**FOR PUBLICATION**

# UNITED STATES COURT OF APPEALS
# FOR THE NINTH CIRCUIT

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| WILLA ROSENBLOOM, derivatively on behalf of Allergan, Inc.; DANIEL HIMMEL; POMPANO BEACH POLICE & FIREFIGHTERS RETIREMENT SYSTEM; WASHINGTON LABORERS-EMPLOYERS PENSION TRUST, AKA Western Washington Laborers Employers Pension Trust,<br>*Plaintiffs-Appellants*,<br><br>v.<br><br>DAVID E. I. PYOTT; HERBERT W. BOYER, AKA Herbert W. Boyer, M.D.; LOUIS J. LAVIGNE, JR.; GAVIN S. HERBERT; STEPHEN J. RYAN, AKA Stephen J. Ryan, M.D.; LEONARD D. SCHAEFFER; MICHAEL R. GALLAGHER; ROBERT A. INGRAM; TREVOR M. JONES, AKA Trevor M. Jones, Ph.D.; DAWN E. HUDSON; RUSSELL T. RAY; DEBORAH DUNSIRE, AKA Deborah Dunsire, M.D.; ALLERGAN, INC., a Delaware corporation; HANDEL E. EVANS; RONALD M. CRESSWELL; LOUIS T. ROSSO; KAREN R. OSAR; ANTHONY H. WILD,<br>*Defendants-Appellees*. | No. 12-55516<br><br>D.C. No. 8:10-cv-01352-DOC-MLG<br><br>OPINION |

Appeal from the United States District Court
for the Central District of California
David O. Carter, District Judge, Presiding

Argued and Submitted
June 2, 2014—Pasadena, California

Filed September 2, 2014

Before: Stephen Reinhardt, John T. Noonan,
and Mary H. Murguia, Circuit Judges.

Opinion by Judge Reinhardt;
Special Concurrence by Judge Reinhardt

## SUMMARY*

### Securities Law / Demand Futility

Reversing the dismissal on the pleadings of a derivative action brought by shareholders of Allergan, Inc., producer of Botox, a well-known cosmetic and therapeutic drug, the panel held that the requirement of a demand on the company's board of directors, requesting that Allergan bring the derivative claims in its own name, was excused.

In their first amended complaint, the plaintiffs alleged that Allergan's board of directors knew about limits on promotion of off-label uses; that the board was aware that violations of

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

federal marketing rules could result in significant penalties; and that Allergan nonetheless repeatedly violated federal laws and regulations from 1997 to 2010, creating a number of programs to promote Botox for off-label uses, such as spasticity, pain, headaches, and migraines.

Reviewing for an abuse of discretion, as required by precedent, and applying Delaware law, the panel held that demand was excused because the plaintiffs' particularized allegations established a reasonable doubt as to whether the board faced a substantial likelihood of liability and as to whether the board was protected by the business judgment rule. The panel remanded the case for further proceedings.

Concurring, Judge Reinhardt set forth his view that the proper standard of review is de novo.

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## COUNSEL

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John C. Hueston, Daniel P. Lefler, and Lillie A. Werner, Irell & Manella, Los Angeles, California, for Nominal Defendant-Appellee.

## OPINION

REINHARDT, Circuit Judge:

Allergan, a specialty pharmaceutical manufacturer, produces Botox, a well-known cosmetic and therapeutic drug. In 2010, faced with allegations that it had acted illegally in marketing and labeling Botox, Allergan settled several *qui tam* suits and pled guilty in a criminal case. Allergan ultimately paid a total of $600 million in part for civil settlements and in part as a criminal fine. Shortly afterward, Plaintiffs, all Allergan shareholders, filed a derivative action alleging that Allergan's directors are liable for violations of various state and federal laws, as well as for breaches of their fiduciary duties to Allergan. Plaintiffs did not, however, first make a demand on Allergan's board requesting that Allergan bring the derivative claims in its own name. The district court dismissed their action on the ground that Plaintiffs failed to allege particularized facts showing that demand was excused, as Federal Rule of Civil Procedure 23.1 requires. In so doing, however, it misapplied governing Delaware law and improperly drew inferences against Plaintiffs rather than in their favor. We conclude that Plaintiffs' particularized allegations establish a reasonable doubt as to whether the Board faces a substantial likelihood of liability and as to whether the Board is protected by the business judgment rule. Accordingly, we conclude that demand is excused and reverse the district court.

## BACKGROUND

### I

Defendant Allergan, Inc. is a Delaware corporation specializing in specialty pharmaceuticals and medical devices.[1] It manufactures Botox, a purified toxin sold for cosmetic and therapeutic purposes.[2] When injected, Botox produces a local and temporary reduction of muscle or gland activity.

From 1989 to 2010, the FDA approved Botox for only a few indications: crossed eyes, involuntary eyelid muscle contractions, involuntary neck muscle contractions, and excessive sweating.[3] Although doctors may prescribe an approved pharmaceutical for purposes other than those listed on the FDA-approved label ("off-label use")—and do so regularly—federal law imposes numerous limits on drug

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[1] Defendants also include current and former Allergan directors: David E. I. Pyott, Herbert W. Boyer, Louis J. Lavigne, Jr., Gavin S. Herbert, Stephen J. Ryan, Leonard D. Schaeffer, Michael R. Gallagher, Robert A. Ingram, Trevor M. Jones, Dawn E. Hudson, Russell T. Ray, Deborah Dunsire, Handel E. Evans, Ronald M. Cresswell, Louis T. Rosso, Karen R. Osar, and Anthony H. Wild.

Plaintiffs include Willa Rosenbloom, Daniel Himmel, Pompano Beach Police & Firefighters' Retirement System, and Western Washington Laborers-Employers Pension Trust, and each plaintiff alleges being a shareholder of Allergan since 2003 or earlier.

[2] The popular use of Botox for cosmetic purposes is not at issue in this case.

[3] Moreover, patients with two of these conditions—crossed eyes and excessive sweating—rarely resort to Botox treatment.

manufacturers' efforts to promote off-label uses of their products.

In 2007, a *qui tam* action was filed against Allergan, alleging violations of the False Claims Act arising from off-label marketing and branding of Botox. That same year, the FBI opened an investigation into Allergan's off-label marketing of Botox. Three years later, after two more *qui tam* actions had been filed, Allergan, the United States, and the relators who had filed the *qui tam* actions entered into a settlement. Under this deal, Allergan agreed to pay $225 million to the United States and various state governments and to enter into a five-year corporate integrity agreement with the Department of Health and Human Services' Office of Inspector General. Later in 2010, the United States filed a criminal information against Allergan in the Northern District of Georgia, charging distribution of a misbranded drug/biologic in violation of the FDCA. Allergan pled guilty and agreed to pay a $375 million fine.

In September 2010, derivative suits against Allergan were filed in the Central District of California and the Delaware Court of Chancery. Ultimately, drawing on the fruits of a third party's demand for books and records under Delaware law, Plaintiffs filed the First Amended Complaint, which is at issue here. Plaintiffs allege that Allergan's board of directors knew about the limits on promotion of off-label uses; that the board was aware that violations of the federal marketing rules could result in significant penalties; and that Allergan nonetheless repeatedly violated federal laws and regulations from 1997 to 2010, creating a number of programs to promote Botox for off-label uses, such as spasticity, pain, headaches, and migraines.

Meanwhile, near-identical litigation proceeded apace in the Court of Chancery. In both courts, Allergan moved to dismiss for failure to adequately allege demand futility. The district court issued its opinion on the demand futility issue first, dismissing the California case in January 2012. It then denied a motion for reconsideration in February 2012.

In June 2012, in a detailed opinion, Vice Chancellor Laster held in the Delaware case that the plaintiffs had shown demand futility. *See La. Mun. Police Emps.' Ret. Sys. v. Pyott*, 46 A.3d 313, 351–59 (Del. Ch. 2012). In his lengthy and thorough analysis of how Delaware law applies to the issue of demand futility, Vice Chancellor Laster expressly criticized and rejected the district court's reasoning. *Id.* at 357–58. On appeal, however, the Delaware Supreme Court reversed Vice Chancellor Laster solely on the ground that the Delaware plaintiffs were collaterally estopped from pursuing their claims in the Court of Chancery due to the earlier-filed dismissal of the complaint in this case. *See Pyott v. La. Mun. Police Emps.' Ret. Sys.*, 74 A.3d 612, 614 (Del. 2013).

## II

Plaintiffs allege that, from 1997 to 2010, Allergan created and expanded nearly a dozen programs designed to aggressively promote the sale of Botox for off-label purposes. Plaintiffs elaborate that these programs were part of a concert of illegal conduct and that off-label Botox sales skyrocketed as a result. From 1996 to 2006, for example, spasticity sales grew by 332%, pain sales by 504%, and headache sales by 1,407%. By 2007, Allergan had over $500 million in annual Botox sales for therapeutic uses, of which 70 to 80% was attributable to off-label indications. This was no small sum to Allergan: Botox sales constituted 24 to 36% of total net

sales across all product lines from 2000 to 2009, and 36 to 39% of total specialty pharmaceutical sales from 2006 to 2009.

Here, we briefly summarize Plaintiffs' central allegations.

### A. The Headache Development Program

"At the direction of the [Board] . . . Allergan aggressively promoted Botox to treat several different types of headache conditions in addition to chronic headache for more than a decade, which caused Botox sales for that indication to increase by over 1,400%." Even though headache treatment was an off-label use until 2010, and even though no evidence at the time proved that Botox treated headaches (in fact, nine out of ten clinical trials for headache had failed), starting in 2003 Allergan sought out headache specialists and promoted Botox to them as a treatment. That same year, while aware that headaches were not an FDA approved indication for Botox, the Board saw a slide presentation that detailed Allergan's "Headache Development Program" and tracked the prevalence of headache disorders. This fact shows the Board's awareness of major headache-focused marketing at Allergan in the early 2000s—the same period in which off-label sales of Botox for headache treatment dramatically increased.

### B. The Cervical Dystonia/Headache Initiative (CDHI)

CD is a rare disorder that affects only approximately 27,000 Americans. Pursuant to the CDHI, Allergan "maximize[d] off-label Botox sales by encouraging doctors to diagnose [off-label] headache and pain symptoms as symptoms of Botox's on-label [CD] indication." Allergan

created this plan when clinical data did not support use of Botox for headaches; it was, in Allergan's words, a "backup strategy to ensure continued expansion into the headache market." Then, after the FDA rejected a request from Allergan to expand the Botox label to cover CD-related "pain," Allergan launched a campaign to persuade doctors that CD is under-diagnosed and that they should diagnose headaches and pain as mild CD to obtain reimbursement. This plan worked: CD quickly became a main driver for off-label Botox sales. The Board was briefed on "Strong Botox Sales" resulting from Allergan's "U.S. CD/pain" market program in a 2005 CEO Report.

### C. Reimbursement Support For Off-Label Uses of Botox

Unlike most drugs, Botox is a "buy and bill" drug, meaning that doctors buy it from Allergan and assume the risk of non-reimbursement on the back end. In the relevant time period, one vial of Botox cost $400 to $500 and most off-label uses of Botox required one to four vials. As Allergan recognized, growth in Botox sales depended on doctors being reimbursed.

To promote off-label use of Botox, Allergan doubled the size of its reimbursement support team in 2003—with the principal goal of minimizing customer barriers for Botox bought to treat headaches, pain, and spasticity. It also established a physician-assistance hotline for doctors to call for help with off-label reimbursement. Plaintiffs allege that, "[t]hrough the Botox Advantage Program, Allergan provided customized reimbursement support services to doctors . . . expended millions of dollars each year to operate the Botox Reimbursement Hotline, and performed detailed audits (or

'interventions') of physician billing records to demonstrate 'the value of Botox to their practice.'" On average, accounts with such "interventions" grew six times faster than did other accounts. Allergan provided doctors with ghost-written materials designed to persuade third-party payers to cover off-label uses of Botox, including treatment of headaches, and recruited physician "advocates" to lobby Medicare and Medicaid decision-makers to expand coverage for off-label use. Plaintiffs allege that the Board knew about the details and purpose of the Botox Advantage Program. They allege, for example, that in 2004 the Board reviewed several Botox Advantage promotional documents. The Board also received multiple reports on reimbursement support as a crucial factor in Botox sales.

### D. Intentional Targeting of Specialists Practicing in Off-Label Fields

Plaintiffs allege that "Allergan promoted Botox by targeting medical specialists who did not routinely treat patients with any of the conditions that Botox was approved to treat." This strategy was crucial to growth in off-label use of Botox. In 2004 alone, for instance, Allergan representatives called on thousands of doctors specializing in off-label fields, including pain and headache specialists. Allergan also undertook cross-promotion agreements with other companies to allow Allergan sales representatives access to physicians specializing in off-label fields. For example, in 2006, "Allergan had no drug approved for the treatment of headache at the time but agreed to double [another] company's sales force selling headache drugs so that Allergan could then also sell Botox to the neurologists who were customers of the other company." E-mails showed that Allergan sought to "Sell More Botox!!!" through this

program. The Board approved these agreements, several of which expressly contemplated cross-promotion of Botox and migraine headache treatments.

With Board approval, Allergan also acquired other companies in order to obtain sales staffs with experience in off-label specialties. For instance, Allergan acquired Espirit Pharma for $370 million in 2007, allegedly to acquire sales staff who could promote Botox for off-label uses to urologists. When the Board held a "Strategic Planning Session" at which this acquisition was discussed, it heard the details of "the Strategic Plan, updated to reflect the impact of Espirit Pharma," and that "the successful launches of our planned new products such as . . . new Botox indications . . . are critical to the success of our plan."

### E. Other Allergan Programs for Promoting Off-Label Use of Botox

In addition to the programs discussed *supra*, Plaintiffs allege that Allergan developed an array of expensive and effective (and unlawful) schemes to promote off-label use of Botox. It instructed sales representatives to promote the message that Botox "works!" for off-label uses, even when no clinical trials had proven the efficacy of Botox as a treatment. It "funded and controlled the content of hundreds of continuing medical education (CME) seminars, injection workshops, and promotional dinner programs at which paid speakers identified by the company as [Key Opinion Leaders] advocated Botox for off-label indications." It created "Centers of Excellence" to create, edit, and control the substance of CMEs that promoted Botox for off-label uses. It paid "honoraria" to high volume Botox injectors to speak at CMEs, and used millions of dollars of medical grants to

reward top purchasers of Botox. It hosted "Advisory Boards" at which it paid physicians $1,500 each to listen to presentations about Botox that covered off-label topics. It created and funded an "independent" neurotoxin educational organization to promote off-label uses of Botox. In dealing with off-label specialists, Allergan developed "Customer Team Units" (CTUs) to coordinate sales initiative and off-label marketing initiatives; these CTUs often included sales, medical affairs, reimbursement, marketing, and management staff. Until January 2007, the CTUs met on a quarterly basis to exchange detailed data about doctors' purchases of Botox for off-label use in selected geographic areas.

## III

Plaintiffs allege that the Board of Directors was involved in and aware of this wrongdoing at Allergan. Specifically, they allege that the Board either adopted plans premised on illegal conduct or made a conscious decision not to take action even when faced with "red flags" of wrongdoing. Plaintiffs support those claims with several dozen paragraphs of particularized allegations, emphasizing more broadly that the Board actively oversaw the growth and sale of Botox from 1997 to 2010, as Botox was one of its star products in that period.

Starting in 1997, Allergan's Board discussed and approved a number of "strategic plans" that expressly depended on a significant and, critically, *immediate* increase in off-label Botox sales. The first such plan covered 1997 to 2001 and was adopted in 1997. In a slide deck summary of the plan, the Board described maximizing Botox sales for spasticity, pain, and migraine, all off-label uses, as a "top corporate priority." The slide deck anticipated major growth

in pain, migraine, and spasticity markets, and described Botox as Allergan's "fastest growing business with great[est] peak year sales of any product & highest margin." The slide deck noted that the Board anticipated FDA approval of Botox for treatment of pain, migraine, and spasticity four to five years later, in 2001 and 2002, but nonetheless stated that a major increase in sales of Botox for these off-label uses "represent[ed] immediate growth" that could "maximize . . . Botox® *now*" as part of an "expansion strategy."[4]

This anticipation of immediate and significant growth in off-label sales of Botox was reflected in the 1997–2001 Strategic Plan itself. The Plan sought to "ensure that we can maximize our immediate opportunities in our core businesses," described Botox as one of Allergan's "five core businesses," and stated that Botox "has tremendous growth potential as we fund opportunities with new indications and uses such as spasticity, pain, migraine and tension headache." The Plan emphasized in its discussion of Botox that the combined value of the global pain and migraine headache markets would exceed $6 billion by 2007, and that "[i]nvestments in [Botox sales for] new indications of pain and migraine headache represents two of the top three future growth opportunities in our portfolio with combined peak year sales of $1.26 billion." Thus, even when the Board admittedly did not anticipate FDA approval for any of these indications for at least four years, and a full thirteen years

[4] Allergan contends that the slides should be read as anticipating major off-label sales only *after* FDA approval, but our review of the slides and of the full document, and our obligation to make reasonable inferences in Plaintiffs' favor, lead us to conclude that the 1997–2001 Strategic Plan anticipated immediate, major growth of off-label sales, and did so independently of the Board's (ill-founded) expectation that new indications would be approved by the FDA in 2001–2002.

before the FDA actually approved of any of these indications, the Board embraced a strategic plan expressly premised on "immediate" and significant expansion of Botox sales for the off-label indications of spasticity, pain, headache, and migraines. This anticipated expansion in off-label sales, the Board concluded, represented one of Allergan's most important opportunities for immediate profit.

The Board closely and continuously monitored Botox sales for on- and off-label indications through 2010. At a meeting in 2004, for example, "the focus for 2005 and beyond" was on projects that included "Botox Headache" and "Botox Urology"—both of which involved only off-label sales and were discussed well after the Board's original expectation of several FDA approvals in 2001 and 2002 had come to naught. In 2005, the Board discussed and then authorized continued funding for nominally "independent" organizations that supported the off-label use of Botox for "acute and chronic pain." In 2007, still focused on the off-label market for Botox, the Board adopted a four-year strategic plan in which it described "successful launches of our planned new products such as [Botox]" as "critical to the success of our plan." At that meeting, the Board also discussed "key assumptions" relating to the acquisition of Espirit Pharma—an acquisition that, according to Plaintiffs, was designed mainly to afford Botox sales representatives access to specialists who practiced in off-label fields. The Board's discussion of the "key assumptions" of that acquisition, we may therefore reasonably infer at this stage in the litigation, included Allergan's plan to use the newly-acquired sales staff to engage in aggressive off-label marketing.

Even as the Board understood that growth of Botox sales for off-label uses was critical to Allergan's success, and even as the Board made growth of such off-label sales a "top corporate priority," the Board was presented with information indicating a direct link between Allergan's Botox promotions and rates of off-label sales. The 2007–2011 Strategic Plan, for example, explicitly noted a connection between sales staff and off-label sales growth: it stated that in "2006 [Allergan] Added 45 New NMCs [sales representatives] & Spasticity grew 25% [and in] 2007 [it] Added 19 New NMCs & Spasticity Est[imated] 18%." The 2006–2010 Strategic Plan also noted a link between off-label promotion and sales: it projected further declines in sales of Botox for pain treatment specifically because there would be "no promotion" for that (off-label) use. In this regard, the 2006–2010 Strategic Plan echoed a similar conclusion from the 2005 Strategic Planning process, which had concluded that sales for pain, headache, and spasticity had been negatively affected by a "decrease in calls to Pain [doctors]/Ped[iatricians]."[5] It is reasonable to infer from these allegations that the Board knew that Allergan's sales and marketing efforts drove the substantial increases in off-label sales of Botox from 2001–2008.

Finally, Plaintiffs argue that the Board was alerted to unlawful conduct at Allergan by a series of FDA letters, and by several complaints from physicians and employees. From

[5] Further, a 2003 Strategy Review noted that "Adult Spasticity, Headache, and Pain will account for 85% of incremental sales in 2003." And Allergan found that "[a]cross all specialties, Botox sales/MD increase with higher call frequency" and that expanding sales calls to rehabilitation doctors would increase sales by $14.3 million over three years.

2001 to 2010, Allergan received several letters from the FDA concerning Botox[6]:

1. August 22, 2001: An FDA warning letter cautioned that Allergan's Botox "promotional activities and materials" were "misleading and lacking in fair balance within the meaning of the [FDAC]." This letter cited five prior FDA letters raising similar concerns, and described the "violations noted in this letter" as "continuing examples of violative promotion or advertising materials disseminated by Allergan."[7]

2. September 5, 2002: An FDA warning letter cautioned Allergan about "misleading statements" in Botox promotional materials.

3. June 23, 2003: An FDA warning letter cautioned that several of Allergan's "advertisements are false and/or misleading because they falsely identify [Botox] as a cosmetic treatment, fail to reveal material facts about

[6] The Board also received an FDA warning letter in September 2005 about misleading promotions for another drug, Lumingan, a letter from the French Government in 2005 concerning Botox-related aspiration and death, and an FDA warning letter in August 2009 about misleading promotions for another drug, ACZONE®. Plaintiffs characterize these letters as part of a battery of FDA warnings that should have alerted the Board to sustained misconduct in Allergan's pharmaceutical promotional activities.

[7] Plaintiffs do not allege that this letter was specifically directed to the Board. They note only that it was covered by the *Los Angeles Times*. Plaintiffs appear to rely on an inference of knowledge. In any event, this letter is, at best, of minor relevance to the ultimate issue of Board knowledge.

the product's use, and minimize the risk information presented."

4. September 21, 2006 and "The Schim Incident": The FDA sent a letter to Allergan's Director of Advertising and Promotional Compliance, concerning a presentation by Dr. Jack Schim on behalf of Allergan at which Schim promoted off-label use of Botox as a headache treatment. The letter requested information about Allergan's relationship with Schim and its CME program material. An investigation in which several board members were involved discovered that Schim had used the relevant slides at eight dinners over the prior twelve months. Allergan ultimately took remedial measures to address Schim's unlawful conduct. Nonetheless, Schim remained one of Allergan's highest paid consultants, speakers, and grant recipients through 2010.

In addition to these FDA warning letters—most of which concerned only general misconduct in the branding and promotion of Botox—the Board was also made aware of several complaints by physicians about off-label marketing, many of them arising from the Schim incident. In 2007 the Board discussed an ethics complaint by an employee who stated that she was resigning after only six weeks at Allergan due to concerns about its off-label marketing program.

## DISCUSSION

### I

As required by precedent, we review for abuse of discretion the district court's ruling dismissing this

shareholder derivative suit on the ground of failure to show demand futility. *See, e.g.*, *Potter v. Hughes*, 546 F.3d 1051, 1056 (9th Cir. 2008); *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 983 (9th Cir. 1999). Although Plaintiffs urge us to apply a *de novo* standard, the authorities that they cite, all of which criticize the abuse of discretion standard, are not intervening, controlling precedents that would compel us to depart from *Potter* and *In re Silicon Graphics*. *See* Blue Br. at 2–5 (citing *Israni v. Bittman*, 473 F. App'x 548, 550 n.1 (9th Cir. 2012), and *Laborers Int'l Union of N. Am. v. Bailey*, 310 F. App'x 128, 130 (9th Cir. 2009)); *see Miller v. Gammie*, 335 F.3d 889, 900 (9th Cir. 2003) (en banc).[8] Accordingly, we follow *Potter* and *In re Silicon Graphics* and review the opinion below for abuse of discretion.

## II

"The derivative form of action permits an individual shareholder to bring 'suit to enforce a corporate cause of action against officers, directors, and third parties.'" *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 95 (1991) (quoting *Ross v. Bernhard*, 396 U.S. 531, 534 (1970)) (emphasis omitted). "Devised as a suit in equity, the purpose of the derivative action [is] to place in the hands of the individual shareholder a means to protect the interests of the corporation from the misfeasance and malfeasance of 'faithless directors

[8] Plaintiffs also cite a Delaware case, *Brehm v. Eisner*, 746 A.2d 244 (Del. 2000) (holding that the Delaware Supreme Court reviews *de novo* all demand futility rulings by the Delaware Court of Chancery). Their reliance on *Brehm* is misplaced for two reasons. First, *Brehm* is eight years older than *Potter* and thus cannot qualify as intervening authority. Second, "the proper standard of review is a question of federal procedure and is governed by federal law." *West v. State Farm Fire & Cas. Co.*, 868 F.2d 348, 350 (9th Cir. 1989).

and managers.'" *Id.* (quoting *Cohen v. Beneficial Loan Corp.*, 337 U.S. 541, 548 (1949)).

"A shareholder seeking to vindicate the interests of a corporation through a derivative suit must first demand action from the corporation's directors or plead with particularity the reasons why such demand would have been futile." *In re Silicon Graphics*, 183 F.3d at 989 (citing Fed. R. Civ. P. 23.1). "The purpose of this demand requirement in a derivative suit is to implement 'the basic principle of corporate governance that the decisions of a corporation—including the decision to initiate litigation—should be made by the board of directors or the majority of shareholders.'"[9] *In re Pfizer Inc. S'holder Derivative Litig.*, 722 F. Supp. 2d 453, 458 (S.D.N.Y. 2010) (quoting *Kamen*, 500 U.S. at 101).

Although Rule 23.1 supplies the pleading standard for assessing allegations of demand futility, "[t]he substantive law which determines whether demand is, in fact, futile is provided by the state of incorporation of the entity on whose behalf the plaintiff is seeking relief." *Scalisi v. Fund Asset Mgmt., L.P.*, 380 F.3d 133, 138 (2d Cir. 2004). Allergan is a Delaware corporation and Delaware law therefore applies.[10]

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[9] *See also In re Veeco Instruments, Inc. Sec. Litig.*, 434 F. Supp. 2d 267, 273 (S.D.N.Y. 2006) ("In contrast to a motion to dismiss pursuant to Rule 12(b)(6), a Rule 23.1 motion to dismiss for failure to make a demand is not intended to test the legal sufficiency of the plaintiffs' substantive claim. Rather, its purpose is to determine who is entitled, as between the corporation and its shareholders, to assert the plaintiff's underlying substantive claim on the corporation's behalf." (internal quotation marks omitted)).

[10] As the Seventh Circuit has explained of this substance/procedure issue:

In Delaware, a shareholder who declines to make a demand on the board of directors may not bring a derivative action "until [he] has demonstrated, with particularity, the reasons why pre-suit demand would be futile." *Khanna v. McMinn*, Civ. A. 20545-NC, 2006 WL 1388744, at *11 (Del. Ch. May 9, 2006) (internal quotation marks omitted). "[F]utility is gauged by the circumstances existing at the commencement of a derivative suit" and concerns the board of directors "sitting at the time the complaint is filed." *In re Am. Int'l Grp., Inc. Derivative Litig.*, 700 F. Supp. 2d 419, 430 (S.D.N.Y. 2010) (alteration in original) (internal quotation marks omitted), *aff'd* 415 F. App'x 285 (2d Cir. 2011). Demand futility "must be decided by the trial court on a case-by-case basis and not by any rote and inelastic criteria." *Id.* (quotation marks omitted). "Plaintiffs are entitled to all reasonable factual inferences that logically flow from the particularized facts alleged, but conclusory allegations are not considered as expressly pleaded facts or factual inferences." *Brehm v. Eisner*, 746 A.2d 244, 255 (Del. 2000).

In this case, Plaintiffs identify two overlapping grounds that excuse their obligation to make a demand on Allergan's

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> [T]he adequacy of [the] pleadings is measured by federal law—in particular, Rule 23.1. The function of the demand futility doctrine, however, is a matter of substance, not procedure. Thus, for instance, although federal law governs the degree of detail that the plaintiff must furnish when it gives its reasons for not obtaining the action or not making the effort, state law will determine whether those reasons are sufficient.

*Westmoreland Cnty. Emp. Ret. Sys. v. Parkinson*, 727 F.3d 719, 721–22 (7th Cir. 2013) (citations and internal quotation marks omitted).

board. First, they allege that the Board decided to pursue a business plan premised on unlawful conduct. Second, they allege that the Board remained consciously inactive despite actual or constructive knowledge of wrongdoing at Allergan. Each of these asserted grounds for demand futility finds stable footing in Delaware corporate law.

When a shareholder challenges a decision of a board of directors, Delaware law provides a two-part, disjunctive test for demand futility:

> The first prong of the futility rubric is whether, under the particularized facts alleged, a reasonable doubt is created that . . . the directors are disinterested and independent. The second prong is whether the pleading creates a reasonable doubt that the challenged transaction was otherwise the product of a valid exercise of business judgment. These prongs are in the disjunctive. Therefore, if either prong is satisfied, demand is excused.

*Id.* at 256 (citing *Aronson v. Lewis*, 473 A.2d 805, 814, 816 (Del. 1984)). This is often called the "*Aronson* test."

Under *Aronson*'s first prong, "[a] director's interest may be shown by demonstrating a potential personal benefit or detriment to the director as a result of the decision." *In re Goldman Sachs Grp., Inc. S'holder Litig.*, Civ. A. 5215, 2011 WL 4826104, at *7 (Del. Ch. Oct. 12, 2011) (alteration in original) (internal quotation marks omitted). For that reason, "[d]irectors who are sued have a disabling interest for pre-suit demand purposes when the potential for liability . . . may rise

to a substantial likelihood." *Ryan v. Gifford*, 918 A.2d 341, 355 (Del. Ch. 2007) (internal quotation marks omitted); *accord Rattner v. Bidzos*, Civ. A. 19700, 2003 WL 22284323, at *9 (Del. Ch. Sept. 30, 2003) ("[A] 'substantial likelihood' of personal liability prevents a director from impartially considering a demand." (internal quotation marks omitted)). To meet that standard when presented with a motion to dismiss under Rule 23.1, plaintiffs must make "a threshold showing, through the allegation of particularized facts, that their claims have some merit."[11] *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993).

Under *Aronson*'s second prong, the question is whether the pleading creates a reasonable doubt that the challenged transaction was the product of a valid exercise of business judgment. *Brehm*, 746 A.2d at 256. "The good faith business decisions of informed, disinterested, and independent directors of Delaware corporations are entitled to deference under the business judgment standard of review." *Hamilton Partners, L.P. v. Highland Capital Mgmt., L.P.*, Civ. A. 6547-VCN, 2014 WL 1813340, at *15 (Del. Ch. May 7, 2014). Nonetheless, "in rare cases a transaction may be so egregious on its face that board approval cannot meet the test of business judgment." *Aronson*, 473 A.2d at 815. These rare cases include those in which a board decides to undertake illegal activity. *See, e.g.*, *In re Massey Energy Co.*, Civ. A. 5430-VCS, 2011 WL 2176479, at *20 (Del. Ch. May 31, 2011) ("Delaware law does not charter law breakers. . . . [A] fiduciary of a Delaware corporation cannot be loyal to a Delaware corporation by knowingly causing it to seek profit by violating the law."); *Metro Commc'n Corp. BVI v.*

[11] Here, Plaintiffs allege that a majority of Allergan's Board faces a risk of liability for, *inter alia*, breaching the duty of loyalty.

*Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 131 (Del. Ch. 2004) ("[A] fiduciary may not choose to manage an entity in an illegal fashion, even if the fiduciary believes that the illegal activity will result in profits . . . .").

While *Aronson* applies to board decisions, the applicable framework is less settled for claims that demand is excused on the ground that a board remained consciously inactive when it knew (or should have known) about illegal conduct. That doctrinal uncertainty is reflected here: whereas Plaintiffs insist that their conscious inaction claims are subject to *Aronson* analysis, Allergan maintains that those claims invoke the theory of oversight liability set forth in *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 971 (Del. Ch. 1996).[12] Demand futility for *Caremark* claims is tested under *Rales v. Blasband*, 634 A.2d 927 (Del. 1993), not *Aronson*. *Rales* requires plaintiffs to allege "particularized facts establishing a reason to doubt that 'the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand.'" *Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008) (quoting *Rales*, 634 A.2d at 934).

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[12] A number of courts have interpreted conscious inaction claims as *Aronson*-type claims of considered board action. *See, e.g.*, *Westmoreland*, 727 F.3d at 725–26 (7th Cir. 2013); *In re Abbott Labs. Derivative S'holders Litig.*, 325 F.3d 795, 808 (7th Cir. 2003); *In re Textron, Inc.*, 811 F. Supp. 2d 564, 572 (D.R.I. 2011); *Pfizer*, 722 F. Supp. 2d at 460. Other courts, however, have taken the view that conscious inaction claims sound in *Caremark*. *See In re SAIC Inc. Derivative Litig.*, 948 F. Supp. 2d 366, 381 (S.D.N.Y. 2013), *aff'd sub nom. Welch v. Havenstein*, 553 F. App'x 54 (2d Cir. 2014); *South v. Baker*, 62 A.3d 1, 6 (Del. Ch. 2012) ("As developed in subsequent cases and endorsed by the Delaware Supreme Court . . . directors can be held liable under [*Caremark*] for knowingly causing or consciously permitting the corporation to violate positive law . . . .").

Here, however, it does not matter whether *Aronson* or *Rales* applies. Under either approach, demand is excused if Plaintiffs' particularized allegations create a reasonable doubt as to whether a majority of the board of directors faces a substantial likelihood of personal liability for breaching the duty of loyalty. *See, e.g.*, *In re SAIC Inc. Derivative Litig.*, 948 F. Supp. 2d 366, 382 (S.D.N.Y. 2013) ("[T]he difference between *Rales* and *Aronson* may blur in cases like this one, since the particularized allegations essential to creating reasonable doubt as to a substantial likelihood of personal liability for breach of fiduciary duties may also implicate the question whether the Board can avail itself of business judgment protections."), *aff'd sub nom. Welch v. Havenstein*, 553 F. App'x 54 (2d Cir. 2014); *Guttman v. Huang*, 823 A.2d 492, 501 (Del. Ch. 2003) ("When . . . there are allegations that a majority of the board that must consider a demand acted wrongfully, the *Rales* test sensibly addresses concerns similar to [*Aronson*]. To wit, if the directors face a 'substantial likelihood' of personal liability, their ability to consider a demand impartially is compromised under *Rales*, excusing demand."). The duty of loyalty, in turn, is violated "[w]here directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities [and] failing to discharge [the non-exculpable fiduciary duty of loyalty] in good faith." *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006). In this case, Plaintiffs allege precisely that kind of violation of the directors' duties.

To summarize: Plaintiffs' claim that the Board decided to pursue a plan premised on illegal conduct is subject to *Aronson* analysis. If Plaintiffs have made sufficient particularized allegations in support of this claim, demand is excused under both *Aronson* prongs, as the Board would face

a substantial likelihood of liability for violating the duty of loyalty and would have lost business judgment protection for undertaking illegal conduct. Plaintiffs' claim that the Board knew or should have known about illegal conduct and made a conscious choice to turn a blind eye can be characterized either as a *Caremark*-type oversight claim or as an *Aronson*-type allegation of considered board action. We need not decide which characterization of Plaintiffs' allegations is correct because, either way, demand is excused if Plaintiffs' particularized allegations create a reasonable doubt as to whether a majority of the Allergan board faces a substantial likelihood of liability for failing to act in the face of a known duty to act.

## III

Turning to the particularized factual allegations before us, we agree with Vice Chancellor Lasker of the Delaware Court of Chancery, who considered a near-identical complaint, that demand is excused. *See La. Mun. Police Emps.' Ret. Sys. v. Pyott*, 46 A.3d 313, 352–53 (Del. Ch. 2012). Because Plaintiffs' allegations that the Board deliberately adopted a plan premised on illegal conduct in many respects builds off the comparatively more modest claim of conscious inaction, we first discuss conscious inaction.

### A. Conscious Inaction

Plaintiffs allege that the Board either knew or, due to a series of red flags, should have known, about Allergan's off-

label promotion of Botox.[13] This claim essentially turns on whether Plaintiffs have adequately alleged scienter. *See, e.g.*, *Rahbari v. Oros*, 732 F. Supp. 2d 367, 383 (S.D.N.Y. 2010); *Desimone v. Barrows*, 924 A.2d 908, 935 (Del. Ch. 2007); *Guttman*, 823 A.2d at 506. If a majority of the Board had actual or constructive knowledge of violations of the law at Allergan involving off-label promotions of Botox and did nothing, it violated its duty of loyalty and faces a substantial likelihood of liability. *See Stone*, 911 A.2d at 370.

Plaintiffs' factual allegations tell a story that begins in 1997 with Board approval of the 1997–2001 Strategic Plan. That year, even as it anticipated that Botox approval for pain, migraine, and spasticity would not occur for at least four or five years, the Board adopted a four-year plan that described maximizing sales for these off-label uses as a "top corporate priority," opportunity for "immediate growth," and a means to "maximize . . . Botox® *now*." Notably, the 1997–2001 Strategic Plan contemplated a short-term increase in Botox sales in North America from $86.1 million to $141.1 million, a growth fueled mainly by sales for off-label uses. The Plan noted "tremendous growth potential" for "spasticity, pain, migraine and tension headache" sales of Botox, carefully reviewed the market for headache and pain treatments, and, most strikingly, described investments in Botox sales for pain and migraine headache as "two of the top three future growth opportunities in our portfolio." It can be reasonably inferred

[13] Although in many cases involving demand futility the parties go director by director to determine whether demand is excused, the parties here do not do so, mainly because Plaintiffs repeatedly allege that a majority of the Board was involved in all (or nearly all) of the programs and decisions at issue. When appropriate, courts may evaluate demand futility by looking to the whole board of directors rather than by going one by one through its ranks. *See, e.g.*, *Pfizer*, 722 F. Supp. 2d at 461.

from this strategic plan that the Board was intensely interested in off-label sales of Botox, saw off-label sales of Botox as a critical driver of growth for Allergan over the upcoming years, and planned on very closely monitoring off-label Botox sales. It can also be inferred that the Board was aware that pain, headache, spasticity, and migraine were all off-label uses, but nonetheless wanted to achieve major growth well before FDA approval. Over the next 13 years, that is precisely what happened: due mainly to a continuing series of illegal Allergan programs, off-label sales of Botox skyrocketed.

Of course, as Allergan observes, it is entirely possible for off-label sales to increase on their own, without any illegal promotion by a drug manufacturer. In fact, such increases occur all the time, spurred by developments and discussions within the medical community. For that reason, the bare facts of the Board's hunger for higher off-label sales and an ultimate increase in those sales do not suffice to show conscious inaction on the part of the Board. *See, e.g.*, *King v. Baldino*, 648 F. Supp. 2d 609, 624 (D. Del. 2009). But contrary to Allergan's insistence that this case reduces solely to that correlation, Plaintiffs offer a battery of particularized factual allegations that strongly support an inference at this stage of the litigation that the Board knew of and did nothing about illegal activity.

First, Plaintiffs allege with particularity that the Board continued to closely and regularly monitor off-label Botox sales. In 2004, the Board focused its attention on projects related to the off-label sale of Botox to treat headaches and urological problems. Then, in 2005, it discussed and decided to continue funding for organizations under Allergan control that publicly championed the off-label use of Botox to treat

pain. In 2007, the Board emphasized that Botox is "critical to the success of our [strategic] plan" and discussed "key assumptions" related to the acquisition of Espirit Pharma, a company that was allegedly purchased mainly to afford Botox sales representatives access to specialists who would prescribe Botox for off-label purposes. We can—and at this stage, must—reasonably infer that the Board's discussion of these matters afforded its members a view of Allergan's illegal conduct.

The Board also took a particular interest in some of the specific Allergan off-label sales programs that Plaintiffs describe as a key part of Allergan's wrongdoing. In 2003, for example, the Board saw a slide show that detailed Allergan's creation of a "Headache Development Program" and tracked the prevalence of headache disorders. The Board, which already knew that nine out of ten clinical trials of Botox for headache treatment had failed and that FDA approval was nowhere in sight, thus learned in 2003 that Allergan was launching a major program to treat headaches. The Board also learned that the four-person "Core Team" involved in the Headache Development Program included a member of Allergan's "Global Strategic Marketing" division. Then, in 2004, the Board reviewed several promotional documents for the "Botox Advantage Program," a program that provided detailed support to physicians seeking reimbursement for off-label uses of Botox and created a hotline for such assistance, all in an attempt to circumvent reimbursement rules governing off-label uses of Botox. In 2005, the Board received a CEO report on Allergan's CDHI program, which was allegedly created after clinical tests for headaches failed in order to persuade doctors to prescribe Botox for off-label purposes (headaches) while reporting an on-label diagnosis of cervical dystonia, even though CD is a rare disorder.

Finally, in 2006 and 2007, the Board approved co-promotion and acquisition agreements that were allegedly designed mainly to facilitate illegal off-label promotion of Botox by sales representatives familiar with specialists in off-label fields. These allegations and the inferences that reasonably follow from them are anything but conclusory. Accepted as true for purposes of this appeal, they show that Allergan's board closely monitored off-label Botox sales and repeatedly discussed or authorized programs even after learning that those programs involved the same illegal conduct for which Allergan was ultimately fined and punished.

Second, even as it carefully monitored Allergan's Botox programs and determined that growth of off-label Botox sales was critical to achieving desired profit margins, the Board received data directly linking Allergan's sales programs to fluctuations in off-label sales. In 2005, for example, it learned that sales for pain, headache, and spasticity were heavily affected by Allergan programs that involved phone calls to pain specialists and pediatricians. In 2006, it projected a decline in sales of Botox for off-label pain treatment due to the absence of Allergan promotion for that use. The 2007–2011 Strategic Plan, in turn, identified an even clearer connection between Allergan programs and off-label sales growth, stating that the addition of 45 new sales representatives in 2006 was accompanied by a 25% increase in spasticity sales, and that the addition of 19 representatives in 2007 was accompanied by an estimated 18% increase in spasticity sales.

This is exactly the kind of correlation—more Allergan promotions for off-label use matching up precisely with more sales, and fewer Allergan promotions for off-label use matching a drop in off-label sales—that qualifies as a "red

flag" of illegal promotions. *See McCall v. Scott*, 239 F.3d 808, 821 (6th Cir. 2001) (concluding that "it would be just as reasonable" for experienced directors to see a suspicious correlation as a sign of "possible improper billing activities" as it would be for them to see it as "the norm," and that their indifference to that correlation supported liability). Whereas Allergan argues that the Board could have viewed the increase in off-label Botox sales as the natural operation of the medical community, at this stage of the case we must make reasonable inferences for Plaintiffs, not against them—and it is reasonable to infer that the data repeatedly presented to Allergan's board linking Allergan programs to fluctuations in off-label sales support a finding of scienter.

Third, the Board received repeated FDA warnings about illegal promotion of Botox. To be sure, many of these warnings concerned only misbranding and other violations of the law, not the specific off-label promotions at issue here. Only one of the warning letters, in fact, specifically addressed off-label promotion, though it is striking that even after learning of the Schim incident in that letter, Allergan kept Schim as one of its highest-paid consultants and advocates. Nonetheless, these letters also constituted a red flag, waved nearly every year for five straight years, that Allergan was breaking federal law in its promotion of Botox. Given how carefully the Board was monitoring Botox sales, its relative inaction in the face of these repeated FDA warnings supports a finding of liability. *See In re Abbott Labs. Derivative S'holders Litig.*, 325 F.3d 795, 808 (7th Cir. 2003) (excusing demand and emphasizing that even though two FDA warning letters contained mere "boilerplate" language, "continuing violations of federal regulations over a period of six years cannot be minimized"). Moreover, this is not a case where the FDA warnings dealt with "unrelated programs" or lacked

"any other connection" to the relevant illegal conduct. *See SAIC*, 948 F. Supp. 2d at 387. Rather this is a case in which one of the FDA letters directly concerned off-label promotions and the parade of other FDA letters addressed issues immediately parallel to the off-label promotions at the heart of the allegations in this lawsuit.

Closely related to the FDA warnings, an employee resigned after filing an ethics complaint in 2007 charging Allergan's sales division with improper off-label promotions. Although Plaintiffs do not allege that this ethics issue was specifically about Botox, there is no evidence that the Board responded to it by investigating wrongdoing. As Vice Chancellor Lamb has remarked, "A claim that an audit committee or board had notice of serious misconduct and simply failed to investigate, for example, would survive a motion to dismiss, even if the committee or board was well constituted and was otherwise functioning." *David B. Shaev Profit Sharing Account v. Armstrong*, Civ. A. 1449-N, 2006 WL 391931, at *5 (Del. Ch. Feb. 13, 2006).

Fourth, the illegal conduct in this case involved one of the most important drugs at Allergan—one that was repeatedly identified as crucial by the Board itself, which described off-label sales of Botox as a "top corporate priority" and as "two of the top three future growth opportunities in our portfolio." In demand futility cases, courts have repeatedly emphasized that it is especially plausible to infer board interest in and knowledge of developments relating to a product that is critical to a company's success or is otherwise of special importance to it. *See, e.g.*, *In re Biopure Corp. Derivative Litig.*, 424 F. Supp. 2d 305, 307–08 (D. Mass. 2006); *In re Veeco Instruments, Inc. Sec. Litig.*, 434 F. Supp. 2d 267, 277

(S.D.N.Y. 2006); *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 387–88 (E.D.N.Y. 2003).

Finally, the illegal conduct was unquestionably of significant magnitude and duration. It persisted for over a decade, involved several divisions at Allergan, and constituted nearly a dozen separate programs, all related to one of Allergan's most important and widely known therapeutic drugs. The combination of *widespread* and *enduring* illegality in Allergan's corporate activity strongly supports an inference of Board knowledge and intentional disregard. *See SAIC*, 948 F. Supp. 2d at 387; *Pfizer*, 722 F. Supp. 2d at 460; *Veeco*, 434 F. Supp. at 278; *In re Oxford Health Plans, Inc.*, 192 F.R.D. 111, 117 (S.D.N.Y. 2000).

Taking all of these allegations together, we conclude that the district court abused its discretion in determining that they do not create a reasonable inference of conscious inaction. It would be surprising, to say the least, if such significant, continuing, and diverse breaches of FDA regulations in relation to a star product at Allergan passed unnoticed by the Board for so long, even as the Board carefully monitored off-label sales, repeatedly discussed and authorized a number of the allegedly illegal programs, and built strategic plans around off-label Botox sales.

We also note that we find persuasive Delaware Vice Chancellor Lasker's explanation in the virtually identical Allergan case in Delaware[14]:

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[14] Although as we have noted, Vice Chancellor Lasker's decision was vacated by the Delaware Supreme Court on the ground of collateral estoppel, decisions vacated for reasons unrelated to the merits may be considered for the persuasive of their reasoning. *See In re Taffi*, 68 F.3d

> The plaintiffs in this case have alleged a direct connection between the Board and a business plan premised on illegal activity. The Complaint pleads that from 1997 onward, the Board discussed and approved a series of annual strategic plans that contemplated expanding Botox sales dramatically within geographic areas that encompassed the United States. The plans contemplated new markets for Botox that involved applications that were off-label uses in the United States. So significant was the scope of the expansion that it necessarily contemplated marketing and promoting off-label uses within the United States. The Board then closely monitored Allergan's dramatic success in increasing its sales of Botox at rates far exceeding what the market for existing on-label uses could support or that could be generated by physicians serendipitously learning about and trying new off-label applications. The Board kept Allergan's business plan in place even

306, 310 (9th Cir. 1995) (following as persuasive authority a decision vacated by the Supreme Court on other grounds); *Orhorhaghe v. INS*, 38 F.3d 488, 493 n.4 (9th Cir. 1994) (following as persuasive authority a decision vacated by the Supreme Court as moot).

> after the Schim incident and FDA inquiries illustrated the extent of Allergan's regulatory exposure.

*La. Mun. Police*, 46 A.3d at 352–53.[15]

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[15] He also noted that other inferences are plausible, but that at this stage in the litigation all reasonable inferences must be drawn in Plaintiffs' favor:

> Obviously this is not the only inference that can be drawn. Alternatively, one could infer that the directors received advice from sophisticated counsel about the difference between legal off-label sales and illegal off-label marketing, understood where the boundary lay, and approved a business plan and management initiatives in the good faith belief that Allergan was remaining within the bounds of the law, although perhaps close to the edge. The directors then closely monitored Allergan's performance with this understanding. Unfortunately for everyone, the directors' good faith belief proved incorrect, and Allergan pled guilty to criminal misdemeanor misbranding for the period from 2000 through 2005, paid criminal fines of $375 million, and paid another $225 million in civil fines. If this scenario proves true, then the directors will not have acted in bad faith and will not be liable to Allergan for any of the harm it suffered.
>
> I cannot presently determine what actually happened at Allergan. I hold only that a reasonable inference can be drawn from the particularized allegations of the Complaint and the documents it incorporates by reference that the Board knowingly approved and subsequently oversaw a business plan that required

The district court reached the contrary conclusion mainly on the grounds that Plaintiffs failed to allege "evidence of a decision by board members to promote off-label marketing," failed to connect off-label promotion programs such as the Headache Development Program to "Botox or any prohibited off-label marketing," and failed to account for the fact that the Board maintained formal compliance policies. In analyzing Plaintiffs' allegations, however, the district court committed a number of errors, and thereby abused its discretion.

First, it considered the factual allegations in isolation from each other rather than in combination, even though in cases like this one an inference of Board involvement or knowledge may depend on a combination of factual allegations. *See, e.g.*, *McCall*, 239 F.3d at 823; *SAIC*, 948 F. Supp. 2d at 387–88; *Veeco*, 434 F. Supp. 2d at 276. Second, it repeatedly drew inferences in the Board's favor, crediting Allergan's reasonable interpretations of the factual allegations over Plaintiffs' reasonable interpretations of those same allegations.[16] *See, e.g.*, *Westmoreland Cnty. Emp. Ret.*

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> illegal off-label marketing and support initiatives for Botox. At this stage of the case, I must credit this inference . . . .

*La. Mun. Police*, 46 A.3d at 356.

[16] For example, the district court refused to view the repeated FDA warnings as at all relevant, even though they involved Botox promotion. It saw no connection between the Headache Development Program, the Board, and off-label sales, despite the allegations discussed *supra*. It dismissed the CDHI allegations as irrelevant on the ground that cervical dystonia was an approved use, disregarding all of Plaintiffs' other allegations. And it suggested that it viewed the Complaint as alleging only that the Board must have known of illegal conduct because sales for

*Sys. v. Parkinson*, 727 F.3d 719, 729 (7th Cir. 2013) ("[T]he district court's focus on other hypothetical explanations for the defendants' conduct improperly ignores the rule that 'any inferences reasonably drawn from the factual allegations of the complaint must be viewed in the light most favorable to the plaintiffs.'" (quoting *Abbott Labs.*, 325 F.3d at 803)); *Brehm*, 746 A.2d at 255. Finally, the district court essentially insisted on a smoking gun of Board knowledge, even though

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off-label uses increased, when in fact the First Amended Complaint contains many, particularized allegations that bear on the question of what the Board knew.

In these and other ways, the district court abused its discretion. As Vice Chancellor Lasker noted while explaining his disagreement with the district court:

> The California Federal Court . . . concluded that a Board-sanctioned "Headache Development" program for Botox "had absolutely nothing to do with marketing; rather, it was a clinical presentation regarding Botox's potential efficacy in treating migraines." The California Federal Court likewise dismissed the sufficiency of the allegation that the Board oversaw a "Cervical Dystonia/Headache Expansion Initiative" by noting that cervical dystonia was an approved FDA use at the time.
>
> In my view, both descriptions adopt one possible and defendant-friendly interpretation of the underlying documents and related allegations. At the pleadings stage, I believe the plaintiffs are entitled to the reasonable inference that the Board oversaw company-wide efforts to promote off-label use of Botox for treating migraine headaches, which was not an FDA-approved use at the time.

*La. Mun. Police*, 46 A.3d at 357–58 (citations omitted).

precedent holds that plaintiffs can show demand futility by alleging particular facts that support an *inference* of conscious inaction.[17] *See Brehm*, 746 A.2d at 255.

Ultimately, this case is in important respects like *Abbott Labs.*, *Pfizer*, and *Westmoreland*—all cases in which particularized allegations made plausible an inference that the directors at issue had remained consciously inactive in the

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[17] Again, we find persuasive Vice Chancellor Lasker's careful analysis of how the district court erred in applying Delaware law:

> [A] plaintiff does not have to point to actual confessions of illegality by defendant directors to survive a Rule 23.1 motion in a *Caremark* case. Particularly at the pleadings stage, a court can draw the inference of wrongful conduct when supported by particularized allegations of fact. Given that off-label marketing is illegal, it would be astounding if the 1997–2001 Strategic Plan or any other board presentation actually used that term. If in-house counsel hoped to keep their jobs, those words only could make it into a board presentation in the context of a statement against the practice. But sadly, sophisticated corporate actors at times engage in illegal behavior and attempt to hide their misconduct with the appearance of legal compliance. Having reviewed the summary slides and the underlying strategic plans, I believe there are sufficient references in the documents to support a reasonable inference that Allergan expected to drive increased sales by promoting off-label use. When, as here, the pled facts can support a reasonable inference that directors *in fact* approved a business plan that contemplated off-label marketing, the plaintiffs receive the benefit of the inference at the pleadings stage.

*La. Mun. Police*, 46 A.3d at 357–58 (citations omitted).

face of wrongdoing at their companies. *See Westmoreland*, 727 F.3d at 727 (finding demand to be excused where the complaint alleged "not only that [the company's] directors consciously flouted . . . FDA regulations, but also that the directors knowingly steered [the company] on a course that was all but certain to prompt the FDA to take enforcement action under [a consent decree]"); *Abbott*, 325 F.3d at 809 ("We find that six years of noncompliance, inspections, 483s, Warning Letters, and notice in the press, all of which then resulted in the largest civil fine ever imposed by the FDA and the destruction and suspension of products which accounted for approximately $250 million in corporate assets, indicate that the directors' decision to not act was not made in good faith and was contrary to the best interests of the company."); *Pfizer*, 722 F. Supp. 2d at 460 (excusing demand where "a fair reading of the particularized allegations of the Complaint is that the defendants, at a minimum, knew of a high probability that Pfizer was continuing to purposely promote off-label marketing and deliberately decided to let it continue by blinding themselves to that knowledge"). To be sure, there are noteworthy differences between those cases and this one. For example, in several of those cases the companies had already been sanctioned by the FDA, whereas here the Board had merely received a number of warning letters relating to Allergan's marketing of Botox. What all of these cases have in common with this one, however, is that, given the combination of non-conclusory facts alleged, Delaware law required a reasonable inference of scienter—and thus conscious inaction—on the part of the board, at least for purposes of a motion on the pleadings.

### B. Adoption of a Plan Premised on Illegal Conduct

Having concluded that we must reverse with respect to Plaintiffs' conscious inaction argument, we only briefly address Plaintiffs' alternative argument that demand is excused on the ground that Allergan's board of directors knowingly adopted a business plan premised on illegal off-label promotions of Botox.

Much like their conscious inaction argument, Plaintiffs' argument on this point begins with the 1997–2001 Strategic Plan and proceeds through the other allegations recited *supra*. Here, though, Plaintiffs make the comparatively bolder claim that Allergan's conduct is reasonably interpreted as the predictable unfolding of a Board-sanctioned effort to massively boost off-label Botox sales while pushing (too) hard on regulatory limits. Thus, in Plaintiffs' view, it can reasonably be inferred that the "red flags" of illegal conduct that actually or constructively alerted the Board to wrongdoing were not signs that the marketing team had gone off the rails. Rather, they were welcome indicators that a massive, Board-approved push for off-label sales of Botox was going according to plan.

We conclude that, at the pleading stage of this case, this is a reasonable inference from the particular facts alleged—and that the district court abused its discretion in concluding that it is not.

Allergan and the district court make much of the fact that Plaintiffs do not allege that the Board formalized or recorded any decision to break the law. They also emphasize that Allergan did, as one would expect of a major pharmaceutical company, maintain some formal policies prohibiting off-label

promotion of drugs. On their view, these facts render implausible the inference that Plaintiffs have asked us to draw from the particularized facts alleged.

These arguments, however, overstate what the law requires of plaintiffs arguing that demand is excused. *See La. Mun. Police*, 46 A.3d at 357 ("[A] plaintiff does not have to point to actual confessions of illegality by defendant directors to survive a Rule 23.1 motion . . . . Particularly at the pleadings stage, a court can draw the inference of wrongful conduct when supported by particularized allegations of fact."). For example, an inference that the Board decided to break the law can be drawn even without a Board-approved document stating, *'we're all going to go promote Botox off-label now and do so in a way that violate the FDA's regulations*.' So long as Plaintiffs' particularized allegations give rise to a reasonable doubt that a majority of the directors adopted a plan premised on illegal off-label marketing of Botox, and therefore face a substantial likelihood of liability for breaching their duty of loyalty, demand is excused.

Applied here, that standard requires reversal. As Vice Chancellor Lasker persuasively explained in his opinion in the Delaware case:

> It is not unreasonable to infer that the Allergan Board, led by a hard-charging CEO who earned the nickname "Mr. Botox," could have believed that Allergan knew better than the FDA which Botox applications were safe, particularly off-label uses already approved (or at least permitted) in other countries. It is not unreasonable to infer that the Board and CEO saw the distinction between off-label

> selling and off-label marketing as a source of legal risk to be managed, rather than a boundary to be avoided. Based on this premise, the CEO and his management team devised, and the Board approved, a business plan that relied on off-label-use-promoting activities, confident that the risk of regulatory detection was low, that most regulatory problems could be solved, and that dealing with regulatory risk was a cost of doing business. As profits increased and the regulatory risk seemed well managed, the extent of off-label use-promoting activities grew. The appearance of formal compliance cloaked the reality of non-compliance, and directors who understood the difference between legal off-label sales and illegal off-label marketing continued to approve and oversee business plans that depended on illegal activity. *See Massey Energy,* 2011 WL 2176479, at *19 (crediting inference that outside directors went "through the motions" rather than making "good faith efforts to ensure that [the company] cleaned up its act").

*La. Mun. Police*, 46 A.3d at 355–56.

Vice Chancellor Lasker's analysis complements the analysis of conscious inaction set forth *supra*. As alleged by Plaintiffs, this is a board that adopted a strategic plan in 1997 expressly predicated on massive, immediate growth in off-label sales of Botox for indications that even the Board did not believe would be approved by the FDA until 2001–2002; that continued to depend on increased off-label sales over the

next decade; that carefully monitored Botox in meetings and reports, and that took an especially keen interest in off-label uses; that heard numerous presentations on some of Allergan's illegal off-label promotions; that approved cross-promotion deals and acquisitions intended mainly to facilitate off-label promotion; that received a stream of FDA warning letters about improper Botox marketing, one of which expressly involved off-label promotions; that heard from at least one employee whistleblower about unethical off-label marketing; and that heard information at several points expressly linking Allergan's expansive off-label marketing programs to fluctuations in the number of off-label sales of Botox.

When these allegations are examined together, certainly it is plausible to conclude that they reveal a board committed to *very* aggressive off-label promotion of Botox—one of its most important products, highest corporate priorities, and most promising sources of revenue. And certainly it is plausible to conclude that such a board might publicly pay lip service to regulations while more quietly urging its officers to push marketing efforts to the regulatory breaking point in an effort to dramatically improve profits in a tough economic climate.

Ultimately, even reviewed for abuse of discretion, the district court's single-page analysis of why this inference is not plausible must be reversed. By declining to draw inferences to which Plaintiffs are entitled, reading Plaintiffs' allegations separately rather than in combination, and incorrectly describing Delaware law as requiring proof of an explicit and memorialized decision to break the law, the district court exceeded its discretion.

## CONCLUSION

We do not know what really happened at Allergan from 1997 to 2010. This case comes before us at the pleading stage—and thus before any discovery—and presents factual uncertainties that are "an unavoidable consequence of Delaware's demand futility rule." *Westmoreland*, 727 F.3d at 729. We therefore hold only that Plaintiffs have satisfied their obligation to show that demand on Allergan's board of directors is excused. Plaintiffs' particularized factual allegations, and, more important, the reasonable inferences that we must draw in Plaintiffs' favor in deciding a Rule 23.1 motion, suffice to show that the Board either did nothing despite actual or constructive knowledge of wrongdoing at Allergan, or knowingly adopted a business plan premised on illegal conduct. In either case, Allergan's directors violated their duty of loyalty and would face a substantial likelihood of liability; in the latter case, they would also have forfeited the protection of the business judgment rule. Accordingly, we reverse and remand for further proceedings.[18]

**REVERSED AND REMANDED.**

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[18] Plaintiffs' appeal from the district court's denial of their motion for reconsideration is dismissed as moot. On appeal, the Directors Defendants urge that we also address the arguments in their motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), even though the district court did not reach those arguments. Following our usual practice, we decline to reach those issues in the first instance. *See United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1022 (9th Cir. 2006) ("We have noted that while we may affirm the district court's judgment on a different ground, we need not do so, and we usually do not." (emphasis and internal quotation marks omitted)). To the extent they have not been waived in the district court, those issues may be raised again on remand.

REINHARDT, Circuit Judge, specially concurring:

Because it is not necessary to decide the question of the applicable standard of review in our opinion, I write separately to set forth my view that the proper standard is *de novo*.

The arguments that Plaintiffs advance against the rule of *Potter v. Hughes*, 546 F.3d 1051 (9th Cir. 2008), and *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970 (9th Cir. 1999), are compelling. The issue is an important and controversial one, as evidenced by the fact that the Supreme Court granted certiorari to resolve a circuit split on this exact point of law just one year ago (although that case settled before oral argument). *See UBS Fin. Servs. Inc. of Puerto Rico v. Union de Empleados de Muelles de Puerto Rico PRSSA Welfare Plan*, 134 S. Ct. 40 (2013).

The problem with *Potter* and *In re Silicon Graphics* is simply stated: Courts of Appeals ordinarily review the sufficiency of a complaint's allegations *de novo*, and there is no reason why that general rule is not fully applicable to motions to dismiss on the pleadings under Federal Rule of Civil Procedure 23.1. Recognizing the problems with abuse of discretion review of motions to dismiss for failure adequately to allege demand futility, several state courts have recently switched to *de novo* review. *See, e.g.*, *Fink v. Codey* (*In re PSE & G S'holder Litig.*), 801 A.2d 295, 313 (2002); *Harhen v. Brown*, 730 N.E.2d 859, 866 (2000); *Brehm v. Eisner*, 746 A.2d 244, 253 (Del. 2000). In the federal system, several circuits have expressed strong concerns about an abuse of discretion standard, *see Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust ex rel. Fed. Nat. Mortgage Ass'n v. Raines*, 534 F.3d 779, 783 n.2 (D.C. Cir. 2008); *Scalisi v.*

*Fund Asset Mgmt., L.P.*, 380 F.3d 133, 137 n.6 (2d Cir. 2004), the First and Seventh Circuits have recently adopted *de novo* review, *see Union de Empleados de Muelles de Puerto Rico PRSSA Welfare Plan v. UBS Fin. Servs. Inc. of Puerto Rico*, 704 F.3d 155, 162 (1st Cir. 2013); *Westmoreland Cnty. Employee Ret. Sys. v. Parkinson*, 727 F.3d 719, 724–25 (7th Cir. 2013), and the Sixth and Eighth Circuits have recently reaffirmed their adherence to *de novo* review, *see Lukas v. McPeak*, 730 F.3d 635, 637 (6th Cir. 2013); *Gomes v. Am. Century Cos., Inc.*, 710 F.3d 811, 815 (8th Cir. 2013). Motivated by similar concerns, two panels of this Court have expressed discomfort with abuse of discretion review in unpublished dispositions. *See Israni v. Bittman*, 473 F. App'x 548, 550 n.1 (9th Cir. 2012); *Laborers Int'l Union of N. Am. v. Bailey*, 310 F. App'x 128, 130 (9th Cir. 2009).

These judges have offered powerful arguments in favor of *de novo* review. As a panel of this Court observed in 2000, we choose "between the *de novo* and abuse of discretion standards by balancing the peculiar need of a full appellate review, against the argument that the district court's . . . determination requires the exercise of discretion and therefore is due the correlative level of deference on review." *Harman v. Apfel*, 211 F.3d 1172, 1176 (9th Cir. 2000). That inquiry, in turn, looks to factors such as "the language and structure of the governing statute," *Pierce v. Underwood*, 487 U.S. 552, 559 (1988); "[t]he non-amenability of the problem to rules, because of the diffuseness of circumstances, novelty, vagueness, or similar reasons that argue for allowing experience to develop," *id.* at 562; whether a decision "ordinarily has . . . substantial consequences" requiring "it to be reviewed more intensively," *id.* at 563; and whether, "as a matter of the sound administration of justice, one judicial

actor is better positioned than another to decide the issue in question," *Miller v. Fenton*, 474 U.S. 104, 114 (1985).

Here, all relevant factors cut in favor of *de novo* review. Nothing in Rule 23.1 indicates a preference for district court decision-making; doctrines of demand futility are reasonably uniform and amenable to general rules that cover a wide range of circumstances; the decision to dismiss a shareholder derivative suit under Rule 23.1 results in the serious consequence of terminating the litigation, and is of particular importance in the Rule 23.1 context due to the high costs associated with filing shareholder derivative suits; and district courts do not have an institutional advantage over appellate courts in determining the legal sufficiency of pleadings.

In view of the above, I strongly urge that when we are presented with a demand futility case in which the standard of review is determinative of the outcome, reconsideration of the applicable standard of review would be in order.