commercializing innovative pharmaceuticals, biologics, and medical devices. (Compl. ¶ 21.) Formed as a Delaware corporation, the Company's stock trades on the New York Stock Exchange under the symbol "AGN." (*Id.*)

Allergan's Board consists of twelve members, all of whom served on the Board when LMPERS' original and amended complaints were filed and have been named defendants to this action. (Compl. ¶¶ 22-41.) Ten of the twelve director defendants have served on the Board since before 2005: (1) David E.I. Pyott (Chief Executive Officer of Allergan since January 1998 and the Chairman of the Board since 2001, and also the President of Allergan from January 1998 until February 2006); (2) Herbert W. Boyer, Ph.D. (board member since 1994 and Chairman from 1998 to 2001); (3) Michael R. Gallagher (board member since 1998); (4) Gavin S. Herbert (founder of Allergan and Chairman Emeritus since 1996, CEO for 30 years and Chairman from 1977 to 1996); (5) Leonard D. Schaeffer (board member since 1993); (6) Stephen J. Ryan, M.D.

[1] As was the case in LMPERS' original and first amended complaints, Plaintiffs' second amended Complaint (cited herein as "Compl. ¶ __") quotes extensively from the Government's press release, which is attached as Exhibit A to the accompanying affidavit of Joseph B. Warden (exhibits to that affidavit are cited herein as "Aff. Ex. __"). (*Compare, e.g.*, Compl. ¶¶ 117-18 *with* Aff. Ex. A.) Plaintiffs' repeated quotation or rewording of that press release demonstrates that the press release has been incorporated by reference and the Court may consider other statements from the same release. *See Sprint Nextel Corp. v. iPCS, Inc.*, 2008 WL 2737409, at *12 (Del Ch. July 14, 2008) ("[O]n a motion to dismiss, a court may consider documents that are integral to or are incorporated by reference to the complaint." (internal quotation marks omitted)). Likewise, because the Complaint expressly relies on and incorporates the settlement agreement between Allergan and the Government, the Court can consider statements from that agreement, which is attached as Exhibit C to the affidavit of Joseph B. Warden.

The Court may also take judicial notice of and consider statements from Allergan's publicly available certificate of incorporation. *See, e.g., Malpiede v. Townson*, 780 A.2d 1075, 1090-92 (Del. 2001) (considering, on a 12(b)(6) motion, statements in a certificate of incorporation because it "could easily be found in the public files of the Secretary of State's office and could properly be noticed judicially by the court"). That certificate is attached as Exhibit B to the affidavit of Joseph B. Warden.

(board member since 2002); (7) Russell T. Ray (board member since 2003); (8) Trevor M. Jones, Ph.D. (board member since 2004); (9) Robert A. Ingram (board member since 2005); and (10) Louis Lavigne (board member since 2005). The remaining two board members, (Deborah Dunsire, M.D. (2006) and Dawn Hudson (2008)), began their service on the Board after 2005—the end date for the period covered by the government plea. (*Id.*) Defendants Boyer, Dunsire, Gallagher, Herbert, Hudson, Ingram, Jones, Lavigne, Ray, Ryan, and Schaeffer each received cash and stock awards for their service as Allergan directors. (*Id.* ¶¶ 29-39.) Those directors also served on various subcommittees of the Board and have worked in other capacities within the health care and pharmaceutical industry. (*Id.* ¶¶ 29-39, 224.)

Plaintiffs are stockholders of the Company and allege that they held and will continue to hold their shares during the relevant time period. (Compl. ¶ 19-20.)

B. Allergan's Director Exculpation Provision

The Allergan Certificate of Incorporation contains a standard 8 *Del. C.* § 102(b)(7) exculpation provision, stating in Article 13:

> A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after the date hereof to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the corporation shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

(Aff. Ex. B at 5.)

C. The BOTOX® Settlement

The Government's investigation of Allergan began in 2007 as a result of allegations that Allergan was engaged in off-label marketing of BOTOX®.[2] (Compl. ¶ 115.) In connection with the eventual settlement, Allergan agreed to plead guilty to a single misdemeanor "misbranding" charge of violating of the Federal Food, Drug, & Cosmetic Act ("FDCA") and to pay the government $375 million. (*Id.* ¶ 118.) That misbranding charge is a strict liability offense and does not involve false or deceptive conduct. *See, e.g., United States v. Park*, 421 U.S. 658, 668-69 (1975) (explaining that a misbranding charge under the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing"); *United States v. Watkins*, 278 F.3d 961, 966 (9th Cir. 2002) ("The misdemeanor provision [of the FDCA] covers a wide range of conduct, imposing strict liability for misbranding. . . .").

As part of that plea, Allergan agreed that between 2000 and 2005, its marketing of BOTOX® covered non-approved uses for the therapeutic treatment of headache, pain, spasticity and juvenile cerebral palsy, which were off-label uses during the relevant time frame.[3] (Compl. ¶¶ 118, 204.) The U.S. Food and Drug Administration (the "FDA") has since approved BOTOX® for the treatment of increased muscle stiffness in the elbow, wrist, and fingers in adults with upper limb spasticity, the most substantial use during the relevant time period, and thus the BOTOX® label now includes directions for that use. (*Id.* ¶ 52 n.7.) On October 15, 2010, Allergan also received FDA approval of BOTOX® for the treatment of chronic migraines. (Compl. ¶ 52 n.7.)

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[2] For a description of the current regulatory environment with respect to off-label marketing and sales of prescription drugs, see the Director Defendants' Opening Brief—which Allergan fully joins—at 5-7.

[3] The Government's investigation and the resultant settlement agreement pertained only to off-label marketing of BOTOX® Therapeutic and "d[id] not address BOTOX® Cosmetic," which "has its own FDA approved label and drug code." (Aff. Ex. A.)

Allergan agreed to pay $225 million to resolve civil claims asserted by the DOJ under the civil False Claims Act. (Compl. ¶ 117.) Allergan consistently denied liability associated with those civil allegations and maintains that the claims have no merit factually or legally. (Aff. Ex. C at 4.) Yet, to resolve the criminal and civil investigation, Allergan entered into the settlement agreement and also agreed to dismiss the legal action the Company filed against the Government in connection with the Government's violations of Allergan's First Amendment rights.[4]

As part of the global resolution of the Government's investigation, Allergan also entered into a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. (Compl. ¶ 121.) Under that agreement, Allergan will maintain its current compliance program and undertake certain additional compliance-related obligations for five years. (*Id.*) The agreement also provides for an independent third-party review organization to assess and report on Allergan's compliance program. (*Id.*)[5]

D. Plaintiffs' Claims Regarding Demand Futility

Plaintiffs admit that they made no demand upon the Board before filing this derivative action. (Compl. ¶ 214.) Plaintiffs appear to argue that such a demand is excused because the Board is at risk of personal liability for the Company's conduct, as a result of the Board's alleged approval of an illegal scheme. That attempt to distinguish the allegations of demand futility in

[4] Allergan had sought a ruling that it could proactively share truthful scientific and medical information with the medical community to assist physicians in evaluating the risks and benefits if they choose to use BOTOX® for the off-label purpose of treating certain forms of spasticity and that the Government's position, that it was a crime for Allergan to do so, violated the First Amendment and was inconsistent with the FDCA. (Compl. ¶ 119.)

[5] In light of this agreement and the stringent additional compliance, monitoring and review requirements it imposes, the Plaintiffs' prayer for relief is superfluous to the extent that it requests that the Court "direct[] Allergan to take all necessary actions to reform and improve" its compliance systems and internal procedures "to protect the company's shareholders from a recurrence of the events at issue in this action." (Compl. § VII.) Not surprisingly, Plaintiffs give no indication in their Complaint what additional protections are required.

the present Complaint from those in the earlier versions relies on citing descriptions of the Board's approval of strategic plans and then recasting those ordinary actions as bad faith endeavors that somehow disqualify the directors from considering any demand. (*See Id.* ¶¶ 215-220.) The strategic plans, however, contain no mention of off-label marketing and Plaintiffs point to no facts demonstrating the Board's alleged involvement in Allergan's conduct leading up to the settlement agreement.

Failing to establish any actual Board involvement in the Company's alleged misconduct, Plaintiffs provide instead conclusory allegations that demand is excused because the directors are not disinterested and independent. (*Id.*) Plaintiffs provide boilerplate, legally insufficient allegations of directors "interest." They note the Board members' roles at the Company and the fact that the Company entered into a guilty plea and argue that this shows the directors are not disinterested and independent. Plaintiffs also conclusorily allege that "the Board is conflicted because there is an extremely high risk of directors' personal liability . . . the Board members failed to perform duties they knew were required . . . and the failure of the Board to prevent civil and criminal acts . . . cannot be the product of business judgment." (*Id.* ¶ 223.) Plaintiffs fail to provide any facts to support those conclusions and from those allegations alone, Plaintiffs maintain that demand is excused. (*Id.* ¶ 229.)

E. Procedural Posture

Allergan and the Government announced that they resolved the BOTOX® investigation on September 1, 2010. Two days later on September 3, LMPERS filed the original derivative complaint. On September 15, 2010, LMPERS served discovery on all defendants. Meanwhile, additional shareholder suits arising from this settlement were filed in the U.S. District Court for the Central District of California. On October 11, 2010, LMPERS amended its complaint. On October 25, 2010, Defendants filed motions to dismiss that amended complaint. Following

Defendants' motions to dismiss, UFCW demanded and obtained extensive copies of Allergan's books and records, pursuant to DGCL Section 220.

On November 30, 2010, days before the hearing on defendants' motions to dismiss, UFCW moved to intervene in the LMPERS case. After briefing and argument on the motion to intervene, the Court denied UFCW's motion to intervene without prejudice and stayed the LMPERS action for a brief time to allow UFCW time to review the 220 documents and bring any complaint to obtain additional documents. In so doing, the Court noted that unless UFCW's complaint in intervention upon obtaining its 220 documents was incrementally different than the LMPERS complaint, he would likely deny intervention. Regarding the first amended complaint, the Court noted that, while it was not "prejudging the motion to dismiss. . . . it was not lost on [the court] . . . that there wasn't a lot, if anything, beyond 'strategic plan' to connect [the alleged off-label marketing] to the board." (Transcript of January 21, 2011 Hearing at 57.)

By March 2011, Allergan had produced more than 6000 pages of board materials and communications with directors in response to UFCW's ever expanding requests for more documents. UFCW then brought suit under DGCL Section 220 to demand production of all of the documents on Allergan's privilege log. Ultimately, the Court permitted UFCW access to a few of these documents and rejected UFCW's requests for more, directing UFCW to file its motion to intervene.

Rather than press the motion to intervene, UFCW and LMPERS reached an agreement to jointly file the present Complaint on July 8, 2011. On July 15, 2011, Defendants filed motions to dismiss the Complaint. This is nominal defendant Allergan's opening brief in support of its motion.

ARGUMENT

I. THE COMPLAINT MUST BE DISMISSED FOR FAILURE TO MAKE A PRE-SUIT DEMAND

The problem with Plaintiffs' Complaint is straightforward. Whether their claims are construed as challenging director action or inaction, Plaintiffs have alleged no particular facts that in any way connect the Board to illegal off-label marketing. Instead, Plaintiffs pile on allegation after allegation about the Board's involvement in approving strategic plans for the sale of BOTOX®. But those allegations, no matter how numerous, cannot give rise to the inferences Plaintiffs want because, even if the Board knew about legal off-label *sales*, it does not show that the Board knew of any illegal off-label *marketing*. Thus, the Board's approval of Allergan's strategic sales plans—a task one would expect any competent Board to undertake—sheds no light on whether the Board had any role in or knowledge of wrongdoing by the Company. Nor do Plaintiffs point to any other facts demonstrating that a conflict affects the Board majority. Consequently, the Complaint does not establish any reason for permitting Plaintiffs to circumvent the Board's role of determining whether legal action should be commenced on behalf of the Company, and the Complaint should be dismissed.

A. Applicable Legal Standards For Demand Futility

The right to bring this action belongs to Allergan. *Spiegel v. Buntrock*, 571 A.2d 767, 773 (Del. 1990); *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984) (noting that this power arises from the "cardinal precept of the General Corporation Law . . . that directors, rather than shareholders, manage the business and affairs of the corporation"), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000); *see* 8 *Del. C.* § 141(a). For Plaintiffs to circumvent Allergan's right and pursue a derivative suit on the Company's behalf, they must "(a) first demand[] that the directors pursue the corporate claim and [show that] the directors have

wrongfully refused to do so; or (b) establish[] that pre-suit demand is excused because the directors are deemed incapable of making an impartial decision regarding the pursuit of the litigation." *Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008); *accord Stone ex rel. AmSouth Bancorp. v. Ritter*, 911 A.2d 362, 362 (Del. 2006).

Because Plaintiffs admit that they made no demand upon the Board before filing this derivative action (Compl. ¶ 214), analysis of whether demand was excused under Rule 23.1 is "logically the first issue for [Plaintiffs'] claims." *In re Dow Chem. Co. Deriv. Litig.*, 2010 WL 66769, at *1 n.1 (Del. Ch. Jan. 11, 2010) (alterations added and omitted). The heightened pleading requirements of Rule 23.1 require that a complaint allege "with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors [or] the reasons for the plaintiff's failure to obtain the action or for not making the effort." *Stone*, 911 A.2d at 367; *see* CT. CH. R. 23.1. Conclusory allegations "are not considered as expressly pleaded facts or factual inferences" and are insufficient to satisfy Rule 23.1. *Wood*, 953 A.2d at 140; *Brehm*, 746 A.2d at 254. Failure to include non-conclusory, particularized allegations results in dismissal of the complaint. *Wood*, 953 A.2d at 140, 143-44.

In assessing demand futility, courts apply one of two tests: the *Aronson* test or the *Rales* test. When a derivative complaint challenges affirmative board action or approval of a transaction, the *Aronson* test applies. *Wood*, 953 A.2d at 140 (holding that *Aronson* applies where a plaintiff alleges particularized facts that the directors made a conscious business decision in breach of their fiduciary duties). Under *Aronson*, demand is excused only if plaintiffs allege "particularized facts creating a reason to doubt that (1) the directors are disinterested and independent [or that] (2) the challenged transaction was otherwise the product of a valid exercise

of business judgment." *Wood*, 953 A.2d at 140 (internal quotation marks and citation omitted) (alterations in original).

When a derivative complaint challenges board inaction or failure of oversight, the *Rales* test applies. *See Stone*, 911 A.2d at 367 ("The standards for determining demand futility in the absence of a business decision are set forth in *Rales*.") (internal quotation marks omitted). The *Rales* test asks whether there is reason to "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 v. Blasband*, 634 A.2d 927, 934 (Del. 1993). As the Court of Chancery has noted, "the first prong of *Aronson* and the test in *Rales* differ only slightly" and often there is "no reason why . . . the demand futility analysis would not be the same under both tests." *MCG Capital Corp. v. Maginn*, 2010 WL 1782271, at *19 n. 117 (Del. Ch. May 5, 2010). Indeed, that is the case here, and, although Plaintiffs appear to invoke both tests by challenging both Board action and inaction, *Rales* and the first prong of *Aronson* can properly be addressed together. Accordingly, the two questions to be answered here are: (1) do the particularized facts alleged by Plaintiffs create any reason to doubt that any Board action was the product of a valid exercise of business judgment (*Aronson's* second prong); and (2) do the particularized facts alleged by Plaintiffs, both with respect to Board action and inaction, create any reason to doubt the Board's disinterest and independence in responding to a demand (*Aronson's* first prong and *Rales*).[6]

[6] Although the question of director independence (addressed by *Aronson's* first prong and *Rales*) is typically addressed before examining whether the conduct at issue was the product of a valid exercise of business judgment (addressed by *Aronson's* second prong), the facts of this case make it helpful to address them in reverse order.

The only affirmative Board actions identified in the Complaint are the approval of strategic plans for the Company.[7] As discussed hereafter, the particularized facts alleged with respect to those plans fail to undermine the legal presumption that the Board was engaged in the valid exercise of business judgment when it approved those plans. Likewise, neither the allegations with respect to the Board's approval of those plans nor the allegations with respect to the Board's inability to prevent alleged misconduct by others creates any reason to doubt that the Board would be disinterested and independent in responding to any demand. The Complaint therefore lacks any particularized facts justifying Plaintiffs' circumvention of the Board's right to decide whether to bring suit on behalf of the Company.

B. Plaintiffs Fail To Plead Particularized Facts Sufficient To Create A Reason To Doubt That The Board's Acts Were the Product of Valid Business Judgment

Under *Aronson's* second prong, demand is excused if Plaintiffs have alleged "particularized facts creating a reason to doubt that . . . the challenged transaction was otherwise the product of a valid exercise of business judgment." *Wood*, 953 A.2d at 140 (internal quotation marks and citation omitted). That prong requires Plaintiffs to plead particularized facts that create either "(1) a reason to doubt that the action was taken honestly and in good faith or (2) a reason to doubt that the board was adequately informed in making the decision." *Dow Chem.*, 2010 WL 66769 at *9; *Brehm*, 746 A.2d at 259. The only Board actions Plaintiffs appear to challenge are the approvals of strategic plans, which include plans for the sale of BOTOX®.[8] (*See, e.g.*, Compl. ¶¶ 15, 125-180.) Plaintiffs have alleged no particular facts showing that those actions in any way promoted off-label marketing or other wrongdoing, however, and, accordingly, Plaintiffs have pled no facts causing a reason to doubt either "that the action[s] were

[7] The Complaint identifies many other actions taken by unnamed others but does not provide any legally sufficient basis for attributing those actions to the Board. *See infra* n. 8.

taken honestly and in good faith" or "that the board was adequately informed in making the decision." *Dow Chem.*, 2010 WL 66769 at *9.

1. Plaintiffs Have Pled No Particularized Facts That Create A Reason To Doubt That the Board's Actions Were Taken Honestly And In Good Faith

Plaintiffs have alleged no particularized facts showing wrongful actions by the directors, which is, by itself, fatal to Plaintiffs' *Aronson* claims because "[d]emand futility under the second *Aronson* prong arises only in an extreme case . . . [in which] a transaction may be so egregious on its face that board approval cannot meet the test of business judgment." *Norfolk County Ret. Sys. v. Jos. A. Bank Clothiers, Inc.*, 2009 WL 353746, at *7 n.50 (Del. Ch. Feb. 12,

[8] Plaintiffs allege numerous other actions committed by unnamed others within the Company, many of which relate to the off-label marketing of BOTOX®. (*See* Compl. ¶¶ 57-114.) The fact that some persons within the Company may have engaged in wrongdoing does not show that the Board knew of that wrongdoing or that it could not disinterestedly investigate that wrongdoing. *See In re Lear Corp. S'holder Litig.*, 967 A.2d 640, 653 (Del. Ch. 2008) (noting "the reality that even the most diligent board cannot guarantee an entire organization will always comply with the law"); *Stone*, 911 A.2d at 373 ("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."); *see also In re Caremark Int'l Deriv. Litig.*, 698 A.2d 959, 969 (Del Ch. 1996) ("[N]either corporate boards nor senior officers can be charged with wrongdoing simply for assuming the integrity of employees and the honesty of their dealings on the company's behalf."). Plaintiffs have alleged no particular facts that show any connection between the wrongdoing of those others and any action by the Board, and those actions are irrelevant for purposes of analyzing demand futility.

Plaintiffs also allege certain acts by a single director, Pyott. Notwithstanding that any allegations related only to Pyott do not demonstrate that a majority of the board is not disinterested, none of those allegations show any direction for or approval of off-label marketing. (Compl. ¶¶ 184-85.) Some of the allegations describe Pyott's presentation at a "Global Business Strategies Conference," which included a slide discussing the "global" impact of BOTOX® and which referenced uses that are off-label in the United States. (*Id.* ¶ 185.) It is uncontested, however, that BOTOX® is approved globally for uses for which it is not approved in the United States, and the inclusion of those global uses on a single slide at a global conference can hardly be considered marketing for off-label use in the United States. The other allegations discuss Pyott's efforts at "pumping up the company's BOTOX® R&D," and at "win[ning] approval from the [FDA]" for new applications of BOTOX®. (*Id.* ¶ 184.) There is no wrongdoing in attempting to expand the approved uses of BOTOX®, however, and so those allegations are irrelevant. That is true also of Plaintiffs' description of Board meetings discussing "the Company's R&D strategy" for development of "BOTOX® Headache" or the "the R&D initiative" regarding "BOTOX® for spasticity." (*Id.* ¶ 15.) Plaintiffs note that the approved uses for BOTOX® at the time of those meetings did not include treatment for headache or spasticity. (*Id.*) Be that so, there is no wrongdoing in promoting research and development of uses that are not yet approved.

2009) (quoting *Aronson*, 473 A.2d at 815), *aff'd mem.* 977 A.2d 899 (Del. 2009); *see also Carauna v. Saligman*, 1990 WL 212304, at *4 (Del. Ch. Dec. 21, 1990) ("The second prong of the demand futility analysis requires examination of the substantive nature of the challenged transaction and the board's approval of that transaction. In other words, the analysis looks at the substance of the transaction and the process by which the board approved it.").

Here, Plaintiffs make only the unsupported assertions that at some unknown point in the Company's history, the "off-label marketing of BOTOX® . . . was a Board-approved decision, and its implementation was a significant piece of the Company's strategic plan." (Compl. ¶ 222.) Those allegations are conclusory, however, and are unaccompanied by any particularized facts showing, for instance, how the Board approved the off-label marketing of BOTOX®, when the approval occurred, or the individual directors who approved the off-label marketing plan. The Complaint identifies no particularized facts showing any involvement whatsoever by the Board in directing, approving, or otherwise condoning off-label marketing. Instead, the Complaint's particularized allegations describe only the Board's approval of strategic business plans, which included goals for BOTOX® sales, but did not even allude to off-label marketing.[9] (*See, e.g.*, *id.* at ¶ 15.) Even if it were fair to assume that the Board "had actual knowledge of the extent of the Company's off-label sales" (*Id.* ¶ 217)—a conclusion Plaintiffs draw only by inference, as there is no mention of off-label sales in the Board minutes—it is immaterial because off-label sales are not illegal, only off-label marketing is. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 n.5 (2001) ("Off-label use is widespread in the

[9] For a detailed discussion of what is included in the strategic plans, see the Director Defendants' Opening Brief at 23-24. As described there, the strategic plans show only that BOTOX® was a high priority and that the Board sought to increase BOTOX® sales. Showing that the Board considered BOTOX® a high priority and made plans to increase its sales, however, is a far cry from showing that the Board made plans to illegally market BOTOX®.

medical community and often is essential to giving patients optimal care, both of which medical ethics, FDA, and most courts recognize." (internal quotation marks omitted)); Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. 16503 (Aug. 15, 1972) ("Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the [FDA] . . . ."). Yet, even after summarizing more than thirty Board meetings taking place over the course of eight years, Plaintiffs have not identified a single instance in which the Board even mentions, let alone directs or approves, off-label marketing of BOTOX®.

Plaintiffs, in fact, acknowledge that, regardless of any off-label sales, Allergan's "'Principles Concerning Off-label Uses of BOTOX®,' . . . explicitly prohibited 'the improper dissemination of off-labeled use information concerning BOTOX®.'" (*Id.* at ¶ 127.) As such, the only particular facts cited by the Complaint show that, whether or not the Board knew of off-label sales, off-label marketing was explicitly prohibited, and the Complaint does not support Plaintiffs' conclusory allegations that the Board members approved or directed any off-label marketing.

That precise conclusion was reached by the court in *In re Allergan, Inc.*, the ongoing California case addressing claims stemming from exactly the same alleged off-label marketing of BOTOX® at issue here. 2011 WL 1429626 (C.D. Cal. April 12, 2011). In dismissing the plaintiffs' claims for failure to make a demand or plead demand futility, the court explained:

> Plaintiffs incorrectly equate off-label *sales* with off-label *marketing*. The Plaintiffs themselves recognize that it is the off-label marketing of an FDA approved drug that is illegal, not the off-label sale. Plaintiffs fail to plead any facts showing that the Board's knowledge of alleged off-label *sales* provided notice to the Director Defendants of the alleged illegal off-label *marketing*. Instead, Plaintiffs rely solely on the assertion that the Director Defendants should

> have inferred the use of illegal marketing due to the high number of sales. Courts have deemed such allegations insufficient for purposes of establishing demand futility.

Id. at *3 (internal citations omitted).

Plaintiffs' unsupported allegations are nothing more than an attempt to invoke the legally untenable premise that because wrongdoing occurred, the Board must have acted wrongfully. *See Stone*, 911 A.2d at 373 (holding dismissal of derivative claims is appropriate where "the plaintiffs' complaint seeks to equate a bad outcome with bad faith"); *King v. Baldino*, 648 F. Supp. 2d 609, 623 (D. Del. 2009) (dismissing complaint alleging director liability for off-label marketing on the same basis). To show actual bad faith, not just a bad outcome, Plaintiffs must show that "defendants completely and 'utterly failed' to even attempt to meet their duties." *Dow Chem.*, 2010 WL 66769 at *10 (citing *Lyondell Chem. Co. v. Ryan*, 970 A.2d 235, 243-44 (Del. 2009)). There are no such allegations, let alone any particularized ones, even touching on this high standard. Plaintiffs' accusations against the directors are centered on approval of strategic plans. Those strategic plans do not mention off-label marketing, however, and the Board's unremarkable role in approving those plans does not give rise to any reasonable inference that the Board directed illegal off-label marketing. Plaintiffs therefore have not shown that the directors' actions were not taken honestly and in good faith.

2. Plaintiffs Have Pled No Particularized Facts That Create A Reason To Doubt That The Board Was Adequately Informed In Making Its Decisions

Plaintiffs allege no particularized facts showing that the directors failed to become fully informed in making decisions regarding Allergan's strategic planning, which is also fatal for their claim of demand futility. Plaintiffs have pled no facts regarding the process the directors employed or alleging that the process employed was fundamentally flawed because, for instance, the directors were grossly negligent in failing to consider all material information reasonably

available to them. *See Brehm*, 746 A.2d at 259 ("In making business decisions, directors must consider all material information reasonably available, and . . . the directors' process is actionable only if grossly negligent."). Rather, Plaintiffs nakedly allege that despite being "aware of other repeated violations of the FDCA," the Board "failed to prevent violations of federal statutes." (Compl. ¶ 223.)

The only basis for Plaintiffs' conclusion that "the Board was aware of other repeated violations of the FDCA" is the allegation that "the Company received several FDA Warning Letters." (Compl. ¶ 223.) But none of those letters even relate to the off-label marketing of BOTOX® for which the Company was charged. (*See id.* ¶¶ 48, 133.) The first of the letters, sent in August 2001, expressed the FDA's concern with the inclusion in BOTOX® materials of data from nonclinical studies—a concern unrelated to off-label marketing. (Compl. ¶ 133.) The other three letters, sent between June 2003 and August 2009, did not discuss BOTOX® at all. One addressed allegedly misleading advertising for Lumigan®, one addressed alleged violations of FDA regulations with respect to ACZONE®, and a third addressed claims of misleading advertising for BOTOX® Cosmetic, (Compl. ¶ 48), which, as already noted, is a distinct product with "its own FDA-approved label and drug code" that was not the subject of the Government's investigation or the settlement, (Aff. Ex. A). Plaintiffs offer no explanation for how letters from the FDA that related to other products or other FDA concerns could impute awareness to the Board of off-label marketing of BOTOX®. Furthermore, although Plaintiffs allege that the Board discussed at least one of the letters, there are no allegations about the process the Board employed in responding to or addressing the allegations identified in any of those letters. (*See id.* ¶ 15.) In short, Plaintiffs' reliance on the FDA warning letters does nothing to suggest that the Board was grossly negligent or failed to consider any information available to it.

The Plaintiffs' inadequate pleadings are not resuscitated by allegations that the education and experience of the various Board members "should have" made them "aware of the problems posed by off-label marketing and promotion, and of violating FDA rules and regulations through the strategic plan that made off-label marketing and promotion of therapeutic BOTOX® a primary corporate priority." (Compl. ¶ 224.) That attempt at imposing "some sort of higher standard of liability on the director defendants" has already been rejected by this Court and should be rejected here as well. *See In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 129 (Del. Ch. 2009). Plaintiffs fail to plead anything, let alone any particularized allegations, regarding how these directors' previous experiences have any relevance to Allergan's involvement with the Government's BOTOX® investigation or how those experiences would have put them on a "heightened alert" to the issues for which Allergan eventually settled. Accordingly, Plaintiffs' sparse allegations fall far short of the particular facts necessary to show that, in approving strategic plans, the Board somehow acted without adequate information.

In essence, all of the Complaint's wholly conclusory allegations with respect to the business judgment rule rely on the conclusion that because alleged wrongdoing occurred, the Board must have failed in its duties. But, as explained by the Delaware Supreme Court, "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." *Stone*, 911 A.2d at 373; *see also Caremark*, 698 A.2d at 969 ("[N]either corporate boards nor senior officers can be charged with wrongdoing simply for assuming the integrity of employees and the honesty of their dealings on the company's behalf."). Yet Plaintiffs insist that the Board's inability "to prevent illegal activity" and to "ensure[] the Company's compliance with applicable laws and regulations" are sufficient to defeat the

business judgment rule, (Compl. ¶ 225-26), effectively ignoring the Supreme Court's instructions.

Plaintiffs' request for this to Court second-guess the merits of the Board's business decisions—decisions made without any apparent knowledge of any wrongful off-label marketing—based on outcome alone is exactly what the business judgment rule was designed to prevent and should be rejected. *See, e.g.*, *Citigroup*, 964 A.2d at 122 ("[S]o long as the court determines that the process employed was either rational or employed in a good faith effort to advance corporate interests" the court will not second-guess a board's business decisions.); *Dow Chem.*, 2010 WL 66769 at *10 ("A business decision made by a majority of disinterested, independent board members is entitled to the deferential business judgment rule regardless of whether it is an isolated transaction or part of a larger transformative strategy."). Because Plaintiffs have failed to allege any particularized facts showing that the Board's approval of strategic plans was not the exercise of sound business judgment, Plaintiffs cannot rely on the second prong of *Aronson* to meet their burden of showing that demand is excused.

3. Plaintiffs Have Pled No Particularized Facts To Support Their Waste Claim

Plaintiffs also include in their Complaint a perfunctory claim for "waste of corporate assets" by the Board. (Compl. ¶¶ 238-241.) "To excuse demand on grounds of corporate waste, plaintiffs must allege particularized facts that the consideration received by the corporation was so inadequate that no person of ordinary sound business judgment would deem it worth that which the corporation has paid." *Ash v. McCall*, 2000 WL 1370341, at *6 (Del. Ch. Sept. 15, 2000) (dismissing waste claims for failure to plead demand futility) (internal quotation marks and citation omitted); *Lear*, 967 A.2d at 647-48, 656-57.

The transaction identified by Plaintiffs as wasteful is the Company's settlement with the Government, resulting in a "waste" of $600 million. (Compl. ¶ 239.) That claim for waste can have merit only if the "consideration received by the corporation" (in this case, the cessation of the Government's criminal prosecution of the Company) "was so inadequate that no person of ordinary sound business judgment would deem it worth that which the corporation has paid." *Ash*, 2000 WL 1370341 at *6. Plaintiffs' pleadings contain nothing more than an assertion of waste, offering no suggestion for why the cessation of the criminal prosecution would be deemed by a person of sound business judgment as inadequate consideration for Allergan's $600 million settlement. Plaintiffs do not identify, for instance, what liability Allergan would have risked had it decided not to settle and the Government had pressed forward with its charges. Accordingly, Plaintiffs' conclusory claim regarding "commission of waste" fails to raise doubt that the settlement was the exercise of sound business judgment and falls far short of satisfying Rule 23.1's requirements for excusing demand.

C. Plaintiffs Fail To Plead Particularized Facts That Create Reason to Doubt the Board's Disinterest or Independence

Plaintiffs have failed to plead particular facts that establish a reason to doubt the directors' disinterest or independence, failing both *Aronson*'s first prong and *Rales*. *See Hartsel v. Vanguard Group, Inc.*, 2011 WL 2421003, at *21 (Del Ch. June 15, 2011) (explaining that a complaint "that does not allege particularized facts sufficient to cause reasonable doubt on the independence or disinterestedness of [defendants]" could not satisfy "either *Aronson* or *Rales*"). Plaintiffs' claims for why the Board is not disinterested or independent come in two forms. First, Plaintiffs make a number of claims rooted in the premise that, because the current directors served on the Board at the time off-label marketing was allegedly occurring, they must have sought to promote and take advantage of off-label marketing and are not disinterested. (Compl.

¶¶ 215-216.) Second, Plaintiffs claim that all of the directors face a substantial likelihood of liability should they commence legal action and are, therefore, not disinterested. (*Id.* ¶ 223.) Both sets of claims are legally insufficient. Moreover, even if those generic allegations could create cognizable interests, which they cannot as a matter of law, Plaintiffs present no facts showing that any of the purported conflicts affect the Board majority.

1. Plaintiffs Have Pled No Particularized Facts Showing That The Directors Are Not Disinterested By Virtue of Having Served On The Board During The Alleged Misconduct

As already discussed, the only affirmative Board actions identified by Plaintiffs are the approval of Allergan's strategic plans. There are no particular facts showing that, when approving those strategic plans, the Board was ever aware of any (let alone condoned) off-label marketing. Thus, the allegations about the Board's approval of those plans create no reason to doubt that the Board would be disinterested or independent in responding to a demand. Nevertheless, Plaintiffs offer four generic explanations for why the directors are not disinterested and independent. (*See* Compl. ¶¶ 216-220.) Each is insufficient as a matter of law.

First, Plaintiffs allege that the directors are not disinterested because they were members "of the Allergan Board at some point during the time of the misconduct which [allegedly] occurred from 2000 into 2009" and each "approved strategic plans that sought to promote and take advantage of the off-label marketing scheme." (Compl. ¶¶ 215-16.) Those allegations are insufficient to excuse demand, however. The mere fact that the director defendants served on the Board at the time of the alleged misconduct is insufficient to show demand futility. *See Jacobs v. Yang*, 2004 WL 1728521, at *4 (Del. Ch. Aug. 2, 2004) ("Allegations as to one's position as a director and the receipt of director's fees, without more . . . are not enough for purposes of pleading demand futility."); *cf. In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *1

(Del. Ch. June 5, 2003) (rejecting as "clearly insufficient" demand futility argument premised on majority of directors named as defendants in complaint). Likewise, allegations that the directors approved strategic plans, unaccompanied by any particularized facts showing that those plans called for off-label marketing, do not show demand futility. *See Aronson*, 473 A.2d at 817 ("In Delaware mere directorial approval of a transaction, absent particularized facts supporting a breach of fiduciary duty claim, or otherwise establishing the lack of independence or disinterestedness of a majority of the directors, is insufficient to excuse demand."). Plaintiffs here have offered only the conclusory allegation that the strategic plans "sought to promote and take advantage of the off-label marketing scheme," (Compl. ¶ 216) but, as already discussed, have alleged no particular facts showing Board direction or approval of off-label marketing. Nor does the Company's guilty plea establish Board knowledge or direction because misdemeanor misbranding violations, like those at issue in the plea agreement, are strict liability offenses that do not turn on awareness of wrongdoing or conscious fraud. *See, e.g.*, *Park*, 421 U.S. at 668-69 (explaining that a misbranding charge under the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing"). Thus, the directors' mere presence on the Board during the time of wrongdoing is irrelevant and does not show that the directors are interested or lack independence.

Second, Plaintiffs allege "that each of the Director Defendants had actual knowledge of the extent of the Company's off label-sales," as demonstrated by various strategic plans and other material summarized in minutes of Board meetings. (Compl. ¶ 217.) As already discussed, however, even if the Court is prepared to accept that knowledge of BOTOX® sales necessarily equates to knowledge of BOTOX® off-label sales, any off-label sales are not illegal, and evidence that the Board knew of off-label sales does not create any doubt that the directors

would be disinterested and independent in responding to any demand. *See* discussion *supra* Part I(B)(i).

Third, Plaintiffs allege that two of the directors are "Company insiders" by virtue of their current and former positions at the Company. (Compl. ¶ 220.) Nothing in this conclusory allegation suggests that "divided loyalties are present," or that "a director has received, or is entitled to receive, a personal financial benefit from the challenged transaction which is not equally shared by the stockholders." *Rales*, 634 A.2d at 933 (holding that these allegations will establish directorial interest). Moreover, even assuming those directors are not disinterested by virtue of their current or previous positions in the Company—which, alone, is insufficient—this allegation addresses only two of the directors, hardly a majority of twelve. It is well-settled that demand is excused only when a majority of the Board is not disinterested or independent. *See, e.g.*, *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1046 (Del. 2004) (requiring that at least half the board be interested to excuse demand); *In re Gen. Motors (Hughes) S'holders Litig.*, 2005 WL 1089021, at *8-10 (Del. Ch. May 4, 2005) (dismissing conflict of interest allegations that only pertained to one of the director defendants), *aff'd*, 897 A.2d 162 (Del. 2006); *see also Malpiede*, 780 A.2d at 1084-85 (affirming Court of Chancery's conclusion that a majority of directors were disinterested when the complaint failed to allege that the one interested director dominated the other directors who approved the transaction). Accordingly, Plaintiffs' assertion that only two Board members are not disinterested, even if it had merit, is insufficient to excuse demand.

Finally, Plaintiffs' allege that the directors are not disinterested and independent because the "revenues derived from the off-label marketing of BOTOX® increased the total revenues" of Allergan and "thereby increased the compensation" to ***one*** of its members, Pyott, creating a

disabling conflict for both him and, somehow, the remaining members of the Board. (Compl. ¶ 220.) That effort suffers from the same flaw as the last: Plaintiffs do not allege how Pyott's compensation affects a majority of the Board. *See Gen. Motors*, 2005 WL 1089021 at *8-10 (holding that allegations that pertain to only one of the director defendants are insufficient to demonstrate demand futility). Moreover, Plaintiffs do not allege that the benefits received by any director defendants are unusual in kind or degree from those received by directors of other corporations. *See Grobow v. Perot*, 539 A.2d 180, 188 (Del. 1988) (holding that interest of directors cannot be pleaded merely on the basis of allegations that they are compensated for their services), *overruled on other grounds by Brehm, supra*; *A.R. DeMarco Enters., Inc. v. Ocean Spray Cranberries, Inc.*, 2002 WL 31820970, at *5 (Del. Ch. Dec. 4, 2002) (dismissing derivative allegations for failure to allege demand futility when plaintiff alleged lack of independence only because the directors received compensation for serving on the board). Consequently, the Court should reject that argument as well.

2. Plaintiffs Have Pled No Facts Showing That The Directors Face A Substantial Threat Of Liability

Plaintiffs argue that the Board could not exercise disinterested business judgment in responding to a demand because the Board could face liability from any suit it initiated. (Compl. ¶ 223.) It is well-established, however, that "[d]emand is not excused solely because the directors would be deciding to sue themselves." *See, e.g., Dow Chem.*, 2010 WL 66769 at *12. Instead, the prospect that the directors could be liable for any suit they institute only "prevents a director from impartially considering a demand" if particularized allegations show that there is "a substantial likelihood of personal liability." *Rattner v. Bidzos*, 2003 WL 22284323, at *9 (Del. Ch. Sep. 30, 2008).

While Plaintiffs allege that the directors suffer from an "extremely high risk" of personal liability in this case (Compl. ¶ 223), the facts do not support that conclusion. Allergan has adopted a § 102(b)(7) exculpation provision in its charter. (Aff. Ex. B at 5). As a result, the directors can only be held personally liable for disloyalty or bad faith. *Stone*, 911 A.2d at 367 (noting that a § 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"); *Lear*, 967 A.2d at 648 (concluding that in light of a § 102(b)(7) provision, "the plaintiffs cannot sustain their complaint even by pleading facts supporting an inference of gross negligence; they must plead a non-exculpated claim"). Therefore, in order to establish that the directors are subject to a substantial likelihood of liability, Plaintiffs must plead particularized facts showing bad faith. *See Stone*, 911 A.2d at 362; *see also Dow Chem.*, 2010 WL 66769 at *12 (stating "demand will be excused. . . only in the ***rare*** case when a plaintiff is able to show director conduct that is so egregious on its face that board approval cannot meet the test of business judgment, and a substantial likelihood of director liability therefore exists.") (internal quotation marks omitted) (emphasis added).

Because Plaintiffs have failed to identify any actual bad acts by the Board, *see supra* Part I(B), they are left only with theories that the Board could face substantial liability for alleged failures of oversight or alleged failures to disclose. Plaintiffs have not met their burden of showing that the Board faces a substantial likelihood of liability under either of those theories.

a. No Particularized Facts Give Rise To A Substantial Likelihood Of Liability For Failures Of Oversight

Plaintiffs make a cursory allegation that "the failure of the Board to prevent civil and criminal acts in this case was an egregious wrong in bad faith and in violation of the law." (Compl. ¶ 223.) However, Plaintiffs fail to make the non-conclusory, particularized allegations

required to support a claim of bad faith necessary to establish a substantial likelihood of director liability. To prevail on a failure of oversight claim, Plaintiffs must demonstrate "a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists." *Caremark*, 698 A.2d at 971; *see also Citigroup*, 964 A.2d at 125 ("[W]hen a plaintiff seeks to show that demand is excused because directors face a substantial likelihood of liability where directors are exculpated from liability except for claims based on fraudulent, illegal or bad faith conduct, a plaintiff must also plead particularized facts that demonstrate that the directors acted with scienter, i.e., that they had actual or constructive knowledge that their conduct was legally improper.") (internal quotations and citations omitted); *Dow Chem.*, 2010 WL 66769 at *12 (noting that to establish oversight liability "a plaintiff must show that the directors knew they were not discharging their fiduciary obligations or that directors demonstrated a conscious disregard for their responsibilities such as by failing to act in the fact of a known duty to act"). Plaintiffs have not done this.

Plaintiffs attempt to impute the actions of the corporation as a whole to the directors, alleging that the "the Company received several FDA Warning Letters" warning of misconduct occurring "over a long period of time." (Compl. ¶ 223.) As already discussed, however, none of those letters were related to any of the off-label marketing at issue in this suit. Moreover, as this Court has long recognized, directors cannot be held personally liable for all activities of their corporation. *See Lear*, 967 A.2d at 653 (dismissing *Caremark* claims for failure to plead demand futility and noting "the reality that even the most diligent board cannot guarantee an entire organization will always comply with the law"); *Stone*, 911 A.2d at 369 (recognizing director liability for failure to exercise oversight only where there is a sustained and systematic failure by the board). That Allergan received four unrelated FDA warning letters between 2001 and 2009

(Compl. ¶ 48), does not demonstrate a sustained or utter failure by the directors to oversee the corporation. Although Plaintiffs acknowledge that the Board discussed one of the letters, the Complaint does not identify how the Board responded. Thus, even if those letters were somehow germane to the conduct at issue in this case, without allegations establishing what the Board's response to the letters was, it is not possible to conclude that the Board's response was inadequate.

The same is true of Plaintiffs' allegations regarding the reported off-label promotion of BOTOX® by a Dr. Schim. (Compl. ¶ 82-84, 174.) Plaintiffs admit that the Board was notified of the report and that, at that time, the Board was told that Allergan's management had already taken steps to address the incident. (*Id.*) Plaintiffs fail to discuss the breadth of the management response, which, as discussed at length in the Opening Brief for the Director Defendants, included written reprimands to the employees involved, warnings that any future incident would result in immediate termination, moving the manager involved out of the BOTOX® sales force, and additional training on compliance. *See* Director Defendants' Opening Brief at 22-23. Plaintiffs do not explain how those steps were somehow insufficient. (Compl. ¶ 174.) But even if they were somehow insufficient so that additional action was needed by the Board, Plaintiffs do not explain how the Board responded to the management report and, thus, without allegations establishing what the Board's response was, it is impossible to conclude that the response was inadequate or that it gives rise to a substantial likelihood of liability.

Plaintiffs have failed to show the "necessary condition for director oversight liability, i.e., a sustained or systematic failure to attempt to assure a reasonable information and reporting system." *Stone*, 911 A.2d at 369 (internal quotation marks and citation omitted). Plaintiffs fail to allege that the Board knew of any inadequate internal controls requiring attention. Nor do

Plaintiffs allege that the Board, much less the individual directors, ignored any problems. Instead, Plaintiffs allege that the directors "by their education and experience" should have been aware of the problems posed by the off-label marketing and promotion that was occurring. (Compl. ¶ 224.) That conclusory allegation of awareness, however, does not establish that the Board or its individual members actually knew of any breakdown in the oversight procedures and process.

To the contrary, Plaintiffs concede that the Board had "procedures and codes of conduct" in place "for supervising the officers and employees to prevent illegal activity" (Compl. ¶ 225) and Audit & Finance and Corporate Governance Committees "for ensuring the Company's compliance with applicable laws and regulations." (*Id.* ¶ 226.) Having acknowledged those oversight procedures, Plaintiffs merely assert, with no supporting facts, that the Board "failed to follow requirements of its procedures and codes" or "of the Audit and Finance Committee Charter and the Corporate Governance Charter." (*Id.* ¶ 225-26.) That bald assertion is not enough. Instead, Plaintiffs need to demonstrate that "the board was ever aware that [the] internal controls were inadequate, that the inadequacies would result in illegal activity, and that the board chose to do nothing about problems it allegedly knew existed." *King*, 648 F. Supp. 2d at 623 (finding no substantial likelihood of oversight liability for the board members after the company pled guilty to FDCA violations). Plaintiffs' failure to plead any inadequacy in the oversight procedures and processes defeats their claim that the directors face an "extremely high risk" of liability for failures of oversight. *See David B. Shaev Profit Sharing Account v. Armstrong*, 2006 WL 391931, at *5 (Del. Ch. Feb. 13, 2006) ("[T]he one thing that is emphatically not a *Caremark* claim is the bald allegation that directors bear liability where a concededly well-constituted oversight mechanism, having received no specific indications of misconduct, failed

to discover fraud."), *aff'd mem.* 911 A.2d 802 (Del. 2006); *Dow Chem.*, 2010 WL 66769, at *13 n.85 (granting motion to dismiss for failure to adequately plead demand futility and asserting that plaintiffs "cannot simultaneously" admit existence of oversight procedures and claim utter disregard of oversight duties without well-pleaded allegations of deliberate failure to monitor).

Plaintiffs also cannot point to the Government's investigation and the subsequent settlement to support a reasonable inference that the Board was aware of and did nothing about any off-label marketing practices. As has already been noted, the misdemeanor charge to which Allergan pled is a strict liability offense, and the settlement is not indicative of any awareness of wrongdoing on the part of the Board. Moreover, Allergan cooperated with the Government's investigation. (Compl. ¶ 121.) Thus, the Board did not ignore or evade its obligations. *See King*, 648 F. Supp. 2d at 625 (finding the Board did not ignore its obligations when it cooperated with each government investigation). To infer awareness and failure to act from the investigation and settlement would impermissibly equate a bad outcome with bad faith. *Stone*, 911 A.2d at 373 (holding dismissal of derivative claims is appropriate where "the plaintiffs' complaint seeks to equate a bad outcome with bad faith"). This is the danger of hindsight of which this Court has warned. *Id.* ("[T]he 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."); *Hartsel*, 2011 WL 2421003 at *27 ("[F]utility is gauged by the circumstances existing at the commencement of a derivative suit," and not afterwards with the benefit of hindsight.").

Without further facts demonstrating the Board knew of and disregarded a breakdown in the reporting process, Plaintiffs are unable to demonstrate that the Board faces a substantial likelihood of liability with regard to Plaintiffs' *Caremark* claim, and it cannot excuse demand.

b. No Particularized Facts Give Rise To A Substantial Likelihood Of Liability For Violating Duties Of Disclosure Through Material Omissions

Plaintiffs have also alleged disclosure violations in the Complaint. (Compl. ¶¶ 205-210.) Because of the exculpation provision in the Company's certificate of incorporation, in order to show a substantial likelihood of liability for a failure to disclose, Plaintiffs must plead particularized facts that suggest "a majority of the defendants knowingly engaged in fraudulent or illegal conduct or breached in bad faith the covenant of good faith and fair dealing." *Wood*, 953 A.2d at 141 (internal quotation marks omitted). The alleged failures to disclose all relate to claimed failures by the Board to disclose off-label marketing or related wrongdoing. (*See, e.g.*, Compl. ¶ 205 ("[T]he Director Defendants[] misrepresented the Company's actual practices with respect to the promotion of off-label uses"); ¶ 206 (stating that the Board "failed to disclose" the Company's dependence "on the off-label marketing of Botox").) However, as set forth above, Plaintiffs have failed to plead any particular facts showing that the Board was ever aware of off-label marketing, and, thus, their allegations do not show that "a majority of the defendants *knowingly* engaged in illegal conduct," by failing to disclose any off-label marketing. *Wood*, 953 A.2d at 141 (emphasis added).

Plaintiffs' allegations fail to meet the standard to establish likelihood of substantial liability. *See Citigroup*, 964 A.2d at 134 (stating "to establish a threat of director liability based on a disclosure violation, plaintiffs must plead facts that show that the violation was made knowingly or in bad faith, a showing that requires allegations regarding what the directors knew and when"). In particular, Plaintiffs fail to identify which members of the Board, if any, prepared the allegedly misleading proxy statements or were responsible for the omissions. Plaintiffs also fail to provide any facts concerning what the Board knew and when. As such, Plaintiffs fail to establish the directors knowingly permitted the alleged omissions.

In sum, Plaintiffs fail to make any allegations that support a substantial likelihood of liability, and the Complaint does not create any reason to doubt that the directors could not be disinterested and independent in responding to any demand. Because the Complaint also fails to create reason to doubt that the Board's approval of strategic plans was a valid exercise of business judgment, Plaintiffs have not established any reason why they, rather than the Board, should be empowered to decide whether suit should be brought on behalf of the Company. The Complaint must be dismissed.

CONCLUSION

For the foregoing reasons, Nominal Defendant Allergan, Inc. respectfully requests that the Court grant its motion to dismiss the Complaint.

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