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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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DISTRICT OF MARYLAND
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AW09 CV 2817

UNITED STATES OF AMERICA

and

ex rel. ALBERT EDWARD HALLIVIS
11321 College View Drive
Silver Spring, MD 20902

Plaintiffs

vs.

ALLERGAN, INC.
a/k/a ALLERGAN USA, INC.
2525 Dupont Dr.
Irvine, CA 92612

Serve : Resident Agent

CSC-LAWYERS INCORPORATING
SERVICE COMPANY
7 St. Paul Street, Suite 1660
Baltimore, MD 21202

Defendant

Case No.
FILED UNDER SEAL
Pursuant to 31 U.S.C. § 3730
(False Claims Act)

COMPLAINT

Relator-Plaintiff Albert Edward Hallivis, by and through his attorneys, Jay P. Holland, Brian J. Markovitz, and the law firm Joseph, Greenwald & Laake, P.A., bring this False Claims Act, 31 U.S.C. §3729-33§ ("FCA") Complaint, on behalf of the United States of America, and sues the Defendant, ALLERGAN, Inc. (hereinafter "ALLERGAN"), and in support thereof, states as follows:

I. INTRODUCTION

1. This case involves a scheme by Defendant ALLERGAN to market and promote its drug, Botox (onabotulinumtoxinA (a botulinum toxin)), which is a neurotoxin protein from

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the bacterium Clostridium botulinum, for the off-label use for control of overactive bladder ("OAB") and incontinence due to neurogenic bladder ("NB"), when ALLERGAN knew that the use of the drug for OAB and NB was not medically accepted and had not been found by the Food and Drug Administration ("the FDA") to be safe and effective.

2. In the course of its off-label marketing scheme, ALLERGAN made false and misleading statements to treating doctors and other medical personnel who can prescribe medicine to the effect that Botox was medically accepted for the off-label uses being promoted, and therefore eligible for Medicare reimbursement. In reliance on ALLERGAN's false statements, treating physicians administered Botox to their patients. ALLERGAN thus caused physicians to present false claims for payment to Medicare. ALLERGAN's false statements caused Botox to be an unapproved new drug pursuant to Title 21, United States Code, Section 355, and its shipment in interstate commerce violated Title 21, United States Code, Section 331(d). Additionally, ALLERGAN's false statements led to the submission of and payment for false claims by the Medicare program, which violated Section 3729(a)(l)(a) and (b) of the FCA.

3. As the direct, proximate and foreseeable result of ALLERGAN's false and fraudulent conduct as set forth above, ALLERGAN (a) caused physicians unwittingly to submit false claims to the Medicare program seeking reimbursement for uses of Botox that ALLERGAN knew were not medically accepted and therefore ineligible for Medicare reimbursement; and (b) used false or fraudulent statements to get the Medicare program to reimburse millions of dollars of false and fraudulent claims submitted by these physicians. ALLERGAN's illegal scheme to promote the use of Botox for indications that were neither FDA approved nor medically accepted, greatly increased Botox sales to the financial benefit of ALLERGAN, but

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caused the Medicare Program to pay millions of dollars for the administration of a drug with no proven medical value to patients suffering from OAB and NB.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732.

5. Venue is proper in this District under 31 U.S.C. § 3732(a) because many of the illegal acts of Defendant ALLERGAN prohibited by 31 U.S.C. §3729 have occurred in this District.

III. PARTIES

6. Relator Albert Edward Hallivis is an adult citizen of the State of Maryland. Relator is the Territory Business Manager for the Southern Baltimore region [comprising of the geographic region from southern Baltimore to Laurel, Maryland] for Defendant. In January 2007, Relator became an employee of Defendant when his prior employer, Espirit Pharma, was acquired by Defendant because Defendant was seeking a sales staff that had experience working with urologists. At that time, Relator became part of Defendant's Urological Management Team. Relator's job duties include selling another drug (Sanctura XR) manufactured by Defendant for OAB (which has FDA approval for such use) and booking speakers in the Southern Baltimore region for Defendant to promote the drugs it produces.

7. Plaintiff, the United States of America, through the Department of Health and Human Services ("HHS"), is charged with administering the Medicare Program through the Centers for Medicare and Medicaid Services ("CMS") formerly known as the Health Financing Administration.

8. Defendant ALLERGAN is a Delaware Corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 92612. ALLERGAN is principally engaged in the development, manufacture and sale of pharmaceuticals, including prescription

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pharmaceuticals subject to regulation by the FDA. During the relevant time period, ALLERGAN owned, manufactured, and sold the prescription drug Botox.

IV. ALLEGATIONS

ALLERGAN's Off-Label Promotion of Botox

9. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-99, governs, among other things, the testing, approval, manufacture, labeling, and distribution in interstate commerce of prescription medicines. Under the FDCA a "new drug" means any drug the composition of which is such that the new drug is not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. §321(p)(l). "New drugs" cannot be distributed in interstate commerce unless the person who seeks to distribute the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses, and there is in effect for such drug an approval of a new drug application (NDA) pursuant to 21 U.S.C. § 355(b), or an abbreviated new drug application (ANDA) pursuant to 21 U.S.C. § 355(j), or an investigational new drug (IND) submission pursuant to 21 U.S.C. § 355(i). *See* 21 U.S.C. §§ 355(a), (d), 331(d). While physicians may prescribe approved drugs for off-label uses, drug manufacturers are prohibited from marketing or promoting a drug for a use that the FDA has not approved. *See* 21 U.S.C. § 331(d) (prohibiting distribution of drugs for non-approved uses); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) (manufacturers that want to promote a drug for uses outside of FDA approval must resubmit drug for FDA testing and approval process).

10. On or about December 9, 1991, the FDA approved an NDA for Botox for the certain treatment of strabismus and blepharospasm, two eye muscle disorders. Since then, the FDA

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has approved NDAs for Botox for other medical treatments. Botox, however, has never been approved by the FDA for the treatment of OAB or NB.

11. The FDA approval of a drug is limited to the specific indications for use listed in the NDA, and the manufacturer may only market the drug for those specific indications. Because a drug approval is limited to those specific uses listed in the NDA, if a manufacturer promotes an approved drug for an indication not in the NDA, it is not covered by the approval, and is therefore an unapproved new drug as to that use.

12. A licensed physician, however, may prescribe most approved drugs for any purpose that the doctor deems medically appropriate, regardless of whether the drug has been approved for that use by the FDA, so long as the use is considered within the reasonable practice of medicine under state law. *United States ex rel. Franklin*, 147 F. Supp. 2d at 44. Prescribing drugs for unapproved, but medically accepted, uses is common in medical practices.

13. Medicare is a federal health insurance program for people aged 65 and older as well as persons under 65 who are blind or disabled. As set forth above, the Medicare program is administered by CMS, a division of HHS. CMS contracts with private companies to process and pay claims submitted by Medicare providers for the treatment of Medicare beneficiaries. Those private companies who process Medicare claims submitted by physicians are called "Medicare Carriers", and those who process Medicare claims submitted by hospitals are called "Medicare Intermediaries."

14. During the time period covered by this Complaint, Medicare provided limited benefits for outpatient drugs. Specifically, Medicare paid for drugs (which would include Botox) in an out-patient context only if the drug was prescribed for an indication or use for which the drug

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had been specifically approved by the FDA. *See* 21 U.S.C. § 331(d) (prohibiting distribution of drugs for non-approved uses).

15. Relator began working for Defendant in January of 2007. As part of his duties, he booked physician speakers throughout the Southern Baltimore territory to promote ALLERGAN drugs to other medical personnel, usually physicians, at dinners and other speaking engagements.

16. Since February of 2009, Relator's direct supervisor has been Jeffrey Fuller, Regional Manager for the Southeast Region, consisting of Baltimore, Maryland to Florida. Prior to that, from November of 2007 through February of 2009, Relator was managed by Robert Gill.

17. Since on or about March of 2009, Relator became reacquainted with Dr. David A. Gordon, an urologist from Chesapeake Urology Associates, P.A. ("CUA") in Owings Mills, Maryland, whom he had made sales to for his prior employer, Espirit Pharma. Dr. Gordon is well known at Defendant. Dr. Gordon is the most sought after speaker for the entire east coast utilized by Defendant for purposes of promoting drugs for the treatment of OAB and NB. Dr. Gordon also is the most sought after trainer for the entire east coast used by Defendant to train other physicians who make presentations for Defendant for drugs related to the treatment of OAB and NB. Several sales people at Defendant, including Melanie Clatchey, Kathleen Dall, and Robert Scanlon routinely use Dr. Gordon as a speaker and/or trainer.

18. Dr. Gordon also is a member of the U.S. advisory boards for Defendant, as well as Pfizer and Novartis. Dr. Gordon is usually compensated well over $1,000.00 to speak on behalf of Defendant. Relator has a professional relationship with Dr. Gordon and speaks with him frequently either in person or on the telephone.

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19. Since on or about April of 2009, Relator has been to Dr. Gordon's office several times and had numerous discussions with Dr. Gordon about the operation of his practice and CUA's practice. Dr. Gordon has explained and Relator has personally observed that the majority of Dr. Gordon's patients are males in their late sixties (60's) and older. Dr. Gordon further has explained to Relator that these male patients suffer from OAB and NB, resulting in urinary symptoms of "frequency and urgency" and that he often treats them with Botox.

20. On or about February of 2009, in the Miami area of Florida, at a training session hosted by Defendant, Dr. Gordon trained over sixty (60) physicians with respect to the promotion of drugs used by Defendant for OAB and NB. Upon information and belief, Dr. Gordon promoted the off-label use of Botox to these physicians and trained them on presenting to other medical personnel that Botox should be used for the treatment of OAB and NB.

21. On or about August through September 2009, Relator had discussions with Dr. Gordon about speaking on Sanctura XR with respect to its uses for OAB. In September of 2009, during one of Relator's discussions with Dr. Gordon about this speaking opportunity, Dr. Gordon mentioned that he would also speak about Botox's uses for OAB and NB. Relator specifically instructed Dr. Gordon not to speak about Botox at all and to limit his discussions to Sanctura XR. Relator's instruction to not talk about Botox was witnessed by two staff members from Dr. Gordon's practice (CUA), including "Traci", Dr. Gordon's assistant.

22. Relator set up a speaking engagement for Dr. Gordon for September 30, 2009 to the Surgical Urological Nurses Association ("SUNA") at the Oregon Grille, a restaurant in Hunt Valley, Maryland with the intent that Sanctura XR would be the topic of discussion.

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23. In attendance at the SUNA speaking engagement were approximately eighteen (18) people. Many of the attendees at this event were nurse practitioners and physician assistants who have the ability to prescribe drugs. The individuals in attendance included Nancy Shachelford, Mary Kelly, Sally Bashaar, Charlene Mahoney and Ann Fabula from Greater Baltimore Medical Center, Maureen French from Kernan Hospital, and Sharon Muller from Carroll Hospital Center.

24. Dr. Gordon began his presentation about pharmaceutical treatments for OAB by Sanctura XR. But approximately five (5) minutes into the presentation, despite being specifically instructed by Relator not to do so, Dr. Gordon went into a pre-arranged and pre-planned discussion about the use of Botox for the control of OAB and NB, especially for severe cases of these medical conditions. Included in the presentation were animated slides describing the origin of botulism and Botox, how Botox is used, and the pros of using Botox to treat OAB and NB. Dr. Gordon specifically described the experience of his patients and other patients within his practice group, at CUA who had been treated for OAB and NB with Botox, including patients from nursing homes. Upon information and belief, Dr. Gordon, as well as Dr. Kenneth F. Langer of CUA, treat patients on Medicare with Botox for OAB and NB.

25. During his presentation, Dr. Gordon noted several times that ALLERGAN was the maker of Botox treatments for OAB and NB and indicated that Botox was superior to other treatments because of its ability to block nerve responses. Dr. Gordon also explained that, because Botox did not have permanent effects, patients such as his would have to return to physician's offices multiple times for multiple treatments. The presentation lasted approximately seventy-five (75) minutes.

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26. During Dr. Gordon's presentation, Relator, who was sitting in the audience next to his supervisor Mr. Fuller, expressed concern to Mr. Fuller that the presentation was "illegal" "off-label marketing". Mr. Fuller told Relator not to worry about the presentation and that Dr. Gordon made the same presentation all the time. As Dr. Gordon is the most frequently booked speaker for Defendant on the East Coast, the presentation has been made with some frequency to a large number of physicians and other medical personnel with the ability to prescribe.

27. During Dr. Gordon's presentation, Relator specifically inquired of Mr. Fuller what he would do should a compliance officer be in attendance at a presentation like the one being given by Dr. Gordon. Mr. Fuller replied that if a compliance officer was present that Relator should interrupt the presentation, take the speaker aside, and remove the slides.

28. After Dr. Gordon's presentation concluded, Relator approached Dr. Gordon and asked him where he got the slides for the presentation. Dr. Gordon explained that Defendant had provided them to him and that they were paid for by a publishing company hired by Defendant. Relator asked if he could have a copy of the slides but Dr. Gordon explained that sales personnel at Defendant that were higher up than Relator did not want any paper copies of the slides provided and had instructed him not to provide a copy of the presentation to anyone.

29. False and misleading presentations were made by physicians contracted by Defendant, including the September 30, 2009 presentation created by Defendant and presented by Dr. Gordon, as well as other trainings given by Dr. Gordon, to Medicare Carriers with the intent to cause the Medicare Carriers to approve off-label prescriptions of Botox for Medicare reimbursement. These false and misleading statements had a natural tendency to influence

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the decision of Medicare Carriers to use Botox off-label and were capable of influencing the decision of Medicare Carriers to seek reimbursement for Botox's off-label use.

30. Physicians could and did rely on the presentations by and trainings of Dr. Gordon (and upon information and belief, other physicians hired by Defendant) to submit claims to carriers for Medicare reimbursement.

31. The illegal promotion of off-label sales of Botox to treat OAB and NB was known by sales force management at the company, including Jeffrey Fuller, the Regional Manager for the Southeast territory and Relator's direct supervisor, and Kristine Grogan, a former Vice President of Marketing for Defendant. Moreover, Defendant's sales staff encouraged the illegal promotion of off-label sales by intentionally creating at least one power point presentation to assist in this illegal promotion. Upon information and belief, other power point presentations similar to the one used by Dr. Gordon have been created by Defendant for use in the same or similar illegal manner to market off-label uses of Botox for treatment of OAB and NB.

32. Every off-label prescription of Botox approved for payment during the relevant statutory time period by a Medicare Carrier was false and/or fraudulent claims for purposes of the FCA.

COUNT I
False Claims Act 31 U.S.C. §3729(a)(1)(a)

33. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs of this Complaint.

34. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(a).

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COUNT II
False Claims Act 31 U.S.C. §3729(a)(1)(b)

35. Relator realleges and incorporates by reference the allegations contained in the foregoing paragraphs of this Complaint.

36. By virtue of the acts described above, ALLERGAN knowingly made, used, or caused to be made or used false records and statements, to get the false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1)(b).

PRAYER FOR RELIEF

WHEREFORE, Relator prays, on behalf of the United States and himself that, on final trial of this case, judgment be entered in favor the United States and against Defendant as follows:

1. On the First Cause of Action under the False Claims Act, as amended, for the amount of the United States' damages, multiplied as required by law, and for such civil penalties as are allowed by law;

2. On the Second Cause of Action under the False Claims Act, as amended, for the amount of the United States' damages, multiplied as required by law, and for such civil penalties as are allowed by law; and

3. For the costs or this action, prejudgment interest, interest on the judgment and for any other and further relief to which Plaintiff, the United States, and Relator may be justly entitled.

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Respectfully submitted,

JOSEPH, GREENWALD & LAAKE, P.A.

By: _____

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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues of triable fact in the foregoing complaint.

_____
Brian J. Markovitz

DATED: 10/26/09

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