



IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

LOUISIANA MUNICIPAL POLICE :  
EMPLOYEES' RETIREMENT SYSTEM, :

Plaintiff, :

-against- :

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. :

Civil Action No. \_\_\_\_\_

**VERIFIED DERIVATIVE COMPLAINT**

Plaintiff, Louisiana Municipal Police Employees Retirement System, alleges upon information and belief based upon, *inter alia*, the investigation made by and through its attorneys, except as to those allegations that pertain to the plaintiff itself, which are alleged upon knowledge, as follows:

1. This is a derivative action brought to seek relief for breaches of fiduciary duty of loyalty and commission of waste by the board of directors of nominal defendant Allergan, Inc., a Delaware corporation ("Allergan" or the "Company"), for aggressively promoting its flagship drug

BOTOX<sup>®</sup> for uses not approved by the United States Food and Drug Administration (“FDA”), for paying kickbacks to doctors, and for other violations of the False Claims Act. On September 1, 2010, the Company announced that it reached an agreement with the United States Department of Justice (“DOJ”) to resolve criminal and civil allegations that the Company actively promoted its top-selling product, BOTOX<sup>®</sup>, for unapproved medical uses, which was a key priority and part of the Company’s strategic plans. The Company has agreed to pay \$600 million in criminal and civil penalties for its sales and marketing practices. This conduct has resulted in substantial injury to the Company.

2. Plaintiff brings this action as a stockholder’s derivative action in the right of and for the benefit of nominal defendant Allergan. Plaintiff seeks to shift the burden of the \$600 million, plus other costs and expenses, from Allergan to the Company’s Board of Directors, who caused the Company to incur these payments.

### **PARTIES**

3. Plaintiff Louisiana Municipal Police Employees Retirement System is a stockholder of the Company and was a stockholder during the misconduct alleged herein and has been such continuously since then. Plaintiff will continue to hold Allergan shares at least through the resolution of this action.

4. Nominal Defendant Allergan is incorporated under the laws of the State of Delaware and maintains its principal executive office at 2525 Dupont, Irvine, CA 92612. Allergan is a global, multi-specialty health care company focused on discovering, developing and commercializing innovative pharmaceuticals, biologics and medical devices. The Company specializes in specialty pharmaceuticals (primarily eye care, skin care and neuromodulators) and medical devices (primarily breast implants, gastric bands for obesity surgery, and injectable dermal fillers used on facial

wrinkles). The Company offers a number of specialty products, including: BOTOX<sup>®</sup> (onabotulinumtoxinA); RESTASIS<sup>®</sup> (cyclosporine ophthalmic emulsion); LUMIGAN<sup>®</sup> (bimatoprost ophthalmic solution); BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA); the JUVÉDERM<sup>®</sup> family of dermal fillers; and the LAP-BAND<sup>®</sup> Adjustable Gastric Banding System.

5. Defendant David Pyott is the Chief Executive Officer of the Company and the Chairman of the Board of Directors. Defendant Pyott has been Chief Executive Officer of Allergan since January 1998 and in 2001 became Chairman of the Board. Defendant Pyott also served as President of Allergan from January 1998 until February 2006.

6. Defendant Louis J. Lavigne has served as a member of the Board of Directors since 2005. Defendant Lavigne is a member of the Audit & Finance Committee and a member of the Science & Technology Committee.

7. Defendant Herbert W. Boyer, Ph.D., has served as a member of the Board of Directors since 1994 and as Vice Chairman of the Board since 2001. Defendant Boyer served as Chairman from 1998 to 2001 and has been a Board member since 1994. He is also a member of the Corporate Governance Committee and a member of the Science & Technology Committee.

8. Defendant Deborah Dunsire, M.D., has been a member of the Board since 2006. She is a member of the Corporate Governance Committee and a member of the Science & Technology Committee.

9. Defendant Michael H. Gallagher has been a member of the Board since 1998. Defendant Gallagher is a member of the Audit & Finance Committee and a member of the Organization & Compensation Committee.

10. Defendant Gavin S. Herbert is the founder of Allergan and has been the Chairman Emeritus since 1996. Defendant Herbert was elected to the Board in 1950. He served as Chief Executive Officer for 30 years and as Chairman from 1977 to 1996.

11. Defendant Dawn Hudson has served as a member of the Board of Directors since 2008. She is a member of the Audit & Finance Committee and a member of the Organization & Compensation Committee

12. Defendant Robert A. Ingram has served as a member of the Board of Directors since 2005. Defendant Ingram is the Chairman of the Corporate Governance Committee and a member of the Organization & Compensation Committee.

13. Defendant Trevor M. Jones, Ph.D., has served as a member of the Board of Directors since 2004. Defendant Jones is a member of the Corporate Governance Committee and a member of the Science & Technology Committee.

14. Defendant Russell T. Ray has served as a member of the Board of Directors since 2003. Defendant Ray is Chairman of the Audit & Finance Committee and a member of the Organization & Compensation Committee.

15. Defendant Stephen J. Ryan, M.D., has served as a member of the Board of Directors since 2002. Defendant Ryan is the Chairman of the Science & Technology Committee and serves as a member of the Audit & Finance Committee.

16. Defendant Leonard D. Schaeffer has served as a member of the Board of Directors since 1993. Defendant Schaeffer is the Chairman of the Organization & Compensation Committee and a member of the Corporate Governance Committee.

## SUBSTANTIVE ALLEGATIONS

17. The Company has over 307 million shares of common stock outstanding, traded on the New York Stock Exchange under the symbol “AGN.”

18. Defendants, as the Company’s directors, owe fiduciary duties of loyalty to the Company, and fiduciary duties of care, good faith, loyalty and candor to its stockholders. The fiduciary duty of loyalty prohibits a director from using his position to do anything that would cause injury to the corporation.

19. The FDA, as the agency in charge of the Federal Food, Drug, and Cosmetic Act (“FDCA”), subjects Allergan’s business to extensive regulations and oversight. The FDCA requires Allergan to establish the efficacy and safety of its drug products before they can be sold.

20. The FDA approves drugs for specific uses and dosages. Any use of a drug that is inconsistent with or outside the scope of the FDA’s approval is an off-label use.

21. The FDCA prevents Allergan from promoting its products for off-label use. Unless a product promoted for off-label use has adequate directions for unapproved use or intended use, it is misbranded. A drug company that promotes a drug for off-label uses violates the FDCA proscription on misbranding by failing to provide adequate instructions for off-label use.

22. There are severe penalties, including criminal prosecution, injunctions and seizure of misbranded or unapproved new drugs, for misbranding. Drug companies may also be subject to liability under the False Claims Act and the federal anti-kickback statute for misbranding.

23. BOTOX<sup>®</sup> is a prescription-only medical product that contains tiny amounts of highly purified botulinum toxin protein refined from the bacterium, *Clostridium botulinum*. When injected at approved and labeled doses into a specific muscle or gland, BOTOX<sup>®</sup> neurotoxin is expected to diffuse locally and expected to produce a safe and effective result by producing a localized and

temporary reduction in the overacting muscle or gland, usually lasting up to approximately 3 to 6.7 months depending on the individual patient and indication.

24. BOTOX<sup>®</sup> was first approved by the FDA 20 years ago for the treatment of strabismus and blepharospasm, two eye muscle disorders. In the United States, BOTOX<sup>®</sup> is also approved to treat the abnormal head position and neck pain that happens with cervical dystonia in adults, symptoms of severe underarm sweating when medicines used on the skin (topical) do not work well enough, and increased muscle stiffness in elbow, wrist and finger muscles in adults with upper limb spasticity. In addition to its therapeutic uses, the same formulation of BOTOX<sup>®</sup> with dosing specific to glabellar lines was approved by the FDA in 2002 under the trade name BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA).

25. Though BOTOX<sup>®</sup> is widely known for its cosmetic use, the FDA has approved the drug for therapeutic treatment in a few rare cases. Nevertheless, for nearly a decade, Allergan made it a top corporate priority to maximize sales in the lucrative off-label market. According to a September 1, 2010 DOJ press release:

In 2003, Allergan doubled the size of its reimbursement team to assist doctors in obtaining payment for off-label Botox injections. Allergan held workshops to teach doctors and their office staffs how to bill for off-label uses, conducted detailed audits of doctors' billing records to demonstrate how they could make money by injecting Botox, and operated the Botox Reimbursement Hotline, which provided a wide array of free on-demand services to doctors for off-label uses. Allergan also lobbied government health care programs to expand coverage for off-label uses, directed physician workshops and dinners focused on off-label uses, paid doctors to attend "advisory boards" promoting off-label uses, and created a purportedly independent online neurotoxin education organization to stimulate increased use of Botox for off-label indications.

26. As the Government's complaint made clear, Allergan's strategic plan made it a top corporate priority to maximize sales of BOTOX<sup>®</sup> for spasticity, migraine headache and pain. Consistent with that strategic plan, the Company promoted the drug for non-FDA approved uses

such as treatment for headaches, pain, spasticity, and juvenile cerebral palsy – all without FDA approval. Allergan has filed for FDA approval of BOTOX<sup>®</sup> for the treatment of chronic migraines. However, the FDA has not yet ruled on the application.

27. Moreover, according to the Government, as part of the off-label promotion of BOTOX<sup>®</sup>, Allergan provided kickbacks to doctors in the form of cash, travel, and meals. The Company also held seminars instructing physicians on how to bill Medicare for off-label procedures. The DOJ alleged that Allergan's promotions included paying doctors \$1,500 each to listen to presentations on off-label uses and sending sales representatives to visit specialists who would not ordinarily administer BOTOX<sup>®</sup> for any of the approved applications

28. Allergan also made false and fraudulent statements regarding BOTOX<sup>®</sup>'s efficacy for those off-label treatments “even when there was little clinical evidence that these uses were effective,” said Sally Yates, U.S. Attorney for the Northern District of Georgia. According to Yates, Allergan made “hundreds of millions of dollars” promoting the off-label uses of BOTOX<sup>®</sup>.

29. Off-label marketing and misbranding practices were widespread at the Company. From at least 2003 through 2009, Allergan received FDA Warning Letters informing the Company of misbranding and other potential violations of the FDCA:

- **June 23, 2003 BOTOX<sup>®</sup> COSMETIC Botulinum Toxin Type A Warning Letter:** directly sent to Peter A. Kresel, former Senior Vice President of Global Regulatory Affairs at Allergan to inform the Company of violations of the FDCA regarding BOTOX<sup>®</sup> COSMETIC Botulinum Toxin Type A by: (1) disseminating false or misleading advertisement that falsely identify the product as a cosmetic treatment, (2) failing to reveal material facts about the product's use, and (3) minimizing the risk information presented.
- **September 6, 2005 Lumigan<sup>®</sup> (bimatoprost ophthalmic solution) 0.03% Warning Letter:** directly sent to Defendant Pyott, who at the time was the President and Chief Executive Officer of the Company and Chairman of the Board, to inform Allergan of misbranding Lumigan<sup>®</sup> by distributing sales aids that are misleading because they present unsubstantiated superiority claims in violation of the FDCA.

- **August 17, 2009 ACZONE® (dapson) Gel, 5% Warning Letter:** directly sent to the attention of Defendant Pyott, Chief Executive Officer and Chairman of the Board, to inform Allergan of violations of the FDCA and FDA implementing regulations regarding ACZONE<sup>®</sup> by: (1) false or misleading advertising overstating the efficacy of ACZONE<sup>®</sup>; and (2) omitting material facts and important risk information associated with the use of the product.

30. The Federal Bureau of Investigation (“FBI”) began investigating Allergan in 2007 when a doctor and an Allergan employee came forward to complain about Allergan’s off-label marketing practices. Whistleblower *qui tam* actions were filed against Allergan. The multi-year investigation revealed that the Company’s off-label marketing practices were widespread, covering a period that commenced in January 2000.

31. As detailed in the Government’s September 1, 2010 press release, “when a pharmaceutical manufacturer violates the integrity of the drug approval process established by Congress and the FDA by paying kickbacks to encourage the off-label use of an unapproved drug, that not only undermines the judgments of health care professionals, it also threatens to put patients’ health and safety at risk.”

32. The Government’s civil complaint states that Allergan had “illegally, vigorously and, without any thought to the possible negative health effects to which it subjected patients, promoted” BOTOX<sup>®</sup> for uses that had not been deemed safe and effective by the FDA. Federal prosecutors also accused the Company of teaching doctors how to obtain reimbursement from Medicare and Medicaid for off-label uses by putting in the codes for an approved treatment. Indeed, Medicaid paid about \$76.5 million for BOTOX<sup>®</sup> treatments from 2002 to 2006, much of it for unapproved uses of the drug, according to the Government’s civil complaint. The complaint cited an Allergan presentation from 2004, indicating that 86 percent of BOTOX<sup>®</sup> treatments reimbursed by Medicaid were for children, primarily for cerebral palsy, an off-label use.

33. In connection with its off-label sales and marketing practices, Allergan has agreed to plead guilty to a single misdemeanor “misbranding” charge covering the period 2000 through 2005 and has agreed to pay \$375 million in connection with the plea, which includes the forfeiture of \$25 million in assets. The misbranding charge is a strict liability offense.

34. As part of its guilty plea, Allergan has also agreed that between 2000 and 2005, its marketing of BOTOX<sup>®</sup> resulted in intended uses for the therapeutic treatment of headache, pain, spasticity and juvenile cerebral palsy. These uses were off-label during the relevant time frame and the labeling for BOTOX<sup>®</sup> did not bear directions for these intended uses, resulting in the product being misbranded.

35. The Company has also agreed, as part of its plea, to dismiss a legal action that the Company had filed, based on alleged violations of its First Amendment rights, against the U.S. Government. The Company’s complaint had alleged that the Government’s legal position – that it is a crime for a drug company to communicate truthful information to physicians about off-label uses of its products – violates the First Amendment and is inconsistent with the Federal Food, Drug & Cosmetic Act.

36. Additionally, the Company will pay \$225 million in civil fines – \$210 million to the federal governments and the rest to several states – to resolve claims asserted by the DOJ under the False Claims Act. However, the Company denies liability for the civil claims. Five whistle-blowers will be awarded a total of \$38.7 million out of the settlement.

37. Allergan currently estimates that it will record total non-recurring pre-tax charges of between approximately \$610 million and \$615 million in its third fiscal quarter in connection with the global settlement with the DOJ. This amount includes estimated interest and certain attorneys’ fees that Allergan is obligated to pay in connection with the global settlement, but does not include

ongoing administrative legal fees and other costs. The Company expects to pay the global settlement costs in its fourth fiscal quarter of 2010.

38. Additionally, as part of the resolution, Allergan entered into a corporate integrity agreement (“CIA”) with the Department of Health and Human Services’ Office of the Inspector General (“OIG”) that requires the Company to submit compliance reports, and to post on its website any payments to doctors, such as honoraria, travel or lodging. Specifically, the CIA will require Allergan to maintain its current compliance program and undertake a series of compliance-related obligations, including additional monitoring, maintenance of specific written standards, auditing, training, education, reporting and disclosure, for five years. The CIA also provides for an independent third-party review organization to assess and report on Allergan’s compliance program.

#### **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

39. This action is brought derivatively on behalf of the Company. Plaintiff is currently a stockholder of the Company and was a stockholder of the Company at the time of the actions complained of herein and has been a stockholder continuously to date.

40. Plaintiff has not made any demand on the Company’s Board of Directors to institute this action against the individual defendants. Under Delaware law, pre-suit demand on the board is excused where the allegations of the complaint create a reasonable doubt that (1) a majority of the directors are disinterested and independent or (2) the challenged transaction was otherwise the product of a valid exercise of business judgment. In an “interested” director transaction, the business judgment rule is inapplicable to the board majority approving the transaction, and the inquiry ceases. In that event, futility of demand has been established by any objective standard.

41. The current Board has twelve members. Ten of the twelve directors (Defendants Pyott, Lavigne, Boyer, Gallagher, Herbert, Ingram, Jones, Ray, Ryan and Schaeffer) were members

of the Allergan Board during the time of the admitted misconduct, which as stated above occurred from 2000 through 2005. Only two of the twelve current Board members (Defendants Dunsire and Hudson) began their service on the Board after 2005. For this reason, well over one half of the Board is interested, since the off-label marketing took place during the period when ten of the twelve current directors were members of the Board, and approved strategic plans that sought to promote and take advantage of the off-label marketing scheme. Indeed, even omitting the two directors who commenced their service on the Board during 2005 (Defendants Lavigne and Ingram) from this calculation, it is clear that at least eight of the current twelve members served on the Board when the strategic plans at issue were formulated and approved. This element alone compels a finding of demand futility.

42. Even in the absence of a traditionally interested (or non-independent) board, demand is excused under the facts at bar. The demand requirement and its exceptions serve to encourage intra-corporate resolution of disputes and to obtain the business judgment of the board as to whether the litigation is in the best interest of the corporation and its shareholders. However, where, as here, a shareholder sues the board of directors over an act that is not the product of a valid exercise of business judgment, such as waste and blatant violations of FDA rules and regulations, Delaware law excuses demand. Delaware law excuses demand whenever the challenged act of the board is not the product of a valid exercise of business judgment, regardless of whether a majority of the board is disinterested and independent.

43. As alleged herein, off-label marketing was part of the Company's strategic plan and was a top priority. Therefore, as with strategic plans generally enacted by boards of public companies, and based on the allegations contained in the Government's complaint, the off-label marketing of BOTOX<sup>®</sup>, which accounted for "hundreds of millions of dollars" to Allergan, was a

Board-approved decision, and its implementation was a significant piece of the Company's strategic plan.

44. Moreover, the Board was aware of other repeated violations of the FDCA, as the Company received several FDA Warning Letters from 2003 through 2009. The misconduct occurred over a long period of time; it was not an isolated conduct. As such, the Board failed to prevent violations of federal statutes, rules and regulations concerning the sales and marketing of drug products. Accordingly, (a) the Board is conflicted because there is an extremely high risk of directors' personal liability were they to institute this action; (b) the Board members failed to perform duties they knew were required, including monitoring the Company's marketing practices, and they knew that such failure would cause serious injury to the Company; and (c) the failure of the Board to prevent civil and criminal acts in this case was an egregious wrong in bad faith and in violation of the law and it cannot be the product of business judgment, *i.e.*, directors are forbidden to cause a company to break the law in order to make a profit.

45. BOTOX<sup>®</sup> is a well-known product with sales last year of approximately \$1.31 billion. The revenues derived from the off-label marketing of BOTOX<sup>®</sup> increased the total revenues and thereby increased the compensation of Defendant David Pyott, Chief Executive Officer and Chairman of the Board. Because of the increased revenue and Pyott's resulting increased compensation, it is unlikely that Defendant Pyott would have reported or stopped the off-label promotion of this product, and this further presents a conflict for the remaining members of the Board.

46. The repeated failure of the Board and its committees to follow requirements of its procedures and codes of conduct for supervising the officers and employees to prevent illegal activity is not protected by the business judgment rule. The Board failed to follow the requirements of the

Company's Code of Business Conduct and Ethics, which contains general requirements for conducting Allergan's business and explicitly requires all business conducted by Allergan employees be in compliance with all applicable laws.

47. According to the Corporate Governance Committee charter, the members of the committee "regularly receive[] comprehensive reports from management regarding compliance-related matters affecting the Corporation and provide[] general compliance oversight to the Corporation." Thus, at a minimum, Defendants Boyer, Dunsire, Ingram, Jones, and Schaeffer, as members of the Corporate Governance Committee, should have supervised and prevented officers and employees from conducting the illegal activity alleged herein.

48. These failures to follow procedures and codes excuse demand.

49. The off-label marketing practices have already caused injury to the Company and will continue to cause harm to the Company by virtue of the fines it has agreed to pay in connection with these illegal sales and marketing practices, as well as all other costs and expenses incurred in connection with the Government's investigation and the *qui tam* complaints.

### **COUNT I**

#### **(Derivative Claim Against All Defendants)**

50. Plaintiff repeats and realleges each of the foregoing paragraphs of this complaint.

51. This count is brought derivatively on behalf of the Company against all defendants for breaches of their duty of loyalty owed to the Company, and for the commission of waste under Delaware law because of violations of state and federal law concerning the marketing and promotions of drug products.

52. The Defendants, as directors, have breached their above-identified fiduciary duty to the Company and have committed waste by the actions complained of herein.

53. As a result of the actions of defendants, the Company has been and will be irreparably harmed by the off-label marketing and promotion of BOTOX<sup>®</sup>.

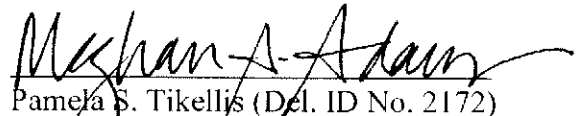
**PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for the following relief:

- A. Determining that the Court may proceed derivatively on behalf of the Company;
- B. An equitable accounting, including disgorgement, in favor of the Company against the Defendants, for the losses that it has and will sustain by virtue of the misconduct alleged herein;
- C. An equitable accounting with disgorgement in favor of the Company against the directors;
- D. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, experts' fees, costs, and expenses;
- E. Directing the Individual Defendants to pay damages to the Company, including both pre- and post-judgment interest at the highest rate allowed by law; and
- F. Granting such other and further relief whether similar or different, as the Court deems appropriate and just.

Dated: September 3, 2010

CHIMICLES & TIKELLIS LLP



Pamela S. Tikellis (Del. ID No. 2172)  
Robert J. Kriner, Jr. (Del. ID No. 2546)  
Meghan A. Adams (Del. ID No. 4981)  
222 Delaware Ave.  
P.O. Box 1035  
Wilmington, DE 19899  
(302) 656-2500

*Attorneys for Plaintiff*

*Of Counsel:*

BARRACK, RODOS & BACINE

Daniel E. Bacine

Jeffrey W. Golan

Julie B. Palley

3300 Two Commerce Square

2001 Market Street

Philadelphia, PA 19130

(215) 963-0600