IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KAYLEIGH SECHI, Plaintiff**,** **v.** McNEIL-PPC, INC., McNEIL CONSUMER HEALTHCARE, and JOHNSON & JOHNSON, INC., Defendants	Case No. _____

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the pain reliever acetaminophen, sold under the trade name "Tylenol."

PARTIES

1. Plaintiff Kayleigh Sechi is a resident and citizen of the Commonwealth of Massachusetts, residing in South Hadley, Massachusetts.

2. Defendant McNeil-PPC, Inc. is, and at all times relevant was, a corporation organized under the laws of the State of New Jersey, with its headquarters and principal place of business at 7050 Camp Hill Rd., Fort Washington, Pennsylvania.

3. Defendant McNeil Consumer Healthcare is, and at all times relevant was, a division of McNeil-PPC, Inc., with its headquarters and principal place of business at 7050 Camp Hill Rd., Fort Washington, Pennsylvania.

4. Defendant Johnson & Johnson, Inc. is, and at all times relevant was, a corporation organized under the laws of the State of New Jersey with its headquarters and principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

5. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

6. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

7. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, labeling, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the Commonwealth of Massachusetts, either directly or indirectly through third parties, subsidiaries or related entities, an acetaminophen product sold under the trade name "Tylenol".

8. At all relevant times, Johnson & Johnson and the other Defendants have maintained that they put the well-being of their customers first and that their "first responsibility is to the people that use our products," as set forth in the Johnson & Johnson "Credo."

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

10. This court has personal jurisdiction over Defendants consistent with the laws of the Commonwealth of Massachusetts and the United States Constitution because Defendants caused tortious injury in the Commonwealth of Massachusetts by an act or omission outside the Commonwealth of Massachusetts by virtue of Defendants' regularly conducting business in the Commonwealth of Massachusetts from which they derived substantial revenue.

11. Venue is proper in this district under 28 U.S.C. § 1391(a)(2) because the court's subject matter jurisdiction is based on diversity and a substantial portion of the events or omissions giving rise to the claim occurred here in Massachusetts.

FACTUAL ALLEGATIONS

A. The Relationship Between Johnson & Johnson and McNeil

12. Johnson & Johnson, founded in 1886 and based in New Brunswick, New Jersey, engages in the research and development, manufacture, distribution and sales of various products in the healthcare field worldwide.

13. Johnson & Johnson is comprised of approximately 250 worldwide "operating companies" organized into business segments, including Consumer Health Care, Medical Devices and Diagnostics, and Pharmaceuticals.

14. The Consumer Health Care segment provides products including over-the-counter pharmaceutical products, including Tylenol.

15. McNeil is an operating company within the Consumer Health Care Segment of Johnson & Johnson, and a member of the Johnson & Johnson corporate partner group.

16. In 1959, Johnson & Johnson acquired McNeil Laboratories, a company focused on direct marketing of prescription products to hospitals, pharmacists and doctors.

17. In 1955, McNeil introduced an acetaminophen based product, Tylenol.

18. A year after acquiring McNeil Laboratories, Johnson and Johnson's McNeil division began selling Tylenol without a prescription.

19. In 1977, McNeil Laboratories created two companies, McNeil Pharmaceutical and McNeil Consumer Healthcare, with McNeil Consumer Healthcare focusing on the manufacture and marketing of a variety of over-the-counter (OTC) products for the U.S. market, including Tylenol.

20. At all times relevant hereto, Defendant McNeil-PPC, Inc. (a wholly owned subsidiary of Johnson and Johnson, Inc.), designed, manufactured, packaged, labeled, marketed and/or distributed the subject products under the trade name "Tylenol".

21. At all times relevant hereto, Defendant McNeil Consumer Healthcare (a division of McNeil-PPC, Inc.), designed, manufactured, packaged, labeled, marketed and/or distributed the subject products with the trade name Tylenol.

22. At all times relevant hereto, Tylenol products were also promoted and marketed extensively by McNeil's parent company, Johnson & Johnson, Inc.

23. Johnson & Johnson, Inc. and/or McNeil maintain ultimate control and authority over the design, manufacture, packaging, marketing, distribution, labeling and sale of Tylenol.

B. <u>Tylenol/Acetaminophen and Liver Toxicity</u>

24. The only active ingredient in Tylenol is the drug "acetaminophen."

25. Acetaminophen is a dose related liver toxin.

26. Defendants have known that acetaminophen, the only active ingredient in Tylenol, is a dose related liver toxin since at least 1975.

27. In approximately 1950, acetaminophen became available as a pain reliever in the United States.

28. Before acetaminophen's introduction into the American market, however, it had been on the market in England for a number of years and was widely reported in the medical literature there to be highly toxic to the liver.

29. In 1959, Tylenol 325 mg. of acetaminophen ("Regular Strength Tylenol") was approved for over-the-counter sale.

30. Johnson and Johnson acquired McNeil in 1959.

31. In 1961, Defendants launched Regular Strength Tylenol tablets as an over-the-counter drug.

32. During the 1970s, it was widely known, and known to Defendants, that over 90% of individuals who took two Regular Strength Tylenol (the recommended dose) received therapeutic pain relief from that amount of acetaminophen.

33. Despite knowledge that over 90% of the population received therapeutic pain relief from the recommended dose of Regular Strength Tylenol, and further despite the fact that Tylenol is a dose-related liver toxin, Defendants filed an application with the FDA in 1971 to market Tylenol 500 mg., which is now referred to as Extra-Strength Tylenol.

34. Defendants have a duty to monitor the worldwide medical literature concerning acetaminophen and its side-effects.

35. Defendants, in fact, did monitor the worldwide literature concerning acetaminophen and its side-effects.

36. The first cases of fatal overdose from acetaminophen were reported in approximately 1966.

37. Extra-Strength Tylenol, with 500 mg. of acetaminophen, was approved by the FDA in 1975.

38. In 1975, Defendants launched Extra Strength Tylenol in capsule form.

39. By 1975 Tylenol products became the 5th best-selling brand of analgesic in the United States.

40. In 1976, Defendants launched Extra Strength Tylenol in tablet form.

41. By July 1976 Tylenol became the number one brand of over-the-counter analgesics in the United States.

42. In 1977 an Advisory Committee to the FDA, in which Defendants participated, recommended that a liver-specific warning similar to "do not exceed recommended dosage because severe left liver damage may occur" be included in the labeling of acetaminophen products, including Tylenol.

43. Defendants chose not to place the liver-specific warning recommended by the FDA Advisory Committee in 1977 on their Tylenol brand products.

44. As early as 1975, the medical literature began to report on the cause-and-effect relationship between acetaminophen ingestion and acute liver failure.

45. As early as 1975, Defendants were aware that acetaminophen ingestion could cause acute liver failure.

46. Tylenol is the only over-the-counter pain reliever that has an antidote to be given in the event an individual goes into acetaminophen-induced acute liver failure.

47. In 1985, the FDA approved N-acetylcysteine ("NAC") as an antidote for acetaminophen.

48. Defendants participated in the development of the antidote, NAC, through both financial and labor contributions.

49. From at least 1986 onward, McNeil has been aware that individuals with

decreased levels of the enzyme glutathione in their liver are more susceptible to liver failure and liver injury from acetaminophen than individuals with a normal store of glutathione.

50. Tylenol (acetaminophen) is metabolized in the liver.

51. During the digestion and metabolization of acetaminophen, a portion of acetaminophen is converted into a toxin referred to as N-acetyl-p-benzoquinone imine ("NAPQI").

52. Under normal conditions, individuals who ingest acetaminophen have sufficient stores of glutathione in their liver to bind with the toxin NAPQI and thus eliminate the toxin without any damage to the liver.

53. Individuals who ingest acetaminophen with depleted levels of glutathione are at an increased risk for liver injury due to acetaminophen as compared to the population as a whole.

54. Certain individuals have less glutathione in their liver than others, thus making those individuals more susceptible to acetaminophen-induced liver damage than the general population.

55. Defendants have been aware of the method by which acetaminophen is metabolized by the liver since at least 1980.

56. Defendants have been aware since at least 1980 that any individual who ingests acetaminophen with depleted levels of glutathione is at an increased risk for liver injury due to acetaminophen as compared to the population as a whole.

57. It has been reported in the medical literature since at least 1985 that individuals who are nutritionally depleted, not eating well, or otherwise fasting, are at an increased risk of acetaminophen-induced liver failure.

58. From at least 1985, Defendants have been aware of medical literature and

underlying medical research suggesting that individuals who are not eating well, nutritionally depleted, or otherwise fasting, are at an increased risk of acetaminophen-induced liver failure.

59. Defendants, as the manufacturer of Tylenol products, have never conducted any studies or tests to assess the effect of decreased nutritional status or fasting on acetaminophen-induced hepatotoxicity.

60. Defendants have never warned the public through their product label that ingestion of acetaminophen while in a state of nutritional depletion or fasting places individuals at a higher risk of developing acetaminophen-induced liver failure.

61. In 1993 an article entitled "Acute Liver Failure" was published in *The New England Journal of Medicine* and noted that acetaminophen toxicity is dose dependent, but that the effect of acetaminophen is exaggerated by fasting, among other conditions.

62. In late 1993, an article published in the *Journal of the American Medical Association* articulated the relationship between decreased nutritional intake and an increased risk of acetaminophen-induced hepatotoxicity.

63. Defendants were aware that as far back as 1975, animal studies were reported in the medical literature which showed a connection between fasting, acetaminophen and liver toxicity.

64. In 1994, McNeil changed Tylenol's warning label, adding an alcohol warning ("1994 alcohol warning").

65. McNeil added its 1994 alcohol warning after the widely publicized trial in *Benedi v. McNeil-PPC, Inc.,* 66 F3d 1378 (1995), where the jury found McNeil liable for the plaintiff's acute liver failure resulting from his moderate alcohol use while also taking Tylenol.

66. McNeil added its 1994 alcohol warning after the publicity surrounding the

publication of medical literature which confirmed the association between alcohol, liver failure, and Tylenol.

67. McNeil's 1994 alcohol warning only addressed the relationship between liver damage and alcohol users, so as to indicate that use of alcohol and acetaminophen was the only circumstance under which liver damage can result.

68. Tylenol sales decreased over 20 million dollars comparing data from January 1994 through January 1995.

69. In 1994 Defendants launched arthritis-strength Tylenol, which increased the amount of acetaminophen to 650 mg. per tablet.

70. During the 1980s and 1990s, Defendants were aware that acetaminophen was causing hundreds of deaths per year not only in the United States, but also in the United Kingdom.

71. In 2002, the FDA convened another Advisory Committee to discuss acetaminophen and its associated liver toxicity.

72. During the 2002 Advisory Committee Meeting, the Acute Liver Failure Study Group reported that there were between 1,000 and 2,000 cases of acetaminophen induced acute liver failure each year in the United States.

73. As of 2002, Defendants were aware of the fact that there were between 1,000 and 2,000 cases of acute failure each year due to acetaminophen.

74. During the 2002 Advisory Committee meeting, an FDA representative reported that research indicated there were over 56,000 emergency department visits, 26,000 hospitalizations, and 458 deaths related to acetaminophen annually. These numbers were for the United States only.

75. During the 2002 Advisory Committee Meeting, a McNeil representative stated that McNeil was recommending an organ specific severe liver damage warning be added to its label.

76. McNeil was aware in 2002 that acetaminophen contributed to hundreds of deaths and thousands of hospitalizations in the United States annually.

77. Despite such knowledge, and contrary to the statements of its representative at the 2002 FDA Advisory Committee Meeting, McNeil did not implement an organ specific liver warning on their products as represented to the FDA panel.

78. Defendants were aware that approximately 23% of individuals who take over-the-counter medications, including Tylenol, take more than the recommended dose.

79. It is foreseeable to Defendants that an individual may take more than the recommended dose of Tylenol.

80. In October 2007, the American Association for the Study of Liver Disease ("AASLD") responded to a FDA request asking for its input and recommendations on how to reduce the incidence of liver injury caused by acetaminophen with the following facts and recommendations concerning acetaminophen and its sale in the United States: (1) acetaminophen-induced liver toxicity in the United States exceeds that of all prescription drugs combined; (2) acetaminophen and associated hepatotoxicity is an important public health consideration; (3) the labeling of acetaminophen products should be changed in order to state that acetaminophen can cause severe, or even fatal, liver injury, and that the chance is higher of such an occurrence if the drug is used at the maximum recommended daily dose (4 grams) when food intake is restricted, or taken in more than half the recommended daily dose (2 grams) while drinking alcohol.

81. The AASLD also noted in its October 2007 response to the FDA that acetaminophen has a narrow therapeutic-to-toxic window.

82. Defendants were aware in 2007 of the AASLD's recommendations concerning acetaminophen generally as well as its view on specific warnings that should accompany acetaminophen, including Tylenol.

83. Defendants chose not to follow any of the AASLD's recommendations put forth in October 2007.

84. Acetaminophen has a narrow therapeutic-to-toxic window.

85. Acetaminophen may cause severe liver damage, even at the previously recommended maximum daily dose of 4 grams of Tylenol per day.

86. Acetaminophen is the leading cause of acute liver failure in the United States.

87. The potential for acetaminophen-induced liver damage and failure has been well documented and well known to the Defendants for many years prior to the incident involving Plaintiff Kayleigh Sechi.

88. At no time prior to the incident involved in this case did Defendants adequately warn the general public or Plaintiff that Tylenol could lead to acute liver failure.

89. Prior to mid November 2009, Plaintiff purchased Tylenol Extra Strength, reviewed the product label, and took the drug several times daily for approximately two weeks before feeling ill, ultimately leading to a diagnosis of acute liver failure and hepatotoxicity.

90. Plaintiff's injuries were caused by the toxic effects of the Tylenol that Plaintiff ingested.

91. The Tylenol taken by Plaintiff, and which proximately caused Plaintiff's suffering and injuries as described herein, was designed, manufactured, packaged, labeled, and placed into

the stream of interstate commerce by Defendants.

FEDERAL STANDARDS AND REQUIREMENTS

92. Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of their Tylenol products including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations.

CLAIMS FOR RELIEF

COUNT I

BREACH OF IMPLIED WARRANTY – DESIGN DEFECT

93. Plaintiff incorporates by reference the allegations contained in Paragraphs 12 through 92 as though set forth fully herein.

94. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Tylenol Extra Strength.

95. At the time the Defendants manufactured, marketed, distributed, supplied and/or sold Tylenol Extra Strength, they knew of the use for which it was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

96. Tylenol Extra Strength is defective and unreasonably dangerous to consumers.

97. Tylenol Extra Strength is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

98. At all times material to this action, Tylenol Extra Strength was expected to reach, and did reach, consumers in the Commonwealth of Massachusetts and throughout the United

States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

99. At all times material to this action, Tylenol Extra Strength was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, Tylenol Extra Strength contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of Tylenol Extra Strength, including but not limited to the risks of developing acute liver failure, which can cause devastating injuries, including liver transplant and death, in an unacceptably high number of its users;

b. When placed in the stream of commerce, Tylenol Extra Strength was defective in design and formulation, making the use of Tylenol Extra Strength more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with other over-the-counter pain relief medications;

c. Tylenol Extra Strength's design defects existed before it left the control of Defendants;

d. Tylenol Extra Strength was insufficiently tested;

e. Tylenol Extra Strength caused harmful side effects that outweighed any potential utility;

f. Tylenol Extra Strength was not accompanied by adequate instructions

and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

100. In addition, at the time that Tylenol Extra Strength left the control of the Defendants, there were practical and feasible alternative designs that would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Tylenol Extra Strength's utility.

101. As a direct and proximate result of Tylenol Extra Strength's defective design, the Plaintiff has suffered severe and permanent physical injuries, including but not limited to acute liver failure resulting in liver transplant.

102. The Plaintiff has endured substantial pain and suffering and permanent injury. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

103. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

104. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, Kayleigh Sechi, demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

BREACH OF WARRANTY – MANUFACTURING DEFECT

105. Plaintiff incorporates by reference the allegations contained in Paragraphs 12 through 104 as though set forth fully herein.

106. At all times relevant to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Tylenol Extra Strength.

107. At the time Defendants manufactured, marketed, distributed, supplied and/or sold Tylenol Extra Strength, they knew of the use for which it was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

108. At all times material to this action, Tylenol Extra Strength was expected to reach, and did reach, consumers in the Commonwealth of Massachusetts and throughout the United States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

109. At all times material to this action, Tylenol Extra Strength was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Tylenol Extra Strength contained manufacturing defects which rendered the product unreasonably dangerous;

b. Tylenol Extra Strength's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Tylenol Extra Strength was not made in accordance with the Defendants' specifications or performance standards;

d. Tylenol Extra Strength's manufacturing defects existed before it left the control of the Defendants;

110. As a direct and proximate result of Tylenol Extra Strength's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries, including but not limited to acute liver failure resulting in liver transplant.

111. The Plaintiff has endured substantial pain and suffering and permanent injury. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

112. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

113. Plaintiff's injuries and damages are permanent and will continue into the future.

114. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, Kayleigh Sechi, demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

BREACH OF EXPRESS WARRANTY

115. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 12 through 114 as though set forth fully herein.

116. Defendants placed Tylenol Extra Strength into the stream of commerce for sale and recommended its use to consumers and the FDA with the express warranty that it was safe and effective as a medication for pain relief, and as such was merchantable and fit for the purpose intended. .

117. This warranty was breached because Tylenol Extra Strength was not safe and effective as a medication for pain relief, as Defendants had represented, and Plaintiff was severely and permanently injured.

118. As a direct and proximate result of Defendants' breach of express warranty, the Plaintiff suffered severe and permanent physical injuries, including but not limited to acute liver failure resulting in liver transplant.

119. The Plaintiff has endured substantial pain and suffering and permanent injury. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

120. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

121. Plaintiff's injuries and damages are permanent and will continue into the future.

122. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, Kayleigh Sechi, demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV

NEGLIGENCE

123. Plaintiff repeats and incorporates by reference the allegations contained in Paragraphs 12 through 122 as though set forth fully herein.

124. Defendants had a duty to exercise reasonable care in the manufacture, design, labeling, marketing, sale and distribution of Tylenol and Tylenol Extra Strength, including a duty to ensure that the products did not pose a significantly increased risk of bodily harm and adverse events.

125. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, warnings, quality assurance, quality control, labeling, marketing, promotion and distribution of Tylenol Extra Strength in that the Defendants knew or should have known that the product created a high risk of unreasonable harm to consumers.

126. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Tylenol Extra Strength in that, among other things, they:

a. Failed to use due care in designing and manufacturing Tylenol Extra Strength so as to avoid the risk the liver injury and liver failure to individuals;

b. Failed to accompany the drug with proper warnings regarding all possible adverse side-effects associated with its use, including liver injury and liver failure, and the comparative severity and duration of such adverse effects. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Tylenol Extra Strength;

d. Marketed Tylenol and Tylenol Extra Strength in an overly aggressive,

deceitful and fraudulent manner, despite evidence as to the products' defective and dangerous characteristics due to their propensity to cause serious injury and/or death;

e. Placed unsafe products into the stream of commerce; and,

f. Were otherwise careless or negligent.

127. Despite the fact that Defendants knew or should have known that Tylenol caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market Tylenol to consumers, including the medical community and Plaintiff.

128. As a direct and proximate result of Defendants' breach of express warranty, the Plaintiff suffered severe and permanent physical injuries, including but not limited to acute liver failure resulting in liver transplant.

129. The Plaintiff has endured substantial pain and suffering and permanent injury. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

130. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

131. Plaintiff's injuries and damages are permanent and will continue into the future.

132. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, Kayleigh Sechi, demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

BREACH OF WARRANTY/NEGLIGENCE – FAILURE TO WARN

133. Plaintiff incorporates by reference the allegations contained in Paragraphs 12 through 132 as though set forth fully herein.

134. Tylenol Extra Strength was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with Tylenol Extra Strength, including but not limited to its propensity to cause acute liver failure and other serious injuries and side effects over other over-the-counter pain relief medications.

135. Plaintiff used the subject product for its intended purpose.

136 Plaintiff could not have discovered any defect in Tylenol Extra Strength through the exercise of reasonable care.

137. The Defendants, as manufacturers and/or distributors of Tylenol Extra Strength are held to the level of knowledge of an expert in the field.

138. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

139. The warnings that were given by the Defendants failed to warn consumers and the medical community of the risk of acute liver failure when using Tylenol Extra Strength.

140. Plaintiff reasonably relied upon the superior knowledge and judgment of the Defendants.

141. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with Tylenol Extra Strength.

142. Had the Plaintiff received adequate warnings regarding the risks of Tylenol Extra

Strength, she would not have used it.

143. As a direct and proximate result of Tylenol Extra Strength's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries, including but not limited to acute liver failure resulting in liver transplant.

144. The Plaintiff has endured substantial pain and suffering and permanent injury. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

145. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

146. Plaintiff's injuries and damages are permanent and will continue into the future.

147. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff, Kayleigh Sechi, demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

Wherefore, the Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding Plaintiff compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

b. Awarding pre- and post-judgment interest to the Plaintiff;

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

d. Awarding reasonable attorney's fees and costs to Plaintiff as provided by law; and

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

PLAINTIFF DEMANDS A TRIAL BY JURY AS TO ALL ISSUES SO TRIABLE.

Plaintiff, by her Attorneys,

_/s/ Michael S. Appel
Michael S. Appel, BBO #543898
Sugarman, Rogers, Barshak & Cohen, P.C.
101 Merrimac Street
Boston, MA 02114
Tel. (617) 227-3030

4823-9923-1250, v. 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) Kayleigh Sechi v. McNeil-PPC, Inc.

2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).

☐ I. 410, 441, 470, 535, 830*, 891, 893, 895, R.23, REGARDLESS OF NATURE OF SUIT.

☐ II. 110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.

☑ III. 120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.

*Also complete AO 120 or AO 121. for patent, trademark or copyright cases.

3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.

4. Has a prior action between the same parties and based on the same claim ever been filed in this court?

YES ☐ NO ☑

5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)

YES ☐ NO ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ NO ☑

6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?

YES ☐ NO ☑

7. Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).

YES ☑ NO ☐

A. If yes, in which division do all of the non-governmental parties reside?

Eastern Division ☐ Central Division ☐ Western Division ☑

B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?

Eastern Division ☐ Central Division ☐ Western Division ☐

8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)

YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Michael S. Appel

ADDRESS Sugarman, Rogers, Barshak & Cohen, 101 Merrimac St., Boston, MA 02114

TELEPHONE NO. (617) 227-3030

JS 44 (Rev. 09/11)

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

Kayleigh Sechi

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Michael S. Appel, Sugarman, Rogers, Barshak & Cohen, P.C., 101 Merrimac Street, Boston, MA 02114 (617) 227-3030

DEFENDANTS

McNeil-PPC, Inc., McNeil Consumer Healthcare, and Johnson & Johnson, Inc.

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

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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

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. sec. 1332

Brief description of cause:
Product liability action alleging defective design and failure to warn

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/27/2012

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 09/11)

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.C.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; 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 the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

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 dollar amount (in thousands of dollars) 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.