IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA *ex rel.* **Amy M. Lang and Charles J. Rushin,**	*	**CIVIL ACTION**
	*	**FILE NO.** 1:07-CV-1288
Relators,	*	
	*	**FILED UNDER SEAL**
v.	*	**PURSUANT TO**
	*	**31 U.S.C. § 3730(b)(2)**
Allergan, Inc.,	*	
	*	**Jury Trial Demanded,**
Defendant.	*	**Pursuant to Fed. R. Civ. P. 38**
	*	

COMPLAINT

Amy M. Lang, M.D. and Charles J. Rushin bring this action to recover damages and civil monetary penalties on behalf of the United States of America arising from Defendant Allergan, Inc.'s ("Allergan") violations of the False Claims Act, 31 U.S.C. § 3729 – 3733 ("FCA").

SUMMARY OF FALSE CLAIMS

1.

Allergan has violated the FCA by engaging in the following four categories of misconduct, each of which resulted in the submission of false or fraudulent

claims for both Allergan's product Botox and physician injection services to Medicare, Medicaid, or other federal health care programs.

(a) *Off-Label* Promotion and False Statements to Doctors: Allergan has made, and has caused others to make, false and fraudulent statements to physicians regarding Botox's efficacy (as well as scientific and clinical evidence in support thereof) for the treatment of headaches and dozens of other conditions (*e.g.*, whiplash, lower-back pain, tennis elbow, TMJ, arthritis, and enlarged prostate) that the drug has never been approved by the FDA to treat (hereinafter "*off-label*" uses). *See, e.g.*, ¶¶ 60-105. These false statements were made through concerted and coordinated efforts of Allergan management and employees in different divisions of the company to aggressively promote Botox for unapproved indications, and the statements resulted in the submission of claims for drugs and injection services that were not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" as is required by the Medicare Statute. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A). These statements were made through, *inter alia*:

(i) Allergan's salesman (currently known as "Neuroscience Medical Consultants") during, *inter alia*, visits to doctors' offices;

(ii) Allergan's medical liaisons (currently known as "Regional Scientific Services Managers") during, *inter alia*, visits to doctors' offices;

(iii) Continuing Medical Education ("CME") programs that were funded, designed, scripted, and controlled by Allergan;

(iv) *off-label* injection training sessions and workshops that Allergan funded, scheduled, and coordinated and which were conducted by doctors Allergan employees selected and identified as "Preceptors," "Key Opinion Leaders," and/or "Thought Leaders;"

(v) articles and abstracts published in journals and magazines that, while ghost-written (in whole or in part) by Allergan employees, were published under the names of others, and were usually published as independent works, without revealing the role of Allergan or its employees in their creation; and

(vi) websites that were funded and controlled by Allergan.

(b) Miscoding and Altering Records: In an effort to conceal the *off-label* and unreimbursable nature of numerous Botox uses, Allergan has taught, coached, and encouraged physicians and their staffs, as well as the staffs of hospitals and other medical institutions, to use false or improper codes (*e.g.*,

ICD-9-CM and CPT codes) or otherwise falsely or improperly document patient conditions and treatments provided:

(i) on claim forms (*e.g.*, CMS 1500 and CMS 1450/UB-92); and

(ii) in electronic or paper records or submissions (*e.g.*, superbills and injection charge sheets) that are provided to physician billing services, clearinghouses, or Medicare contractors (Medicare Carriers, Medicare Fiscal Intermediaries, and the newly formed Medicare Administrative Contractors, hereinafter jointly referenced as "Medicare Contractors") or otherwise used to communicate, record, and/or support such claims. *See, e.g.*, ¶¶ 106-115.

(c) Kickback's to Induce Use of Botox Paid for by Federal Health Care Programs: Allergan has violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, by offering and providing illegal renumeration to physicians, in the form of cash, travel, lodging, and meals, as an inducement to do the following:

(i) prescribe Botox to patients for both *off-label* and approved indications; and

(ii) provide corresponding injection services. *See, e.g.*, ¶¶ 116-135.

Because prescriptions for Botox are accompanied by corresponding injection procedures performed by physicians, each time these doctors prescribed Botox for a Medicare beneficiary, two claims to the Government result - one for the Botox used (which is bought by the doctor and resold to the Medicare beneficiary) and the other for the doctor's service injecting of the product. Thus, Allergan's kickbacks resulted in false claims for both Botox and physician injection services to the federal Medicare and Medicaid programs, both of which condition the payments of claims and participation in the programs on compliance with the federal Anti-Kickback Statute.

(d) False Statements to Medicare Contractors to Impact Coverage Determinations: Allergan has made, and caused others to make, false and fraudulent statements regarding Botox's efficacy (as well as scientific and clinical evidence in support thereof) for the *off-label* treatment of headaches to Medicare Contractors, Medicare Contractors' advisory committees (that act as the Medicare Contractors' agents), and physicians who Allergan solicited to contact these Medicare Contractors and the advisory committees. These statements were made to cause the Medicare Contractors to issue Local Coverage Determinations approving coverage and reimbursement for these unapproved Botox treatments, which Allergan knew at the time of

these acts were not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" as is required by the Medicare Statute. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); ¶¶ 136-143.

THE COURT'S JURISDICTION & VENUE

2.

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, because this case arises under the federal False Claims Act, 31 U.S.C. §§ 3729 – 3733, and 31 U.S.C. § 3732(a), which expressly confers jurisdiction on this Court for actions brought under to 31 U.S.C. § 3730.

3.

The false claims allegations of this Complaint are not subject to any of the limitations identified in 31 U.S.C. § 3730(e). In particular, this action is not based upon: (a) the facts underlying a pending FCA action, *see* 31 U.S.C. 3730(b)(5); or (b) the public disclosure of allegations or transactions in the defined categories of hearings, reports, and news media identified in 31 U.S.C. § 3730(e)(4)(A). In addition, if there has been a public disclosure of any of the allegations underlying

this action, Relators qualify as "original source[s]" of such information, pursuant to 31 U.S.C. § 3730(e)(4)(B).

4.

The Court has personal jurisdiction over Defendant Allergan pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." Section 3732(a) also authorizes nationwide service of process. At all times relevant to this action, up to and including the date of this filing, Defendant Allergan has resided and transacted business in the Northern District of Georgia. In addition, Allergan has committed numerous FCA violations in the district, as more particularly described herein.

5.

Venue is proper in this Court pursuant to 28 U.S.C. 1391(c), because Defendant Allergan resides in the Northern District of Georgia in that it has contacts in the district that would be sufficient to subject it to personal jurisdiction if the district were a separate state, and 31 U.S.C. § 3732(a), because Allergan can be found, and transacts business, in the Northern District of Georgia. At all times relevant to this action, Allergan regularly conducted substantial business within the

Northern District of Georgia, maintained employees in the district, and made significant sales within the district. In addition, Allergan has committed numerous FCA violations in the district, as more particularly described herein.

THE PARTIES

ALLERGAN, INC.

6.

Defendant Allergan is a global corporation formed under the laws of the state of Delaware, with its principle executive offices at 2525 Dupont Drive, Irvine, California 92612. Allergan specializes in manufacturing and marketing 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).

7.

In 2006, Allergan reported company-wide net sales of over $3 billion (a 36% increase over its 2005 net sales) and operating income of over $1 billion. The corporation has publicly estimated that it plans to report global net sales of between $3,500,000.00 and $3,665,000.00 for 2007, necessitating 17% - 22% sales growth.

BOTOX

8.

Allergan manufactures a pharmaceutical formulation of botulinum toxin type A, a purified neurotoxin to which it received the rights in 1991 when it acquired Oculinum, Inc., the drug's developer. Allergan currently markets and sells the toxin in the United States under two distinct trade names: "Botox" and "Botox Cosmetic." While the botulinum toxin in these products are exactly the same, Allergan uses separate trade names to distinguish the toxin being sold for therapeutic uses ("Botox") from that sold for cosmetic uses ("Botox Cosmetic"). This action concerns Allergan's marketing of the former, therapeutic Botox.

Botox's Limited FDA Approval

9.

Botox has ***limited*** approval and licensing by the Food and Drug Administration ("FDA") as a biological product and drug. Although perhaps best known for its use in connection with cosmetic facial aesthetics, Botox was first approved for the treatment of certain neuromuscular disorders. Botox has received FDA approval for the following indications during the years identified.

Date	Name and Description of Condition	Full Indication
Dec. 1989	**Blepharospasm** Involuntary contraction/closure of eyelid muscles	– The treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above – Importantly, Botox is not approved for certain severe strabismus patients.
Dec. 1989	**Strabismus:** Misalignment of the eyes, crossed-eyes, or wall-eyes	
Dec. 2000	**Cervical Dystonia:** Abnormal head and neck posture with sustained or intermittent, involuntary movements and commonly associated with pain	– The treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with the condition
July 2004	**Severe primary axillary hyperhidrosis:** Severe underarm sweating	– The treatment of severe primary axillary hyperhidrosis that is inadequately managed by topical agents, such as prescription antiperspirants

10.

Because the FDA approves biological products for ***specific uses*** only (rather than general use), Botox is not FDA approved for any therapeutic uses other than blepharospasm, strabismus, cervical dystonia, and severe primary axillary hyperhidrosis.

11.

While Botox is only FDA-approved for four relatively rare therapeutic indications, Allergan's 2006 domestic net sales of therapeutic Botox totaled $321,100,000, a 14.9% increase over 2005. Looking forward, Allergan's management has set a 2007 net sales target of $370,000,000 for therapeutic Botox, necessitating a 15.2% sales increase for the product.

RELATOR LANG

Dr. Amy M. Lang and Her Initial Contacts with Allergan

12.

Relator Amy Lang is a Medical Doctor, earning her M.D. degree from Southwestern Medical School and completing a residency and internship at Emory University School of Medicine. Dr. Lang is certified by the American Board of Physical Medicine & Rehabilitation and has a subspecialty board certification in Pain Medicine.

13.

Dr. Lang is a resident of Lawrenceville, Georgia, where she was in private practice until the end of 2006. In early 2007, Lang decided to return to Emory University, accepting a position as an Assistant Clinical Professor at the University and the Emory Clinic.

14.

In 1994 after reading articles suggesting that Botox showed promise in treating myofascial pain (an *off-label* use), Dr. Lang began using Botox to treat some of her patients with this condition.

15.

In 1995, Allergan recruited Dr. Lang to lecture at Continuing Medical Education ("CME") programs on the topic of Botox's use for myofascial pain (an *off-label* use), and Dr. Lang agreed to lecture about such treatments. Since that time, Lang has performed several dozen lectures and a larger number of small group injection training sessions. The overwhelming majority of these lectures and training sessions concerned *off-label* uses of Botox.

16.

Between 1996 and early 2007, Dr. Lang continued to use Botox for her patients who suffered from conditions that the drug had not been approved to treat, including myofacial pain. A predominant factor in Lang's decision to inject these patients with Botox was Allergan's promotion of the drug as an effective treatment for these *off-label* conditions.

Dr. Lang Has Observed Allergan's *Off-Label* Marketing Both as a (1) Physician Being Solicited and (2) Lecturer Provided with Access to the Company's Correspondence and Marketing Plans

17.

As a physician in private practice as well as a lecturer and trainer for Allergan, Dr. Lang was in a unique position to view Allergan's *off-label* and deceptive marketing efforts. More particularly, she was both (a) solicited by Allergan's sales force to use Botox for *off-label* indications and fraudulently misled by these solicitations' mischaracterization of the results of clinical studies and the drug's effectiveness for these *off-label* uses and (b) able to observe how Allergan was (i) controlling, and in many cases completely scripting, the content of supposedly independent CME programs and articles in professional journals, (ii) providing physicians with cash, travel, lodging, and meals in an attempt to affect their prescribing habits and induce them to increase their Botox use and billing, (iii) coaching and encouraging physicians and their staffs to use false or improper billing codes on forms submitted to Medicare Contractors for payment from federally funded health care programs and (iv) misrepresenting Botox's efficacy for numerous unapproved uses to Medicare Contractors with the intent to improperly influence these Contractors' coverage determinations for those uses.

RELATOR RUSHIN

Charles J. Rushin & His Ongoing Successful Allergan Employment

18.

Relator Charles Rushin is currently employed by Allergan as a Neuroscience Medical Consultant ("NMC") in the company's Neurosciences Division. In this position, Rushin is responsible for making sales calls on physician offices with the objective of increasing these doctors' Botox use in their practices. Rushin is a resident of Acworth, Georgia, and his sales territory currently includes the northern half of Atlanta and all of North Georgia.

19.

Rushin joined Allergan in the early 2003, after working roughly three years (2000 – 2003) as a pharmaceutical sales representative for Pfizer, Inc. Prior to joining Pfizer, Rushin served on active duty in the United States Marine Corps for six years (1993 – 1999) and completed an additional two years of reserve duty during his Pfizer employment. Rushin left the Marines with an honorable discharge and the rank of Sergeant (E-5) in January of 2001.

20.

Rushin has been a very successful Allergan employee. During his first year with the company, he was named Allergan "Rookie of the Year" for 2003 based on

his sales achievements and he earned a position in Allergan's "President's Club" the same year. Since that time, Rushin has consistently attained positive sales results. Rushin received the following scores (on a four point scale) on his annual employee reviews: (a) 3.6 in 2003; (b) 3.6 in 2004; (c) 3.6 in 2005; and (d) 3.4 in 2006.

Rushin Was Trained to Market Botox for *Off-Label* Uses and Has an Insider's Perspective on the Corporation's Illegal Marketing Practices

21.

As an NMC, Rushin is in daily contact with the doctors in his sales territory, is aware of other Allergan employees' (*e.g.*, reimbursement specialists and medical liaisons) activities in his territory, receives sales reports detailing each of these doctor's Botox purchases, and is instructed to be a conduit for many communications between the company and these physicians. As such, Rushin is well-positioned to observe Allergan's multi-pronged and centrally coordinated strategy to maintain Botox's sales growth by promoting Botox for a myriad of *off-label* uses, regardless of its lack of efficiency for many, and potentially all, of these uses. In this position, Rushin has had the following exposure to Allergan's misconduct:

(a) Rushin completed Allergan's introductory sales training (known as "Foundation Training") in April of 2003 and completed the corporation's advanced sales training (known as "Accelerated Training") in Irvine, California the following year. Importantly, both of these training programs provided substantial content and instruction regarding sales techniques and product information designed to market Botox for *off-label* uses;

(b) Rushin has been instructed by his direct supervisor to select physicians for Allergan to invite to receive $1,500 in cash and an all-expense-paid weekend trip to a resort in Newport Beach, California under the pretense of providing "consulting services" to the company during the weekend, when no legitimate services were ever requested or provided;

(c) Rushin has observed attempts by Allergan's

(i) Regional Scientific Services Managers (Allergan's medical liaisons) to coach doctors into changing patient diagnoses (for instance, from headache to cervical dystonia) in order to justify the use of, and reimbursement for, Botox; and

(ii) Reimbursement Business Managers (Allergan employees who instruct doctors' billing staffs on coding, billing, and reimbursement issues) coach physicians and their staffs on using generic, partial, or

inaccurate ICD-9-CM diagnosis codes and CPT procedure codes to obtain reimbursement from Medicare or Medicaid for services that would not be reimbursable if more specific and accurate codes were used for the *off-label* Botox treatment.

LEGAL AUTHORITY

THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729 – 3733)

22.

Dr. Amy Lang and Charles Rushin have brought this action under the FCA on behalf of the United States to recover damages and civil monetary penalties from Allergan for the fraudulent conduct detailed herein. The FCA provides that any person who knowingly presents, or causes to be presented, to the government a false or fraudulent claim for payment or approval is liable for (a) three times the amount of the damages sustained by the Government and (b) a civil penalty ranging from $5,500 to $11,000 for each such claim. *See* 31 U.S.C. § 3730(a); 28 C.F.R. § 85.3(a)(9).

FCA's History, Purpose, and Provisions

23.

Originally enacted in 1863 in response to widespread corruption, fraud, and misuse of federal funds during the Civil War, the FCA was weakened by a 1943

amendment which considerably decreased the application and use of the statute. *See* 132 CONG. REC. H6474 (Sept. 9, 1986) (statement of Rep. Glickman). However, in response to a wave of procurement scandals in the mid-1980s, Congress substantially amended the FCA in 1986 to provide more effective means of identifying, stopping, and remedying fraud against the Government. *Id.* Among other things, the 1986 amendments reduced the burden of proof (to a preponderance standard), 31 U.S.C. § 3731(c), lowered the mens rea requirement (reducing it to reckless disregard of the truth or falsity of the submitted claim), § 3729(b)(3), increased the available damages and penalties (imposing treble damages and civil monetary penalties), § 3729(a), and extended the statute of limitations (providing between six and ten years to file an action), § 3731(b). *See generally*, 100 Stat. 3153; Pub L. 103-272.

24.

The 1986 FCA amendments also increased the incentives for private whistleblowers to invest their own time and resources into uncovering, reporting, and pursuing FCA violations. Under certain circumstances, these whistleblowers (known as "relators") may bring civil FCA actions (known as "*qui tam*" suits) on behalf of the United States to recover damages and penalties. *See* 31 U.S.C.

§ 3730(b). Relators who bring successful *qui tam* actions may receive a percentage-share (normally between 15% – 30%) of the Government's recovery.

FCA *Qui Tam* Suits Have Recovered Billions Stolen from the United States and Federal Health Care Programs

25.

Since the FCA's 1986 amendments became effective, private *qui tam* actions have comprised a sizable majority of new FCA matters (including referrals, investigations, and filed cases) reported by the United States Department of Justice. More particularly, *qui tam* actions comprised 59.1% of all new FCA matters — 5,514 out of 9,326 — between October 1, 1986 and September 30, 2006. Furthermore, during the same period *qui tam* actions were responsible for an even higher percentage of overall FCA recoveries through judgments or settlements, accounting for 60.8% of all FCA damages and penalties recovered from defendants ($11,062,851,302 of $18,183,518,606).

26.

Furthermore, in FCA health care cases (like this action) brought during the same 20-year period, *qui tam* actions and recoveries comprised larger shares of all claims brought, and damages/penalties paid, by defendants:

(a) 83.8% of all the new FCA matters reported by the Department of Health and Human Services (*i.e.*, 2,853 of 3,404 matters) and

(b) 68.7% of all the recoveries from FCA defendants in health care cases (*i.e.*, $7,941,539,679 of $11,553,971,634).

THE FOOD DRUG AND COSMETICS ACT (21 U.S.C. §§ 301 - 397) & PUBLIC HEALTH SERVICE ACT (42 U.S.C. § 262, *et seq.*)

FDA Jurisdiction and Biological License Applications

27.

Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 – 397, and the Public Health Services Act ("PHSA"), 42 U.S.C. § 262, *et seq.*, the Federal Food and Drug Administration ("FDA") is charged with, *inter alia*, ensuring that drugs and biological products are reasonably safe and effective as well as properly labeled.

28.

Botox qualifies as a "drug" under the FDCA because it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "intended to affect the structure or function of the body of man." 21 U.S.C. § 321(g)(1). In addition, Botox qualifies as a "biological product" under the PHSA because it is a "toxin...applicable to the prevention, treatment or cure of a disease or condition of human beings." 42 U.S.C. § 262(i); *see also* 21 C.F.R. § 600.3(h)

(defining "[b]iological product" as "any . . . toxin . . . or analogous product applicable to the prevention, treatment of cure of disease or injuries of man"). As a biologic, Botox must obtain a biological license for each of its intended uses, *see* 42 U.S.C. § 262, but otherwise must comply with all other federal prescription drug regulations, *see* 42 U.S.C. § 262(j).

29.

Biological products ("biologics"), such as Botox, are drugs derived from living material, rather than chemical synthesis. In light of additional manufacturing, storage, and safety issues raised by biologics, they undergo a different FDA approval process than other drugs and are issued a "biologics license," when they are approved. Other than the initial licensing process, all drug regulations in the FDCA apply to biologics with equal force and effect. *See* 42 U.S.C. § 262(j).

30.

No biological products may be introduced into, or distributed through, interstate commerce unless the sponsor of the product obtains a biologics license and properly labels the product. 42 U.S.C. § 262(a)(1). To obtain a biologics license, the sponsor must submit a biological license application ("BLA") to the application ("BLA") to the FDA, 21 C.F.R. § 601.2, providing evidence that the

biologic is "safe, pure, and potent," 42 U.S.C. 262(a)(2)(C)(i)(I), which means that the product has been proven effective for a specific use "by appropriate laboratory tests or by adequately controlled clinical data." 21 C.F.R. § 600.3(s). The FDA approves new biologics based on an evaluation of the products' safety and efficacy demonstrated by randomized, prospective, and double-blind clinical trials. 21 C.F.R. § 601; FDA Release "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products," May 1998.

31.

The indication and dosages approved by the FDA are set forth in the biologics' labeling, the content of which is also reviewed by the FDA as part of the BLA process. *See, e.g.*, 21 C.F.R. §§ 600.3(dd); 601.2(b); 601.12. The label must also reveal all medically relevant information regarding the appropriate use of the biologic, such as dosage, directions for administration, known precautions, warnings, and contraindications. *Id.*

FDA Prohibition on *Off-Label* Marketing

32.

Once a drug is approved for a particular use the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing *off-label* prescriptions coincides with the FDA's mission to

regulate pharmaceutical industry without directly interfering with the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

33.

While physicians are permitted to prescribe drugs for *off-label* purposes, the FDCA and PHSA prohibit drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. *See* 21 U.S.C. § 331(a), (d); 42 U.S.C. §§ 262(a)(1), (b); 21 C.F.R. § 601.12. Under the FDCA, a manufacturer illegally "misbrands" a drug if its labeling includes information about any of the drug's unapproved uses. *Id.*

Allergan Is Prohibited from Marketing Botox for *Off-Label* Uses

34.

Botox is approved to treat only four non-cosmetic conditions (*i.e.*, blepharospasm, strabismus, cervical dystonia, and severe primary axillary hyperhidrosis), and Allergan is prohibited from actively promoting other, "off-label," uses of Botox.

35.

Allergan is well aware of the prohibitions on *off-label* marketing. For example, Allergan's SEC Form 10-K annual report to shareholders for the calendar year ending December 31, 2006, acknowledges in the "Risk Factors" section that:

> Physicians may prescribe pharmaceutical and biologic products, and utilize medical device products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate a physician's choice of treatment, the FDA does restrict a manufacturer's communications on the subject of *off-label* use. ***Companies cannot actively promote FDA-approved pharmaceutical, biologic or medical device products for off-label uses***, but they may disseminate to physicians articles published in peer-reviewed journals. To the extent allowed by law, we disseminate peer-reviewed articles on our products to targeted physicians. If, however, our promotional activities fail to comply with the FDA's or another regulatory body's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or another enforcement agency. (Emphasis added).

THE MEDICARE AND MEDICAID STATUTES
(42 U.S.C. §§ 1395 - 1395ccc, 1396 - 1396v)

36.

The Medicare and Medicaid programs were created through 1965 amendments to the Social Security Act, adding Title XVIII (Medicare) and Title XIX (Medicaid) to the Act. Pub. L. No. 89-87. In 2006, the federal government spent over $390 billion on the Medicare program and a combined $190 billion on the fifty separate state Medicaid programs.

The Medicare Program Structure

37.

The Medicare program is a federally funded and federally administered nationwide social health insurance system that currently contains four main parts: A, B, C, and D.

Medicare Claims

38.

Medicare claims under Part A are made on Form CMS 1450/UB-92, and Medicare claims under Part B are made on Form CMS 1500. Medical diagnoses are identified on these claim forms using the *International Classification of Diseases*, Ninth Edition, Clinical Modification (or ICD-9-CM code), and the most common ICD-9-CM codes corresponding to diagnoses for which Botox injections may be covered by Medicare for FDA-approved indications are as follows: 333.83 (Spasmodic Torticollis), 333.81 (Blepharospasm), 378.00 – 378.90 (Strabismus), and 705.21 (Severe Primary Axillary Hyperhidrosis). Drugs and biologicals are identified on these claim forms using the *Health Common Procedure Coding System* (or HCPCS code), and the HCPCS code for Botox is J0585. Medical services and procedures are identified on these claim forms using the *Current Procedure Terminology* (CPT codes), and the CPT codes that Medicare will cover

for Botox use (assuming that the CPT code corresponds to a properly covered diagnosis [ICD-9-CM] code) are as follows: 64612 (Chemodenervation Craniofacial), 64613 (Chemodenervation Cervical), 64614 (Chemodenervation Trunk and Extremities), 64640 (Destruction by neurolytic agent), 64650 (Chemodenervation of Eccrine Gland), and 67345 (Chemodenervation of Extraoccular Muscles).

39.

Medicare reimbursement for drugs and biologics is currently based on an Average Sales Price ("ASP") methodology, under which the Government reimburses physicians 106% of a drug's average sales price, as reported by pharmaceutical manufacturers each quarter.

40.

Currently, the ASP for Botox (HCPCS code J0585) is $4.81/unit (and the 106% reimbursement rate is $5.10/unit). Assuming a treatment for cervical dystonia or headache requires 200 units of the toxin, a physician will be reimbursed roughly $1,020.00 for the Botox used during a single treatment.

41.

Above the price of the drug, each Medicare claim for Botox also includes a charge by the physician for injecting the drug. Depending on the particular Botox

use, the Government pays physicians roughly $165 to $200 for their services during each treatment.

Medicare Provider/Supplier Enrollment

42.

All providers and suppliers must complete a Medicare enrollment form before receiving payments from the programs. The following forms must be completed and submitted to the applicant's proper Medicare Contractor in their given region: (a) provider entities complete the CMS Form 855A to enroll in Medicare Part A; (b) supplier entities (*e.g.*, clinics and group practices) complete the CMS Form 855B to enroll in Medicare Part B; and (c) individuals (*e.g.*, physician and other practitioners) complete CMS Form 855I to enroll in Medicare Part B. All three CMS 855 forms contain a materially identical certification that the applicant agrees to abide by all Medicare laws, regulations, and program instructions and understands that payment of every claim is conditioned upon the transaction underlying the claim complying with the same laws, regulations and instructions "including, but not limited to, the Federal anti-kickback statute and the Stark law" and "on the [provider/supplier's] compliance with all applicable conditions of participation in Medicare." *See* CMS 855A at 37; 855B at 30; 855I at 25.

43.

Thus, all Medicare providers and suppliers have certified their understanding that compliance with the Federal Anti-Kickback Statute is a prerequisite to payment and no claims may be submitted for payment if the transactions underlying those claims do not comply with the Anti-Kickback Statute. *See generally, e.g., United States ex rel. Pogue v. Diabetes Centers of America, Inc.*, 238 F. Supp. 2d 258, 263-66 (D.D.C. 2002) (upholding FCA claims for violations of the Federal Anti-Kickback Statute).

Medicare's *"Reasonable and Necessary"* Requirement

44.

Notably, no items or services will be covered by Medicare that are not both "reasonable and necessary for the diagnosis or treatment of injury or illness . . .." 42 U.S.C. § 1395y(a)(1)(A). With respect to drugs and biologicals, "reasonable and necessary" requires the drug or biologic to be prescribed for a "safe and effective" use, meaning (a) FDA-approved drug uses, or (b) medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or "accepted standards of medical practice." Medicare Benefit Policy Manual Chapter 15, § 50.4. These decisions are made by the Medicare contractors that process Medicare claims under contracts with the Centers for

Medicare and Medicaid Services ("CMS"). Medicare Benefit Policy Manual, Ch. 15, section 50.2K ("Carriers and fiscal intermediaries will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition.").

Medicare Part A
Coverage for Drugs and Biologicals

45.

Medicare Part A covers, *inter alia*, expenses associated with inpatient hospital care, skilled nursing facility care, certain home health services, and hospice care. These benefits are paid for through the federal Hospital Insurance Trust Fund, which is financed from payroll tax contributions from workers and employers.

46.

Among other things, Medicare Part A coverage includes the cost of inpatient prescription drugs, 42 U.S.C. § 1395x(b)(2), subject to, *inter alia*, the requirement that the drug is reasonable and necessary for the diagnosis or treatment of injury or disease, 42 U.S.C. § 1395y.

Medicare Part B
Coverage for Drugs and Biologicals

47.

Medicare Part B is a voluntary subsidized insurance program covering, *inter alia*, physicians' services, outpatient hospital care, and laboratory services. Part B's benefits are paid from the federal Supplemental Medical Insurance Trust Fund, which is financed by individual premiums and general federal tax revenues.

48.

Medicare Part B pays for "medical and other health care services" provided by a physician, subject to specific exclusions, *see* 42 C.F.R. § 424.24, as well as drugs and biologics that are provided incident to the service of a physician, *see* 42 U.S.C. §§ 1395x(s)(2)(A); 42 C.F.R. § 410.26. Incident to the services of a physician means the drug is provided in the office of a physician and under the physician's or practitioner's direct supervision. 42 C.F.R. § 410.26(b); 410.29(a); 42 U.S.C. §§ 1395x(s)(2)(A).

The Medicaid Program
Structure and Funding

49.

The federal Medicaid statute, 42 U.S.C. §§ 1396 - 1396v, offers federal matching funds to states that establish Medicaid plans providing certain vulnerable

populations with access to basic health care. All fifty states have created Medicaid programs, which are overseen by the Secretary of Health and Human Services, but administered by Medicaid agencies and directors in the individual states.

50.

The state Medicaid programs are jointly financed by the federal and state governments. In general, the federal government pays between 50% - 83% of the cost of health care provided in each state program. The percentage allocated to the federal government (known as the "Federal Medical Assistance Percentage" or "FMAP") is determined separately for each state — based upon that state's per capital income — and is recalculated annually.

51.

For the 2007 fiscal year (October 1, 2006 – September 30, 2007), the FMAP for Georgia's Medicaid Program is 61.97%, and this figure has fluctuated between 59% and 60.6% in the years between 2000 and 2006, inclusive. The FMAPs assigned to Georgia's Medicaid Program during these years are as follows: (a) 2006: 60.6%; (b) 2005: 60.44%; (c) 2004: 59.58%; (d) 2003: 59.60%; (e) 2002: 59.0%; (f) 2001: 59.67%; and (g) 2000: 59.88%.

52.

The federal government spent roughly $190 billion on state Medicaid programs in 2006, making it the third largest social program in the federal budget, behind Medicare and Social Security. In 2006, Georgia spent $7.8 billion on its Medicaid program, and all fifty states combined spend roughly $305 billion.

Medicaid Payment for Drugs and Biologicals

53.

With narrow exceptions, reimbursement for pharmaceuticals under Medicaid is available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). A drug may qualify as a ***"covered outpatient drug"*** only when it is used for a ***"medically accepted indication."*** 42 U.S.C. § 1396r-8(k)(2) – (3) (emphasis added). A "medically accepted indication" means any (a) FDA approved use of a drug or (b) use which is included and approved in at least one of the statutorily specified drug compendia identified in 42 U.S.C. 1396r-8(g)(1)(B)(i). 42 U.S.C. § 1396r-8(k)(6).

54.

Botox's FDA-approved therapeutic uses only include the treatment of stabismus (1989), blapharospasm (1989), cervical dystonia (2000), and severe primary axillary hyperhidrosis (2004). Because headache, myofascial pain, lower-back pain, arthritis, and most of the other *off-label* Botox uses promoted by

Allergan are not included in approved compendia (*i.e.*, the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System), ***they are not "medically accepted indications."*** Thus, with respect to these *off-label* uses, neither Botox nor physician services associated with injecting it may form the basis of a Medicaid claim.

ALLERGAN'S FALSE AND FRAUDULENT PRACTICES

CORPORATE KNOWLEDGE AND INTENT

Allergan's Therapeutic Botox Sales Figures and Growth Targets Require Massive *Off-Label* Marketing and Sales

55.

Botox's FDA-approved therapeutic indications include limited treatments for the following four conditions: (a) blepharospasm, (b) strabismus, (c) cervical dystonia, and (d) severe primary axillary hyperhidrosis that cannot be properly managed by topical agents. Botox sales for these four conditions comprised the minority of Allergan's $321,100,000 in 2006 therapeutic Botox sales, and Allergan cannot sincerely believe that its on-label therapeutic sales could possibly generate the $60 million in revenue growth required to satisfy its $370,000,000 million 2007 sales target for therapeutic Botox.

56.

First, the four conditions that Botox has been approved to treat are relatively rare in comparison to many of the *off-label* conditions that Allergan actively promotes it to treat (*e.g.*, headache, lower-back pain, whiplash). With respect to cervical dystonia — the only one of the four FDA-approved indications that may itself account for more than 10% of therapeutic Botox sales — Allergan's own training materials estimate that the condition likely occurs in only 9 people out of 100,000, which would correlate to 27,000 Americans developing the condition in the current population. Assuming Allergan's figures are accurate, that the entire 27,000 potential population of cervical dystonia patients developed the disease early in life (rather than between 35-50 years of age, which is most common), that all seek Botox treatment, that none have contraindications, and that all use the maximum dose (300 units, at the current Medicare reimbursement rate of $5.102/unit) at the most frequent intervals (four treatments per year), Botox sales for the treatment of cervical dystonia would still fall far short of Allergan's $321,000,000 in 2006 therapeutic Botox sales (27,000 x 300 x 5.102 x 4 = $165,304,800 = 52% of $321,000,000).

57.

Second, patients with two of the conditions for which Botox has been approved — strabismus and severe primary axillary hyperhidrosis — rarely resort to Botox treatment. Indeed, the FDA has only approved Botox for hyperhidrosis cases after topical agents (including prescription strength antiperspirants) have failed to adequately manage the condition. Likewise, strabismus patients almost uniformly employ (and benefit from) less expensive and invasive treatments (*e.g*, corrective lenses, eye exercises, and eye patches) before electing to have a neurotoxin injected into the muscles surrounding their eyes.

58.

Third, the amount of Botox used to treat two of its four FDA-approved conditions is relatively small. The amounts of Botox commonly used to treat strabismus range from 1.25 to 5.0 units (0.05 to 0.15 ml) in any one affected eye muscle; and 1.25 to 2.5 units (0.05 to 0.1ml) at four sites in the peri-orbital muscles for 10 units (0.4 ml) per side or 20 units (0.8 ml) for bilateral treatment of blepharospasm respectively, are far smaller than the amounts suggested for the drug's *off-label* uses, such as headache treatments, 100 to 200 units (4.0 – 8.0 ml) and myofascial pain, 200 to 400 units (8.0 – 16.0 ml).

59.

Given the relative rarity of Botox's FDA-approved therapeutic uses, it is inevitable that the majority of Allergan's 2006 therapeutic Botox sales were generated from *off-label* uses of the product. If Allergan limited its promotion of Botox to FDA-approved uses, its revenue from the product would be finite and far lower than the company's current figures and projections. In light of these limitations, Allergan decided to expand the market for Botox as a treatment for more common conditions, even though Botox had not been FDA approved for use in the treatment of those conditions. Even more, Allergan's current 2007 sales target for therapeutic Botox (*i.e.*, $370,000,000, or 15.2% sales increase from 2006) assumes that its sales force (as well as other divisions of the company) will do more, not less, illegal *off-label* marketing.

ALLERGAN'S FRAUDULENT *OFF-LABEL* MARKETING PRACTICES

60.

Despite the prohibition against promotion of drugs for *off-label* use and the restrictions on Allergan's communications regarding *off-label* use, Allergan has for years engaged in a sophisticated and comprehensive effort to promote the *off-label* use of Botox.

61.

The FDA has never approved Botox as a treatment for any of the following conditions: headaches, tics, lower-back pain, tennis elbow, TMJ, leg cramps, arthritis, enlarged prostate, overactive bladder, benign prostatic hypertrophy, focal limb dystonia, esophageal achalasia, anismus, anal fissure, amputee stump pain, phantom limb pain, plantar fasciitis, disorder, bruxism, spasmodic dysphonia, trigeminal neuralgia, myofascial pain, muscle spasm, leg cramps, failed back syndrome, piriformis syndrome, whiplash associated disorders and neck pain, spasticity, palmar hyperhidrosis, sialorrhea, occupational dystonia. Nevertheless, Allergan has promoted Botox's use for each of these indications.

ILLUSTRATIVE ALLERGAN *OFF-LABEL* MARKETING CAMPAIGN: PROMOTING BOTOX FOR THE TREATMENT OF HEADACHE

"The Data Just Isn't There for Headache"

62.

In April 2005, Allergan announced plans to move forward with a Phase III clinical trials to investigate the safety and efficacy of Botox as a prophylactic therapy in a subset of migraine patients with chronic daily headache.

63.

Allergan was actively promoting Botox as a prophylactic therapy to treat migraine patients long before April 2005. Since April 2005, Allergan has continued to actively market Botox as a prophylactic therapy to treat migraine patients with chronic daily headache, despite the fact that such treatment is not an approved therapeutic indication for the use of Botox in the United States.

64.

Allergan has known for years, since reviewing the results of its Phase II clinical trials, that these studies did not support Botox use as a prophylactic therapy for various forms of headache, including tension type headache, episodic migraine, and chronic daily headache. Despite that fact, Allergan continues to actively promote Botox for *off-label* use as a headache preventative.

65.

Allergan's lack of evidence showing that Botox is an effective treatment for headaches is evidenced by an admission made by Chandra Coleman, an Allergan Regional Scientific Services Manager, to Dr. Lang on February 20, 2007. During a business conversation about Allergan's poor prospects for obtaining FDA approval to treat headaches, Coleman acknowledged that "***The data just isn't there for headache***." Coleman based this statement on her review of all the clinical trials

that Allergan has conducted since the late-1990s, the same trials that Allergan directs doctors to cite when giving lectures about *off-label* uses. Despite this knowledge within the company, Allergan continues to promote the use of Botox to prevent headache.

Ghostwritten Articles
Promoting *Off-Label* Botox Use

66.

As part of its comprehensive effort to promote the *off-label* use of Botox, Allergan has had its employees ghostwrite and edit articles and abstracts which are then submitted to professional journals under the names of practicing physicians.

67.

In 2005 the *Journal of Managed Care Medicine* published a supplement entitled "Acute and Prophylactic Treatment of Chronic Headache Disorders." This supplement was developed during a session on managing chronic headaches at the 2005 National Association of Managed Care Physicians Fall Managed Care Forum. The supplement shows the faculty members for this session as Andrew Blumenfeld, M.D. and Kenneth L. Schaecher, M.D.

68.

Although a disclosure reveals that Dr. Blumenfeld serves on the Allergan speakers bureau, there is no disclosure that the supplement was actually written (in

whole or in part) and edited by two Allergan employees, Eric First and Ryan Irvine.

69.

Similarly, an abstract entitled "Long-Term Efficacy and Adverse Events of Botulinum Toxin in Headache Patients" was presented by Lawrence D. Robbins, M.D. at the 28th Scientific Session of the Midwest Pain Society in 2004.

70.

The abstract fails to disclose that it was actually written (in whole or in part) and edited by Eric First, an Allergan employee.

71.

Similarly, an article appears in the September 2004 issue (Vol. 44, Issue 8) of *Headache: The Journal Of Head and Face Pain* entitled "Botulinum Neurotoxin Type A in the Preventative Treatment of Refractory Headache: A Review of 100 Consecutive Cases." The authors of that article are listed as Stewart J. Tepper, M.D.; Marcelo E. Bigal, M.D., Ph.D.; Fred D. Sheftell, M.D. and Alan M. Rapoport, M.D.

72.

What is not disclosed is that this article was edited by Scott Traub, an Allergan Regional Scientific Services Manager.

73.

Allergan employee Eric First and Eric Kassel also authored an articled entitled "Use of Neurotoxins in and for the Treatment of Myofacial Pain." Allergan sought to have Lang appear as the sole author of that article. When Dr. Lang insisted that Allergan employees Eric First and Eric Kassel also be listed as co-authors, Allergan retracted the article in order to conceal its employees' participation in ghostwriting it.

Allergan Uses Company-Controlled Websites to Market Botox's *Off-Label* Use in Treating Headache

74.

Allergan also uses websites, purportedly maintained by third parties but actually funded and controlled by Allergan, to promote the *off-label* use of Botox.

75.

For example, Allergan sponsors a website at the web address: www.neurotoxininstitute.org, which purports to be operated by The Neurotoxin Institute, and given its ".org" top level domain name, claims to be a noncommercial public interest organization. However, the domain name is registered to Healthworld, located at 100 Avenue of the Americas in New York City. Healthworld is part of Ogilvy Healthworld, an international health care advertising agency with more than 50 offices around the world. Importantly,

Ogilvy Healthworld and its predecessor entities have a long history of providing marketing services to Allergan.

76.

Allergan's NMCs, including Rushin, are specifically trained to refer physicians to the websites sponsored by Allergan, including The Neurotoxin Institute website. That website contains, among other materials, videos of CME programs sponsored by Allergan and written materials prepared by Allergan for use in CME programs and otherwise. In fact, Rushin and other NMCs have recently issued so-called "NTI Awareness Cards," with the Neurotoxin Institute website information on them. These cards identify the Neurotoxin Institute as "a multidisciplinary organization created to serve as a comprehensive and independent source of information related to the basic science and the clinical applications of neurotoxin therapies." This website promotes *off-label* uses of Botox and Allergan has directed its NMCs to distribute NTI Awareness Cards to ***all*** doctors during sales calls.

Allergan Trains Its Employees to Market Botox's *Off-Label* Use to Treat Headache and Pain

77.

All NMCs undergo formalized training developed by Allergan. Initially all NMCs undergo an intensive course known as Foundation Training, a two-week course that takes place near Allergan's headquarters in Irvine, California.

78.

Foundation Training includes specific and repeated discussions of *off-label* uses of Botox, including the use to treat headache and pain. In Foundation Training NMCs are specifically trained to promote the *off-label* use of Botox for headache and pain. These training sessions include role playing sessions in which residents from local hospitals are brought in to play the role of physicians to whom the NMCs will promote the *off-label* use of Botox.

79.

It is representative of Allergan's approach to the promotion of *off-label* uses for Botox that the Foundation Materials binder provided to Rushin contains only two pages regarding marketing prohibitions (which include the statement that NMCs cannot "sell for *off-label* uses and close for increased business for those uses") compared to forty-eight pages on *off-label* Botox headache use (which

include sections on the history of Botox treatment for headaches and Allergan's hypotheses explaining Botox's supposed positive effects on headache pain).

80.

These materials include statements that misrepresent the outcome of Allergan-sponsored studies. For example, the materials claimed that a 2000 Silberstein study published in *Headache* (Vol. 40:445-50) concluded that Botox reduces migraine severity. In fact the data was mixed, inconclusive, and the study is regarded as negative, even by Allergan.

81.

Allergan NMCs also undergo what is known as "Acceleration Training." This intensive training, which includes extensive written materials prepared by Allergan, lasts approximately one week.

82.

As with Foundation Training, "Acceleration Training" includes role playing by NMCs in which they practice and perfect their attempts to market Botox for *off-label* uses, including headache and pain.

83.

In addition to Foundation Training and Acceleration Training, Allergan NMCs also undergo approximately ten to fifteen hours of sales training at each National Sales Meeting, which is usually held in January or February.

84.

Off-label marketing is a major component of Foundation Training, Acceleration Training, and the annual training at National Sales Meetings.

Allergan Used Regional CTUs to Coordinate Its Marketing of Botox's *Off-Label* Use for Treatment of Headache

85.

Allergan assigns various titles to its personnel that suggest their roles are only to be helpful to physicians, *e.g.*, "Neuroscience Medical Consultant" (NMC), "Regional Scientific Specialist" (RSS), and "Reimbursement Account Manager" (RAM).

86.

In fact, despite their ornate titles, each of these persons is involved in sales and marketing and each of them is part of a "Customer Team Unit" ("CTU").

87.

Until late 2006, CTU meetings were held quarterly and involved all three components of Allergan's marketing efforts, Sales (NMCs), Reimbursement

(RAMs), and Medical (RSSs). These meetings were typically attended by Lynn Salo, the Vice President of Marketing for Neuroscience Products, the Region Manager (in charge of the NMCs), the RSS Manager (in charge of the RSSs) and others.

88.

At these quarterly CTU meetings, the participants would exchange materials and information collected by members of the unit to analyze and direct the CTU's coordinated efforts to increase Botox sales through *off-label* promotion and maximizing reimbursement to physicians for Botox use. The CTU participants would review these materials together to jointly track: (a) physician attendance at Allergan-sponsored CME programs promoting the *off-label* use of Botox; (b) the number of *off-label*, Allergan-sponsored, injection-training sessions coordinated by each NMC; (c) sales figures, including detailed physician-specific Botox usage data; and (d) individual physician's use of ICD-9-CM and CPT codes and third-party payor reimbursement rates for those physicians.

89.

Quarterly CTU meetings were also used to target specific physicians for invitations to CME programs that promoted *off-label* uses of Botox; visits by RSSs

to reinforce the *off-label* use of Botox, and RAM visits to increase physician reimbursement for *off-label* Botox use.

90.

Quarterly CTU meetings were also used to identify physicians who utilized high volumes of Botox for invitations to become "preceptors," whom Allergan would pay to train other physicians in *off-label* uses of Botox or "Key Opinion Leaders," whom Allergan would pay to lecture at CME programs about *off-label* Botox use.

91.

Each regional CTU, would share information obtained from physicians. For example, RAMs would distribute detailed data obtained from physicians, ostensibly to assist them in obtaining reimbursement, so that the members of the CTU would know what diagnosis codes a particular physician was using on Medicare and private insurance claims for Botox and whether the codes used by that physician were being accepted by Medicare contractors and insurance companies. With this information, RSSs would then suggest, or reinforce suggestions already made by RAMs or NMCs, that the physician might want to use certain inaccurate, but reimbursable, codes for his or her patients.

92.

Physicians were not told that information given to RAMs, which included patient names and diagnosis codes, would be shared with other Allergan personnel, who then used the information to market to physicians.

93.

Allergan's *off-label* marketing efforts are so aggressive that NMCs are encouraged to make sales calls to physicians whose practices do not even treat patients with any of the four conditions for which the FDA has approved the use of Botox. Prior to 2006, Allergan's NMCs (then known as "BMCs," Botox Medical Consultants) marketed only Botox, but they were directed to call on numerous specialists (*e.g.*, headache clinics and pediatricians) whose only use for Botox was *off-label.*

94.

Allergan has not disciplined any NMC or RSS for promoting the *off-label* use of Botox. NMCs have, however, been criticized by their superiors for not being sufficiently persistent or innovative in promoting the *off-label* use of Botox.

Allergan Produced Videos Promoting Botox's *Off-Label* Use Treat Headaches

95.

Allergan's efforts to promote *off-label* uses of Botox have extended to the preparation of a video tape entitled "Focus On Headache," promoting the use of Botox to treat headache.

96.

A specific example of such a misrepresentation is found in a DVD funded by Allergan entitled "Focus On Headache."

97.

In the "Focus On Headache" DVD, Stephen D. Silberstein, M.D. makes various false and misleading statements regarding Botox research and the effectiveness of Botox in the treatment of headaches.

98.

Dr. Silberstein has conducted numerous studies funded by Allergan, has been paid to lecture at CME programs sponsored by Allergan, and has been paid by Allergan to instruct other physicians in the *off-label* use of Botox to prevent and relieve headaches.

99.

The "Focus On Headache" DVD shows Dr. Silberstein injecting patients with Botox. At the end of the DVD, Dr. Silberstein makes the following statement:

> When patients desire to have a treatment, it's their right to have it.
>
> What can we conclude? ***The scientific evidence suggests that both headache pain and quality of life improves as a result of botulinum treatment.***

100.

The "Focus On Headache" DVD containing these statements was widely disseminated by Allergan. Allergan NMCs were given numerous copies of the DVD and instructed to give it to physicians who might treat headache patients with Botox. The DVD was also made available on websites sponsored by Allergan, including The Neurotoxin Institute website, which NMCs have been told to direct ***all*** physicians to visit.

101.

Dr. Silberstein's statements in the "Focus On Headache" video were false and misleading. Patients do not have a right to whatever treatment they may desire, nor do they have the right to have Medicare or Medicaid pay for whatever treatment they desire. Moreover, "the scientific evidence" does not "suggest" that

Botox improves headache pain and quality of life. In fact, numerous studies on the use of Botox for headache have failed to show a significant effect on the primary outcomes measures. As of December 2006, these were ten randomized, placebo-controlled studies of Botox in patients with headache. Botox faired no better than placebo on the primary outcomes measures in nine of these studies. In addition to misstating the outcomes of headaches studies involving Botox, Allergan's marketing materials, CME presentations and publications have deliberately created a false impression regarding the efficacy of Botox by omitting or mischaracterizing negative study results.

102.

Allergan has compounded the misleading nature of these characterizations of the clinical research by blurring the distinction between different categories of headache. For example, the "Focus On Headache" DVD concludes that Botox "improves headache pain." It fails to mention, however, that no class I or II study to date has found Botox to be effective for chronic tension-type headache or episodic migraine. In fact, an article in the journal *Clinical Evidence* concluded that Botox for chronic tension-type headache was "likely to be ineffective or harmful." Nicholas Silver, *Headache (chronic tension-type)*, Clinical Evidence, July, 2004. Similarly, a clinical trial concluded in 2004 that the findings "did not

support the hypothesis that [Botox] is [an] effective . . . treatment [for] migraines." S. Evers, J. Vollmer-Haase, S. Schwaag, A. Rahmann, I-W. Husstedt, A. Frese, *Botulinum Toxin A in the Prophylactic Treatment of Migraine – a Randomized, Double-Blind, Placebo-Controlled Study*, 24 Cephalalgia 838 (2004).

103.

Despite these negative research outcomes, Allergan has done everything it can to "suggest" that Botox is an effective treatment for headache. This effort has included the review and repackaging of study data to create the impression that Botox is effective.

104.

Even Allergan's researchers have begun to rebel against this approach. This is evidenced in a February 28, 2007 email from David W. Dodick — the Lead Investigator for one of Allergan's Phase III headache studies — to an Allergan "Key Opinion Leader" discussing a portion of an Allergan-sponsored CME program under review. After reviewing the presentation, Dodick rejected its presentation of the Botox headache studies as a distortion of the data for promotional purposes: "The post-hoc and subgroup analyses ***makes it look like the data has been sliced and diced to create positive spin from negative studies***."

This accurately describes Allergans' efforts to mischaracterize the clinical research.

105.

In the same email, the researcher concluded that he could no longer be involved in the Allergan CME presentation, stating that "the best thing for me to do is step away."

ENCOURAGING FRAUDULENT DIAGNOSIS AND CODING TO OBTAIN MEDICARE REIMBURSEMENT

106.

Allergan's efforts to promote the *off-label* use of Botox also includes efforts to artificially expand the diagnosis of cervical dystonia (an FDA-approved and Medicare-covered diagnosis for Botox) into the province of myofascial pain and headache (two non-FDA-approved and non-Medicare-covered diagnoses for Botox), as well as a number of pain-related conditions. This strategy of Allergan involves efforts by NMCs and RSSs to convince treating physicians that any headache or myofascial pain "could" or "probably does" have its origins in some form of cervical dystonia.

107.

As part of this effort to expand the diagnosis for cervical dystonia, Allergan NMCs and RSSs are instructed to suggest that cervical dystonia is being "under

diagnosed" in the medical community, that cervical dystonia is commonly the cause of cranial pain that is misdiagnosed as a headache, and that cervical dystonia is very difficult to diagnose in its earlier and more mild forms.

108.

In 2004, David Squillacote, Allergan's former Southeastern Regional Director of Medical Affairs and Rushin visited Dr. Lang's medical office. Upon arrival, Squillacote announced that he was there to discuss how Botox injections for myofascial pain could be coded as medically reimbursable injections. In particular, Squillacote was advocating that two diagnosis codes covered by Medicare — "torticollis unspecified" (ICD-9-CM code 723.5) and "spasm of muscle" (ICD-9-CM code 728.85) — could be used on CMS 1500 claim forms for myofascial pain, which is not covered by Medicare and is properly recorded on claim forms as "myositis unspecified/unspecified musculoskeletal disorder" (ICD-9-CM code 723.9). In support of his position, Squillacote told Dr. Lang that another physician in Mississippi, Dr. Terry Millette, was using one of the covered codes (*i.e.*, ICD-9-CM code 723.5, for "torticollis unspecified") for Botox injections treating myofascial pain, and Squillacote emphasized that "Dr. Millette is getting paid for it."

109.

Squillacote tried to convince Lang to mischaracterize her patients' actual diagnoses and record inaccurate and fraudulent diagnoses in an effort to obtain reimbursement from the Government for Botox used to treat myofascial pain (an *off-label* use that is ***not*** covered by Medicare).

110.

Rushin was present for a similar set of events in October of 2004, during a two-day period when David Squillacote was accompanied Rushin on sales calls to physicians. During at least two of these sales calls — to Dr. Jeff English and Dr. Leslie Kelman — Squillacote attempted to persuade the doctors to record incorrect diagnoses for their headache patients so Medicare would cover the Botox treatments they were providing to these patients. In both cases, Squillacote initiated a conversation about how both physicians were using Botox for patients who were likely suffering "cranial cervical headache," a term that neither of the doctors had previously encountered, and Rushin believes that Squillacote or Allergan had fabricated the entire diagnosis. Squillacote was attempting to link headaches (a diagnosis that ***would not*** support Medicare reimbursement for Botox injections) with cervical dystonia (a diagnosis that ***would*** support Medicare

reimbursement for Botox injections). Dr. English and Dr. Kelman rejected Squillacote's proffered diagnosis.

111.

On other occasions, Squillacote has encouraged physicians to misdiagnose (a) head forward posture – a problem common to the aging spine – as "torticollis unspecified" (ICD-9-CM code 723.5), which is a form of cervical dystonia; and (b) mechanical neck and back pain as "spasm of muscle" (ICD-9-CM code 728.85). In both instances, Squillacote was advocating that physicians replace a diagnosis that will not support Medicare-covered Botox treatments with a diagnosis covered under the botulinum toxin policies for Medicare, Medicaid, and other federal and commercial insurers.

112.

Allergan's has made clear attempts to persuade physicians to misdiagnose two conditions for which Botox treatment is not covered by Medicare — myofascial pain and headache — as a condition for which Botox treatment is reimbursable by Medicare, cervical dystonia. These efforts to distort medical diagnoses by promoting fabricated links between completely distinct medical conditions and cervical dystonia are attempts to circumvent the FDA's proscription on *off-label* promotion and CMS's decision not to cover Botox used in the

treatment of myofascial pain and headache. These attempts also evidence a dangerous propensity by Allergan and its employees to distort public medical knowledge and patients' rights to have their ailments (a) accurately diagnosed by a physician relying on the best available information and (b) properly treated according to sound medical practice.

113.

These efforts have caused false claims to be submitted, and paid by, the United States. For example, these efforts resulted in the submission of a claim for the injection of one vial of Botox, with the diagnosis "spasm, muscle," ICD-9-CM code 728.85, for patient "S.L." on August 3, 2006. The Botox was administered by Andre I. Serbanescu, M.D. of the Peachtree Neurological Clinic, 550 Peachtree Street, N.E., Suite 1200, Atlanta, Georgia 30308-2237. The charge for the Botox was $600.00 and the charge for injecting that Botox was $250.00. Patient "S.L." was a Medicare patient and Medicare paid $554.21 for the Botox and the injection on or about September 6, 2006.

114.

This claim was false because the patient did not suffer from spasm of muscle, but rather from migraine headaches, an *off-label* condition for which neither Botox treatment nor injection is reimbursable under Medicare.

115.

The patient also received subsequent injections of Botox from the same physician, and payment was sought and received from Medicare for the Botox used and the injection services provided.

ALLERGAN KICKBACKS TO PHYSICIANS

116.

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits any person from knowingly and willfully offering or paying any renumeration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, order, arrange for, or recommend purchasing or ordering any good, service, or item for which payment may be made (in whole or in part) under a Federal health care program.

117.

Allergan has knowingly and willfully offered and paid renumeration directly to physicians to induce those physicians to purchase, order, or arrange for the purchasing or ordering of Botox where payment would be made (in whole or in part) under a Federal health care program.

118.

Allergan has also knowingly and willfully offered and paid renumeration directly to physicians to induce those physicians to order a service, consisting of the injection of Botox, for which payment may be made (in whole or in part) under a Federal health care program.

119.

One of the ways in which Allergan violated the Federal Anti-Kickback Statute was through its Allergan Institute of Distinction ("AIOD"), a series of invitation-only Botox marketing programs that high-injecting physicians are paid $1,500 to attend while they stay in a full-service resort in Newport Beach, California free-of-charge.

120.

Allergan NMCs, including Rushin, have been required by their supervisors to recommend physicians for AIOD invitations.

121.

As required by Allergan, Rushin submitted the names of several physicians for invitation to the AIOD to his supervisor, Jose Bonilla, who holds the position of Allergan's Southeastern Region Manager of Sales.

122.

Bonilla did not reject any of Rushin's recommendations, and every physician whom Rushin recommended was invited to an AIOD program.

123.

Allergan sales and marketing personnel selected physicians for invitation to an AIOD program.

124.

The only criteria for recommending a physician for an AIOD program was that physician's willingness to travel to California (free of charge) and his or her history of high Botox use. This later criteria is revealed in an email Relator Rushin was copied on from fellow NMC, Daniel Liberator, in which Liberator writes Allergan's Senior Product Manager of the Neuroscience Division, Debbie Garner. In this email, Liberator asks for Garner's assistance in accommodating a particular doctor who Liberator wanted to invite to an upcoming AIOD. Liberator tellingly describes the prospect in the following fashion; "Dr. Vanessa Hinson (pacing 400K in 2005)." No further description was provided, or necessary.

125.

Allen Freeman, M.D., is one of the physicians whom Rushin recommended be invited to an AIOD program.

126.

Over one-third of Dr. Freeman's patients who received Botox were Medicare patients, and these included patients who received Botox for *off-label* uses.

127.

Another physician who Rushin recommended for an AIOD program was Matthews Gwynn, M.D.

128.

Dr. Gwynn also had a substantial number of Medicare patients, and prescribed a great amount of Botox for *off-label* uses, including headache.

129.

Physicians who accepted an invitation to an AIOD were flown to California and provided accommodations at The Balboa Bay Club and Resort in Newport Beach, California. The physicians' travel expenses, lodging expenses, and meals were all paid for by Allergan. Allergan also paid each physician $1,500 to attend an AIOD program.

130.

A major focus of the presentations at all AIOD programs is *off-label* uses of Botox. Allergan knew and intended that physicians joining AIOD programs would

frequently prescribe Botox for *off-label* therapeutic uses and would present false or fraudulent claims to the United States Government for payment for the Botox and related services, including the injection of Botox. Importantly, while each AIOD attendee was paid $1,500 as a "consulting fee" for attending the AIOD program, this was a sham consulting arrangement. As illustrated in a string of emails to Rushin from Bonilla concerning the AIOD trips, Allergan viewed the program as an "opportunity to get our physicians closer to Marketing and Sr. Management," "spend quality time with the physicians," and "support our customers and create loyalty." As doctors who have attended these programs have reported to Rushin, Allergan used the program to market ***to*** the physicians, not to obtain consulting services ***from*** those physicians.

131.

Allergan knew that each Medicare and Medicaid provider is required to enter into a provider agreement with the government (CMS Form 855A, 855B, or 855I), and that under the terms of that agreement each Medicare or Medicaid provider certifies that it will comply with all laws and regulations concerning proper practices for those providers. One of the laws included in this certification is the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(B).

132.

A Medicare or Medicaid provider's compliance with the provider agreement is a condition for receipt of payments under the Medicare or Medicaid program.

133.

Physicians who receive payments in violation of the Anti-Kickback Statute violate their certifications and are disqualified from receiving payment as part of the Medicare or Medicaid programs.

134.

As a result of Allergan's payments to physicians in violation of the Anti-Kickback Statute, and their receipt of those payments, the physicians became ineligible to receive payment under the Medicare or Medicaid programs.

135.

Allergan knew and intended that providers who were ineligible under the Medicare and Medicaid programs (as a result of Allergan's payments to them, and their receipt of those payments, in violation of the Anti-Kickback Statute) would submit claims for payment to the Medicare and Medicaid programs for the purchase of, and injection of, Botox. These claims by these physicians were false and Allergan caused their submission.

FALSE AND FRAUDULENT STATEMENTS TO CONTRACTORS REGARDING EFFICACY OF BOTOX FOR *OFF-LABEL* USE TO GET FAVORABLE COVERAGE DETERMINATIONS

136.

In violation of the FCA, Allergan made false and fraudulent statements regarding the efficacy of its product, Botox, for numerous *off-label* uses, including contrived and exaggerated claims of positive studies to Medicare Contractors or contractor advisory committees that act as the contractors' agents. Allergan could foresee, and indeed intended, for these statements to Medicare contractors or contractor advisory committees to make favorable Local Coverage Determinations for Botox's *off-label* uses, thereby approving payments for drugs and services that Allergan knows are not "reasonable and necessary" as required by the Medicare Statute. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A). Through such false and fraudulent statements, Allergan was successful in convincing the following three Medicare Contractors to enact coverage determinations reimbursing physicians for the use of Botox to treat migraine headaches: (a) Cigna, with responsibility for Tennessee, North Carolina, and Idaho; (b) AdminiStar, with responsibility for Indiana, Kentucky; and (c) Palmetto, with responsibility for Ohio, West Virginia, South Carolina.

137.

Because these claims are based on false or fraudulent statements relevant to the central purpose of the government payment (the reasonableness and necessity of the drug and medical service to the health of the Medicare beneficiary), Allergan has (1) caused a false claim to be made, *see* 31 U.S.C. § 3729(a)(1); and/or (2) caused a false record or statement to be made to get a false claim paid, *see* 31 U.S.C. § 3729(a)(2).

138.

The Centers for Medicare and Medicaid Services ("CMS") contracts with various Medicare Contractors (*i.e.*, Medicare Carriers, Fiscal Intermediaries, and Medicare Administrative Contractors), the companies that administer the Medicare program in different regions of the country and process Medicare claims.

139.

When the Medicare statute and regulations do not control whether a particular claim is covered, Medicare Contractors make the coverage determination by applying National Coverage Determinations ("NCDs"), which are adopted by the Secretary of Health and Human Services on a national level, *see* 42 U.S.C. § 1395ff(f)(1)(B), and Local Coverage Determinations ("LCDs"), which are made by the Medicare Contractor processing those claims.

140.

The Secretary adopts NCDs to exclude certain items and services from coverage on a national level that are not "reasonable and necessary" under the agency's interpretation of the Medicare statute. *See* 42 U.S.C. § 1395ff(f)(1)(B). These determinations are binding on all Medicare contractors nationwide.

141.

When no NCD applies to a category of claims, Medicare Contractors may create an LCD for those claims. Medicare Contractors may use LCDs when the contractor identifies an item or service that it wishes to provide coverage for, or exclude from, on a categorical basis. LCDs are used only on a contractor-wide basis and may differ between contractors in different regions of the country. 42 U.S.C. § 1395ff(f)(2)(B).

142.

Chief among the fraudulent and misleading statements made, or caused to be made, by Allergan, are those made in a letter written to Earl J. Berman, M.D., the Medical Director of Cahaba GBA, the Medicare Contractor for Part B claims from Alabama, Georgia, and Mississippi. In August of 2004, Allergan drafted a "Consensus Statement" that it encouraged physicians to have their name added to before submitting it to Dr. Berman. This letter was an attempt to convince Cahaba

to enact a Local Coverage Determination expanding Medicare coverage to include Botox treatments for two types of headaches. This letter contains numerous untrue statements, all involving the proven efficacy of Botox as a headache treatment. For instance, the letter states that "[s]ince the mid-1990s[,] clinical evidence has emerged to support the use of botulinum toxin type-A as an effective prophylactic therapy for patients suffering from refractory migraine, tension type headache, and chronic daily headache." This is not true. No scientifically-reliable studies support this conclusion.

143.

In addition, Allergan has drafted letters for individual physicians to submit to Medicare Contractors in support of enacting Local Coverage Determinations providing Medicare coverage for Botox use in the treatment of headaches. One such letter that Allergan wrote on Dr. Lang's behalf flatly mischaracterizes Botox as the "only treatment in fact that does not have systemic or cognitive affects, doesn't interfere with any other medications, and ***provides meaningful relief*** from migraines and chronic daily headaches." (emphasis added). This is not true. Botox is not proven to provide any such relief.

FALSE CLAIMS ACT
(31 U.S.C. §§ 3729(a)(1), (a)(2) and (a)(3))

144.

Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 143 of the Complaint.

145.

This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

146.

Defendant, by and through its officers, agents, and employees, knowingly caused to be presented to an officer or employee of the United States Government a false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

147.

Defendant, by and through its officers, agents, and employees, knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States Government in violation of 31 U.S.C. § 3729(a)(2).

148.

As set forth in the preceding paragraphs, Defendant conspired with private physicians, other health care providers, and other third-party interests who assisted Defendant in its illegal *off-label* marketing campaign to defraud the United States by getting false and/or fraudulent Medicare and Medicaid claims paid in violation of 31 U.S.C. § 3729(a)(3).

149.

Defendant, by and through its officers, agents, and employees, authorized and encouraged the actions of its various officers, agents, and employees to take the actions set forth above.

150.

As a result of the acts Defendant, the United States Government reimbursed physicians for treatments that it otherwise would not have had Defendant not presented false or misleading information to the physicians in an effort to promote *off-label* and medically unnecessary treatments.

151.

Each prescription that was written as a result of Defendant's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such *off-label* or illegally

induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

152.

By reason of Defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for *off-label* prescriptions for indications that were not approved by the FDA, not reasonable and necessary to diagnose or treat patients, and/or otherwise induced and caused by Defendant's fraud. These prescriptions and the corresponding claims to federally funded health care programs were a foreseeable and intended result of Defendant's illegal acts.

153.

As set forth in the preceding paragraphs, Defendant has knowingly violated 31 U.S.C. § 3729 *et seq.* and has thereby damaged the United States Government by its actions in an amount to be determined at trial.

WHEREFORE, Relators, on behalf of themselves and the United States Government, pray that judgment be entered against Defendant and that forms of relief required by law and justice be awarded including:

(a) Judgment against Defendant in an amount equal to three times the amount of damages the United States Government has sustained because of its actions, plus a civil penalty of $5,500 to $11,000 for each violation of 31 U.S.C. § 3729, Relators' attorneys' fees and litigation expenses, and other costs of this action, with interest, including the costs of the United States Government for its expenses related to this action;

(b) An award to Relators in the event that the United States Government continues to proceed with this action, of an amount for bringing this action in the amount of at least 15 percent of the proceeds of the action or settlement of the claims;

(c) An award to Relators in the event that the United States Government does not proceed with this action, in the amount of at least 25 percent of the proceeds of the action or settlement of the claims,

(d) Trial by jury on all issues;

(e) Relief to the United States Government and Relators both at law and at equity, to which they may reasonable appear entitled.

Respectfully submitted, this 5th day of June, 2007.

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CERTIFICATION

The above-signed counsel hereby certifies that this Complaint has been prepared pursuant to the formatting requirements of Local Rules 5.1 and 7.1, utilizing Times New Roman, font size 14.

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Georgia Bar No. 266413