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,	)	**REDACTED PUBLIC VERSION** **E-Filed: November 11, 2011**
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 REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE VERIFIED SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Allegations of company wrongdoing do not establish demand futility or personal liability for a company's board of directors. Recognizing the deficiency in that underlying theory, Plaintiffs[1] oppose Defendants' motions to dismiss by asserting that "[t]he Complaint identifies specific documents reflecting the Board's approval of the Company's off-label promotion and marketing of BOTOX®." (Opp. at 1.) Yet, despite that assertion, neither the Complaint nor the fifty-one page Omnibus Memorandum of Law in Opposition to Defendants' Motions to Dismiss the Second Amended Derivative Complaint (the "Opposition"), identifies a single document or well-pled allegation that the Board played any role in promoting BOTOX® for off-label uses. Instead, Plaintiffs identify documents showing that the Board engaged in routine corporate matters related to the Company's flagship product. For example, Plaintiffs allege that the Board: considered BOTOX® to be a high priority for the Company; knew of legal off-label sales; made efforts to expand the FDA approved indications for BOTOX®; and encouraged Allergan to keep up with expanding sales demand for BOTOX®—none of which are indicative of illegal behavior or a breach of fiduciary duties. The Opposition also makes numerous allegations regarding the behavior of other individuals within the Company, none of which are alleged to have occurred under the direction or approval of the Board. To the extent any of those other acts could be

[1] Defined terms used in Nominal Defendant Allergan, Inc.'s Opening Brief in Support of Its Motion to Dismiss the Second Amended Derivative Complaint (D.I. 61) ("Allergan's Opening Brief"), are likewise adopted herein. Thus, "Complaint" shall mean the Verified Second Amended Derivative Complaint; "Plaintiffs" shall mean Louisiana Municipal Police Employees' Retirement System and U.F.C.W. Local 1776 & Participating Employers Pension Fund, collectively; "Allergan" or the "Company" shall mean Defendant Allergan, Inc.; the "Director Defendants" shall mean Defendants 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" shall mean Allergan and the Director Defendants collectively; and the "Board" shall mean the board of directors of Allergan.

considered off-label marketing—and the vast majority cannot—they likewise do not provide a basis to impute any wrongdoing to the Board.

Lacking any particularized allegations showing Board misconduct, Plaintiffs instead recite every detail of every action the Board ever took with respect to BOTOX®, in an apparent hope that the sheer volume of allegations will create the illusion of wrongdoing. Yet despite summarizing nearly eight years' worth of Board meeting minutes, Plaintiffs are unable to identify any act or omission by which the Board played a role in directing or approving off-label marketing of BOTOX®. Consequently, neither the Complaint nor the Opposition establishes that the Board made decisions that were other than the valid exercise of business judgment or that the Board would not be disinterested in considering any demand. As a result, Plaintiffs have failed to meet their threshold pleading burden and the Complaint should be dismissed for failure to make a demand.

ARGUMENT[2]

The right to bring suit on behalf of Allergan belongs to the Company's Board. *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). Plaintiffs can supplant the Board's role only if Plaintiffs have first demanded that the Board take the requested action—which, here, they have not—or if they have "established 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); *see also* Court of Chancery Rule 23.1.

As explained in detail in Allergan's Opening Brief, (*see* Allergan's Op. Br. at 9-12), when a plaintiff challenges affirmative Board action, implicating the test for demand futility articulated in *Aronson*, demand is excused only if the plaintiff pleads particularized facts creating a reason to doubt either (1) that challenged action was the product of a valid exercise of business judgment; or (2) that as a result of the challenged act, the Board is able to act disinterestedly and independently in responding to any demand. *Wood*, 953 A.2d at 140. When a plaintiff challenges board inaction, implicating the test articulated in *Rales v. Blasband*, the plaintiff must plead particularized facts creating 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

[2] Allergan does not recite the facts here, but fully incorporates by reference the statement of facts included in its Opening Brief.

judgment in responding to demand." 634 A.2d 927, 934 (Del. 1993). The *Rales* test and the first prong of the *Aronson* test are often substantially the same. *See, e.g., MCG Capital Corp. v. Maginn*, 2010 WL 1782271, at *19 n. 117 (Del. Ch. May 5, 2010) (explaining that "the first prong of *Aronson* and the test in *Rales* differ only slightly" and that often there is "no reason why . . . the demand futility analysis would not be the same under both tests"). When a plaintiff seeks to satisfy either of those tests by arguing that directors are not disinterested because they are being asked to sue themselves, demand is excused only if the particularized allegations show that the directors face "a substantial likelihood of personal liability." *Rattner v. Bidzos*, 2003 WL 22284323, at *9 (Del. Ch. Sep. 30, 2008).

In the Opposition, Plaintiffs implicate both the *Aronson* and *Rales* tests, arguing that demand is excused for three reasons: (1) they argue demand is excused under *Aronson's* second prong because the Board allegedly performed affirmative acts—primarily in the form of approving strategic plans and expenditures for the Company—to direct and approve off-label marketing, which acts Plaintiffs claim were not the product of a valid exercise of business judgment, (Opp. at 20-26); (2) bootstrapping to their first basis, they argue that demand is excused under *Aronson's* first prong because the Board faces a substantial likelihood of liability as a result of performing those affirmative acts and is, therefore, not disinterested, (Opp. at 26-35); and (3) they argue that demand is excused under *Rales* because the Board faces a substantial likelihood of liability as a result of its failure to curtail off-label marketing of which it was, or should have been, aware or to otherwise exercise its duties of oversight, (Opp. at 27-29, 44-47). Those arguments lack merit and are addressed in turn, below.

I. THE COMPLAINT ALLEGES NO PARTICULARIZED FACTS SHOWING THAT ANY BOARD ACTION WAS OTHER THAN THE PRODUCT OF VALID BUSINESS JUDGMENT OR THAT THE BOARD FACES A SUBSTANTIAL LIKELIHOOD OF LIABILITY AS A RESULT OF ANY ACTION

To support demand futility based on the Board's alleged failure to act with valid business judgment in approving strategic plans and expenditures or based on a substantial likelihood of personal liability for those approvals, the Complaint must contain particularized allegations showing that, in making those approvals, the Board somehow played a role in the off-label marketing of BOTOX®. Despite summarizing nearly eight years' worth of Board meeting minutes and other documents obtained through protracted and seriatim inspection requests under 8 *Del. C.* § 220, however, Plaintiffs have not identified any such role. Instead, the allegations identified by Plaintiffs fall primarily into one of three categories, all of which identify legal and unremarkable conduct or conduct not associated with the Board: (1) allegations that the Board was aware of legal off-label sales; (2) allegations that the Board sought to expand the FDA approved indications for BOTOX®; and (3) allegations of actions taken by others in the Company, without the direction or approval of the Board. Those allegations do not establish that the Board ever directed or otherwise approved of off-label marketing of BOTOX®, and, thus, fail to show that any Board decision was not the product of valid business judgment or that the Board faces any likelihood—let alone a substantial likelihood—of liability. As a result, Plaintiffs' complaint fails to show demand futility based on any challenged Board action.

A. The Allegations in the Complaint, and Plaintiffs' Accompanying Arguments, Demonstrate Legal Conduct Unrelated to Off-Label Marketing

1. Allegations Regarding the Board's Approval of Sales and Revenue Forecasts that May Incorporate Off-Label Sales Do Not Demonstrate Any Alleged Approval of Illegal Off-Label Marketing

Much of Plaintiffs' argument focuses on the Board's unremarkable and legal approvals of strategic plans containing sales and revenue forecasts that, according to Plaintiffs, "were impossible to meet without off-label sales." (Opp. at 9.) From there, Plaintiffs make the unsupported inferential leap that the Board's approval of those targets "was blatantly improper on its face." (Opp. at 24.) Plaintiffs' position is not supported by the allegations in the Complaint, cannot be reconciled with the law, and cannot establish demand futility.

Even assuming that the allegations in the Complaint support the conclusion that the Board-approved forecasts "were impossible to meet without off-label sales," (Opp. at 9), there would have been nothing improper or illegal about the Board approving those targets. It is undisputed that off-label sales of BOTOX® are legal. *See, e.g.*, *In re Allergan, Inc.*, 2011 WL 1429626, at *2 (C.D. Cal. Apr. 12, 2011) ("The Plaintiffs themselves recognize that it is the off-label marketing of an FDA approved drug that is illegal, not the off-label sale."); 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] . . . ."). In fact, it is well-recognized that off-label use of an approved drug is not only legal, but may often be the most appropriate standard of care for some conditions. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 n.5 (2001) ("Off-label use is widespread in the medical community and often is essential to giving patients

optimal medical care, both of which medical ethics, FDA, and most courts recognize." (internal quotation marks omitted).); *United States v. Caronia*, 576 F. Supp. 2d 385, 393 (E.D.N.Y. 2008) ("It is generally recognized (even by the FDA) that off-label prescriptions can constitute a medically recognized standard of care and, therefore, that it is important for physicians to have accurate information about off-label uses.").

Plaintiffs do not, because they cannot, argue that the Board committed wrongdoing simply because it was aware of off-label sales. Nonetheless, Plaintiffs implicitly try to equate knowledge of off-label sales with wrongdoing by arguing that it "was blatantly improper on its face" for the Board to approve revenue targets that forecast continued off-label sales. (Opp. at 24.) Plaintiffs offer no explanation for why, when off-label sales are both legal and medically appropriate, a Board of directors cannot factor any such sales into its financial forecasts. Plaintiffs appear to suggest that, while off-label sales are legal, a Board of directors that becomes aware they have occurred must ignore them for purposes of forecasting future sales. Such a contention finds no support in the law. When a Board of directors becomes aware that legal off-label sales have been and may continue to be a material portion of sales for a company, the reasonable course of action is for that Board to factor any such sales into its financial forecasts, so long as those forecasts do not call for illegal promotion of those sales. *Cf. King v. Baldino*, 648 F. Supp. 2d 609, 623 (D. Del. 2009) *aff'd sub nom. King ex rel. Cephalon Inc. v. Baldino*, 2010 WL 5078008 (3d Cir. Dec. 14, 2010) (explaining that an "increase [in sales of a drug] does not lead to the conclusion that the increase in sales was due to illegal activity"). Plaintiffs' argument fails to show that the Board's approvals of Company sales and revenue targets were not valid exercises of business judgment or that the Board somehow faces a substantial likelihood of liability as a result of having approved those targets.

Moreover, many of the allegations Plaintiffs rely on for their assertion that the Board approved of sales and revenue forecasts incorporating off-label sales do not support that conclusion. For instance, Plaintiffs cite a portion of the Company's 1997-2001 strategic plan that called for maximizing BOTOX® sales for treatment of cerebral palsy, spasticity, and pain—all of which are off-label uses in the United States. (Opp. at 42 (citing, e.g., AGN-UFCW 003934[3]).) The portion of the strategic plan cited by Plaintiffs, however, outlines Allergan's growth strategy for Europe and Latin America, both of which include countries in which BOTOX® is approved as a treatment for the described conditions. (AGN-UFCW 003934.) That same strategic plan contains a separate North American strategy that makes no mention of increasing sales for any of those conditions. (AGN-UFCW 003933). The North American strategy instead identifies Allergan's goal of seeking new approved indications for BOTOX®. (*Id.*) Thus, while the allegations regarding that strategic plan may demonstrate that the Board approved of financial forecasts incorporating BOTOX® sales for non-FDA approved uses, the allegations do not show that the Board approved of forecasts anticipating that those sales would occur in the United States. Therefore, while any Board approval of forecasts incorporating off-label sales would have been legal and unremarkable, the allegations cited by Plaintiffs do not even support the conclusion that such approval took place.[4]

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[3] AGN-UFCW 0003928-4074 is attached as Exhibit D to the Director Defendants' Opening Brief in Support of Their Motion to Dismiss (D.I. 62). Although it was not included as an exhibit to the Complaint, it is one of the strategic plans relied on by the Complaint, and was, therefore, incorporated by reference. On a motion to dismiss, the Court may consider documents that are integral to or incorporated by reference into a complaint. *Stone*, 911 A.2d at 372. This particular document is also relied on and cited by Plaintiffs in their Opposition.

[4] Plaintiffs also cite a strategic plan describing a correlation between increases in sales personnel and increases in spasticity sales, which Plaintiffs argue shows the Board knew that sales-personnel were promoting off-label uses. (Opp. at 23 (citing Compl. at ¶ 176).) The Complaint does not allege whether the increases in personnel and in sales were in the United

Plaintiffs' related arguments that the Board approved various expenditures "[t]o meet the Board-approved [sales and revenue] projections," (Opp. at 10-12), or that the Board otherwise made "efforts to expand capacity and to modify existing facilities to be able to meet anticipated increased" sales are also unremarkable, (Opp. at 5-6). Any responsible board of directors recognizing that existing facilities would be insufficient to meet forecasted demand for legal sales would, of course, consider efforts at expanding those facilities. Those allegations fail to show any failure to exercise valid business judgment and do not support any likelihood of personal liability.[5]

2. *Allegations Regarding the Board's Approval and Funding of Efforts at Obtaining Expanded Indications for BOTOX® Do Not Demonstrate Any Alleged Approval of Illegal Off-Label Marketing*

Plaintiffs also argue that the Board illegally promoted off-label uses of BOTOX® through Allergan's efforts at developing uses for BOTOX® that were not yet FDA approved. For instance, Plaintiffs highlight "that 'BOTOX® Headache' was one of the Company's top ten projects in terms of development spending, even though BOTOX® was not approved to treat headaches at the time," that the "BOTOX® migraine project continued to be a main topic of conversation at many Board meetings throughout 2005," and that the Board twice considered reports on "the Phase II headache studies." (Opp. at 6-7 (internal quotation marks omitted).) Likewise, Plaintiffs note the Board's plans for "acceleration of growth in therapeutic indications" for BOTOX®. (Opp. at 6 (quoting Compl. at ¶ 138).) Those acts are not off-label marketing of

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States or in countries where BOTOX® is an approved-of treatment for spasticity, however, and cannot therefore be the basis for concluding that the Board played any role in promoting off-label marketing.

[5] Plaintiffs' Opposition also dedicates four pages to outlining the importance of BOTOX® to Allergan's business. (Opp. at 4-8.) Other than as marginally interesting background, it is not clear how those facts are relevant to whether the Board ever directed or approved of off-label marketing of BOTOX®.

BOTOX®; rather they are efforts at obtaining new on-label indications of BOTOX®—efforts that, in fact, paid off, as BOTOX® was approved for treatment of migraine headaches in October 2010, (Compl. at ¶ 52 n.7). Plaintiffs never explain how allegations regarding those efforts support a conclusion that the Board was not exercising its valid business judgment or that the Board could somehow incur personal liability as a result of those efforts. Those allegations, therefore, do not provide any basis for meeting Plaintiffs' burden of excusing demand.[6]

B. Allegations Regarding Action Taken by Other Allergan Employees, Without Knowledge of the Board, Do Not Establish Personal Wrongdoing by or Liability for the Board

1. Allegations Regarding Corporate Programs Funded or Administered by Allergan Do Not Establish Board Liability

Plaintiffs identify several corporate programs funded by or affiliated with Allergan that Plaintiffs argue demonstrate off-label marketing, but they fail to connect this Company conduct to the individual Board members. (Opp. at 22 (citing Compl. at ¶¶ 72, 77).) As described below, the Complaint is devoid of allegations that the Board was ever aware of any of these programs. Even if the Complaint alleged that the Board had been aware of the programs, which it does not, the particularized allegations identified by Plaintiffs do not describe any off-label marketing, despite Plaintiffs' assertions to the contrary. Consequently, the allegations with respect to those programs are insufficient to plead demand futility.

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[6] In a similar vein, Plaintiffs' cite the Board's approval of budgets that "included millions of dollars used to lobby Medicare and Medicaid to expand coverage for off-label uses of BOTOX®" as evidence of the Board's involvement in off-label marketing. (Opp. at 10-13.) Plaintiffs likewise cite Allergan's funding of "Alliance for Patient Access," an organization that "assists with lowering coverage barriers," as evidence that the Board had engaged in off-label marketing. (Opp. at 22 (citing Compl. at ¶ 76).) Plaintiffs do not explain how the Company's participation in legal lobbying efforts aimed at expanding coverage for legal sales somehow constitutes illegal marketing. Moreover, the Complaint does not allege that the Board directed or was even aware of the funding provided to Alliance for Patient Access.

The first of the Company programs identified by Plaintiffs is the "BOTOX ADVANTAGE® Program." (Opp. at 22 (citing Compl. at ¶ 72).) The Complaint alleges that, as part of that program, Allergan funded a third-party hotline that assisted physicians in resolving disputes with insurance companies over reimbursement for off-label prescriptions. (Compl. at ¶ 72.) In their Opposition, Plaintiffs assert that the funding for this program was provided "under the direct supervision and with the Approval of the Board" and that it constituted "marketing and promoting BOTOX® for off-label uses." (Opp. at 22.) Those assertions are inconsistent with both the Complaint and with the law, however.

First, despite the Opposition's assertion that this program was "under the direct supervision and with the Approval of the Board," (*id.*), the Complaint does not anywhere allege that the Board was aware that the Company funded the third-party hotline or that the hotline provided assistance in obtaining reimbursement for off-label sales. Indeed, no mention of the hotline—or even of the "BOTOX ADVANTAGE® Program—is made in the eight-years' worth of summarized Board meeting minutes included in the Complaint. (*See* Compl. at ¶ 15.) Moreover, Plaintiffs do not cite any statute, case, or regulation suggesting that funding a third-party program that aids doctors in obtaining reimbursement for sales that have already taken place could somehow be construed as off-label marketing. Thus, the allegations with respect to the BOTOX ADVANTAGE® Program fail to show that any off-label marketing occurred, let alone that off-label marketing occurred at the direction or with the approval of the Board.[7]

[7] In addition to the third-party hotline identified above, the Complaint cites other efforts at assisting physicians in obtaining reimbursements for legal off-label sales. (*See, e.g.*, Compl. at ¶ 70.) As with the hotline, the Complaint does not allege that the Board directed or knew of these efforts, nor do Plaintiffs' cite any legal authority suggesting that assisting physicians in obtaining reimbursements for legal off-label sales constitutes illegal off-label marketing.

Plaintiffs next cite Allergan's "Temporary Price Allowance" program, under which the Company provided discounts on BOTOX® to certain physicians. (Opp. at 22 (citing Compl. at ¶ 72).) The Complaint does not allege that these discounts were somehow tied to sales of BOTOX® for off-label uses, however. (*Id.*) It alleges only that certain targeted physicians received discounts. (*Id.*) Thus, it is unclear how the allegations regarding this program have anything to do with promoting off-label uses of BOTOX®. In addition, the Complaint lacks the critical allegations that the Board supposedly directed or was aware of this program. (*Id.*) Once again, the program is never mentioned in the eight years of summarized meeting minutes. (Compl. at ¶ 15.)

Next, Plaintiffs cite Allergan's support of the "WE MOVE" organization, which the Complaint alleges was funded by Allergan, as another example of a program that they allege promoted off-label sales of BOTOX®. (Opp. at 22 (citing Compl. at ¶ 77).) According to the Complaint, the "WE MOVE" program provided physicians with "medical literature" regarding non-approved uses of BOTOX®. (Compl. at ¶ 77.) As with the programs discussed above, "WE MOVE" is nowhere mentioned in the eight-years of summarized minutes, (*see* Compl. at ¶ 15), nor does the Complaint elsewhere allege that the Board directed or knew of the program.

Moreover, even if Plaintiffs sufficiently alleged that the Board had known of the program, which they do not, the Complaint does not identify anything illegal about the program. The FDA expressly allows companies to distribute medical literature "concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug or device," subject to certain regulatory requirements. 21 C.F.R. 99.101. In neither the Complaint nor their Opposition do Plaintiffs even cite that FDA regulation, nor do they make any allegations showing that the literature distributed by WE MOVE did not comply with the

regulatory requirements. Thus, once again, Plaintiffs have failed to show either that this program constituted off-label marketing or, even if it did, that the program was directed or approved by the Board.

Finally, Plaintiffs cite the "Physician Partnership Program" as another program "under the direct supervision" of the Board that constituted "marketing and promoting BOTOX® for off-label uses." (Opp. at 22 (citing Compl. at ¶ 72).) The totality of allegations regarding this program are that it "allowed Allergan to use and pay physicians to be 'traveling mentors' to promote off-label uses and doses for BOTOX®." (Compl. at ¶ 72.) The conclusory assertion that the Company had in place a program allowing it "to promote off-label uses and doses for BOTOX®" falls far short of the kind of particularized allegations necessary to plead demand futility. *See Wood*, 953 A.2d at 140 (explaining that "[c]onclusory allegations are not considered as expressly pleaded facts or factual inferences" (internal quotation marks omitted)). Moreover, as with all of these programs, the "Physician Partnership Program" is nowhere mentioned in the summarized Board minutes, and the Complaint does not otherwise allege that the Board directed or was aware of the program.

In sum, the Complaint does not contain any allegations suggesting that the Board had any role in or knowledge of the various corporate programs identified by Plaintiffs in support of their allegations of demand futility. Thus, regardless of the substance of those programs, Plaintiffs' allegation do not establish that any Board action was not the valid exercise of business judgment, nor could any Board member face a substantial likelihood of liability as a result of those programs. Moreover, other than one conclusory allegation with respect to one of the programs, Plaintiffs have not identified allegations showing that those programs constituted off-label marketing or were otherwise illegal. Thus, even if Plaintiffs sufficiently alleged that the Board

had directed or approved those programs, that direction or approval would presumptively have been a valid exercise of business judgment and no Board member would face a substantial likelihood of liability as a result. Consequently, Plaintiffs' allegations and argument regarding the various corporate programs sponsored by Allergan fail to support a claim of demand futility.

2. Allegations Regarding Allergan's Sales Employee Training Do Not Establish Board Liability

The Opposition also cites a number of allegations regarding employee training to support their claims of demand futility. (Opp. at 17 (citing Compl. at ¶¶ 73-75).) Even if the training described in those allegations did constitute off-label promotion of BOTOX®, the Complaint does not allege that the training was under the direction of the Board or that the Board otherwise approved of it, or was even aware of it. For example, the Complaint describes Allergan's "Foundation Training" course as promoting off-label uses of BOTOX® by, for instance, training sales persons to call on physicians that did not typically treat patients who had conditions for which BOTOX® was an approved treatment. (Compl. at ¶ 73.) As with the corporate programs discussed earlier, however, this training program is not mentioned in any of the eight-years' worth of summarized Board minutes, (*see* Compl. at ¶ 15), and the Complaint does not otherwise allege that the Board was responsible for the program or that it ever became aware of the program.

Plaintiffs' Opposition relies on similar allegations regarding other training that they claim promoted off-label uses of BOTOX®. (*See, e.g.*, Opp. at 17 (citing Compl. at ¶ 74 (describing sales meetings in which participants exchanged information related to off-label uses of BOTOX®)); Opp. at 11-12, 22 (citing Compl. at ¶ 78 (alleging that sales employees were instructed to refer physicians to a website that contained information about off-label uses of BOTOX®)).) Yet, as with Allergan's "Foundation Training" described above, the various

training programs are not mentioned in the summarized Board meeting minutes or otherwise associated with the Board by any other allegations in the Complaint. A Board of directors does not face liability simply because wrongdoing may have occurred within the company. *See, e.g.*, *In re Lear Corp. S'holder Litig.*, 967 A.2d 640, 653 (Del. Ch. 2008) (dismissing claims against directors because of "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 (noting that even directors acting in good faith "may not invariably prevent employees from violating criminal laws, or from causing the corporation to incur significant financial liability, or both"). Thus, because the Board did not direct or otherwise approve of those programs, the allegations regarding them cannot show that the Board made any decision that was not the product of valid business judgment.

This is not a case about whether off-label marketing occurred at Allergan. This case is about whether the Board faces personal liability because it supposedly participated in the alleged illegal conduct. Plaintiffs attempt to equate alleged wrongdoing on the part of unnamed individuals within the Company with wrongdoing on the part of the directors. But Plaintiffs do not plead particularized facts that the Board authorized or knew of the underlying conduct. As such, the Company's acts do not provide a basis to conclude that any Board decision was not the valid exercise of business judgment or that the Board faces a substantial risk of liability for any of its decisions. Plaintiffs cannot meet their burden of establishing Board liability by arguing directorial wrongdoing through guilt by association. Accordingly, Plaintiffs have not met their burden of showing that demand is excused as a result of any challenged Board action.

II. THE COMPLAINT ALLEGES NO PARTICULARIZED FACTS SHOWING THAT THE DIRECTORS FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY FOR ANY INACTION

In addition to arguing that the directors face a substantial likelihood of liability as a result of their alleged approval of off-label marketing, Plaintiffs argue that the directors face a substantial likelihood of liability because of alleged failures to curb off-label marketing and to exercise their oversight responsibilities. (Opp. at 27-29; 35-44-47.) Allergan has adopted an 8 *Del. C.* § 102(b)(7) exculpation clause, which prevents the Board members from facing any personal liability for breaches of due care. Thus, for the directors to face a substantial likelihood of liability for any alleged failures of oversight, Plaintiffs' particularized allegations would have to show that the directors breached their fiduciary duties of loyalty through failures of oversight, thus stating a non-exculpated *Caremark* claim, which has been described as "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." *In re Caremark Int'l Deriv. Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996). To state such a claim, Plaintiffs would have to show at least that (1) the Board was apprised of red flags concerning illegal off-label marketing of BOTOX® therapeutic and (2) the Board failed to take appropriate action in response. *See Beam Ex Rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 833 A.2d 961, 976 (Del. Ch. 2003).

Plaintiffs support their claim by identifying and describing two groups of unrelated events as "red flags," which they argue "should have given the Director Defendants notice . . . that illegal marketing was widespread at Allergan," (Opp. at 45), and which show that "the Board failed to institute a proper reporting system," (Opp. at 29.) As discussed below, neither of those purported "red flags" supports the conclusion that the Board faces liability for a claim of director inaction because the allegations show that the illegal marketing brought to the Board's

attention was isolated, not "widespread," and that the Company did have an effective reporting system in place.[8]

A. Allegations Regarding Purported Off-Label Marketing by Dr. Schim at the CORE Speaker Program Do Not Establish a Failure of Oversight

Plaintiffs cite allegations regarding a presentation given by Dr. Jack Schim at Allergan sponsored programs as evidence of a lack of oversight on the part of the Board. (Opp. at 28 (citing Compl. at ¶¶ 82-84).) Yet these allegations actually demonstrate that the Company and the Board took off-label marketing issues very seriously. According to the Complaint, Dr. Schim had given presentations at several Allergan sponsored CORE speaker programs over a period of ten months, which included information promoting the off-label use of BOTOX® for headache treatment. (Compl. at ¶¶ 82-83.) After the FDA sent Allergan a letter inquiring about one of these presentations, Douglas Ingram, Allergan's General Counsel, wrote an e-mail update to the Board informing them of the issues and the Company's response. (Compl. at ¶ 82.) [redacted]

[redacted]

[8] Plaintiffs also support their argument by attempting to analogize this case to *Pfizer Inc. Shareholder Derivative Litigation*, 2010 WL 2747447 (S.D.N.Y. July 31, 2010) and *Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795 (7th Cir. 2001). For the reasons addressed thoroughly in the Director Defendants' Reply Brief in Further Support of Their Motion to Dismiss Plaintiffs' Second Amended Derivative Complaint, the allegations in Plaintiffs' Complaint bear no meaningful resemblance to the allegations that supported demand futility in *Pfizer* and *Abbott Labs*. (*See* Director Defs. Reply Br. at §§ I.B.2-3.) Allergan fully joins in and incorporates the arguments presented by the Director Defendants.

[9] As with the strategic plan discussed *supra* note 3, the e-mail from Ingram was not attached as an exhibit to the Complaint but is specifically cited and incorporated by reference in the Complaint. (See Compl. at ¶¶ 82-84.) It is also relied on by Plaintiffs in their Opposition.

[redacted]

Contrary to Plaintiffs' characterizations, those facts do not support the conclusion that "illegal marketing was widespread at Allergan," (Opp. at 45), or that "the Board failed to institute a proper reporting system," (Opp. at 29.) Instead, Plaintiffs' allegations reveal an isolated incident involving a single doctor, and show that the Company had systems in place allowing it to immediately and effectively respond to such incidents. Indeed, the Complaint does not allege that there were any additional incidents involving the CORE speaker program subsequent to the remedial efforts identified by Ingram.[10]

[10] In the Opposition, Plaintiffs assert that even after the steps taken by Ingram, the "illegal promotion scheme – virtually in all of its aspects – continued unabated." (Opp. at 15.) The Opposition does not cite any allegation in the Complaint to support that assertion. (*Id.*) Moreover, while it promises that support for the assertion will be "detailed below," nowhere else does the Opposition cite any allegations in support. A thorough examination of the Complaint shows that there is no basis for that claim, as there are no allegations of any other incidents related to Dr. Schim or the CORE program.

Far from demonstrating a lack of reporting systems and controls, the facts surrounding the CORE speaker program are evidence of a reporting and control system doing precisely what is intended—ensuring that the Board is made aware of isolated acts of wrongdoing before they become widespread and ensuring that proper measures are taken to remedy the wrongdoing. As such, the allegations regarding that program do not show that any director faces a substantial likelihood of liability for any failures of oversight and do not support Plaintiffs' claims for demand futility.

B. Allegations Regarding Unrelated FDA Warning Letters Are Not Red Flags Establishing Oversight Liability

Plaintiffs next cite the receipt of four FDA warning letters over a period of eight years as examples of "widespread" illegal marketing. As explained in Allergan's Opening Brief, none of those letters were related to the off-label marketing of BOTOX® for which the Company was charged and for which it agreed to pay a fine. (*See* Compl. at ¶¶ 48, 133; *see also* Allergan's Op. Br. at 17.) The first letter, sent in August 2001 raised concerns with the inclusion of data from nonclinical studies in BOTOX® related material. (Compl. at ¶ 133.) The second letter, sent in June 2003, addressed claims of misleading advertising for BOTOX® Cosmetic, (Compl. at ¶ 48), which 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, (*see* Warden Aff.[11] Ex. A). The third letter, sent in September 2005, addressed alleged misleading advertising for Lumigan®. (*Id.*) The final letter, sent in August of 2009, addressed alleged misleading advertising for ACZONE®. (*Id.*) Only one of those four letters was related to BOTOX® at all, and none dealt with off-label marketing, let alone the alleged off-label marketing at issue in this case.

[11] Citations to "Warden Aff." are to the Transmittal Affidavit of Joseph B. Warden filed concurrently with Allergan's Opening Brief (D.I. 61).

Moreover, the fact that the FDA sent four warning letters over a period of eight years does not support Plaintiffs' conclusion "that illegal marketing was widespread at Allergan," (Opp. at 45), particularly when none of the issues addressed in the four letters are alleged to have ever reoccurred. Additionally, the Complaint does not allege that the Board's response to these letters was in any way inadequate. (Compl. at ¶¶ 48, 133.) Rather, the Complaint is silent as to what response the Board took in response to the four letters. (*Id.*) An absence of allegations regarding the Board's response cannot possibly be construed as particularized allegations showing that the directors face a substantial likelihood of liability and that demand is, therefore, excused. *Cf. Martha Stewart Living*, 833 A.2d at 976 (explaining that a "key element" of a *Caremark* claim is that "the directors took no steps in a good faith effort to prevent or remedy [the] situation").

Because Plaintiffs have not identified any particularized allegations demonstrating that demand should be excused under either the *Aronson* or *Rales* test, the Complaint must be dismissed for failure to make a demand.[12]

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[12] Plaintiffs also make two other arguments that were thoroughly addressed in Allergan's Opening Brief and warrant little discussion here. First, Plaintiffs argue that the Board failed in its oversight duties because the fact that wrongdoing occurred by others within the company shows that the Board failed to abide by its own written procedure of ensuring compliance with all laws and regulations. (Opp. at 29 & n.12.) This Court has warned against "equat[ing] a bad outcome with bad faith" and has explained 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." *Stone*, 911 A.2d at 373. Thus, the fact that the Board may not have prevented all wrongdoing cannot be the basis for finding that the Board failed in its oversight duties.

Second, in response to Defendants' explanation for why payment of the $600 million settlement could not be considered corporate waste, Plaintiffs' try to resurrect their waste claim by arguing that they "are not contending that it was corporate waste for the Board to agree to settle the criminal and civil claims . . . by paying $600 million." (Opp. at 48.) But only a cursory reading of the Complaint shows that that is precisely what Plaintiffs contend. The Complaint states the Board committed waste by causing the incurrence of damages that

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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"currently exceed $600 million" and that "include the settlement payment the Company was required to make." (Compl. at ¶ 83.) While the Complaint refers generally to other damages that may have constituted waste, the $600 million settlement is the only specific transaction identified, and this Court has explained that a claim for waste requires identification of a specific transaction. *See, e.g., Postorivo v. AG Paintball Holdings, Inc.*, 2008 WL 553205, at *9 n.42 (Del. Ch. 2008) (dismissing a claim for corporate waste because "the Complaint [did] not allege a specific transaction"). With respect to the one identified transaction—the $600 million settlement payment—as noted above, Plaintiffs now take the position that that transaction was not corporate waste (nor could it be, for the reasons identified in Allergan's Opening Brief at 19-20). Consequently, Plaintiffs do not have a viable waste claim, and waste does not provide any basis for excusing demand.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 11th day of November, 2011, she caused to be served by LexisNexis Files & Serve a copy of the foregoing NOMINAL DEFENDANT ALLERGAN, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE VERIFIED SECOND AMENDED COMPLAINT (REDACTED PUBLIC VERSION) upon the following counsel of record:

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