$400 CFK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MARY ANNE LAPORTE,

Plaintiff,

v.

ALLERGAN USA, INC.,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No. 18 5092

FILED
NOV 23 2018
KATE BARKMAN, Clerk
By_____ Dep. Clerk

COMPLAINT

COMES NOW, Plaintiff, by and through the undersigned counsel, and brings this complaint against Defendant and alleges as follows:

1. This Complaint is brought on behalf of Plaintiff, MARY ANNE LAPORTE, who suffered damages as a direct and proximate result of the negligent and wrongful misconduct of Defendant, ALLERGAN USA, INC. (hereinafter referred to as "Defendant") in connection with the research, testing, development, design, licensing, manufacture, packaging, labeling, distribution, sale, marketing, and/or introduction into interstate commerce of Viberzi (eluxadoline). As a result of ingestion of Viberzi, Plaintiff MARY ANNE LAPORTE (hereinafter referred to as "Plaintiff") was caused to suffer acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for future medical treatment and follow-up.

JURISDICTION AND VENUE

2. The Court has jurisdiction over this action pursuant to 28 U.S.C §1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and the Defendant as Defendant is incorporated and has their principal place of business in a state other than Plaintiff's home state of Pennsylvania.

3. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. §1367.

4. Further, a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this district. Pursuant to 28 U.S.C. §1391, venue is proper in this district.

PARTIES: PLAINTIFFS

5. Plaintiff is a citizen of the United States of America, and a resident of Bethlehem, Pennsylvania.

6. Upon information and belief, Plaintiff was prescribed, used and ingested Viberzi.

7. Upon information and belief, the injuries and damages sustained by Plaintiff were caused by Defendant' drug Viberzi.

8. Upon information and belief, Plaintiff read magazines, newspapers, and watched television and other media, all of which communicated Defendant's Viberzi advertisements which minimized the risks of Viberzi and overstated its benefits and indications, all of which shaped Plaintiff's favorable perception of Viberzi.

9. As a result of using and ingesting Viberzi, Plaintiff was caused to suffer serious injuries.

PARTIES: DEFENDANT

10. Defendant Allergan USA, Inc. is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

11. Upon information and belief, and at all relevant times, Defendant was engaged in the business of researching, testing, developing, designing, licensing, manufacturing, packaging, labeling, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Viberzi.

12. Upon information and belief, and at all relevant times, Defendant conducted regular and sustained business in Pennsylvania by selling and distributing its products in Pennsylvania, and engaged in substantial commerce and business activity in Pennsylvania.

FACTUAL BACKGROUND

13. This is an action against Defendant on behalf of Plaintiff, who was prescribed the drug Viberzi which is indicated for the treatment of irritable bowel syndrome with diarrhea.

14. Plaintiff ingested the prescribed dosage of Viberzi in accordance with the prescription written for Plaintiff.

15. Viberzi causes serious and sometimes fatal injuries including, but not limited to, acute pancreatitis and its sequelae.

16. At all times relevant herein, Defendant, either directly or through their agents, servants and employees, designed, manufactured, marketed, advertised, distributed and sold Viberzi for the treatment of irritable bowel syndrome with diarrhea.

17. Persons who were prescribed and ingested Viberzi, including Plaintiff, have suffered serious and permanent personal injuries.

18. Viberzi is a mu-opiod receptor agonist indicated in adults for the treatment of

irritable bowel syndrome with diarrhea. It was approved for use in May 2015.

19. Acute pancreatitis is a sudden inflammation of the pancreas. Pancreatitis can cause serious complications, including infection, kidney failure, respiratory failure, diabetes and pancreatic cancer.

20. Acute pancreatitis is diagnosed by medical history, physical examination, and blood test for digestive enzymes of the pancreas (amylase and lipase). Imaging may also be utilized.

21. While acute pancreatitis may be suspected in patients with severe acute upper abdominal pain, a diagnosis cannot be established without biochemical or radiologic evidence.

22. Despite their collective resources, Defendant failed to fully and adequately test or research Viberzi and its association with pancreatitis to the detriment of Plaintiff, Viberzi users, the public, the medical community, and prescribing doctors.

23. Upon information and belief, Defendant failed to design and/or implement clinical trials that would capture and analyze data to determine the incidence of acute pancreatitis in those patients with and without gallbladders.

24. Upon information and belief, Defendant did not require biochemical or radiological testing to confirm suspected instances of acute pancreatitis during clinical trials.

25. Upon information and belief, Defendant did not enforce required biochemical or radiological testing to confirm suspected instances of acute pancreatitis during clinical trials.

26. The lack of biochemical or radiological testing during the clinical trials led to undiagnosed instances of pancreatitis, resulting in misleading and inaccurate trial results.

27. For example, during the clinical trial phase, there were at least 40 instances of abdominal pain that led to trial discontinuation after starting Viberzi. Approximately half of

those events occurred within 24 hours of Viberzi initiation. Of the approximately 40 with abdominal pain, the vast majority lacked biochemical or radiological testing to determine if the patient suffered from acute pancreatitis.

28. For example, during the clinical trial phase, there were 484 adverse events identified as possibly related to Sphincter of Oddi spasms (SOD). At least 47 lacked biochemical or radiological testing to determine whether the SOD clinical symptoms were actually instances of pancreatitis. Of the 484, only 37 were reviewed by a specialized committee. Of the 37, 18 (~half) were categorized as pancreatitis or biliary events. All 18 had taken Viberzi.

29. Properly designed and executed clinical trials would have led the original May 2015 label to contraindicate use in patients without gallbladders. Because the FDA did not have the benefit of data from adequately designed and executed clinical trials, it did not require contraindication in patients without a gallbladder.

30. The original May 2015 Viberzi Prescribing Label provided for two dosing regimens: 1) 100 mg twice daily; and 2) 75 mg twice daily for those patients who, inter alia, do not have a gallbladder.

31. On March 15, 2017, the FDA issued a Drug Safety Communication advising Viberzi should not be prescribed for patients without a gallbladder due to the risk of pancreatitis that could result in hospitalization or death. The FDA communication discussed 120 serious cases of pancreatitis, 27 of which resulted in hospitalization and 2 in death. The FDA noted that of the 84 cases reporting a time to onset, 48 occurred after only one or two doses of Viberzi.

32. On April 17, 2017, the Viberzi Prescribing Label was changed to contraindicate Viberzi use in patients without a gallbladder.

33. Plaintiff was 60 years old when she was prescribed Viberzi in December of 2016.

34. At the time of Plaintiff's prescription, the Viberzi label contained no contraindication for patients without gallbladders.

35. Plaintiff had previously undergone a cholecystectomy.

36. Prior to December 2016, Defendant knew or should have known that Viberzi use in patients without gallbladders could cause or was causally associated with acute pancreatitis.

37. Prior to December 2016, Defendant had received numerous spontaneous reports of acute pancreatitis and/or SOD, the vast majority of which were dosed at 75 mg, indicating use by patients with prior cholecystectomies.

38. Prior to December 2016, the European Medicines Agency (EMA) informed Defendant that it would contraindicate Truberzi (the company's name for Viberzi in Europe) use in patients without a gallbladder. Discussing the decision on July 21, 2016, the EMA noted:

> A more confident conclusion that the occurrence of SO-spasm events can be reduced can be drawn if cholecystectomy is labeled as a contraindication because no such event was observed in a population with intact biliary tract. . . . Given the limited clinical relevance of the efficacy results, all populations at increased risk of SO-spasm and pancreatitis (with previous such disease, high alcohol intake and without gall-bladder) are consequently excluded from the treatment. This assumption has found preliminary confirmation through the evaluation of the early post-marketing data from the US (where no such contra-indication is imposed) and which show reports of pancreatitis and/or SO-spasm events, with their overwhelming majority affecting patients without gall-bladder.

39. Plaintiff began her usage of Viberzi on December 2, 2016. She was admitted to St. Luke's Hospital (Bethlehem, Pennsylvania) on December 4, 2016. Lab tests and imaging confirmed pancreatitis.

40. Plaintiff remained hospitalized for two days. She was discharged on December 5, 2016. Viberzi was discontinued as it was believed to be the cause of Plaintiff's event.

41. Plaintiff continues to suffer health consequences from her initial pancreatic event.

42. An episode of pancreatitis increases a patient's risk that she will later develop pancreatic cancer. Fear of developing pancreatic cancer subsequent to pancreatitis is reasonable.

43. Plaintiff remains at an increased risk for recurrent acute pancreatitis and/or chronic pancreatitis and pancreatic cancer, which she fears, and she continues to be monitored for health issues.

FEDERAL REQUIREMENTS

44. Defendant had an obligation to comply with the law in the manufacture, design, and sale of Viberzi.

45. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

46. With respect to Viberzi, the Defendant, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs, including, but not limit to, one or more of the following violations:

(a) Viberzi is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false and/or misleading;

(b) Viberzi is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. §352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(c) Viberzi is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

(d) Viberzi is misbranded pursuant to 21 U.S.C. §352 because it is dangerous to patient health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(e) Viberzi does not contain adequate directions for use pursuant to 21 CFR §201.5 because, among other reasons, the omission, in whole or in part, or incorrect specification of (1) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used, (2) quantity of dose, including usual

quantities for each of the uses for which it is intended and usual quantities for persons of different physical conditions, (3) frequency of administration or application, (4) duration of administration or application, and/or (5) route or method of administration or application;

(f) Defendant violated 21 CFR §201.56 because the labeling was not informative and accurate;

(g) Viberzi is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available causing the labeling to become inaccurate, false, and/or misleading;

(h) Defendant violated 21 CFR §201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Viberzi causing pancreatitis;

(i) Defendant violated 21 CFR §201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took Viberzi;

(j) Viberzi is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

(k) Viberzi violates 21 CFR §210.122 because the labeling and packaging materials do not meet the appropriate specifications;

(l) Viberzi violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding

Viberzi were not followed;

(m) Viberzi violates 21 CFR §310.303 because Defendant failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

(n) Defendant violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associate with Viberzi as soon as possible or at least within 15 days of the initial receipt by Defendant of the adverse drugs experience;

(o) Defendant violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associate with Viberzi, and evaluating the cause of the adverse event;

(p) Defendant violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

(q) Defendant violated 21 CFR §312.32 because they failed to review all information relevant to the safety of Viberzi or otherwise received by Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from

foreign regulatory authorities that have not already been previously reported to the agency by the sponsor; and

(r) Defendant violated 21 CFR §§314.80 by failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

47. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendant liable under Pennsylvania law.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

48. The running of any statute of limitation has been tolled by reason of Defendant's fraudulent conduct. Defendant, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with taking Viberzi.

49. As a result of Defendant's actions, Plaintiff and Plaintiff's prescribing physicians were unaware and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendant's acts and omissions.

50. Furthermore, Defendant is estopped from relying on any statute of limitations because of their fraudulent concealment of the truth. Defendant was under a duty to disclose the true character, quality and nature of Viberzi because this was non-public information over which Defendant had and continue to have exclusive control, and because Defendant knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or to Plaintiff's health facilities. In addition, Defendant is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

51. Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendant, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and Plaintiff's medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendant's representations.

COUNT ONE: NEGLIGENCE

52. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

53. Defendant had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of Viberzi, including a duty to assure that Viberzi did not cause unreasonable, dangerous side-effects to users.

54. Defendant failed to exercise ordinary care in the manufacture, labeling, sale,

marketing, quality assurance, quality control and distribution of Viberzi into the stream of commerce, in that the Defendant knew or should have known that the drug created a high risk of unreasonable harm in patients without gallbladders.

55. The negligence of the Defendant, their agents, servants and/or employees included, but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, developing, designing, assembling, selling and distributing Viberzi without thorough and adequate testing;

(b) Manufacturing, producing, promoting, advertising, formulating, creating, developing, designing, assembling and distributing Viberzi while concealing and suppressing test results;

(c) Not conducting sufficient studies and tests to determine whether Viberzi was safe for its intended use, because Defendant knew or had reason to know that Viberzi was indeed unsafe and unfit for use by reason of the dangers it presents to users;

(d) Failing to warn Plaintiff, the medical and healthcare community, including Plaintiff's physicians, the general public, and/or the FDA as soon as Defendant knew or should have known of the dangers of the use of Viberzi in patients without gallbladders;

(e) Concealing, suppressing, failing to warn about and/or failing to follow up on the adverse results of clinical testing that occurred, which indeed indicated that Viberzi had a high risk of serious and dangerous adverse health effects and consequences;

(f) Failing to provide a contraindication for the use of Viberzi in patients without gallbladders;

(g) Advertising and recommending the use of Viberzi while suppressing and concealing its known dangers;

(h) Representing that Viberzi was safe for its intended use when it was actually unsafe for its intended purpose in patients without gallbladders;

(i) Suppressing, concealing, omitting and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of Viberzi in patients without gallbladders; and

(j) Failing to conduct adequate post-marketing surveillance to determine the safety of Viberzi, failing to comply with post-marketing requirements of FDA regulations, failing to perform adequate Pharmacovigilance, and otherwise careless or negligent acts.

56. Defendant' conduct, as described above, was extreme and outrageous. Defendant risked the lives of consumers and users of Viberzi, including Plaintiff, by suppressing this knowledge from the general public.

57. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendant, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendant individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT TWO:
NEGLIGENT MISREPRESENTATION

58. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

59. Defendant had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that Viberzi had been tested and found to be safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea. The representations made by Defendant, in fact, were false.

60. Defendant failed to exercise ordinary care in the representations concerning Viberzi while they were involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented Viberzi was safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea.

61. Defendant breached their duty in representing that Viberzi was safe and effective for all persons who suffered from irritable bowel syndrome with diarrhea.

62. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendant, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and

continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendant individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

COUNT THREE: PUNITIVE DAMAGES

63. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

64. Viberzi was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed and released into the stream of commerce by Defendant after Defendant knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Viberzi in patients without gallbladders.

65. The acts, conduct, and omissions of Defendant as alleged throughout this Complaint were willful and malicious. Defendant committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Viberzi users and for the primary purpose of increasing Defendant's profits from the sale and distribution of Viberzi. 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.

66. Prior to the manufacturing, sale, and distribution of Viberzi, Defendant knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical,

mental, and emotional injuries. Further, Defendant, through their officers, directors, managers and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using Viberzi.

67. Despite its 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 Viberzi and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Viberzi. Defendant and their agents, officers and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of Viberzi knowing these actions would expose persons to serious danger in order to advance Defendant's pecuniary interest and monetary profits.

68. The aforesaid conduct of Defendant was committed with knowing, conscious indifference, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter them from similar conduct in the future.

69. Defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, and/or the entire want of care raises the presumption of conscious indifference to the consequences.

70. When warning of risks of Viberzi, Defendant recklessly and/or fraudulently represented to the medical and healthcare community, the FDA, Plaintiff and the public in general that Viberzi had been tested and was found to be safe and/or effective for its indicated use, including in patients without gallbladders.

71. Defendant concealed their knowledge of Viberzi's defects from Plaintiff, the

FDA, the public in general and/or the medical community specifically.

72. Defendant maliciously concealed their knowledge of the defects in Viberzi from Plaintiff and Plaintiff's physicians, hospitals, pharmacists, the FDA and the public in general.

73. Defendant knowingly withheld or misrepresented information required to be submitted under the FDA's regulations, which information was material and relevant to the harm in question.

74. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendant, Plaintiff was caused to suffer from acute pancreatitis, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

WHEREFORE, Plaintiff demands judgment against the Defendant individually, jointly and/or severally and demand compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

a. Awarding compensatory damages resulting from Defendant's violation of their duties;

b. Awarding compensatory damages resulting from Defendant's breach of warranties;

c. Awarding medical monitoring damages to Plaintiff;

d. Awarding actual damages to Plaintiff incidental to Plaintiff's purchase and use of Viberzi in an amount to be determined at trial;

e. Awarding punitive damages to Plaintiff;

f. Awarding pre-judgment and post-judgment interest to Plaintiff;

g. Awarding the costs and the expenses of litigation to Plaintiff;

h. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

i. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: November 20, 2018

/s/ Scott D. Levensten
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PRO HAC VICE TO BE SUBMITTED

Attorneys for Plaintiff

CFK

5:18-5092

JS 44 (Rev 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Mary Anne LaPorte

DEFENDANTS
Allergan USA, Inc

18 5092

(b) County of Residence of First Listed Plaintiff Northhampton, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Morris, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for Nature of Suit Code Descriptions

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☒ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise				☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application		☐ 893 Environmental Matters
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	FEDERAL TAX SUITS	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 896 Arbitration
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 871 IRS—Third Party 26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*
28 U.S.C. 1332

Brief description of cause

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)* JUDGE — DOCKET NUMBER

NOV 23 2018

DATE 11/20/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Scott D. Levensten SDL3792

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG JUDGE NOV 23 2018

NOV 23 2018

JS 44 Reverse (Rev 06/17)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows.

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553. Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

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CFK

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

18 5092

DESIGNATION FORM
(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 400 Bridle Path Road, Apt TH41, Bethlehem, PA 18017

Address of Defendant: 5 Giralda Farms, Madison, New Jersey 07940

Place of Accident, Incident or Transaction: Bethlehem, PA

RELATED CASE, IF ANY:

Case Number _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions.

1 Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes ☐ No ☑

2 Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes ☐ No ☑

3 Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? Yes ☐ No ☑

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes ☐ No ☑

I certify that, to my knowledge, the within case ☐ is / ☑ is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE 11/23/18 Scott Levensten PA 70122

Attorney-at-Law / Pro Se Plaintiff *Attorney I D # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
☐ 2 FELA
☐ 3. Jones Act-Personal Injury
☐ 4. Antitrust
☐ 5. Patent
☐ 6 Labor-Management Relations
☐ 7. Civil Rights
☐ 8 Habeas Corpus
☐ 9 Securities Act(s) Cases
☐ 10 Social Security Review Cases
☐ 11 All other Federal Question Cases
(Please specify) _____

B. Diversity Jurisdiction Cases:

☐ 1. Insurance Contract and Other Contracts
☐ 2 Airplane Personal Injury
☐ 3. Assault, Defamation
☐ 4 Marine Personal Injury
☐ 5. Motor Vehicle Personal Injury
☑ 6. Other Personal Injury *(Please specify)* Viberzi Injury ition drug injury - prescription drug
☐ 7. Products Liability
☐ 8. Products Liability Asbestos
☐ 9. All other Diversity Cases
(Please specify) _____

ARBITRATION CERTIFICATION
(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Scott Levensten, counsel of record *or* pro se plaintiff, do hereby certify

☑ Pursuant to Local Civil Rule 53 2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000 00 exclusive of interest and costs.

☐ Relief other than monetary damages is sought.

DATE 11/21/2018 PA 70122

Attorney-at-Law / Pro Se Plaintiff *Attorney I D # (if applicable)*

NOTE A trial de novo will be a trial by jury only if there has been compliance with F R C P 38

Civ 609 (5/2018)

NOV 23 2018

CFK

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Mary Anne LaPorte

v.

Allergan, USA, Inc

AN

CIVIL ACTION

18 5092

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

11/21/18	Scott Lerenstein	Mary Anne LaPorte
Date	**Attorney-at-law**	**Attorney for**
215-545-5600	215-545-5156	SDL@LerensteinLawFirm.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

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Civil Justice Expense and Delay Reduction Plan
Section 1:03 - Assignment to a Management Track

(a) The clerk of court will assign cases to tracks (a) through (d) based on the initial pleading.

(b) In all cases not appropriate for assignment by the clerk of court to tracks (a) through (d), the plaintiff shall submit to the clerk of court and serve with the complaint on all defendants a case management track designation form specifying that the plaintiff believes the case requires Standard Management or Special Management. In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

(c) The court may, on its own initiative or upon the request of any party, change the track assignment of any case at any time.

(d) Nothing in this Plan is intended to abrogate or limit a judicial officer's authority in any case pending before that judicial officer, to direct pretrial and trial proceedings that are more stringent than those of the Plan and that are designed to accomplish cost and delay reduction.

(e) Nothing in this Plan is intended to supersede Local Civil Rules 40.1 and 72.1, or the procedure for random assignment of Habeas Corpus and Social Security cases referred to magistrate judges of the court.

SPECIAL MANAGEMENT CASE ASSIGNMENTS
(See §1.02 (e) Management Track Definitions of the Civil Justice Expense and Delay Reduction Plan)

Special Management cases will usually include that class of cases commonly referred to as "complex litigation" as that term has been used in the Manuals for Complex Litigation. The first manual was prepared in 1969 and the Manual for Complex Litigation Second, MCL 2d was prepared in 1985. This term is intended to include cases that present unusual problems and require extraordinary treatment. See §0.1 of the first manual. Cases may require special or intense management by the court due to one or more of the following factors: (1) large number of parties; (2) large number of claims or defenses; (3) complex factual issues; (4) large volume of evidence; (5) problems locating or preserving evidence; (6) extensive discovery; (7) exceptionally long time needed to prepare for disposition; (8) decision needed within an exceptionally short time; and (9) need to decide preliminary issues before final disposition. It may include two or more related cases. Complex litigation typically includes such cases as antitrust cases; cases involving a large number of parties or an unincorporated association of large membership; cases involving requests for injunctive relief affecting the operation of large business entities; patent cases; copyright and trademark cases; common disaster cases such as those arising from aircraft crashes or marine disasters; actions brought by individual stockholders; stockholder's derivative and stockholder's representative actions; class actions or potential class actions; and other civil (and criminal) cases involving unusual multiplicity or complexity of factual issues. See §0.22 of the first Manual for Complex Litigation and Manual for Complex Litigation Second, Chapter 33.