IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

DOUGLAS M. RAY, Jr.,	)	
Plaintiff,	)	
	)	
v.	)	Civil No.: 3:10cv00136
	)	
ALLERGAN, INC.,	)	
ALLERGAN USA, INC.	)	
	)	
and	)	
	)	
JOHN DOES 1-25.	)	
Defendant.	)	

FIRST AMENDED COMPLAINT

Plaintiff, Douglas M. Ray, Jr., moves for judgment against defendants Allergan, Inc., Allergan USA, Inc. and John Does 1-25 on the grounds and in the amount set forth below:

NATURE OF THE ACTION

l. Plaintiff was injured from use of Botox, a prescription injectable medication which was designed, developed, tested, licensed, manufactured, labeled, marketed, and sold by Allergan, Inc. and/or Allergan USA, Inc.

PARTIES

2. Plaintiff Douglas M. Ray is an individual who resides in Fredericksburg, Virginia. He received Botox injections for dystonic tremor and writer's cramp of the right hand from January through July 2007. With the third Botox treatment on July 17, 2007, Plaintiff sustained an acute severe immune reaction to the Botox requiring hospitalization three days later. The Botox reaction resulted in a devastating injury to Mr. Ray's brain leaving him totally disabled.

3. Defendant Allergan, Inc. is a Delaware corporation that has its principal place of business in the State of California.

4. Defendant Allergan USA, Inc. is a Delaware corporation that has its principle place of business in the State of California. Upon information and believe, it is a wholly owned subsidiary of and totally controlled by Allergan Inc.

5. Defendants Allergan Inc. and Allergan USA, Inc. will be collectively referred to herein as "Allergan."

6. Allergan designed, developed, manufactured, tested, marketed, promoted, distributed, and sold Botox. In doing so, Allergan placed the product in the stream of commerce in Virginia and throughout the United States. Allergan has received, and will continue to receive, substantial benefits and income through its activities. Allergan authorized the actions attributed to it herein through its officers, directors, and managing agents.

7. At all relevant times alleged herein, Defendant Allergan was in the business of researching, designing, developing, licensing, compounding, testing, producing, manufacturing, assembling, processing, packaging, inspecting, labeling, warranting, marketing, promoting, advertising, distributing, selling, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Botox.

8. At all times relevant hereto, Defendant Allergan designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold Botox in interstate commerce and in the City of Richmond, Virginia. Defendant conducted substantial business at this location in the City of Richmond, advertised Botox in this city, received substantial compensation and profits from sales of Botox in this city, and made material omissions and misrepresentations and committed breaches of warranties in this city.

9. A substantial part of the events or omissions giving rise to Plaintiff's claims occurred in City of Richmond, Virginia.

FACTUAL ALLEGATIONS

10. Upon information and belief, at all times relevant hereto, Allergan, by and through its employees, agents, affiliates, subsidiaries, and representatives, were involved in developing, designing, testing, manufacturing, and/or marketing Botox.

11. Defendant Allergan developed, designed, manufactures, and markets an injectable pharmaceutical known as Botox. Botox is Defendant Allergan's name for Botulinum Toxin Type A. Botulinum toxin is the most potent neurotoxin known to man. It is several hundred times stronger than cyanide. It has been researched by the United States Government as a biological weapon, and is considered to be one of the most toxic substances on the planet.

12. Botox's intended localized effect is to paralyze the muscle. It is approved by the United States Food and Drug Administration ("FDA") for certain therapeutic uses, such as to treat rare conditions known as cervical dystonia, strabismus and blepharospasm. Although its side effects were not widely known at the time Plaintiff was injected, Botox can migrate outside the injected muscles and cause side effects including botulism and severe autoimmune reactions with resulting brain damage.

13. Prior to July 2007, Allergan never disclosed in the United States in any warnings, promotional or marketing materials that Botox can spread outside the injected muscle and cause severe autoimmune responses and brain injury. Instead, Allergan sponsored Botox injection conferences for doctors and represents that Botox is "well-tolerated," "safe" and "effective." These Allergan sponsored medical conferences promote Botox as a panacea for over 100 ailments, including cerebral palsy, movement disorders, whiplash, and headaches. Allergan has publicly stated that Botox is a miracle drug and has often compared it to penicillin. Side effects are rarely mentioned and consistently understated.

14. Botox has limited FDA approval in the United States; it has been approved for treatment of strabismus, blepharospasm, cervical dystonia, and hyperhidrosis. However, the majority of Allergan's sales of Botox are "off-label," or in other words not approved by the FDA, and it heavily promotes Botox for a wide variety off-label uses including dystonic hand tremors and writer's cramp.

15. Botox is not approved by the FDA to treat dystonic hand tremors or writer's cramp, and therefore this use was a so-called "off-label" use of the product. Allergan has a corporate plan to illegally promote the off-label use of Botox by physicians. This plan includes encouraging physicians to use Botox for a wide variety of indications and never identifying in any meaningful fashion which are approved by the FDA. Allergan created and funded organizations such as the Neurotoxin Institute to promote Botox for off-label uses, including hand dystonia and writer's cramp. Allergan's sales representatives were specifically trained to refer doctors to the online neurotoxin education organization and to distribute "Awareness Cards," with the website's information on them, to all doctors during sales calls. Similarly, Allergan has established and funded an organization known as WE MOVE for the express purpose of promoting off-label use of its products. WE MOVE, at the direction of Allergan, has published numerous online and printed materials which encourage the off-label use of Botox including use for dystonic hand tremors and writer's cramp. Allergan also has funded and/or ghost-written numerous medical articles touting the benefits of Botox for off-label uses including dystonic hand tremors and writer's cramp. Additionally, Allergan sales representatives and other employees encourage off-label use by sponsoring Allergan dinners, Botox talks and Botox demonstrations for injecting physicians. Finally, Allergan encouraged off-label use by teaching injecting physicians and their staff how to get reimbursed for these non-approved uses by third-

party payors. Allergan recently plead guilty to off-label promotion and agreed to pay $600 million in civil and criminal penalties to the United States government.

16. More specifically, Allergan plead guilty to misbranding under 21 U.S.C. §331(a). Under this section, Allergan's labeling for Botox was presumptively inadequate. This section prohibits "introduction or delivery into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded." Under this statute, a product's labeling, which has a broad definition, must provide adequate directions for use. According to regulations, this means "directions under which the layman can use the drug safely and for the purposes for which it was intended." 21 C.F.R. § 201.5. Because Allergan intended that Botox be used for and actively promoted Botox to treat hand tremors, the off-label uses of Botox to treat hand tremors required proper labeling. Since the Botox labeling did not provide directions for hand tremors, the labeling is presumptively inadequate under the Food, Drug and Cosmetic Act.

17. Plaintiff Douglas M. Ray, Jr. is a 65-year-old male, married with two adult children, who resides in Spotsylvania County, Virginia. Prior to his Botox injuries, Mr. Ray was a high-functioning, articulate, retired telecommunications engineer, with a modest dystonic movement disorder of his right hand, but otherwise in good health.

18. As promoted by Allergan, Mr. Ray's physicians recommended Botox treatment for the dystonic movement disorder of his right hand. He received three series of Botox injuries. The first took place on January 10, 2007 when he received 80 units of Botox for therapeutic use. The second was on or about April 3, 2007, when he received 220 units of Botox, also for therapeutic reasons. On or about July 17, 2007, he received his third dosage, in the amount 235 units. Within hours after the third injection, Mr. Ray began to experience fatigue, weakness and fever, followed by a diffuse, pruritic rash.

19. His complications from the Botox injection required that he be admitted to the hospital on July 20, 2007 and his condition eventually progressed into a severe acute immune reaction, resulting in a significant and catastrophic injury to the brain.

20. As a consequence of Mr. Ray's Botox treatment, he has sustained a severe dementing encephalopathy, with devastating brain injury. Previously an articulate and high-functioning individual, he is now fully dependent on this wife and home nursing care givers for all activities of daily living. He cannot independently bath, shave or dress. He is incontinent of urine and wears adult diapers 24 hours a day. He needs assistance/support with walking. Frequently he needs assistance to feed himself. He is frequently confused or disoriented and therefore has difficulty communicating his thoughts.

21. These neurological deficits are thought to be permanent and life-long and are proximately due to the Botox treatment.

22. As a result of the Botox injections, Mr. Ray has suffered and will continue to suffer the following damages: past and future medical bills, past and future physical impairment, past and future pain and suffering, and mental anguish. Furthermore, as a result of said injuries, the plaintiff has received and in the future will continue to receive medical and hospital care and treatment furnished by the United States of America. The plaintiff, for the sole use and benefit of the United States of America, under the provisions of title 42, U.S.C. Sections 2651-2653, and with its expressed consent, asserts a claim for the reasonable value of said past and future care and treatment.

FIRST CAUSE OF ACTION: PRODUCT LIABILITY/FAILURE TO WARN (BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

23. The plaintiff repeats and re-alleges the allegations set forth above in the foregoing paragraphs as though fully stated herein, against Allergan.

24. Allergan wholly failed to warn the plaintiff and others that Botox: a) can cause brain damage and severe autoimmune reactions; b) can cause life-threatening systemic effects; c) can migrate out of the muscle(s) into which it is injected; d) has other serious side effects; e) has a dose related effect meaning the higher the dose the more likely side effects are to occur. Because of this failure-to-warn defect, Botox was unreasonably dangerous to an ordinary person, like plaintiff, who used Botox in a manner in which it was intended by Allergan to be used or in a manner in which Allergan could have reasonably foreseen. The risks of the Botox were known by Allergan or were reasonably scientifically knowable at the time Botox injured plaintiff.

25. An ordinary user of Botox would not foresee the risk of severe auto-immune reaction, brain injury or poisoning, or spread of toxin particularly in light of Allergan's intentional minimization of the risks of Botox.

26. The lack of sufficient warnings was a substantial factor in causing the plaintiff's injuries and damages. If Allergan had informed the plaintiff or plaintiff's health care providers of the known risks of Botox, they would have refused to use Botox.

27. As a direct and proximate result of the defects in Botox and the conduct of Allergan, Mr. Ray has suffered and will continue to suffer the following damages: past and future medical bills, past and future physical impairment, past and future pain and suffering and mental anguish. Furthermore, as a result of said injuries, the plaintiff has received and in the future will continue to receive medical and hospital care and treatment furnished by the United States of America. The plaintiff, for the sole use and benefit of the United States of America, under the provisions of title 42, U.S.C. Sections 2651-2653, and with its expressed consent, asserts a claim for the reasonable value of said past and future care and treatment.

SECOND CAUSE OF ACTION: PRODUCT LIABILITY/MANUFACTURING DEFECT (BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

28. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

29. Allergan is the manufacturer, distributor, and supplier of Botox. The product reached the plaintiff without a substantial change in its condition upon leaving the Defendant.

30. The Botox given to the plaintiff contained a defect in its manufacture. This defect in Botox existed at the time Botox left the possession and control of Allergan.

31. The defect in Botox caused it to fail during the time of use. This failure caused Plaintiff to suffer injuries and damages detailed herein.

32. Botox was used by Plaintiff in a manner foreseeable to Allergan.

33. As a direct and proximate result of the manufacturing defect in Botox and the conduct of the Allergan, Mr. Ray has suffered and will continue to suffer the following damages: past and future medical bills, past and future physical impairment, past and future pain and suffering and mental anguish. Furthermore, as a result of said injuries, the plaintiff has received and in the future will continue to receive medical and hospital care and treatment furnished by the United States of America. The plaintiff, for the sole use and benefit of the United States of America, under the provisions of title 42, U.S.C. Sections 2651-2653, and with its expressed consent, asserts a claim for the reasonable value of said past and future care and treatment.

THIRD CAUSE OF ACTION: NEGLIGENCE (BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

34. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

35. Defendant Allergan was negligent in designing and marketing Botox and such negligence was a proximate cause of injuries and damages to the plaintiff. Allergan, through its agents, employees and/or servants, designed, manufactured, produced, inspected, tested, maintained, sold and/or made Botox available to the plaintiff. The negligence on the part of Defendant Allergan included, but was not limited to: marketing and making available Botox to the plaintiff even though it was a dangerous, defective and deficient drug; and failing to provide Plaintiff and health-care providers with sufficient information as to the product's known dangers and risks, including severe autoimmune effects, brain damage and spread of toxin.

36. Defendant Allergan was negligent in designing Botox and such negligence was a proximate cause of injuries and damages to the plaintiff. Allergan, through its agents, employees and/or servants, designed, manufactured, produced, inspected, tested, maintained, sold and/or made available Botox to the plaintiff.

37. As a consequence of Allergan's negligence, careless conduct, and failure to exercise ordinary and reasonable care and caution, Mr. Ray has suffered and will continue to suffer the following damages: past and future medical bills, past and future physical impairment, past and future pain and suffering and mental anguish. Furthermore, as a result of said injuries, the plaintiff has received and in the future will continue to receive medical and hospital care and treatment furnished by the United States of America. The plaintiff, for the sole use and benefit of the United States of America, under the provisions of title 42, U.S.C. Sections 2651-2653, and with its expressed consent, asserts a claim for the reasonable value of said past and future care and treatment.

FOURTH CAUSE OF ACTON: BREACH OF IMPLIED WARRANTY
(BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

38. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

39. Prior to the time that Botox was used by the plaintiff, Allergan, through its agents, employees, subsidiaries, representatives and affiliates, impliedly warranted to the plaintiff and his health care providers that Botox was of a merchantable quality and safe and fìt for the use for which it was intended.

40. The plaintiff and his health care providers were, and remain, unskilled in the research, design, and manufacture of Botox and reasonably relied entirely on the skill, judgment, and implied warranty of Allergan in using the aforementioned Botox.

41. Allergan knew or had reason to know that the plaintiff and his physicians relied upon the skill and judgment of the defendant as a leader in the pharmaceutical industry to create, market, test, and sell a suitable and safe product.

42. Botox was neither safe for its intended use nor of merchantable quality, as warranted by Allergan, in that Botox had dangerous propensities when put to its intended use and would cause severe injuries to the user.

43. At the time it was manufactured and at all subsequent times, Botox was not as warranted, but was unfit for the particular purpose for which it was intended in that it was defective, causing the plaintiff to suffer damages and consequential damages.

44. As a result of Allergan's breach of the implied warranty of fitness for a particular purpose and the resulting dangers associated with the use of Botox, the plaintiff suffered the injuries and damages set forth above.

FIFTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY:
(BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

45. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

46. Allergan expressly warranted to the public and the plaintiff through his physicians that Botox was safe, effective, fit, and proper for its intended use through its advertising and marketing. Allergan also expressly warranted to the plaintiff that Botox was fit for off-label uses. Allergan did so through statements that it made orally and in publications, through Allergan-sponsored Botox conventions for medical professionals, package inserts, promotional and other written, oral, and electronically disseminated statements and materials provided to the medical trade journals and to massmarket publications.

47. The plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Allergan when he decided to use Botox. These warranties and representations were false since Botox was not safe and was unfit for the uses for which it was intended, among other things.

48. As a result of Allergan's breaches of warranty, the plaintiff suffered the injuries and damages as set forth above.

SEVENTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION (BY THE PLAINTIFF AGAINST ALL DEFENDANTS)

49. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

50. Defendant, from the time that Botox was first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to plaintiff, his health care providers, and the general public, including but not limited to the misrepresentation that Botox was safe, fit, and effective for human consumption.

51. At all times relevant hereto, Allergan conducted a sales and marketing campaign to promote the sale of Botox and willfully deceived the plaintiff, his health care providers, and the general public as to the health risks and consequences of the use of Botox. Defendant made the following misrepresentations without any reasonable ground for believing them to be true:

a. Representing to the plaintiff, his physicians, and the general public that Botox was safe, fit, and effective for human consumption, knowing that said representations were false, and concealing from each user, their physicians, and the general public that Botox had a serious propensity to cause injuries to users;

b. Engaging in an advertising program and media campaign designed to create the image, impression and belief by consumers and physicians that the use of Botox was safe for a variety of therapeutic and cosmetic uses and concealing its poisonous properties, even though the Defendant knew these representations to be false, and even though the Defendant had no reasonable grounds to believe Botox was safe for the general public;

c. Purposely downplaying and understating the health hazards and risks associated with Botox;

d. Issuing promotional literature and commercials and conducting mass-media and news promotional interviews deceiving potential users of Botox by relaying positive information, including manipulating and/or omitting statistics to suggest widespread acceptability and safety, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Botox; and

e. Representing that Botox cannot spread to sites distant to the site of injection, cannot cause severe autoimmune reactions, cannot cause brain damage, and cannot adversely affect the central nervous system.

52. These misrepresentations were made directly by Defendant, by sales representatives and other authorized agents of said Defendant, and in publications, mass media outlets, and other written materials directed to physicians, patients, and the general public, with the intention of inducing reliance and the prescription, purchase, and use of Botox. Allergan has previously represented in its advertisements to the general public that Botox has a 25-year track record of safety and likening the toxin to the discovery of penicillin. In addition, Defendant's most recent advertising campaign regarding Botox, "Express Yourself," fails to mention the topic of safety. Allergan refers to its product as "purified," which is intended to misrepresent that Botox is in actuality a highly lethal poison that can cause spread to sites distant from the site of injection and cause brain damage and severe auto immune reactions.

53. Allergan sponsors Botox conferences for physicians and medical professionals numerous times every year. Allergan represents that Botox is "safe" and "well-tolerated" for all of these purposes, despite knowing that said representations are unsubstantiated and often false, and, meanwhile, conceals from physicians and the general public, and ultimately each user, that Botox has serious propensity to cause injuries to users.

54. The foregoing representations by Defendant were in fact false, in that Botox is not safe, fit, and effective for human consumption, the use of Botox is hazardous to health, and Botox has significant propensity to cause serious injuries to users, including but not limited to the injuries suffered by the Plaintiff as described above. The foregoing misrepresentations by

Defendant were made with the intention of inducing reliance and the prescription, purchase, and use of Botox.

55. In reliance on the misrepresentations by Defendant, the plaintiff was induced to purchase and use Botox, and his health care providers were induced to prescribe it. If each of them had known of the true facts and the facts concealed by Defendant, the plaintiff would not have used Botox and his health care providers would not have prescribed it. Their reliance upon Defendant's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

56. As a result of the foregoing negligent misrepresentations by Defendant, the plaintiff suffered injuries and damages as described above.

PUNITIVE DAMAGES ALLEGATIONS

57. The plaintiff repeats and re-alleges the allegations set forth in the foregoing paragraphs as though fully stated herein.

58. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint, were willful and malicious and were done with a conscious disregard for the rights of the Plaintiff and other recipients of Botox and for the primary purpose of increasing Defendant's profits from the sale, marketing and distribution of Botox. Defendant's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendant in an amount appropriate to punish and make an example of Defendant Allergan.

59. Prior to the manufacturing, marketing, sale and distribution of said prescribed medication, Defendant knew that said toxin was in a defective condition as previously described herein and knew that those who were prescribed the toxin would experience and did experience severe physical, mental, and emotional injuries. Further, Defendant, through its officers,

directors, managers, and agents, had knowledge that the prescription toxin presented a substantial and unreasonable risk of harm to the public, including the plaintiff and as such, said consumers of Botox were unreasonably subjected to risk of injury or death.

60. Despite such knowledge, Defendant, acting through its officers, directors, and managing agents for the purpose of enhancing Defendant's profits, knowingly and deliberately failed to remedy the known defects in Botox and failed to warn the public, including the Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Botox. Defendant and its individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of Botox knowing that the public, including the plaintiff, would be exposed to serious danger in order to advance Defendant's pecuniary interests and monetary profits.

61. Defendant acted with oppression, fraud and malice in that Defendant knew or had reason to know prior to plaintiff's use specified herein that Botox was unreasonably dangerous and intentionally misrepresented or concealed this fact from plaintiff and his health care providers. Defendant acted with full awareness of the harm that could result and as a consequence, is liable for punitive damages.

RELIEF REQUESTED

WHEREFORE, the Plaintiff prays for judgment against Defendant Allergan, Inc., and as appropriate to each cause of action alleged and as appropriate to the standing of the plaintiff as follows:

1. Past and future general damages, past and future economic and special damages, past and future medical expenses, and past and future pain and suffering and mental anguish in an amount not to exceed twenty million dollars.
2. Punitive or exemplary damages not to exceed three hundred and fifty thousand dollars;

3. Costs of suit incurred herein;

4. Pre-judgment interest as provided by law; and

5. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, by his undersigned counsel, hereby demands a trial by jury on all counts in this Complaint and all issues so triable.

DOUGLAS M. RAY, JR.

By /s/
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CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of December, 2010, I will electronically file the foregoing document with the Clerk of the Circuit court using the CM/ECF system, which will then send notification of such filing to the following:

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By /s/