IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, and
THE DISTRICT OF COLUMBIA, ex rel.
CARYATID, LLC,
1455 Pennsylvania Ave., N.W., Suite 400,
Washington, D.C., 20004

Plaintiffs

v.

ALLERGAN, INC.

Defendant.

FILED UNDER SEAL

COMPLAINT

The United States of America and the District of Columbia, by and through their qui tam Relator, Caryatid LLC, bring this action under the Federal False Claims Act, 31 U.S.C. § 3729-3733, and the District of Columbia False Claims Act, D.C. Code §§ 2-308.14, et seq., against Allergan, Inc., to recover all damages, penalties, and other remedies provided by the False Claims Acts on behalf of the United States, the District of Columbia and the Relator, and for their Complaint allege:

I. Parties

1. Plaintiff is Caryatid LLC (hereinafter Plaintiff, Caryatid, or Relator), a limited liability company organized under the laws of the District of Columbia. Caryatid is engaged in the business (among others) of acquiring information regarding, and investigating alleged violations of the Federal (31 U.S.C. § 3729, et seq.) and District of Columbia (D.C. Code §§ 2-308.14, et seq.) False Claims Acts.

2. Defendant Allergan, Inc. (hereinafter "Allergan"), is a Delaware corporation headquartered in Irvine, California.

3. Allergan is principally engaged in the development, manufacturing, marketing and sale of pharmaceutical drugs, including prescription pharmaceuticals falling under the jurisdiction and regulation of the United States Food and Drug Administration ("FDA").

II. Jurisdiction and Venue

4. Jurisdiction in this Court is proper pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. § 1331. Jurisdiction in this Court under the District of Columbia False Claims Act is proper pursuant to the Federal False Claims Act, 31 U.S.C. § 3732(b).

5. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 because the acts proscribed by 31 U.S.C. §§ 3729 et seq., and complained of herein took place in part in this district and Defendant transacted business in this district.

6. Pursuant to 31 U.S.C. § 3730(b)(2) and D.C. Code § 2-308.15, the Relator has prepared and will serve with this Complaint on the Attorney General of the United States, the United States Attorney for the District of Columbia, and the Attorney General of the District of Columbia a statement of all material evidence and information currently in its possession and of which it is the original source. This disclosure statement is supported by material evidence known to the Relator at the time of filing establishing the existence of Defendant's false claims. Because the statement includes attorney-client

communications and work product of Relator's attorneys, and is submitted to those Federal and District of Columbia officials in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential.

III. Legal Background

7. Under the Food, Drug, and Cosmetic Act and FDA regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. 21 U.S.C. §§ 331, et seq. Such unapproved uses are referred to as "off-label."

8. The Medicaid program reimburses Medicaid beneficiaries for prescription drug expenses which are medically necessary. In addition, States (including the District of Columbia) may exclude from Medicaid reimbursement drugs prescribed for an off-label use unless that use is supported by one or more citations in certain pharmaceutical compendia. 42 U.S.C. § 1396r-8.

9. Other Federal healthcare programs either purchase medically necessary prescription drugs directly, or reimburse enrollees and beneficiaries for their cost, including Medicare, the Veteran's Administration, TRICARE (the Department of Defense health insurance program), the Federal Employees Health Benefit Program, and the Public Health Service. *See, for example*, 32 C.F.R. § 199.4(g)(15)(i)(A) (TRICARE regulations).

IV. Facts

10. Allergan sells Acular LS™ (ketorolac tromethamine ophthalmic solution 0.4%), an ophthalmological non-steroidal anti-inflammatory prescription drug ("NSAID"). The FDA has approved Acular LS only for the "reduction of ocular pain and burning/stinging

following corneal refractive surgery." The FDA-approved recommended dose for Acular LS is "one drop four times a day in the operated eye as needed for pain and burning/stinging for up to 4 days following corneal refractive surgery." The term "corneal refractive surgery" refers to surgical techniques to shape a patient's corneas to correct for vision problems; these techniques include, among others, photorefractive keratectomy (also known as PRK), and LASIK.

11. Allergan also sells Pred Forte™ (prednisolone acetate), a glucocorticoid. The FDA has approved Pred Forte only for the "treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe."

12. Allergan also sells Zymar™ (gatifloxacin), a flouroquinone anti-infective drug. The FDA has approved Zymar only for the "treatment of bacterial conjunctivitis caused by susceptible strains" of six specific types of bacteria.

13. Allergan also sells Acuvail™ (keterolac tromethamine ophthalmic solution 0.45%), and ophthalmological NSAID. The FDA has approved Acuvail only for the "for the treatment of pain and inflammation following cataract surgery." The FDA-approved recommended dose for Acuvail is one drop two times a day in the operated eye beginning one day prior to surgery and continuing two weeks after surgery. Allergan launched Acuvail as a commercial product after the FDA approved it for sale in July, 2009.

Patient Kits

14. Allergan has provided ophthalmologists with free or below-market cost patient kits which included Acular LS, Pred Forte, and Zymar. In addition to these prescription drug

products, Allergan's patient kits included several ophthalmological care items, such as eye patches and dressings, sunglasses and a carrying case labeled with Allergan's logo and/or the name and logo of the ophthalmologist.

15. Allergan's patient kits violated the prohibition against off-label promotion by promoting the use of Acular LS for cataract surgery patients, an unapproved indication.

16. Allergan's patient kits violated the prohibition against off-label promotion by promoting the use of Pred Forte for the prevention of post-surgical inflammation, an unapproved indication.

17. Allergan's patient kits violated the prohibition against off-label promotion by promoting the use of Zymar for the prevention of non-specific post-surgical infection, an unapproved indication.

18. Allergan's patient kits further violated the Antikickback Statute, 42 U.S.C. § 1320a-7b, because their contents, offered either for free or well below market value, comprised an inducement for physicians to prescribe Acular LS instead of competing NSAIDs.

19. On information and belief, Allergan sales representatives threatened to cease providing ophthalmologists free or below-market Patient Care Kits if the physician prescribed an NSAID other than Acular LS for use with the Patient Care Kits.

Detailing Cataract Specialists

20. Allergan, by and through its sales representatives (and at times prior to the 2009 launch of Acuvail), have targeted ophthalmological surgeons specializing in cataract surgery and promoted the use of Acular LS for cataract surgical patients, although the FDA has not approved Acular LS for any treatment relating to cataract surgery.

Off-Label Promotion of Acuvail

21. Beginning with Allergan's launch of Acuvail in August, 2009, Allergan has promoted Acuvail for the treatment of retinal diseases, including cystoid macular edema, an off-label use.

22. Allergan's promotion of Acuvail for retinal uses has included, among other methods, sales representatives' highlighting for physicians Acuvail's concentration at the "back of the eye"; Allergan and physicians understand this phrase to refer to the retina, which is located in the posterior segment of the eye (versus the anterior segment, where the on-label use of cataract removal takes place).

The Submission of False Claims

23. Due to the ubiquity of Federal healthcare programs in America medicine, it is certain that claims were submitted to Federal healthcare programs and the Medicaid program of the District of Columbia for reimbursement of Acular LS, Pred Forte, Zymar, and Acuvail when the uses of those drugs were off-label and medically unnecessary.

COUNT I – FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729, et seq.

24. Plaintiff repeats each and every allegation of Paragraphs One through 23 of this Complaint with the same force and effect as if set forth herein.

25. As a result of the foregoing conduct, Defendant Allergan knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1).

COUNT II – DISTRICT OF COLUMBIA FALSE CLAIMS ACT, D.C. CODE §§ 2-308.14, et seq.

26. Plaintiff repeats each and every allegation of Paragraphs One through 23 of this Complaint with the same force and effect as if set forth herein.

27. As a result of the foregoing conduct, Defendant Allergan knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval to the District of Columbia, in violation of the District of Columbia False Claims Act, D.C. Code §§ 2-308.14, et seq.

JURY TRIAL DEMAND

28. Plaintiff demands a jury trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court enter judgment against Defendant Allergan as follows:

(a) that the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Complaint, as the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq., provides;

(b) that civil penalties of $11,000 be imposed for each and every false claim that Defendant caused to be presented to the United States and/or its grantees;

(c) that the District of Columbia be awarded damages in the amount of three times the damages sustained by the District of Columbia because of the false claims alleged within this Complaint, as the District of Columbia False Claims Act, D.C. Code §§ 2-308.14, et seq., provides;

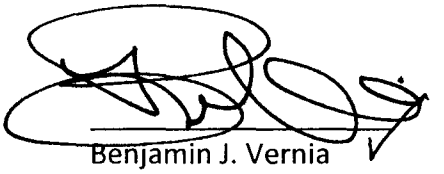
(d) that civil penalties of $10,000 be imposed for each and every false claim that Defendant caused to be presented to the District of Columbia and/or its grantees;

(e) that attorneys' fees, costs, and expenses that the Relator necessarily incurred in bringing and pressing this case be awarded;

(f) that the Relator be awarded the maximum amount allowed to it pursuant to the False Claims Act; and

(g) that this Court award such other and further relief as it deems proper.

Respectfully submitted,



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COUNSEL FOR CARYATID LLC

Date: 1-11-10

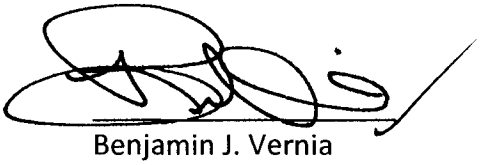
Certificate of Service

I hereby certify that a copy of the foregoing Complaint filed under seal along with a disclosure of information in the Relator's possession and of which it is the original source, pursuant to 31 U.S.C. § 3730 and D.C. Code § 2-308.15 was served on the following:

Hon. Eric Holder, Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530-0001

Hon. Channing D. Phillips, United States Attorney for the District of Columbia
555 4th Street, NW
Washington, DC 20530

Hon. Peter Nickles, Attorney General of the District of Columbia
Government of the District of Columbia
One Judiciary Square
441 4th Street NW
Suite 1145S
Washington, DC 20001



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