IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF GEORGIA

ATLANTA DIVISION

UNITED STATES OF AMERICA	:	
	:	
	:	
	:	
	:	CRIMINAL ACTION NO.
v.	:	1:10-CR-375-ODE
	:	
	:	
	:	
	:	
ALLERGAN, INC.,	:	
	:	
	:	
Defendant.	:	

GOVERNMENT MEMORANDUM IN SUPPORT OF BINDING PLEA AND SENTENCING MEMORANDUM

The United States of America submits this memorandum in support of the proposed Rule 11(c)(1)(C) plea agreement and sentence in this case. The defendant, Allergan, Inc. ("Allergan" or "the Company"), is prepared to plead guilty to a one count Criminal Information of introducing into interstate commerce a misbranded drug by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352(f). For the reasons set forth below, the Government submits that this Court should accept the guilty plea and sentence Allergan in accordance with the terms of the negotiated plea agreement.

I. THE PROPOSED GLOBAL RESOLUTION

The proposed global resolution in this case represents the culmination of a complex investigation regarding the sales, promotion and marketing practices of Allergan for its flagship drug, Botox. The components of the resolution are as follows:

1. Allergan agrees to plead guilty to one count of introducing into interstate commerce a misbranded drug by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352(f) and to pay a criminal fine in the amount of three hundred and fifty million dollars ($350,000,000) and a forfeiture of twenty-five million dollars ($25,000,000);

2. Allergan agrees to settle its Federal False Claims Act

civil liability for a total amount of two hundred and twenty-five million dollars ($225,000,000);

3. Allergan agrees to dismiss with prejudice its lawsuit, *Allergan, Inc. v. United States of America, et al.*, Civil Action No. 09-1879 (JDB), filed in the United States District Court for the District of Columbia;

4. The United States agrees not to prosecute Allergan for conduct described in the plea agreement paragraph 5;

5. Allergan agrees to comply with the terms of a new corporate integrity agreement; and

All aspects of the global agreement, including the civil and administrative remedies and the dismissal with prejudice, are contingent upon the Court's acceptance of the plea and sentence as proposed by the parties.

II. THE FOOD, DRUG AND COSMETIC ACT CHARGE

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq, sets out the authority and framework for the regulation of prescription drugs by the FDA. The purpose of the FDCA is to protect the public health and a "violation of the FDCA is presumed to harm the public." *United States v. Kasz Enterprises*, 855 F. Supp. 534, 543 (D.R.I. 1994). Botox is 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)(l). In addition, Botox is a "biological product" under the Public Health Services Act, ("PHSA"), 42 U.S.C. §§ 262 et seq., 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 or cure of disease or injuries of man"). As a biological product, Allergan was required to obtain a Biologic License Application ("BLA") for each of the intended uses of Botox. *See* 42 U.S.C. § 262. A product that has a BLA under the PHSA is not required to also have an approved New Drug Application ("NDA") under the FDCA; in every other respect, however, the FDCA applies, including the provisions applicable to adulteration and misbranding of drugs. 42 U.S.C. § 262(j). Botox is also a "prescription drug" because it is one that is not safe for use except under the supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1)(A).

A. Misbranding: 21 U.S.C. § 331(a)

The FDCA prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). Under this statute, a product's labeling, which has a broad definition under the FDCA, must provide adequate directions for its use. 21 U.S.C. § 352(f). According to the regulations, this means

"directions under which the layman can use a drug safely and for the purposes for which it is intended," and "[d]irections for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) Statements of all conditions, purposes, or uses for which such drug is intended, [. . . and] (b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions." 21 C.F.R. § 201.5.

In addition, "intended uses" are defined in 21 C.F.R. § 201.128 as follows:

> The words intended uses or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended use of an article may change after it has been introduced into interstate commerce by its manufacturer. . . . But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such uses to which the article is to be put.

Under this definition, the off-label uses of Botox to treat pain, headache, spasticity, and juvenile cerebral palsy were

"intended," and thus required proper labeling. Since the labeling cannot provide directions for an unapproved use, it is presumptively inadequate if the manufacturer intended, as Allergan did, that the drugs be used off-label.

Introduction of a misbranded or unapproved new drug into interstate commerce is a misdemeanor violation without regard to the defendant's scienter. *United States v. Dotterweich*, 320 U.S. 277, 281 (1947). *See also United States v. Hiland*, 909 F.2d 1114, 1127-1128 (8th Cir. 1990); *United States v. Mitcheltree*, 940 F.2d 1329, 1350 (10th Cir. 1991) ("Misdemeanor criminal responsibility does not require consciousness of wrongdoing").

B. The essential elements of the offense

The Criminal Information charges one count of misbranding under the FDCA, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). Section 331 lists prohibited acts, including:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331(a).

Under section 352 of the FDCA, 21 U.S.C. 352, a drug is "misbranded" under several circumstances, including (as relevant here):

A drug or device shall be deemed to be misbranded –

* * * *

> (f) Unless its labeling bears (1) adequate directions for use . . . .

21 U.S.C. § 352(f).

Section 333 sets forth penalties, 21 U.S.C. 333, including:

> (1)Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2)Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

The Criminal Information in this case charges a misdemeanor under this statute. 21 U.S.C. § 331(a)(1). Thus, to prove the crime of misdemeanor misbranding, the government must establish the following elements beyond a reasonable doubt:

- that Botox is a drug and/or a biologic
- that Botox as misbranded, in that it lacked adequate directions for the uses intended by Allergan, and
- that it was introduced into interstate commerce.

It is not illegal for a doctor to prescribe off-label, using his or her best medical judgment. However, it constitutes misbranding for a drug manufacturer who promotes an off-label use to a doctor, such as Allergan, to distribute the drug without adequate directions for the off-label use.

III. THE FACTS AT TRIAL

If this case were to proceed to trial, the Government would prove these facts beyond a reasonable doubt, as well as other allegations set forth in the Criminal Information.

INTRODUCTION

A. Botox's Limited FDA Approval

Allergan manufactures Botox[1], a prescription biological product containing purified botulinum toxin protein. Botox is injected into the muscles or the skin to block overactive nerve impulses that trigger excessive muscular contractions or glandular activity. The effect of Botox are temporary and last from one to six months, depending on the patient and the indication. Until very recently, Botox was approved by the Food and Drug Administration ("FDA") to treat only four rare conditions: (1) strabismus (misalignment of the eyes); (2) blepharospasm (involuntary eye muscle contraction); (3) cervical dystonia (involuntary neck muscle contraction); and (4) hyperhidrosis (excessive sweating) (hereinafter collectively referred to as "on-label uses").

Earlier this year, in March 2010, FDA approved the use of

[1]Allergan markets and sells botulinum toxin in the United States under the trade names "Botox" for therapeutic use and "Botox Cosmetic" for cosmetic use, but the toxin found in each is exactly the same. This case concerns only Botox for therapeutic use, and all references to "Botox" in this Memorandum relate solely to Botox Therapeutic, unless otherwise noted.

Botox for the treatment of increased muscle stiffness in the elbow, wrist and finger muscles in adults with upper limb spasticity.[2] For many years, Botox is and has been the standard of care for the treatment of various forms of spasticity. In fact, Botox has also been approved for a number of years in a number of countries outside of the United States to treat spasticity. Physicians are likely to continue to use Botox for other off-label conditions, including lower limb spasticity and spasticity in juveniles suffering from cerebral palsy.

There is a risk of adverse "distant spread of toxin" associated with the injection of botulinum toxin generally, including Botox. In connection with this risk, the FDA ordered all manufacturers of botulinum toxin, including Allergan, to add a special "boxed warning" to the existing label and package insert, and to adopt a Risk Evaluation and Mitigation Strategy ("REMS"). In connection with its decision, however, the FDA noted that its intention was not to discourage the use of botulinum toxins for spasticity, as they remain "very effective" and "commonly used."[3]

---

[2]The FDA has not approved Botox to treat spasticity in other parts of the body or to treat children with any form of spasticity. This new FDA approval comes after close to a decade of off-label marketing and promoting of Botox for spasticity by Allergan.

[3]Ellis Unger, Office of New Drugs, Ctr. For Drug Evaluation and Research, Food & Drug Admin., Remarks at the FDA Media Briefing on Botulinum Toxin Products (April 30, 2009) http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/ucm169170).

Medicare and Medicaid pay, or provide coverage for, drugs prescribed for off-label uses if those uses are "medically accepted indications." Although "medically accepted indications" is defined slightly differently for various federal programs, the term generally refers to uses supported by citations in certain published drug compendia specified by statute. The three statutory compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex Information System. Some of the off-label indications illegally promoted by Allergan were "medically accepted indications" covered by federal healthcare programs. For example, from 2001 to 2008, Medicare and Medicaid paid $232 million for claims with a primary diagnosis of spasticity. However, other off-label indications promoted by Allergan were not medically accepted indications, and were not covered by federal healthcare programs.

Allergan has also recently sought FDA approval of Botox for the treatment of "chronic migraine" (specifically, individuals who suffer from fifteen or more headaches per month, at least half of which are attributable to migraines). That application is still pending with the FDA. However, during the relevant time period, Botox was not approved to treat headache, Allergan lacked clinical support for its headache claims, and only a handful of federal healthcare programs covered Botox injections for headaches. Morever, even if the FDA approves Botox as a preventative treatment

for chronic migraine, the product will still not have approval for the other headache types that Allergan was marketing and promoting, such as tension type headache, episodic migraine, and post-whiplash headache.

B. Allergan Was Prohibited from Marketing Botox for Off-Label Uses.

In its 1997 Strategic Plan, long before getting FDA approval for the off-label indications, Allergan made it a top corporate priority to maximize Botox sales for the treatment of off-label uses, including spasticity, migraine, and pain, and highlighted migraine and pain as two of Allergan's top three future growth opportunities. Even though Botox's on-label uses were very limited at the time, the 1997 Strategic Plan identified the brand as Allergan's fastest growing business, with the greatest peak year sales, and highest margins. In fact, several of Allergan's Strategic Plans forecast that Botox's on-label sales would shrink and that all growth from Botox Therapeutic would come from off-label sales. In order to meet the ambitious Botox sales goals demanded by its Strategic Plans, Allergan had to expand sales beyond the four narrow FDA-approved indications.

As a result of this unlawful off-label marketing scheme, Botox sales skyrocketed. Between 1999 and 2006, spasticity sales grew by 332 percent, headache sales grew by 1,407 percent, and pain sales grew by 504 percent. By 2007, Allergan had over $500 million in annual Botox sales for therapeutic uses, and 70 to 80 percent of

those sales were attributable to off-label indications, primarily for spasticity, headache and pain.

Allergan knew that marketing and promoting Botox for off-label uses was unlawful. On June 21, 2002, Allergan distributed to all sales and marketing personnel the PhRMA Code on Interaction with Healthcare Professionals and the "Allergan Field Reference Guide." The Allergan Field Reference Guide emphasized that "you may not promote any Company product for uses that are not addressed in the approved product labeling or insert . . . This promotional ban applies not only to sales calls, but to all marketing efforts such as product launches, sales meetings and activities of third-parties controlled by Allergan."

Allergan's SEC Form 10-K annual report to shareholders for the calendar year ending December 31, 2004, acknowledges this promotional ban as well:

> 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.... If, however, our promotional activities fail to comply with the FDA's...regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or another enforcement agency.

Essentially the same language appeared in Allergan's 10-K filings for 2005 and 2006.

In this case, the four FDA-approved indications for Botox - strabismus, blepharospasm, cervical dystonia ("CD"), and hyperhidrosis - are extremely rare. Studies reflect that the prevalence rate of CD in the population of the United States is only 27,000 people.[4] As a practical matter, patients with strabismus and hyperhidrosis rarely resort to Botox treatment. Botox treatments for hyperhidrosis are indicated only after prescription antiperspirants fail to adequately manage the condition, and strabismus patients almost always choose alternative treatments such as eye surgery, corrective lenses, or eye exercises. Yet, Allergan has made it a top corporate priority to maximize sales of Botox for off-label indications. *See also* 2003 Strategy Review that "Adult Spasticity, Headache, and Pain will account for 85% of incremental sales in 2003".[5] Indeed, Allergan

---

[4]With respect to cervical dystonia ("CD"), Allergan's 2003 Botox Foundation Training Materials estimated that in the United States the prevalence of the condition is slightly less than 9 people out of 100,000, which would correlate to approximately 27,000 Americans who have the condition in a population of approximately 300 million. *See also* "Overview of the Epidemiology of Botox Indications: Risk Management and Epidemiology Allergan, Inc." at 39 (September 2007)("With a current US population of 281,421,906 (U.S.Census Bureau, 2000) and given a CD prevalence of 8.9/100,000 (Nutt et al., 1988), the estimated number of people affected in the US is 25,047.").

[5]The references made throughout this Memorandum are to Allergan documents which the Government is prepared to provide to the Court should the Court be interested.

instructed its sales representatives to promote Botox for pain, spasticity and headache - even when at the time it had no clinical support for these indications.

In pharmacology, the term "mechanism of action" ("MOA") refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. Allergan also employed a "mechanism of action" for its promotional and marketing activities related to off-label sales of Botox. Allergan had a well-developed MOA for its off-label sales and marketing efforts. Allergan's MOA is reflected in strategic plans, marketing initiatives, employee training, internal communications, staffing decisions, and even corporate structure. Allergan's MOA included providing "value-added" reimbursement support services; lobbying healthcare payers to expand coverage for off-label uses; funding and controlling continuing medical education programs; paying doctors to attend Advisory Boards, promotional dinners, or to tout Botox's efficacy for off-label uses; creating and funding organizations to promote off-label uses of Botox; and providing selective discounts to doctors who predominantly treated off-label conditions. For example, in January 2002, at an annual sales meeting in Whistler, British Columbia, Canada, Allergan unveiled its "MOA" for increasing sales of Botox for spasticity, headache,

and pain.[6] This is a blueprint for the illegal promotional and marketing activity of Allergan.

Allergan developed Botox "Customer Team Units," or "CTUs," which in effect coordinated these sales initiatives and off-label marketing messages. CTU's included representatives from sales, medical affairs, reimbursement, marketing and management. The CTU became or evolved into a mechanism for coordinating the promotional activities among the numerous different departments participating in the CTU. Specifically, until January 2007, CTU teams met on a quarterly basis to exchange detailed information about each physician's off-label use in a given territory and plan future sales calls on physicians to be made by the different areas. Through the CTU mechanism, the formal organizational separations

---

[6]In these various slide decks, Allergan acknowledges that it is pursuing future approval for these off-label indications but such approvals are years away. Yet notwithstanding the trajectory for the future approvals, Allergan heavily marketed and promoted these off-label uses. In fact, Allergan's projected target date for approval by FDA for these off-label indications constantly gets moved backed in time. *See, e.g.*, Therapeutic Marketing Plan - 2002, "Development Assumptions for Strategic Plan Period" (September 24, 2001)(Allergan's assumption about likely FDA-approval for Adult Spasticity is projected for the second quarter of 2005; pediatric spasticity, headache, and pain have no specific projected FDA-approval date, as the development assumption for these indications goes into the future beyond the 2005 date on the power point slide). In Allergan's 2004 Marketing Plan for U.S. Botox, approval for spasticity is now projected to be in the second quarter of 2007, headache approval is projected for 2009 and there is no approval projections for either juvenile spasticity or pain. "US Botox Therapeutic Team, 2004 Marketing Plan, 'Claim Real Estate,' Recruit More Injectors; Escalate Productivity."

between the sales, medical affairs, and reimbursement divisions were effectively circumvented, resulting in a de facto exchange of sales and marketing information between CTU participants.

Doctors got the message. In a 2003 survey commissioned by Allergan, doctors reported that Allergan sales representatives routinely discussed "migraine treatment and spasticity" and communicated that "Botox is effective in managing migraine headaches and regional myofascial pain." Off-label sales grew exponentially, and by 2007, Allergan identified Botox as its "#1 growth driver." Thus, Allergan succeeded in making Botox its flagship brand.

C. Allergan Targeted Off-Label Specialties.

Allergan aggressively promoted Botox to medical specialists who did not customarily treat patients with any of the conditions that Botox was approved to treat, including headache clinics, anesthesiologists, pain specialists, and pediatricians. For example, in 2001, Allergan sought to establish Botox in the "back pain market" by calling on "1,000 pain specialists." *See, e.g.*, Botox Therapeutic Team 2004 Marketing Plan (identifying Allergan's 2003 goals for new injectors by medical practice category, including a target of 110 new pediatrician injectors and 230 new pain specialty injectors).[7] More recently, in its 2007 Call Plan,

[7]It is not surprising that Allergan targeted off-label specialists given the training its sales people received. For example, in February 2003, Allergan's Foundation Training

Allergan sought to target 20 percent more pain and headache specialists and pediatricians than it had in 2006.

Allergan also leveraged other companies' relationships with doctors in off-label specialties by entering into "co-promotion" agreements. In 2002, Allergan agreed to sell another manufacturer's medical device to doctors who treated spasticity, thereby giving Allergan representatives an opportunity to discuss Botox as an adjunctive therapy for spasticity and pain. Similarly, in 2006, Allergan entered into a co-promotion agreement with a top-tier pharmaceutical company to gain an audience with neurologists who treated headache. Allergan had no drug approved for the treatment of headache, but agreed to double its sales force to sell the top-tier pharmaceutical company's headache drugs to the top-tier pharmaceutical company's neurologists. Although Allergan was eligible to receive a $10 million "performance payout" from this top-tier pharmaceutical company if it met certain sales targets, internal documents reflect that a significant motivation for the deal was to "Allow us to Sell More Botox!!!" In fact, when Allergan was not on track to meet either the 2006 or 2007 sales

---

materials, which are the training materials provided to all new sales and marketing employees in the Botox Division, contained approximately 6 pages of boilerplate compliance admonitions on off-label promotion and 48 pages addressing off-label use of Botox as a treatment of headache, including sections on the history of Botox treatment for headaches. Allergan provided extensive training to its sales force on promoting and selling Botox off-label years before the Company was in any position to file a new application to legitimate those unapproved uses.

targets of the top-tier pharmaceutical company, Allergan's Senior Director of Marketing reported that "there was no concern expressed" by Allergan executives because "we've seen the positive impact the deal has had on Botox." Allergan was successful in converting the top-tier pharmaceutical company's neurologists to Botox, and about half of its new Botox injectors in 2007 were the top-tier pharmaceutical company's targets. Indeed, based on the "success in Neurology following the [top-tier pharmaceutical] expansion," Botox Marketing Department executives requested additional funding to expand its sales force to call on more physical medicine and rehabilitation doctors ("PM&Rs").

D. Allergan Promoted Botox at a Time When The Efficacy of the Drug had Not Been Demonstrated.

Allergan aggressively promoted Botox for unapproved uses such as headache and pain at a time when the efficacy of the drug to treat those conditions had not been demonstrated by clinical trials. For example, while Allergan vigorously promoted Botox for pain management and instructed its sales representatives to promote the message that "it works!," it recognized in the same internal document that there was no clinical support and "a lack of successful [Double-Blind, Placebo-Controlled] trial(s)" for using Botox injections to relieve pain. *See* ("Key Pain Messages - Neurology - It works");("Clinical Data Support is Modest");("Teach [sales representatives] how to discuss the role of Botox in pain management"; "Lack of peer reviewed, credible data to support this

use"). Indeed, after years of clinical trials involving the treatment of back pain, Allergan placed its FDA application in inactive status in 2003 after its Phase 3 studies were "[n]ot successful." Despite these negative results, Allergan sought to "drive market development of back pain" by "focus[ing] on areas where there is the path of least resistance 'upper back' lower back." Looking back in 2007, Allergan itself recognized that for more than a decade, it had marketed Botox in "areas where there was not even supportive clinical literature, such as 'pain.'"

Likewise, Allergan aggressively promoted Botox to treat several different types of headache conditions, in addition to chronic headache, and caused sales for that indication to increase over 1,400 percent. At the same time, Allergan recognized that it lacked scientific evidence that Botox was more effective in treating headache than a placebo. Allergan's phase 2 FDA headache trials were not successful. In fact, nine out of ten trials failed to meet their primary endpoint and Allergan concluded that these trials were "negative." In December 2004, the FDA agreed, finding that the "Botox headache primary efficacy results for the extensive phase 2 development plan have been largely negative." The FDA also expressed its concern about the existing public perception about the "broad utility" of Botox, and required Allergan to refrain from funding any medical education programs for headache until it had published all of the phase 2 headache studies. Although Allergan

ultimately published the studies, it directed its employees to refer to the trials as "inconclusive" - not "negative." Although at the time its employees candidly recognized that the "data just isn't there for headache," Allergan continued to promote Botox as an effective treatment for headache.[8]

E. Allergan Used a Variety of Tactics to Carry Out Its Unlawful, Off-Label Marketing Scheme.

In addition to its sales representatives' pitches to doctors that Botox was a safe and effective treatment for headache, pain and spasticity, Allergan used a variety of tactics to carry out its illegal off-label marketing campaign. As stated earlier, Allergan laundered its off-label message through a variety of mechanisms including: providing "value-added" reimbursement support services; lobbying healthcare payers to expand coverage for off-label uses; funding and controlling continuing medical education programs; paying doctors to attend Advisory Boards, promotional dinners, or to tout Botox's efficacy for off-label uses; and creating and funding organizations to promote off-label uses of Botox.

---

[8]Numerous documents reflect that marketing guided Allergan's headache development program. For example, an e-mail from the lead scientist for Allergan's headache development program to the Marketing Department inquired, "if both trial[s] failed to meet the primary [endpoint], would marketing want to give up pursuit of the indication?" Likewise, an Allergan executive reported that Allergan reimbursement personnel planned to develop a "Headache Contingency Plan," which she described as "critical communication and key activities for payers to maintain current coverage and continue to gain coverage for headache," even if "phase II data [is] not positive."

1. Allergan Provided "Value-Added" Reimbursement Support Services to Grow Off-Label Sales.

The commercial success of Botox heavily depended on the ability of doctors to obtain reimbursement from federal healthcare programs. Botox is an expensive treatment considering the high drug and administration costs and the fact that its effects are temporary and palliative (not curative). During the relevant time period, one vial of Botox cost approximately $400-$500 for 100 units, and treatment of most off-label uses of Botox required injections of anywhere between 100 to 400 units or more. Since Botox's effect on a muscle wears off over time, patients have to get re-injected at periodic intervals, generally every three months. Doctors can also bill a healthcare payer for the cost of performing the Botox injection procedure, and any associated diagnostic tests, which provide a source of revenue for a doctor's practice. However, unlike most drugs where the doctor writes a prescription and the patient purchases the drug from a pharmacy, Botox is a "buy and bill" drug, meaning that doctors purchase Botox directly from Allergan and assume the risk of reimbursemen on the back-end by a healthcare payer after submitting the claim. Consequently, doctors were not going to inject Botox for off-label uses if they could not get reimbursed.

Indeed, Allergan recognized that the "biggest obstacle" to growing Botox sales was the lack of reimbursement for off-label uses. Even though Government and private healthcare payers covered

Botox for every FDA-approved indication, Allergan doubled the size of its reimbursement support team in 2003 to "minimize customer barriers" for headache, pain and spasticity. The Botox reimbursement team was an extension of the sales force, and its express goal was to "Improve Injector Economics = (Sell More Botox)." The pitch for the Botox reimbursement programs - collectively referred to as the "Botox Advantage Program" - was: "Improving the Reimbursement Environment for Today and For the Future by Providing Comprehensive Reimbursement Assistance, Reducing Reimbursement Issues, Saving You Time and Effort!"

Through the Botox Advantage Program, Allergan provided customized reimbursement support services to doctors and their office practice managers, expended millions of dollars each year to operate the Botox Reimbursement Hotline, and performed detailed audits (or "interventions") of physician billing records to demonstrate "the value of Botox to their practice" (*i.e.*, you can make money injecting Botox). Allergan cited "high value [reimbursement] services" as a key driver of Botox sales, and touted their reimbursement support as one of the "most valued services Allergan provides." Indeed, Allergan was able to quantify the success of its reimbursement services, noting that on average, accounts with an intervention grew by $6,000 versus $1,000 at accounts without an intervention.

2. Allergan Lobbied Healthcare Payers to Expand Coverage for Off-Label Uses.

Notwithstanding the lack of scientific support for headache or pain, Allergan initiated a carefully orchestrated campaign to (1) expand Botox coverage for off-label uses, and (2) eliminate any payer-imposed limitation on the amount of Botox injected into patients (*i.e.*, "dosing caps"). *See* "Reimbursement Operations, Deployment 2006," September 12, 2005(observing that "[w]ithout indications or significant Double-Blind/Placebo-Controlled data, challenging to block competitors and grow coverage at the same time"). Allergan recruited and used physician "advocates" to lobby Medicare and Medicaid decision-makers to expand coverage for off-label uses. Allergan also funded and controlled a patient advocacy group, which is an organization whose mission is to "expand patient access to Botox." Doctors were paid $1,000 each to attend regional physician advocacy workshops where Allergan reimbursement personnel coached them how to successfully lobby healthcare payers to cover off-label uses of Botox.

Allergan viewed physician advocates as the ultimate "critical success factor" for gaining policy expansions for pain and headache and referred to the advocates as the company's "Trojan horses." *See* Email dated February 08, 2008, (reporting that a healthcare payer's medical director "would not talk to Allergan but they respected this advocate so [Allergan] used him as a trojan horse."). With respect to headache, Allergan's reimbursement team

created the package of materials for the advocate to submit to the payer, which included a cover letter requesting the policy expansion, a consensus statement signed by "headache experts" (doctors with whom Allergan had financial ties) stating that Botox was an effective treatment for headache, selected medical literature about the use of Botox for headache, and an annotated literature review. Allergan did not disclose its role in this process, and none of the documentation that the advocate submitted to Medicare disclosed Allergan's involvement. Indeed, the reimbursement team went to great lengths to ensure that the "ghostwritten" materials that were submitted to different healthcare payers did not look too much alike if anyone were to compare them. Two Allergan employees went so far as to request an in-person meeting with a Medicare Part B Carrier Medical Director to find out why he expanded the policy to cover headache "even though [they] kn[e]w the process that took place," because it would be a "[g]ood opportunity to learn more on process side using naïve approach on HA [headache] situation. (Or to learn what he may know/perceive as to what our involvement was)."

3. Allergan Directed Physician Training, Workshops, and Dinners.

Allergan also funded and controlled the content of hundreds of continuing medical education (CME) seminars, injection workshops, and promotional dinner programs at which paid speakers identified by the company as "Key Opinion Leaders" ("KOLs") advocated Botox

for off-label indications. For example, in 2004 a CME provider worked with Allergan to develop purported CME programs to address pain and spasticity. And Allergan created the Centers of Excellence as an "independent" CME to drive headache growth. Indeed, it was a "Management Business Objective" for Allergan's scientific services group to create, edit and control the substance of off-label CMEs, including headache.

4. Allergan Paid Doctors to Attend "Advisory Boards."

Allergan hosted numerous "Advisory Boards," purportedly designed to elicit feedback from doctors about their experience with Botox. However, the frequency, context, and content of these "Advisory Boards" demonstrate that they were merely another opportunity for Allergan to promote Botox for off-label indications and "build loyalty and solidify important relationships." For example, in 2005 and 2006, over 200 top-prescribing doctors attended the "Allergan Institute of Distinction" ("AIOD"), a two-day, invitation-only Botox marketing program held at Allergan's corporate headquarters and the Balboa Bay Club and Resort in Newport Beach. Doctors attending the AIOD provided no consulting services, but were paid $1,500 to listen to the presentations that included off-label topics. Rather, these "Engagement Plans" reveal Allergan's intent to reward hundreds of its top injectors with consulting fees and corporate attention in an effort to further develop these doctors' use of Botox.

5. Allergan Created and Funded Organizations to Promote Botox for Off-Label Uses

In addition to the patient advocacy group, Allergan created and funded a purportedly independent on-line neurotoxin education organization to "stimulate increased use of Botox." In 2003, Allergan had a website designed by a large health care marketing corporation to appear as the educational arm of an independent public interest entity. Allergan had an on-line neurotoxin institute created and directed its operation with the intent to seed the medical and scientific community with off-label promotional material about its unapproved uses of Botox. The Mission Statement for the on-line neurotoxin education organization was to "validate and disseminate consistent information regarding the expanding uses of Botox." However, an Allergan executive admitted its control over the organization, stating that "they act under our direction in creating the content and setting direction." From 1999 to 2007, Allergan gave approximately $10 million in "unrestricted" grants to the on-line neurotoxin education organization. The on-line neurotoxin education maintained a web site to disseminate information about off-label uses, including videos of CME programs sponsored by Allergan and other written materials prepared by Allergan. Allergan's sales representatives were specifically trained to refer doctors to the on-line neurotoxin education organization website, and to distribute "Awareness Cards," with the website's information on them, to all

doctors during sales calls.

F. Allergan's Unlawful Marketing Campaign Drove the Tremendous Growth of Off-Label Uses of Botox.

The tremendous growth in off-label Botox sales were caused by Allergan's sales and marketing organization, as the contemporaneous documents produced by Allergan demonstrate that Allergan's efforts drove the majority of increased off-label sales. First, Allergan recognized that doctors "that are naïve to Botox demonstrate limited interest in picking up the needle," and that "[t]he barrier to entry into the [Botox] world is still relatively high for clinicians [with i]ssues of interventional invasive treatments and lack of prior training." Studies commissioned by Allergan found that doctors had a "Limited Interest in Learning How to Inject" Botox, and that "Non-Users of Botox for HA still 'on the fence'" in part because "Non-users perceive the published data supporting use of Botox in chronic HA to be . . . unimpressive." Allergan concluded that a threat to increased sales of Botox was the "[l]imited perception of need; apathy" of potential injectors.

Second, Allergan dramatically expanded its therapeutic Botox field sales force far beyond levels justified by the drug's approved indications. Between February 2003 and February 2008, Allergan almost tripled its payroll of sales personnel, while obtaining only one very narrow label extension (severe primary axillary hyperhydrosis. The clearest connection between the number of sales representatives and off-label sales growth was made in

Allergan's 2007-2011 Strategic Plan, which stated that in "2006 [Allergan] Added 45 New NMCs [sales representatives] & Spasticity grew 25% [and in] 2007 [it] Added 19 New NMCs & Spasticity Est[timated] 18%." In its 2005 Strategic Planning process, Allergan concluded that sales for pain, headache and spasticity were negatively affected by a "decrease in calls to Pain [doctors]/Ped[iatricians]." Allergan also projected further sales declines for pain in its 2006-2010 Strategic Plan because there would be "no promotion" for that indication (and at the same time projecting increases for other indications, presumably because Allergan's promotion would continue). The 2006 Marketing Plan recognized that "Growth is Detail Sensitive" and that "BMCs [sales representatives] Have Impact on Sales." Allergan's studies supported the conclusion that Allergan's sales and marketing efforts drove higher sales. In particular, Allergan found that "Across all specialties, Botox sales/MD increase with higher call frequency" and that expanding sales calls to rehabilitation doctors would increase sales by $14.3 million over three years. As stated above, the evidence is overwhelming that Allergan's sales and marketing efforts drove the substantial increases in off-label sales of Botox from 2001-2008.

G. Allergan Coached and Encouraged Doctors to Diagnose Headache and Pain as "Symptoms" of Cervical Dystonia

Allergan encouraged doctors to diagnose headache and pain as symptoms of its on-label cervical dystonia indication. CD, also

known as "spasmodic torticollis," is a rare movement disorder, the number of people in the United States that currently have the condition is approximately 27,000 individuals. However, with its headache development program in jeopardy and no prospect of obtaining a pain indication, Allergan exploited its approved CD indication to grow headache and pain sales. In 2003, Allergan developed the "CD/HA Initiative" as a "rescue strategy in the event of negative phase II data" and a "backup strategy to ensure continued expansion into the headache market" with the goal of establishing a connectivity between CD and headache to "augment existing use of Botox in the treatment of headache and give an entry point for use of Botox in headache for skeptical markets." As part of this initiative, Allergan asked the FDA to expand the Botox label to include treatment of headache associated with CD and the treatment of "pain" - not merely "neck pain" - associated with CD. The FDA rejected both requests, and an Allergan executive pondered how to proceed: "It's too bad that there is no easy way to obtain 'headache' in our label (even as part of CD). . . . Has the US Marketing group exploited the notion of much higher prevalence of CD in the population?"

Soon thereafter, Allergan launched a new Botox marketing campaign premised on the idea that CD is "underdiagnosed" and "misdiagnosed" and to "strategically move toward emphasizing symptoms of mild/moderate CD (i.e., HA, Pain, Tremors) instead of

severe CD." The company's "key messages" for the campaign emphasized that doctors could diagnose CD based on headache and pain symptoms, even when a doctor "doesn't see any cervical dystonia."

Allergan's new CD campaign worked. Allergan acknowledged that the sales and reimbursement teams had successfully convinced doctors to change patients' diagnoses from headache to cervical dystonia. Specifically, upon learning that one doctor was audited by Medicare and asked to pay back over $120,000 for purported "CD claims," Allergan sales and marketing management called for the field to "be more aggressive during their consults" with doctors. Management emphasized that sales representatives should stress "the need for more thorough chart documentation in order to justify a CD diagnosis, especially in those situations where a patient may have been diagnosed with headache previously, but the doctor is changing the diagnosis based upon a better understanding of CD and how a patient may present with CD (we are routinely reviewing with a physician the symptoms of CD - HA, muscle contractions, abnormal posture, pain, etc.)" Allergan's VP of Neurosciences listed the "CD expansion campaign" as one of the "key drivers" for Botox sales, but at the same time worried whether Allergan could "actually defend [723.5] ‘unspecified torticollis’ as a labeled indication?"

III. Allergan Offered Discounts and Other Services to Doctors to Cause the Doctors to Use Botox Off-Label.

Allergan used a wide array of tactics to cause doctors to prescribe more Botox. Those tactics ranged from the blatant - paying substantial honoraria to high-volume injectors - to the more nuanced - providing significant "value-added" reimbursement support. Allergan recognized the strategic imperative of keeping its most valuable customers happy, particularly considering that Botox's most lucrative uses were off-label. As recently as its 2007 Business Plan, Allergan recognized as "imperative," "employ[ing] . . . reimbursement support to retain 'buy and bill' physicians." Similarly, it saw honoraria and speakers bureau engagements as methods of buying "loyalty" and "solidifying relationships" with large customers. Its sales representatives' tactics to increase Botox use included paying money to doctors through the Speaker's Bureau, CMEs, and one-on-one training. Allergan also used its medical grants, in part, as an extension of sales and marketing, to reward top purchasers and grow sales of Botox. An Allergan executive recognized the leverage provided by medical grants, saying that "[b]efore we give [this grant request] further thought, would you check whether [the requesters] are significant users of Botox . . . . Upon receiving your reply, I will decide how to handle." And the Vice-President of Medical Affairs understood marketing's importance to the grant making

process, deciding that "[o]bviously, [grant] proposals that would negatively impact the goals of Marketing should not be funded and studies that would support Marketing goals should be given careful consideration."

These programs were widespread. For example, in 2005, Allergan paid hundreds of thousands of dollars to doctors for Speaker's Bureau and "Practice with the Experts" dinner programs. In 2004 and 2005, Allergan paid approximately $2.5 million in grants to individual doctors. These so-called grants were a priority for the marketing and sales teams, and paid great dividends to Allergan, allowing its off-label sales of Botox to climb dramatically through the decade. In 2006, Allergan sponsored over 1,200 programs, with each program having at least one paid physician.

Perhaps Allergan's most innovative mechanism of action relates to the extensive value-added reimbursement support services Allergan provided doctors. Allergan recognized that reimbursement issues were the "biggest obstacle" to increasing Botox sales. It realized that providing doctors with valuable reimbursement services would allow it to sell more Botox. Beginning as early as 2003, Allergan doubled the size of its reimbursement support team to "minimize customer barriers" for headache, pain and spasticity and grow off-label uses. Allergan cited "high value [reimbursement] services" as a key driver of Botox sales, and

touted their reimbursement support as one of the "most valued services Allergan provides." This reimbursement support included a wide-range of services, including individual patient record audits to maximize payments to the doctors.

In its analysis of these services, Allergan concluded that doctors who received these services would increase their purchases of Botox by six times as much as doctors who did not. It is no surprise that Allergan taught its sales force to aggressively tout the reimbursement services to induce additional off-label use of Botox.

IV. COMPLIANCE

An effective compliance and ethics program must promote and instill an organizational culture that encourages ethical conduct and a commitment to compliance with the law. On June 21, 2002, Allergan distributed to all sales and marketing personnel the PhRMA Code on Interaction with Healthcare Professionals and the Allergan Field Guide. The "Allergan Field Reference Guide" emphasized that "you may not promote any Company product for uses that are not addressed in the approved product labeling or insert . . . This promotional ban applies not only to sales calls, but to all marketing efforts such as product launches, sales meetings and activities of third-parties controlled by ALLERGAN." Generally with regard to promotional activity, the Field Guide states that no Allergan employee or representative may promote a drug in a manner

that is inconsistent with FDA-approved labeling.

The investigation revealed that Allergan had been working (and at times succeeding) to improve its compliance culture and compliance plan. No compliance plan is perfect, however. For example, on Wednesday, August 9, 2006, an Allergan-sponsored dinner program was presented by a physician-speaker at the Capital Grille in Baltimore, MD. When a speaker such as this doctor makes such a presentation, Allergan correctly views the speaker as a representative of Allergan and his presentation is considered a "promotional" Allergan activity, regardless of the credentials of the speaker or the audience. At the dinner program the Allergan physician-speaker illegally promoted Botox for the treatment of headache. The Allergan physician-speaker made other similar presentations across the country about the off-label use of Botox for headache. After a complaint was lodged by a doctor-attendee of one of these dinners, FDA investigated the incident and required Allergan to send out "Dear Doctor" letters apologizing for the misconduct. Allergan reprimanded the manager of the sales representative by removing him to a different division of Allergan and placed letters of reprimand in the personnel file of several employees in the chain of command of the sales manager.

As a result in part of this incident, on November 7, 2006, the then-Chief Administrative Officer, Executive Vice President, General Counsel and Secretary, issued a cover letter accompanying

Allergan's new Healthcare Law Compliance, Policies and Procedures Manual (the "Manual"). The cover letter specifically states that "Allergan expects you to understand the laws and Allergan policies that apply to your job responsibilities and will hold you personally responsible for compliance with the Manual."

The Manual itself is dated January 1, 2007, and begins with a "Message From the Chief Executive Officer," Chairman of the Board and Chief Executive Officer of Allergan. That message states:

> There are laws, regulations, and industry guidance that govern the way we do business, including our interactions with customers, healthcare professionals and the Government. Allergan expects you to understand and comply with these standards in order toinsure your actions remain ethical and appropriate in all circumstances.

The message closes with the statement "Remember . . . THERE IS NO RIGHT WAY TO DO THE WRONG THING." The Manual goes on to summarize the extant body of law, industry guidance and federal regulations in this area.

A good compliance program has and publicizes a system which typically includes mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual misconduct without fear of retaliation. The government's investigation revealed, however, a corporate culture that did not encourage such type of conduct with regard to significant questions or concerns about the company's promotion of Botox.

As indicated, Allergan did ramp-up its compliance efforts after the distribution of this manual. Allergan continued to experience noncompliance, however. The government investigation uncovered instances supporting a conclusion that Allergan's efforts at off-label marketing overwhelmed its compliance efforts from time to time. Notwithstanding this, the Government's investigation revealed that Allergan made strides to increase its compliance efforts, which have paid off. The Government anticipates that Allergan will address in greater detail its compliance efforts.

V. THE SENTENCING CONSIDERATION

A. The Fine[9]

The stipulated criminal fine of $350 million is the result of

---

[9]Although Chapter 8 of the United States Sentencing Guidelines ("U.S.S.G.") applies generally, the fine guidelines in Chapter 8, U.S.S.G. §§ 8C2.2 through 8C2.9, apply only to specified types of offenses. *See* U.S.S.G. §§ 8A1.1, app. n. 2; 8C2.1. To determine whether the fine guidelines apply to this FDCA violation, the Court must look at U.S.S.G. § 8C2.1 (Applicability of Fine Guidelines). This section states that the fine guidelines apply to "each count for which the applicable guideline offense level is determined under" one of those listed in subsections (a) and (b).

The applicable guideline offense level for a misdemeanor violation of 21 U.S.C. § 333(a)(1) is determined under U.S.S.G. § 2N2.1. *See* U.S.S.G. Appendix A. Section 2N2.1 is not listed under § 8C2.1(a) or (b). Accordingly, the fine guidelines of Chapter 8 do not directly apply to Allergan's FDCA violation.

In the absence of an applicable fine guideline, U.S.S.G. § 8C2.1 instructs the Court to apply U.S.S.G. § 8C2.10 (Determining the Fine for Other Counts). Section 8C2.10 states: "For any count or counts not covered under § 8C2.1 ("Applicability of Fine Guidelines"), the Court should determine an appropriate fine by applying the provisions of 18 U.S.C. §§ 3553 and 3572."

Determining an appropriate fine for Allergan's FDCA offense, therefore, requires evaluating the general factors to be considered in imposing a sentence under 18 U.S.C. § 3553(a) and to the factors specific to fines set forth in 18 U.S.C. § 3572, including, "the need to deprive the defendant of illegally obtained gains from the offense." 18 U.S.C. § 3572(a)(5). Among the 3553(a) factors are: (1) the nature and circumstances of the offense and the history and characteristics of the defendant; (2) the need for the sentence imposed (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; and (B) to afford adequate deterrence to criminal conduct. Many of the same considerations before the Court in a statutory analysis are considerations under a guidelines analysis. Where there is no applicable sentencing guideline the Court must "have due regard for the relationship of the sentence imposed to sentences prescribed by guidelines applicable to similar offenses and offenders." 18 U.S.C. § 3553(b).

intensive negotiations between the parties over the appropriate factual drivers and other considerations.[10] It represents a just and reasonable resolution of the charge against Allergan, the parent-operating company, for its off-label marketing, particularly when coupled with the significant civil settlement and the obligations imposed by the Corporate Integrity Agreement. The total package is the largest resolution in this district's history. The proposed criminal resolution accomplishes the goals of sentencing without being overly harsh. The statute and regulations that prohibit off-label marketing do so because the practice undermines FDA's process for ensuring that drugs are safe and effective, and in certain cases can interfere with doctor-patient relationship, may be misleading to doctors, and can even result in harm to patients. The agreed-upon plea and sentence also properly takes into account Allergan's conduct. It reflects the fact that the

[10]For example, the criminal fine amount takes into account that there is some percentage of the off-label growth of Botox that resulted from factors independent of Allergan's illegal marketing and promotional activities (so-called "organic growth"), including that Botox was the standard of care for certain types of spasticities, experimentation by physicians, FDA trials, and legitimate continuing medical education.

The fine amount also takes into account that Medicare and Medicaid pay, or provide coverage for, drugs prescribed for off-label uses if those uses are "medically accepted indications." Some of the off-label indications illegally promoted by Allergan were "medically accepted indications" covered by federal healthcare programs. However, other off-label indications promoted by Allergan were not medically accepted indications, and were not covered by federal healthcare programs.

Company has no prior conviction, balanced against the breadth and length of the illegal conduct. The Government believes that the global resolution will deter the Company from further unlawful promotions, particularly in light of the fact that the parent-operating company, Allergan, Inc., is pleading guilty. According to the statutory framework of the FDCA, a second misdemeanor violation, which requires no proof of mens rea, results in a felony conviction. Thus, a plea by the parent-operating company, coupled with a fine of this nature, together with all of the other aspects of this global resolution, will also be just punishment for the offense, and serve as general deterrence to others who might be tempted to go down the road of off-label marketing. All of these factors are difficult to quantify, but the parties have engaged in lengthy discussions aimed at reaching a fair resolution of this matter.

The Government also considered other similar cases. Over the last 5 years or so, in similar off-label marketing cases, the pharmaceutical industry has paid more than $3 billion to the United States to resolve Food, Drug, and Cosmetic Act ("FDCA") charges and False Claims Act (FCA) claims. The resolution proposed in this case fits within the range of criminal fines and civil settlements for the type of conduct alleged in the Criminal Information and described more fully in this Memorandum. Specifically, in other cases where the parent-operating company has pleaded guilty to off-

label marketing, they have pleaded to a misdemeanor FDCA charge and paid large fines.

The Government therefore asks the Court to accept the plea and impose the agreed-upon sentence.[11]

B. Probation

The Government did not seek a period of probation because of the comprehensive five year Corporate Integrity Agreement ("CIA") that was executed between Allergan and the Office of the Inspector General of the Department of Health and Human Services ("OIG"). As part of the CIA, Allergan is obligated to conduct extensive internal and external monitoring, train its employees, report regularly to OIG, and fulfill other obligations as set forth in the

[11]Although Allergan states in its Sentencing Memo that there is "much controversy" about the application of the First Amendment to off-label promotion by a drug manufacturer, the Government does not understand that Allergan asserts a First Amendment challenge in this case. The primary (although not the only) way that the FDCA and regulations affect promotional speech about unapproved uses is by treating such speech as evidence of intended use, which in turn triggers various obligations under the misbranding and new drug approval provisions. The Supreme Court has held that evidentiary use of speech to prove intent or other elements of an offense is permissible under the First Amendment. *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)((First Amendment "does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent."). *See also Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004). Thus, to the extent that Allergan is complaining about restrictions that ultimately rest on the use of promotional speech as evidence of intended use, its claims are without merit. Generally speaking, the FDCA and regulations do *not* prohibit Allergan from discussing health risks associated with unapproved uses of its products. The labeling and advertising provisions of the Act and regulations are directed at speech that promotes particular uses of a drug.

agreement.[12] The OIG has entered CIAs with hundreds of other providers and has a well-established CIA monitoring process. Accordingly, the Government submits that OIG is in the best position to effectively monitor the conduct of Allergan going forward.

C. Victims and Restitution

Allergan has pled guilty to distributing a misbranded drug into interstate commerce, a violation of the Food, Drug, and

---

[12]The CIA requires enhanced accountability, increased transparency, and wide-ranging monitoring activities conducted by both internal and independent external reviewers. The agreement requires, among other things, that:

- the Audit Committee of Allergan's Board of Directors annually review the Company's compliance program and certify as to its effectiveness; that Allergan's Board of Directors (or a Committee of the Board) annually review the company's compliance program and certify as to its effectiveness;
- senior executives from certain key areas (including sales and marketing) annually certify about compliance;
- Allergan notify doctors about the settlement and establish a mechanism doctors can use to report questionable conduct by an Allergan representative; and
- Allergan post on its web site information about payments to doctors, such as honoraria for speaking, payments for other consulting services, and reimbursement for travel and lodging.

If Allergan fails to comply with its obligations, it risks exclusion from Federal health care programs (for a material breach) and monetary penalties (for other breaches).

Cosmetic Act. 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f). The Victim and Witness Protection Act, 18 U.S.C. § 3663 ("VWPA") and the Mandatory Victim Restitution Act ("MVRA"), 18 U.S.C. § 3663A, are not directly applicable in this case because the misbranding offense to which Allergan pleaded guilty is not covered by these statutes. *See* 18 U.S.C. § 3663(a) (covering restitution only for offenses under Title 18; 21 U.S.C. §§ 841, 848(a), 849, 856, 861 & 863; and 49 U.S.C. §§ 5124, 46312, 46502 & 46504 except when the MVRA applies); 18 U.S.C. § 3663A(c)(1) (covering restitution only for crimes of violence under 18 U.S.C. § 16; offenses against property under Title 18 or 21 U.S.C. § 956(a); and offenses described in 18 U.S.C. § 1365). Although the Court has the authority to order restitution as a condition of probation, 18 U.S.C. § 3563(b)(2), or supervised release, 18 U.S.C. § 3583(d), and pursuant to U.S.S.G. § 5E1.1(a)(2), as mentioned above, the Government does not seek a period of probation or supervised release in this case because of the existence of a comprehensive CIA between Allergan and the Department of Health and Human Services ("HHS"). More importantly, however, under any of these provisions, even if they were to apply, the Court may decline to make an order of restitution if it determines that the complication and prolongation of the sentencing process outweighs the need for restitution. 18 U.S.C. §§ 3663(a)(1)(B)(ii), 3663A(c)(3)(B). *See also* U.S.S.G. § 5E1.1(b)(2). Determining actual victims from the

conduct, and the harm resulting therefrom, is a complicated process. Indeed, should even a single entity or individual make a claim for restitution in this matter, the Court would likely be required to hold a mini-trial to determine whether the claimant is a victim at all, and, if so, whether the claimant suffered any losses. The Government contend that determining complex issues of fact related to the cause or amount of any victim's losses would complicate and prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

Furthermore, the Government contend that the Court should decline to issue a restitution order in this matter in light of the pending civil settlements. As part of this proposed settlement, Allergan and the United States have reached an agreement as to civil claims, which requires the payment of two hundred and twenty-five million dollars ($225,000,000). Accordingly, the Court should decline to issue a restitution order.

D. Forfeiture

The forfeiture component of the plea agreement and Information arises from the FDCA's provision for seizing misbranded drugs. 21 U.S.C. § 334 (allowing proceedings on libel of information, for condemnation, against drugs that are misbranded or adulterated so that the Government can seize, destroy or sell them). These proceedings are by their nature classic civil forfeiture

proceedings. Under federal forfeiture law, the Government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress which contains a civil forfeiture remedy. *See* 28 U.S.C. § 2461(c)(allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized . . . ."). Thus, if civil forfeiture is authorized in a statute such as the FDCA, then criminal forfeiture is as well. As the misbranded drugs are no longer available for seizure or destruction, the Government can seek substitute assets as it has done here. *See* 28 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. §853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

V. CONCLUSION

The United States therefore respectfully recommends and requests that the Court accept Allergan's plea of guilty and enter the agreed-upon sentence set forth in the Negotiated Plea Agreement and herein.

Dated this 4th day of October, 2010.

Respectfully submitted,

SALLY QUILLIAN YATES
UNITED STATES ATTORNEY

/s/ Randy S. Chartash
RANDY S. CHARTASH
ASSISTANT UNITED STATES ATTORNEY
Georgia Bar No. 121760

/s/ Douglas W. Gilfillan
DOUGLAS W. GILFILLAN
ASSISTANT UNITED STATE ATTORNEY
Georgia Bar No. 294713

600 RICHARD B. RUSSELL BUILDING
75 SPRING STREET, S.W.
ATLANTA, GEORGIA 30303
404.581.6009
404.581.6181