**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF KENTUCKY**
**CENTRAL DIVISION**

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| CATHY ROMERO,<br><br>Plaintiff,<br><br>v.<br><br>PFIZER, INC. ,<br><br>Defendant. | ) | **CASE NO.**<br><br>**COMPLAINT**<br><br>**DEMAND FOR JURY TRIAL** |

1. This is an action brought by Cathy Romero ("Plaintiff" or "Ms. Romero") against Pfizer, Inc. ("Defendant" or "Pfizer") to recover damages for severe injuries including a stroke caused by her ingestion of Pfizer's pharmaceutical drug Xeljanz.

2. Pfizer entirely failed its duty to adequately warn of the hazards of Xeljanz which was a direct and proximate cause of Ms. Romero's injuries and associated damages.

3. Pfizer designed a defective product in Xeljanz that was unreasonably dangerous to consumers and that was a direct and proximate cause of Ms. Romero's injuries and associated damages.

4. Pfizer's conduct was fraudulent and constitutes gross negligence.

5. Ms. Romero thus brings this action to recovery compensatory and punitive damages as well as all other damages available at law.

## PARTIES

6. Ms. Romero is a citizen of the United States and the State of Kentucky and resides in Shelby County.

7. Pfizer is a corporation incorporated in the State of Delaware with its principal place of business in the State of New York.

## FACTUAL ALLEGATIONS

### A. Pfizer is the manufacturer of Xeljanz.

8. Pfizer is a corporation in the business of researching, designing, developing, testing, manufacturing, marketing, selling, and distributing pharmaceutical drugs.

9. Pfizer researched, designed, developed, tested, manufactured, marketed, sold, and distributed Xeljanz as a pharmaceutical treatment for patients with rheumatoid arthritis throughout the United States, including Kentucky.

10. Pfizer still researches, develops, tests, manufactures, markets, sells, and distributes Xeljanz as a pharmaceutical treatment for patients with rheumatoid arthritis throughout the United States, including Kentucky.

11. Pfizer has earned billions of dollars from its sales of Xeljanz.

12. "There is an inherent tension between the desire for profit and scientific decisions that suggest warnings may well shrink the customer base because of the cautionary tone struck by the warnings." *Hodges v. Pfizer, Inc.*, 14-cv-4855, 2015 WL 13804602, at *10 (D. Minn. Dec. 17, 2015).

13. Pfizer prioritized its desire for profits over its duties to give complete and adequate warnings regarding the hazards of its drug Xeljanz.

### B. Xeljanz was subject to the FDCA and FDA regulations before it was sold to patients.

14. The Food, Drug, and Cosmetic Act ("FDCA") requires manufacturers developing a new drug to file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") before marketing a drug or selling it in interstate commerce. 21 U.S.C. § 355.

15. Essentially, the FDCA requires that the manufacturer prove that the drug is safe and effective and that the proposed label is accurate and adequate. 21 U.S.C. § 355(b)(1), (d).

16. The FDA must approve the NDA before the drug can be sold in interstate commerce. 21 U.S.C. § 355.

17. Within the NDA, the manufacturer must submit the labeling proposed to be used for the drug. 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i).

18. The drug's label is required to include, among other things:

- prominent "boxed" warnings about risks that may lead to death or serious injury;
- contraindications describing any situation in which the drug should not be used because the risk of use outweighs any therapeutic benefit;
- warnings and precautions about other potential safety hazards; and
- any adverse reactions for which there is some basis to believe a causal relationship exists between the drug and the occurrence of the adverse event. 21 C.F.R. § 201.57(c).

19. Pfizer filed their NDA for Xeljanz with the FDA in December 2011 seeking approval to sell the drug to adult patients with moderate to severely active rheumatoid arthritis.

20. On November 6, 2012, the FDA approved Pfizer's Xeljanz NDA so that the 5 mg dose could be prescribed twice daily to treat rheumatoid arthritis.

21. In February 2016 the FDA approved Xeljanz XR for treatment of rheumatoid arthritis.

22. In 2017, the FDA approved Xeljanz for treatment of psoriatic arthritis.

23. In 2018, the FDA approved Xeljanz so that the 10 mg dose could be prescribed twice daily to treat ulcerative colitis.

**C. Pfizer was required and capable under the law to change its label.**

24. A "central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times." *Wyeth v. Levine*, 555 U.S. 555, 570-71, 129 S.Ct. 1187, 173 L.Ed.2d 41 (2009).

25. The manufacturer is "charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 571, 129 S.Ct. 1187, 173 L.Ed.2d 41 (2009).

26. While a drug is already on the market, a manufacturer may file a Prior Approval Supplement ("PAS") with the FDA requesting a change to the drug's label.

27. The FDA will review the PAS and determine whether the label change is appropriate.

28. Rather than filing a PAS and awaiting a decision from the FDA, a manufacturer of a drug may act under the Changes Being Effected ("CBE") regulation to immediately change its label without FDA approval.

29. The CBE regulation allows the manufacturer to include a warning about a clinically significant hazard as soon as there is reasonable evidence of the hazard's causal association with the drug. The causal relationship does not have to have been definitively established. 21 C.F.R. § 201.57(c)(6).

30. The CBE regulation also allows the manufacturer to add or strengthen a contraindication, warning, precaution, or adverse reaction. 21 C.F.R. § 314.70(c)(6)(iii)(A).

31. Finally, the CBE regulation allows the manufacturer to add or strengthen an instruction about dosage and administration so to increase the safe use of the drug. 21 C.F.R. § 314.70(c)(6)(iii)(C).

32. The FDA is simply notified of this label change through a supplemental submission made by the manufacturer. 21 C.F.R. § 314.70(c)(6)(iii).

33. The amended label will then be reviewed by the FDA and will be approved if it is based on new reasonable evidence of a causal association with the drug and a clinically significant hazard. 21 C.F.R. § 201.57(c)(6)(i).

34. The FDA can also act on its own initiative to require a label change if it becomes aware of new information that should be included on the drug's label.

**D. Ms. Romero was prescribed Xeljanz and later suffered a stroke.**

35. Ms. Romero was born in 1964.

36. Ms. Romero was diagnosed with rheumatoid arthritis in or about March 2017.

37. Ms. Romero has been a smoker since she was a teenager.

38. Ms. Romero was first prescribed Xeljanz from August to October 2019 by her rheumatologist.

39. Ms. Romero was again prescribed Xeljanz on February 28, 2020 and took the medication until April 17, 2021.

40. Ms. Romero purchased, ingested, and was injured by the drug Xeljanz in Shelby County.

41. On April 17, 2021 Ms. Romero experienced complete numbness on the right side of her body and collapsed on the floor.

42. She was rushed to the hospital by ambulance and was quickly brought into the operating room for surgery as she had been diagnosed with a stroke.

43. After the surgery she regained use of the right side of her body.

44. She spent three days in the hospital.

45. Immediately after her stroke she was advised to discontinue her use of Xeljanz.

46. Prior to her stroke, Ms. Romero was never warned that Xeljanz could cause a stroke.

47. Ms. Romero's stroke and associated damages were caused by her ingestion of Xeljanz.

48. Ms. Romero still suffers from the consequences of her stroke today including physical limitations and limitations with regards to her memory.

**E. Xeljanz is sold as a treatment for rheumatoid arthritis.**

49. At the time of its approval, Xeljanz was a new molecular entity.

50. Xeljanz was the first drug in its class as a Janus associated kinase (JAK) inhibitor designed to treat rheumatoid arthritis.

51. In simple terms, rheumatoid arthritis is a chronic condition in which the body's immune system attacks its own tissue, typically joint tissue, leading to swelling, pain, and eventually bone erosion and joint deformity.

52. Cytokines are proteins that are active in the signaling of the body's immune system.

53. JAK inhibitors like Xeljanz attempt to decrease cytokine proteins in the body of rheumatoid arthritis patients to suppress their immune systems and reduce its attack of joint tissue.

**F. Information regarding the dangers of Xeljanz was known to Pfizer and should have prompted a change to its warning label.**

54. Pfizer conducted multiple safety and dose ranging studies prior to submitting its NDA to the FDA. These studies were relied upon by the FDA in determining whether to allow Pfizer to sell their dangerous drug to Americans with rheumatoid arthritis.

55. In first reviewing Pfizer's NDA, the FDA identified numerous limitations in the referenced datasets and methods utilized by Pfizer that limited precise quantification of the risks of Xeljanz.

56. Rather than approving the NDA, the FDA worked with Pfizer to conduct further focused safety analyses, pooling results from a number of studies.

57. Pfizer conducted the additional safety analyses and submitted the results as major amendments to its NDA in August of 2012.

58. Even after all of Pfizer's work with the FDA, the FDA found that the pre-marketing clinical trial experience of Xeljanz may not be sufficient to capture the full extent of safety concerns that may arise with long-term use.

59. The FDA concluded that uncertainty remained regarding the cardiovascular safety of patients taking Xeljanz due to observed lipid profile alterations.

60. Pfizer's premarketing data showed that treatment with Xeljanz is associated with an increase in cholesterol levels, which raised the FDA's concern of an increase in cardiovascular adverse events for those taking the drug.

61. The FDA determined that analyzing spontaneous adverse event reports under 505(k)(1) of the FDCA would be insufficient to assess the serious risks of cardiovascular adverse events.

62. The FDA similarly determined that the new pharmacovigilance system established by section 505(k)(3) of the FDCA would also be insufficient to assess the serious risks of cardiovascular adverse events.

63. Thus, the FDA required Pfizer to conduct a large clinical trial under Section 505(o)(3) of the FDCA to evaluate the long-term safety of Xeljanz as it relates to cardiovascular adverse events.

64. Pfizer was required under Section 505(o)(3)(E)(ii) of the FDCA to periodically report on the status of the clinical trial.

65. Pfizer was required under Section 506B of the FDCA as well as 21 C.F.R. 314.81(b)(2)(vii) to report annually on the status of the clinical trial.

**G. The design of the large clinical trial.**

66. The post-marketing authorization clinical trial ordered by the FDA to evaluate the safety of Xeljanz began enrolling patients in March 2014.

67. The study was sponsored and funded by Pfizer, who provided the trial medication.

68. The study was designed to compare the safety of Xeljanz versus TNF inhibitors[1] with respect to major adverse cardiovascular events and malignancies in patients suffering from rheumatoid arthritis.

69. Specifically, the co-primary endpoints of the study were adjudicated malignancies (excluding non-melanoma skin cancer) and adjudicated major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke).

70. The study also was to collect and evaluate data regarding other safety events, including non-melanoma skin cancers, hepatic events, infections, and efficacy.

71. Patients in the study had active rheumatoid arthritis despite methotrexate treatment and were 50 years of age or older with at least one cardiovascular risk factor.

[1] A TNF inhibitor is a drug used to limit inflammation in rheumatoid arthritis patients.

72. The additional cardiovascular risk factors were current cigarette smokers, diagnosis of hypertension, diabetes mellitus, family history of premature coronary heart disease, history of coronary artery disease including a history of revascularization procedure, coronary artery bypass grafting, myocardial infarction, cardiac arrest, unstable angina, acute coronary artery syndrome, and presence of extra-articular disease associated with RA.

73. Patients were divided into three groups. One group was given a 5 mg dose of Xeljanz twice daily (1455 patients), another group was given a 10 mg dose of Xeljanz twice daily (1456 patients), and the final group was given a TNF inhibitor (1451 patients).

74. During the study, in February 2019, the 10 mg twice daily dosage of Xeljanz was stopped and the group's dosage switched to 5 mg twice daily because a dose-dependent signal of venous thromboembolic events was observed.

75. The trial was concluded in July of 2020.

**H. The post-marketing clinical trial revealed that patients taking Xeljanz were at extreme risks of major adverse cardiovascular events.**

76. The regulatory authorities in the United States and Europe followed the post-marketing authorization study closely.

77. On July 26, 2019 the FDA approved new black box warnings regarding the risk of blood clots and death for patients taking the 10 mg twice daily dose of Xeljanz to treat ulcerative colitis.

78. This July 2019 change was based on interim data from the post-marketing clinical trial of Xeljanz.

79. The FDA noted that it would continue to assess data from the clinical trial as it became available.

80. On October 31, 2019 Europe's Pharmacovigilance Risk Assessment Committee ("PRAC")[2] concluded that the product information for Xeljanz in Europe would be updated to list blood clots as a side effect of the drug occurring between 1 in 1,000 and 1 in 100 patients.

81. PRAC also recommended on the same date that the physician's guide and patient alert card be updated to advise patients on ways to minimize the risk of blood clots.

82. These recommendations were endorsed by the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP").[3]

83. On November 14, 2019 the European Medicines Agency concluded that Xeljanz should be used with caution in patients at a high risk of blood clots because Xeljanz could further increase the risks of that outcome. The Agency came to this conclusion after a review of the available data and consultation with experts in the field.

84. With this announcement, the European Medicines Agency provided certain information to patients, including:

- Xeljanz could increase the risk of blood clots of patients who are already at a high risk;
- If you are being treated with Xeljanz your doctor will review your risk of blood clots and modify your treatment if necessary; and
- To evaluate the risk your doctor will consider your age, whether you are obese, have diabetes, have elevated blood pressure, or smoke.

85. On February 4, 2021 the FDA alerted the public that preliminary results from the post-marketing clinical trial of Xeljanz showed an increase risk of serious heart-related problems.

[2] PRAC is often referred to as the European Medicines Agency's "safety committee."
[3] CHMP is often referred to as the European Medicines Agency's "human medicines committee."

86. In June 2021 the Pharmacovigilance Risk Assessment Committee ("PRAC") of the European Medicines Agency noted that major adverse cardiovascular events were observed in patients treated with Xeljanz.

87. The PRAC ordered that the product information for Xeljanz be edited to state that patients over 65 years of age, patients who are current or former smokers, and patients with other cardiovascular risk factors should only be prescribed Xeljanz if no alternative treatment is available.

88. On September 1, 2021, based upon results of the post-marketing clinical trial, the FDA concluded that the boxed warning for Xeljanz should be edited to include a warning that patients taking Xeljanz suffer major adverse cardiovascular events including stroke at higher rate than patients taking other rheumatoid arthritis medications.

89. The trial found that even individuals prescribed a lower dose of Xeljanz are at a higher risk of blood clots and death.

90. Pfizer now warns that rheumatoid arthritis patients fifty years of age or older with at least one other cardiovascular risk factor treated with either 5 mg twice daily or 10 mg twice daily of Xeljanz had a higher rate of major adverse cardiovascular events compared to those treated with another rheumatoid arthritis drug. Pfizer additionally warns that current or past smokers are at an even greater risk.

91. Pfizer now instructs doctors to consider the benefits and risks of Xeljanz for individual patients prior to initiating or continuing the prescription of Xeljanz, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors.

92. Pfizer now instructs doctors to inform patients that taking Xeljanz may increase their risk of major adverse cardiovascular events.

93. Pfizer now instructs doctors to instruct all patients, especially current or past smokers or patients with other cardiovascular risk factors, to be alert for the development of signs and symptoms of cardiovascular events.

94. Pfizer now instructs doctors to discontinue Xeljanz in patients who have suffered a stroke.

95. These warnings and instructions were not given by Pfizer prior to updates to the label in December 2021.

96. These warnings and instructions should have been given sooner.

## JURISDICTION AND VENUE

97. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

98. This Court has subject matter jurisdiction in this matter under 28 U.S.C. § 1332 because there is diversity of citizenship amongst the parties and the amount in controversy exceeds $75,000. Ms. Romero is a citizen of the State of Kentucky and Pfizer is a citizen of the States of Delaware and New York.

99. Venue is appropriate in this Court under 28 U.S.C § 1391(a) & (b) as a substantial part of the events and omissions giving rise to this action occurred in this district, and because Plaintiff resides and was injured in this district.

100. This Court has specific jurisdiction over Pfizer because Pfizer marketed, sold, and failed to warn of the risks associated with the defectively designed Xeljanz pills bought and ingested by Plaintiff in this district.

## CAUSES OF ACTION

### COUNT I – FAILURE TO WARN

101. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

102. At no time during her use of Xeljanz did Ms. Romero know or have reason to know that major adverse cardiovascular events such as a stroke could be caused by her ingestion of Xeljanz.

103. Ms. Romero took Xeljanz in the manner intended by Pfizer and consistent with her doctor's advice and instructions.

104. Ms. Romero could not have reasonably discovered the defects and risks associated with Xeljanz prior to the time she consumed the drug. Ms. Romero relied upon the skill, knowledge, experience, expertise, and judgment of Pfizer to know and disclose the serious health risks associated with Xeljanz.

105. At all relevant times hereto, Pfizer had control over the Xeljanz label subject to FDA regulations.

106. At all times relevant hereto, Xeljanz was a defective drug which was unreasonably dangerous to consumers.

107. Pfizer is a manufacturer, seller, and/or distributor of Xeljanz and thus is held to the knowledge standard of an expert in the field.

108. Pfizer researched, designed, developed, tested, manufactured, marketed, sold, and distributed Xeljanz, placed the drug into the stream of commerce, specifically in the State of Kentucky, and further advertised and marketed the drug to healthcare providers as well as patients.

Pfizer therefore had a duty to adequately warn of the risks, including stroke risk, associated with the use of Xeljanz.

109. Pfizer had a duty to adequately test Xeljanz to ensure that the risks and benefits of the drug were sufficient for the safe and effective use of the drug for its approved indications and to warn healthcare providers and Plaintiff of the risks and dangers associated with use of the drug.

110. Pfizer's duties are applicable before and after Xeljanz was approved for sale by the FDA and extend to the present day.

111. Pfizer had a duty dating back to its first sale of Xeljanz to adequately warn the drug's users, including Plaintiff, and their healthcare providers of the dangerous risks associated with its drug.

112. Pfizer has a continuing duty up to today to adequately warn Xeljanz users and their healthcare providers of the dangerous risks associated with the drug.

113. Xeljanz was defective because it did not contain adequate warnings or instructions concerning its dangerous characteristics and the risks it poses to patients.

114. Xeljanz and its labels reached patients and their healthcare providers in the condition it left Pfizer's hands and as Pfizer intended.

115. Pfizer concealed from the public at large, including the federal government, doctors, and their patients, its knowledge regarding the unreasonably dangerous risks of its drug Xeljanz.

116. Pfizer received significant "newly acquired information" regarding Xeljanz after it began selling the drug to the public that should have resulted in a label change warning of the risks of stroke for patients taking Xeljanz.

117. Pfizer had ample opportunity to strengthen its label and failed to do so.

118. Pfizer's label was only modified to warn of the risk of stroke after the FDA demanded such a change, which occurred after Ms. Romero's stroke.

119. Pfizer's label was only modified to warn of an even more significant risk of stroke to past or present smokers taking Xeljanz after the FDA demanded such a change, which occurred after Ms. Romero's stroke.

120. As described herein, at no time prior to Ms. Romero's stroke did the Xeljanz warning label adequately warn of the risks of stroke associated with its drug to rheumatoid arthritis patients prescribed the drug at any dosage level.

121. Pfizer could have strengthened the Xeljanz label at any time under the CBE regulation without prior FDA approval to add stronger warnings that were more adequate, accurate, and reflective of what Pfizer knew or should have known.

122. Pfizer failed and deliberately refused to fully investigate, study, or test for the dangerous effects its drug Xeljanz may have on foreseeable users and thus did not promulgate that information to foreseeable users or their healthcare providers, including Plaintiff.

123. Pfizer knew or should have known that Xeljanz posed serious risks to patients and failed to exercise reasonable care to warn those patients or their healthcare providers of those risks. These risks were known or scientifically knowable to Pfizer through appropriate research, testing, and diligence from the time they began selling the drug until today.

124. Pfizer knew or should have known that the minimal or entirely missing warnings disseminated with Xeljanz were inadequate, failed to communicate important information, and failed to communicate warnings and instructions that would make Xeljanz safe for its ordinary, intended, and reasonably foreseeable use.

125. Pfizer failed to adequately warn patients and their healthcare providers that patients at risk for adverse cardiovascular events, especially smokers, could not take the drug without significant risk of stroke.

126. Pfizer failed to adequately warn patients and their healthcare providers that patients taking Xeljanz, especially those at an increased risk for adverse cardiovascular events, should be on alert for the signs and symptoms of cardiovascular events.

127. Pfizer failed to adequately warn patients and their healthcare providers of the increased risks of major adverse cardiovascular events associated with Xeljanz.

128. Pfizer failed to adequately warn patients and their healthcare providers that Xeljanz had not been sufficiently and/or adequately tested for safety risks, including major adverse cardiovascular events.

129. Pfizer failed to adequately warn patients and their healthcare providers that there was an ongoing, large clinical trial designed to determine whether patients taking Xeljanz were at an increased risk of suffering major adverse cardiovascular events.

130. The information that Pfizer did provide failed to contain relevant, adequate warnings and precautions that would have enabled healthcare providers to prescribe Xeljanz for use in a safe manner and consumers to consume Xeljanz safely.

131. Had Pfizer provided an adequate warning and instructions regarding the risks associated with Xeljanz, Ms. Romero would have avoided suffering a stroke.

132. Pfizer failed to warn of the risks, including stroke risks, of its drug Xeljanz.

133. Pfizer failed to adequately test Xeljanz to ensure that the risks and benefits of the drug were sufficient for the safe and effective use of the drug for its approved indications and to warn healthcare providers and Plaintiff of the risks and dangers associated with use of the drug.

134. Pfizer failed to update its label with "newly acquired information" regarding Xeljanz after it began selling the drug to the public.

135. As a direct and proximate result of Pfizer's failure to adequately warn of the risks associated with Xeljanz and major adverse cardiovascular events, especially to those predisposed to those risks including smokers, as described herein, Ms. Romero suffered a stroke and sustained significant damages.

**COUNT II – DESIGN DEFECT**

136. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

137. Xeljanz was in a defective condition unreasonably dangerous to the Plaintiff.

138. The unreasonably dangerous nature of Xeljanz is shown by the clinical trials conducted before and after the drug had received FDA approval, and before the Plaintiff had been prescribed the drug.

139. Even the early clinical trials showed an increase in cholesterol levels for patients treated with Xeljanz, a primary indicator of an increased risk of major adverse cardiovascular events.

140. As the clinical trials progressed, more and more red flags were raised suggesting that there were significant risks associated with Xeljanz, as discussed herein.

141. The significant risks associated with Xeljanz far outweigh the drug's benefits.

142. Xeljanz was marketed and sold despite the fact that it presented extremely high risk of major adverse cardiovascular events, and those risks were significantly higher to individuals already at risk of a major adverse cardiovascular event, especially smokers.

143. The Xeljanz pills taken by the Plaintiff had not been changed in condition in any way after they were sold by Pfizer.

144. Multiple other treatments for rheumatoid arthritis were available on the market at the time the Plaintiff ingested the drug which would have subjected the Plaintiff to less risks, and was practicable in that the Plaintiff could have obtained those treatments and experienced similar or better outcomes related to her rheumatoid arthritis.

145. These alternative drugs such as TNF inhibitors posed a much lower risk of major adverse cardiovascular events than Xeljanz.

146. As a direct and proximate result of Pfizer's designing of a defective product that was unreasonably dangerous to consumers, Ms. Romero suffered a stroke and sustained significant damages.

**COUNT III – FRAUD AND FRAUDULENT INDUCEMNET**

147. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

148. Pfizer has a duty to ensure that the Xeljanz label is accurate and contains all of the relevant scientific information for the safe and effective use of the drug. 21 C.F.R. § 201.56.

149. Pfizer cannot disseminate prescription labeling that constitutes a misrepresentation of the material facts regarding the risk and benefits of its drug Xeljanz. 21 C.F.R. § 1.21.

150. Pfizer has a duty to ensure that the warnings on the Xeljanz label are accurate, adequate, and not false or misleading in any way.

151. Pfizer has a duty to conduct sufficient post market safety surveillance, to review all adverse drug event information, to report any safety information bearing on the risk-benefit profile

associated with Xeljanz to the medical community, and to update its labeling and educate patients taking Xeljanz and their healthcare providers about new safety information.

152. Pfizer breached its duty to the medical community, Plaintiff's healthcare providers, and Plaintiff by failing to provide accurate and adequate information about Xeljanz in terms of warnings, precautions, and adequate instructions.

153. Pfizer breached its duty to the medical community, Plaintiff's healthcare providers, and Plaintiff by failing to conduct adequate safety assessments and surveillance of Xeljanz and by failing to report all of the significant safety and efficacy data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Xeljanz.

154. Pfizer breached its duty to the medical community, Plaintiff's healthcare providers, and Plaintiff by failing to adequately assess and review all adverse events and reporting, disclosing, and informing healthcare providers about this safety information that bore upon the adequacy and/or accuracy of the Xeljanz warning, including the risks of side effects caused by Xeljanz.

155. Pfizer breached its duty to the medical community, Plaintiff's healthcare providers, and Plaintiff by failing to periodically review all medical literature and failed to report significant data concerning the efficacy and safety of Xeljanz, including but not limited to an increased risk of strokes.

156. Pfizer knew or should have known through the exercise of reasonable care, that the package insert and label for Xeljanz substantially failed to state all, or grossly understated, the relative risks and/or degree of risks of severe side effects associated with Xeljanz that are described herein.

157. Pfizer made misrepresentations of material facts and omitted and/or concealed material facts from the medical community, Plaintiff's healthcare providers, and Plaintiff during

the life cycle of the product as the information identified herein emerged through Pfizer's own clinical trials.

158. Pfizer deliberately and intentionally misrepresented material facts and omitted and/or concealed material facts from the medical community, Plaintiff's healthcare providers, and Plaintiff regarding the safety of Xeljanz. These misrepresentations and omissions included:

- That Xeljanz was a safe drug.
- That Xeljanz was a safe drug when prescribed to patients with rheumatoid arthritis.
- That Xeljanz did not increase the risk of stroke.
- That Xeljanz did not increase the risk of stroke to rheumatoid arthritis patients.
- That Xeljanz did not increase the risk of stroke to rheumatoid arthritis patients who were already at an increased risk of stroke due to another, non-rheumatoid arthritis factor.
- That Xeljanz did not increase the risk of stroke to rheumatoid arthritis patients who were current or past smokers.

159. Pfizer concealed known facts as alleged herein in order to ensure increased sales of Xeljanz without providing all of the essential scientific information for the sale and effective use of the product.

160. Pfizer had a duty to disclose the foregoing risks and failed to do so, despite possessing information concerning those risks. Defendant's representations that Xeljanz was safe for its intended purpose were false and misleading.

161. Pfizer failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Xeljanz.

162. Pfizer failed to exercise reasonable care in communicating the information concerning Xeljanz to the medical community, Plaintiff's healthcare providers, and Plaintiff.

163. Pfizer concealed facts known to it regarding the hazards associated with Xeljanz.

164. Neither Plaintiff nor Plaintiff's healthcare providers were aware of the falsity of the foregoing representations. Neither Plaintiff nor Plaintiff's healthcare providers were aware that material facts concerning the safety of Xeljanz had been concealed or omitted.

165. In reliance on Pfizer's misrepresentations, and in the absence of disclosure of the serious stroke risks associated with Xeljanz, Plaintiff ingested Xeljanz. Had Plaintiff or Plaintiff's healthcare providers known of the risks of Xeljanz, Plaintiff would not have taken the drug.

166. The reliance by Plaintiff and Plaintiff's prescribing physician upon Pfizer's misrepresentations was justified because misrepresentations and omissions were made by individuals and entities in a position to know the true facts concerning the risks of Xeljanz, and individuals with a legal duty to accurately state or otherwise disclose these risks.

167. Pfizer's misrepresentations and omissions induced Plaintiff's healthcare providers to prescribe Xeljanz and induced Plaintiff to take the drug.

168. As a direct and proximate result of Pfizer's misrepresentations, omissions, fraud, and fraudulent inducement, Ms. Romero suffered a stroke and sustained significant damages.

**COUNT IV – NEGLIGENT DESIGN**

169. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

170. Plaintiff alleges that Pfizer was negligent in its design of Xeljanz,

171. Pfizer breached its duty to design a product that was not unreasonably safe to consumers.

172. As discussed throughout, the risks associated with Xeljanz were significant and included injuries as severe as major adverse cardiovascular events, cancer, and death.

173. Xeljanz is capable of causing strokes in patients taking the drug, and patients such as the Plaintiff who are already at an increased risk of stroke are even more likely to suffer a stroke.

174. These risks were known and knowable to Pfizer at the time Mrs. Romero took their drug.

175. These risks were outweighed by the benefits associated with the drug.

176. Multiple other treatments for rheumatoid arthritis were available on the market at the time the Plaintiff ingested the drug which would have subjected the Plaintiff to less risks, and were practicable in that the Plaintiff could have obtained those treatments and experienced similar or better outcomes related to her rheumatoid arthritis.

177. These alternative drugs such as TNF inhibitors posed a much lower risk of increased cholesterol levels and major adverse cardiovascular events than Xeljanz.

178. As a direct and proximate result of Pfizer's negligent design, Ms. Romero suffered a stroke and sustained significant damages.

**COUNT V – NEGLIGENT FAILURE TO WARN**

179. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

180. Plaintiff alleges that Pfizer was negligent in its failure to warn consumers and their healthcare providers of the risks associated with Xeljanz.

181. Pfizer knew from its pre- and post-market authorization clinical trials of Xeljanz's potential to cause strokes.

182. The clinical trials revealed that individuals taking the drug had increased levels of cholesterol which can cause strokes.

183. Pfizer observed strokes in the clinical trials that it conducted.

184. These strokes occurred at a higher rate in patients already at an increased risk for stroke, and even more so in smokers.

185. This information was available to Pfizer even before the Plaintiff took Xeljanz for the first time.

186. Pfizer knew from this information that patients taking Xeljanz would suffer strokes.

187. Despite this knowledge and information, Pfizer did not adequately warn Ms. Romero or her healthcare providers of Xeljanz's ability to cause strokes.

188. As a direct and proximate result of Pfizer's negligent failure to warn of the risks associated with Xeljanz and major adverse cardiovascular events, especially to those predisposed to those risks including smokers, as described herein, Ms. Romero suffered a stroke and sustained significant damages.

**COUNT VI – GROSS NEGLIGENCE**

189. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

190. Pfizer's conduct constitutes a wanton and reckless disregard for the safety of persons such as the Plaintiff.

191. Pfizer's conduct was so outrageous that it constitutes malice.

192. Pfizer sold a drug to the public with knowledge that it could subject them to life threatening consequences and did not adequately warn patients or healthcare providers of these risks, as discussed herein.

193. As more information became available to Pfizer consistent with the fact that Xeljanz could result in major adverse cardiovascular events, Pfizer took no action to adequately warn patients or their healthcare providers of this information.

194. Pfizer engaged in an aggressive marketing campaign for a first in class drug without taking any steps to protect patients, especially patients that Pfizer knew were at an even increased risk of major adverse cardiovascular events.

195. As a direct and proximate result of Pfizer's gross negligence Ms. Romero suffered a stroke and sustained significant damages.

**PUNITIVE DAMAGES**

196. Plaintiff hereby re-alleges and incorporates by reference all of the preceding paragraphs.

197. Pfizer's fraudulent conduct and gross negligence described above entitles Plaintiff to recover punitive damages

198. Pfizer acted with flagrant indifference to the rights of the plaintiff and with an awareness that its own conduct would result in death and bodily harm.

199. Pfizer's conduct spans more than a decade.

200. Pfizer knew at the time of Ms. Romero's stroke the significant likelihood that patients could suffer major adverse cardiovascular events given all of the conduct described herein and especially the knowledge available to Pfizer.

201. The knowledge available to Pfizer gives rise to a significant likelihood that patients taking Xeljanz would suffer strokes.

202. Pfizer has made billions of dollars by selling Xeljanz, one of the most profitable drugs in the company's history.

203. While Pfizer has taken actions to remedy its misconduct after Ms. Romero's stroke, no actions were taken prior to her stroke despite Pfizer's knowledge regarding the hazards of Xeljanz.

204. Pfizer's conduct should result in punitive or exemplary damages to punish the company and discourage it and others from similar conduct in the future.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Pfizer, awarding Plaintiff any and all damages available under the law, including but not limited to:

1) General damages;
2) Economic damages;
3) Non-economic damages;
4) Punitive damages;
5) Prejudgment and postjudgment interest;
6) Reasonable attorneys' fees;
7) Costs of this action;
8) Any other relief available under the law or that the Court finds appropriate.

## JURY DEMAND

Plaintiff hereby demands a jury trial for all issues so triable in this action.

Dated: March 31, 2022

Respectfully submitted,

*/s/ Alex C. Davis*

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