UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	§ § § § § §	**MDL NO. 2436** **2:13-md-02436** **HON. LAWRENCE F. STENGEL**
This Document Relates to: Rana Terry, as Personal Representative and Administrator of the Estate of Denice Hayes, Deceased, Plaintiff, vs. McNEIL-PPC, Inc., McNeil Consumer Healthcare, and Johnson & Johnson, Inc., Defendants.	§ § § § § § § § § § § § § § §	Civil Action No. 2:12-cv-07263

M E M O R A N D U M

Stengel, J. **November 13, 2015**

A popular adage by Paracelsus, the father of modern toxicology, goes to the heart of this case: "The dose makes the poison." The plaintiff claims that her sister died of acute liver failure after taking Extra Strength Tylenol.[1] Defendants Johnson & Johnson and McNeil manufacture and market Extra Strength Tylenol, a brand-name over-the-

[1] See Compl., 12-cv-07263, Doc. No. 1.

counter pain reliever. The plaintiff claims the defendants knew or should have known that consumers may develop acute liver failure after taking Extra Strength Tylenol at or just above the dose recommended when her sister died. The plaintiff claims that the defendants could have re-designed Extra Strength Tylenol to make it safer.

This case is part of a Multidistrict Litigation (MDL) involving claims of liver damage from the use of Tylenol at or just above the recommended dosage.[2] This is the first "bellwether" scheduled for trial.[3] The defendants moved for summary judgment on the plaintiff's design defect claim, arguing that the plaintiff has not offered sufficient evidence of this claim and/or the claim is preempted by federal law. For the reasons explained below, I will deny the defendants' motion.

I. A HISTORICAL OVERVIEW OF TYLENOL[4]

The plaintiff's claims are different than those previously asserted against the defendants about the safety of Tylenol. While previous cases have questioned whether Tylenol can cause liver damage, this case and others in this MDL question the extent of

[2] See Master Compl., 13-md-2436, Doc. No. 32. There are close to two hundred other cases included in this MDL, along with several similar cases in New Jersey state court.

[3] A "bellwether" case is a test case. "Bellwether" trials should produce representative verdicts and settlements. The parties can use these verdicts and settlements to gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible. See FEDERAL JUDICIAL CENTER, MANUAL FOR COMPLEX LITIGATION, FOURTH EDITION 360 (2004); DUKE LAW CENTER FOR JUDICIAL STUDIES, MDL STANDARDS AND BEST PRACTICES 16-21 (2014).

[4] Some of the information offered by the plaintiff relates to events that happened after the decedent's death. Whether this information can be presented at trial will depend upon the outcome of a pending motion in limine and objections based on the Federal Rules of Evidence. I offer it here to provide a holistic picture of the background of Extra Strength Tylenol. Some of the information may be admissible or relevant in this case and/or subsequent cases in the MDL. In making my determinations about sufficiency of the evidence, I do not rely solely on this evidence but offer it as potential evidence that, with other admissible evidence, could affect a jury's decision.

such damage and the quickness with which it can occur. A historical overview of the regulation and science of Tylenol is helpful.[5]

a. TYLENOL, ACETAMINOPHEN, AND LIVER DAMAGE

Extra Strength Tylenol is an over-the-counter (OTC) pain reliever; consumers do not need a prescription to buy it. The active ingredient in Extra Strength Tylenol is acetaminophen, which is an analgesic and antipyretic or pain reliever and fever reducer.[6] Defendant McNeil manufactures and markets many different Tylenol products, including Extra Strength Tylenol and Regular Strength Tylenol. The two products differ in that one tablet of Extra Strength Tylenol contains 500 mg of acetaminophen while a tablet of Regular Strength Tylenol only contains 325 mg of acetaminophen per tablet. Johnson & Johnson is the parent company of McNeil and is involved in managing its operations.

Acetaminophen was first synthesized as a pain reliever in the 1890s and has been available OTC since the 1960s.[7] Tylenol is one of more than 600 acetaminophen-containing products on the market in the United States in OTC and prescription formulations.[8] Acetaminophen is one of the most widely used OTC drugs.[9] Twenty

[5] In addition, I rely on exhibits offered in the plaintiff's response to the defendants' motion for summary judgment on her failure-to-warn claim. Information in these exhibits helps to offer a more holistic view of the background of this case. The defendants' motion for summary judgment on the failure-to-warn claims can be found at Doc. No. 49; their motion for summary judgment on the design defect claim can be found at Doc. No. 50 (under seal). The plaintiff's response to the Failure-to-Claim MSJ is docketed at Doc. No. 95 (under seal) and her response to the Design Defect MSJ can be found at Doc. No. 90.

[6] E.g., http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm165107.htm (last visited May 31, 2015); A. Temple Dep., Feb. 18, 2014 at 310 (Doc. No. 90, Ex. 1).

[7] See, e.g., FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9).

[8] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm336581.htm (last visited Oct. 13, 2015).

percent of Americans—60 million people—ingest an acetaminophen-containing product each week.[10] The Food and Drug Administration (FDA) has found acetaminophen to be a "safe and effective OTC analgesic" when taken in recommended doses and used according to the label.[11] However, acetaminophen has been known to cause severe liver damage.[12]

i. Acetaminophen's Link to Acute Liver Failure

Acetaminophen is different from other OTC pain relievers in two ways: 1) it has an antidote and 2) its maximum total daily limit is the same for both OTC and prescription products.[13] Acetaminophen is a "dose-related toxin," meaning it can be safely used at certain doses but harmful at higher doses.[14] As a result, there is evidence that it has a "narrow therapeutic margin"—i.e., there is little difference between the

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[9] See Kaufman DW, et al., Recent patterns of medication use in the ambulatory adult population of the United States: the Slone Survey, J. Am. Med. Assoc. (2002), 287:337-44 (Doc. No. 49-1, Ex. A); Slone Epidemiological Center at Boston University, Patterns of Medications Use in the United States 2005: A Report from the Slone Survey, *available at* http://www.bu.edu/slone/research/studies/slone-survey (last visited Oct. 13, 2015).

[10] Kaufman DW, et al., Recent patterns of medication use in the ambulatory adult population of the United States: the Slone Survey, J. Am. Med. Assoc. (2002), 287:337-44 (Doc. No. 49-1, Ex. A); Slone Epidemiological Center at Boston University, Patterns of Medications Use in the United States 2005: A Report from the Slone Survey, *available at* http://www.bu.edu/slone/research/studies/slone-survey (last visited Oct. 13, 2015).

[11] See Defendants' Statement of Facts at ¶ 9; Plaintiff's Statement admitting this fact; 42 Fed. Reg. 35346, 35413 (Jul. 8, 1977)(Doc. No. 49-2, Ex. B).

[12] See 42 Fed. Reg. 35356, 35447 (Jul. 8, 1977); Lee, et. al., MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6); Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9).

[13] See CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8).

[14] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6).

current maximum recommended dose of acetaminophen and the doses that could cause liver injury.[15] The parties debate how narrow this margin is.

A simplistic explanation of how the body metabolizes acetaminophen helps frame the issues in this case. Typically, glutathione—an antioxidant found in the liver—will bind to the toxic parts of acetaminophen, to neutralize them and prevent them from harming the body.[16] These neutralized toxins are then excreted.[17] However, if the body does not have enough glutathione, those toxins can build up in the liver, causing acute liver failure (ALF). Glutathione stores may be low when a person is malnourished or when the liver has been neutralizing a lot of toxins at once.[18]

"Acute liver failure (ALF) is a rapid deterioration of the organ's ability to function."[19] Patients who experience ALF can fall into a coma or die.[20] They may require a

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[15] See, e.g., CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8)("Acetaminophen has a narrow therapeutic margin, that is, there is little difference between the current maximum recommended dose of acetaminophen and the doses that are associated with a potentially elevated risk of hepatotoxicity."); AASLD Memo, Apr. 27, 2007 (Doc. No. 95, Ex. 19); Christina Chang, M.D., M.P.H., Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products, of the FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

[16] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6); Whitcomb & Block, Association of Acetaminophen Hepatotoxicity with Fasting and Ethanol Use, 272 JAMA 23, 1845-1850 (1994)(Doc. No. 95, Ex. 13).

[17] See 42 Fed. Reg. 35381 (Jul. 8, 1977)(explaining studies of acetaminophen's effect on the liver)("The administration of acetaminophen to patients with impaired renal function results in increased accumulation of acetaminophen conjugates in the plasma because of poor excretory capacity but only in minor changes in the plasma concentrations of free acetaminophen.").

[18] See 74 Fed. Reg. 19397 (Apr. 29, 2009)("Malnourished individuals have been shown to have reduced glutathione levels."); 63 Fed. Reg. 56796-02 (Oct. 23, 1998)("In addition to dosage, hepatotoxicity due to acetaminophen use is also dependent on factors such as liver glutathione stores, nutritional state, age, and in some cases, chronicity of usage.").

[19] FDA, Some Drugs and the Liver Don't Mix, May 2014 (Doc. No. 49-5, Ex. E).

[20] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17); Characterization of Acetaminophen Overdose and Related Hepatotoxic Events, Joint Meeting of the Drug Safety and Risk Management,

liver transplant.[21] A person who has recovered from ALF may still be at risk of redeveloping it, if the person again consumes too much acetaminophen.[22]

If acetaminophen-induced ALF is recognized quickly, acetaminophen's antidote (*N*-acetylcysteine or NAC) can be given to a patient to supply glutathione and prevent or decrease liver injury.[23] However, persons who have developed ALF from an unintentional acetaminophen overdose may not realize their liver injury because symptoms of ALF are not readily apparent or may look like the symptoms the acetaminophen is being used to treat (i.e., flu symptoms).[24]

ii. Actions to Address Acetaminophen-Induced Acute Liver Failure

The majority of acute liver failure cases in the United States are related to the use of acetaminophen.[25] Each year, acetaminophen is responsible for hundreds of deaths and

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Nonprescription and Anesthetic and Life Support Drugs Advisory Committees of the FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

[21] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6).

[22] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6).

[23] See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6); Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9).

[24] 42 Fed. Reg. 35356 (Jul. 8, 1977). See also CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8)("The symptoms of acetaminophen overdose may not appear for up to three days, so people may continue to take acetaminophen and increase the damage. The symptoms of liver injury may mimic the condition that they are treating (e.g., flu symptoms).").

[25] See FDA, Some Drugs and the Liver Don't Mix, May 2014 (Doc. No. 49-5, Ex. E); Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6). See also Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21); A. Temple Dep. at 224 (Feb. 18, 2014)(Doc. No. 90, Ex. 1).

liver transplants, in addition to tens of thousands of hospitalizations.[26] These acetaminophen-induced liver injury patients include both people who are intentionally trying to harm themselves (i.e., attempting suicide) and those who take acetaminophen for therapeutic reasons (i.e., to treat physical pain).[27] There is evidence that patients taking acetaminophen at 4 grams per day—the recommended maximum daily dose until recently—may be at risk of developing acute liver failure.[28]

Medical literature began questioning the safety of acetaminophen at or just above therapeutic dosing levels as far back as the 1980s.[29] During the 1990s, members of the medical community continued to raise concerns about acute liver failure occurring in patients at or even lower than the maximum daily dose of 4 grams.[30]

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[26] See FDA Background Package for June 29-30, 2009 Advisory Committee Meeting (Doc. No. 95, Ex. 8); FDA Safety Analysis Power Point, Sept. 19, 2002 (Pl. Ex. 11). See also Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17).

[27] See FDA Background Package for June 29-30, 2009 Advisory Committee Meeting (Doc. No. 95, Ex. 8); FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 95, Ex. 11); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17); Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21); Characterization of Acetaminophen Overdose and Related Hepatotoxic Events, Joint Meeting of the Drug Safety and Risk Management, Nonprescription and Anesthetic and Life Support Drugs Advisory Committees of the FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

[28] See 71 Fed. Reg. 77314 (Dec. 26, 2006)(2006 Proposed Rule on Liver Warnings)(Doc. No. 95, Ex. 10); Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 95, Ex. 11). See also CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8).

[29] There is also evidence the McNeil executives were aware of this medical literature. See McNeil Memorandum Nov. 19, 1987 (Doc. No. 95, Ex. 14); P. Gussin Dep., Dec. 12, 2013 at 198 (Doc. No. 95, Ex. 15).

[30] See Erikkson, L.S., et al., Hepatotoxicity due to repeated intake of low doses of paracetamol, J Intern Med, 1992: 231:567-570 (Doc. No. 95, Ex. 16).

Throughout this same time period, McNeil was also actively engaged in the research and development of a drug or combination of ingredients that would reduce or eliminate acetaminophen's potentially toxic effects on the liver.[31] One alternative design considered by McNeil was to add methionine to acetaminophen.[32] Methionine could supplement depleted glutathione in the event of an overdose.[33] This drug combination was sold abroad after concerns about acetaminophen-induced liver damage were raised in other countries.[34] It was available as early as the 1990s.[35] McNeil also considered a combination of acetaminophen with the antidote diallyl sulfone and funded a patent for that combination in the mid-1990s.[36]

Neither drug combination was introduced in the United States market. The plaintiff offers evidence that the defendants were concerned that the introduction of an acetaminophen/antidote combination would indicate to customers that acetaminophen alone was not as safe as it was always advertised to be.[37] The defendants claim the drug

[31] See A. Temple Dep., Feb. 18, 2014 at 48-49, 125-26, 164, 176-77 (Doc. No. 90, Ex. 1).

[32] See A. Temple Dep., Feb. 18, 2014 at 123-24, 164, 176-77 (Doc. No. 90, Ex. 1); McNeil Memo re: Acetaminophen Plus Methionine, Jun. 3, 1994 (Doc. No. 90, Ex. 20).

[33] See A. Temple Dep., Feb. 18, 2014 at 123 (Doc. No. 90, Ex. 1); McNeil Internal Memo from P.E. Stewart, Jun. 17, 1994 (Doc. No. 90, Ex. 19).

[34] See A. Temple Dep., Feb. 18, 2014 at 225 (Doc. No. 90, Ex. 1); McNeil Memo re: Acetaminophen Plus Methionine, Jun. 3, 1994 (Doc. No. 90, Ex. 20).

[35] See Letter re: Methinione Combination, Feb. 17, 1999 (Doc. No. 90, Ex. 18).

[36] See McNeil Memo re: Acetaminophen Plus Methionine, June 3, 1994 (Doc. No. 90, Ex. 20); Patent application, Dec. 12, 1995 (Doc. No. 90, Ex. 17).

[37] See A. Temple Dep., Feb. 18, 2014 at 253-54 (Doc. No. 90, Ex. 1).

combinations had their own harmful side effects which did not make them feasible alternatives.[38]

McNeil also considered creating a new drug altogether, which would have the same therapeutic effects as acetaminophen but reduce or eliminate the risk of liver damage.[39] Research and development on that drug began in the early 1990s, was put on hiatus in the late 1990s, and then resumed in 2009.[40] That research and development project has not produced a new drug or analog as of yet that is market-ready.[41]

In 2002, the FDA, which regulates OTC drugs, convened an Advisory Committee to discuss ways to prevent liver injury caused by unintentional acetaminophen overdose.[42] During the Committee Meeting, the FDA presented findings from medical literature: 1) that hepatotoxicity may occur "at recommended doses of APAP [or acetaminophen]," 2) that such cases were linked to risk factors such as alcohol use and/or fasting, and 3) that some cases of unintentional overdose led to death.[43] The FDA also presented its own findings from a review of its internal Adverse Event Reporting (AER) database. The FDA found hepatotoxicity (i.e., liver damage) in persons who have

[38] See, e.g., McNeil Memo re: Acetaminophen Plus Methionine, Jun. 3, 1994 (Doc. No. 90, Ex. 20).

[39] See E. Kuffner Dep., Mar. 5, 2014 at 29-30, 32-36, 54-55 (Doc. No. 90, Ex. 3).

[40] See, e.g., E. Codd, Acetaminophen Analogs: Project Update and Request for Support, Powerpoint, Jun. 17, 2010 (Doc. No. 90, Ex. 5); E. Kuffner Dep., Mar. 5, 2014 at 111-112 (Doc. No. 90, Ex. 3).

[41] See Internal Emails, Nov. 14, 2011 (Doc. No. 90, Ex. 6).

[42] See FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 95, Ex. 11); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17).

[43] See FDA Safety Analysis (Doc. No. 95, Ex. 11). See also Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7)(explaining how fasting may enhance toxicity and how unintentional "overdose" seemed possible at recommended dosing levels).

ingested less than 4 grams/day and which had risk factors like alcohol and "poor nutritional status."[44] At that meeting, the American Association of the Study of Liver disease (AASLD), a group of medical professionals specializing in health effects of the liver, and the FDA offered specific recommendations for enhancing safety warnings and instructions of acetaminophen-based products.[45]

In 2006, the FDA proposed a rule to strengthen warnings regarding the risk of liver damage from taking acetaminophen. The AASLD made a public comment regarding the proposal.[46] AASLD recommended that the maximum daily dose of acetaminophen be reduced to 3 g to "add a measure of increased safety for all patients" because "acetaminophen has a narrow therapeutic window."[47] After receiving and reviewing public comments, the FDA promulgated a final rule outlining the liver warnings it found to be necessary. [48] This final rule, issued in 2009, is explained further below.

In February 2008, the Acetaminophen Hepatotoxicity Working Group for the Center for Drug Evaluation and Research (CDER) of the FDA met to discuss ways to address unintentional acetaminophen overdose.[49] The Group outlined several

[44] See FDA Safety Analysis at Slide 44 (Doc. No. 95, Ex. 11). This data was later published in the Federal Register as part of FDA's Proposed Rule for the 2009 Label Change, discussed below. See 71 Fed. Reg. 77314 (Dec. 26, 2006)(Doc. No. 95, Ex. 10).

[45] See FDA Safety Analysis at Slide 44 (Doc. No. 95, Ex. 11).

[46] See also AASLD Public Comment, Apr. 27, 2007 (Doc. No. 95, Ex. 19).

[47] See AASLD Public Comment to FDA on Proposed Rule, Apr. 27, 2007 (Doc. No. 90, Ex. 12).

[48] See also Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21)(offering the history of the FDA's efforts to address unintentional acetaminophen-induced ALF).

[49] CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13).

recommendations, including a reduction in the maximum tablet strength from 500 mg to 325 mg.[50] The reduction in tablet strength was intended to reduce the overall recommended daily dose of Tylenol from 4,000 mg to 3,250 mg.[51] This recommendation was made over the objection of an unnamed acetaminophen manufacturer which asserted the data did not support a need for the change; the Group looked at Adverse Events Reports (AERs) showing that daily doses of 4 grams presented a risk for some individuals.[52] Survey data also showed that "people routinely and knowingly take more than the recommended dose of OTC pain relievers."[53]

In June 2009, several advisory committees within the FDA held a joint meeting to discuss the issue of liver injury related to acetaminophen use.[54] At that meeting, the committee members voted to recommend that the current maximum single dose of OTC acetaminophen (i.e., 2 x 500 mg) be made available only by prescription.[55] If this recommendation were put into effect, Extra Strength Tylenol could only be sold by prescription according to its current dosing. The majority of committee members

[50] CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13).

[51] CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13).

[52] See CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13).

[53] CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13).

[54] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[55] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

recommended that the maximum single dose of acetaminophen be lowered to 650 mg (i.e., two tablets of Regular Strength Tylenol).[56]

In response, McNeil proposed changing its dosing instructions to recommend that consumers take one tablet, wait to see if that was effective at relieving pain, and then take a second tablet if needed. This concept, known as dose titration, was one McNeil already had included on other products such as Motrin.[57] McNeil never implemented "dose titration" on Extra Strength Tylenol instructions though the FDA approved this change.

b. THE REGULATORY FRAMEWORK FOR TYLENOL

OTC drugs are approved by the FDA through two separate routes: the New Drug Application (NDA) process and the monograph system.[58] During the forty or so years Extra Strength Tylenol has been available OTC, it has been regulated under both FDA regulatory processes that may govern OTC drugs.

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[56] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[57] See McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29-20, 2009, Powerpoint at C-8, C-63 (Doc. No. 95, Ex. 22)("Clinical trial data confirms that 1000 mg is more efficacious than 650 mg"). See also McNeil Powerpoint Response regarding Advisory Committee Meeting on Jun. 29-30, 2009 (Doc. No. 95, Ex. 23); E. Kuffner, McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29, 2009 (Doc. No. 95, Ex. 50)("McNeil is recommending changing the current dosing directions on both the 325-milligram and 500-milligram formulations, seen here on your left, from take two tablets every four to six hours while symptoms last, to the proposed directions shown on the right, take one tablet, and if pain or fever does not respond to one tablet, two tablets may be needed. This dose titration model is identical to the directions on the current over-the-counter ibuprofen label. This significant change will encourage patients to use the lowest effective dose and should, therefore, decrease overall acetaminophen exposure within the general population."); Letter from FDA to McNeil re: Proposed Dose Titration Instructions, Jun. 10, 2010 (Doc. No. 95, Ex. 51)("The proposed maximum dose of no more than 3000 mg acetaminophen per 24 hours is allowed the tentative final monograph (TFM)…. The doses and dosing intervals in the proposed titration directions, to take 500 mg every 4 to 6 hours while symptoms persist and a maximum of 1000 mg every 4 to 6 hours if pain or fever does not respond to 500 mg, are all at levels allowable under the TFM.").

[58] E.g., "How Drugs are Developed and Approved – OTC (Nonprescription) Drugs," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209

i. New Drug Application v. Monograph Process

The NDA process requires specific products be approved for sale with specific labeling. [59] The monograph system allows for the marketing of OTC drugs containing particular ingredients, which were already on the market before the FDA established the monograph system in 1972.[60] These active ingredients, which include acetaminophen,

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647.htm; "How Drugs are Developed and Approved – Over-the-Counter (OTC) Drug Monograph Process," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedand Approved/ucm317137.htm; Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

A detailed recitation of the regulatory process and history is also included in: the Declaration of Judith Jones, Ph.D. (May 20, 2015)(Doc. 49-19 to 49-28); FDA/CDER, Guidance for FDA Staff and Industry, Marketed Unapproved Drugs—Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs, Sep. 19, 2011 (Doc. 49-20)(Ex. C attached to J. Jones Report, Def. Ex. S); the expert report of Cheryl Blume, Ph.D. (May 5, 2014)(Doc. No. 95, Ex. 26), and the Affidavit of Gerald Rachanow, Esq. (Doc. No. 95, Ex. 25). All three experts—Jones (for the defendants) and Blume and Rachanow (for the plaintiff)—have offered expert opinions about the FDA's regulatory process. Each side has filed a Daubert motion to exclude the other's opinion(s); these Daubert motions are still pending.

[59] E.g., "How Drugs are Developed and Approved – OTC (Nonprescription) Drugs," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209 647.htm; "How Drugs are Developed and Approved – Over-the-Counter (OTC) Drug Monograph Process," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedand Approved/ucm317137.htm.

See also Mut. Pharm. Co., Inc. v. Bartlett, – U.S. –, 133 S. Ct. 2466, 2470-71 (2013)("An NDA is a compilation of materials that must include 'full reports of [all clinical] investigations,' § 355(b)(1)(A), relevant nonclinical studies, and 'any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source,' 21 C.F.R. §§ 314.50(d)(2) and (5)(iv) (2012). The NDA must also include 'the labeling proposed to be used for such drug,' 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i), and 'a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling,' 21 C.F.R. § 314.50(d)(5)(viii); § 314.50(c)(2)(ix). The FDA may approve an NDA only if it determines that the drug in question is 'safe for use' under 'the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.' 21 U.S.C. § 355(d)."); In re: Fosamax, 751 F.3d 150, 159 (3d Cir. 2014)("Under the FDCA, a manufacturer must seek approval from the United States Food and Drug Administration ('FDA') to market a new drug and, in doing so, must first file a New Drug Application ('NDA') and then prove the drug's safety and efficacy and propose accurate and adequate labeling. 21 U.S.C. § 355(b)(1), (d)."); In re: Celexa and Lexapro Marketing & Sales Pracs. Litig., 779 F.3d 34, 35-36 (1st Cir. 2015).

[60] See "How Drugs are Developed and Approved – Over-the-Counter (OTC) Drug Monograph Process," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedand Approved/ucm317137.htm.

were ones which had been found to be generally safe and effective through general usage.[61] Therefore, they were allowed to remain on the market OTC.

Because Extra Strength Tylenol's active ingredient is acetaminophen, it was automatically regulated by the monograph system as of 1972. In 1975, the FDA approved Extra Strength Tylenol as "safe and effective for use as recommended in the submitted labeling," pursuant to a New Drug Application (NDA 17-552).[62] In the FDA's letter approving Extra Strength Tylenol for OTC sale and use under the NDA, the FDA also noted that "upon publication in the FEDERAL REGISTER of the OTC Monograph for acetaminophen, revision of the labeling or other action affecting the marketing of [Extra Strength Tylenol] may be required."[63] In 1998, McNeil voluntarily withdrew the NDA for Extra Strength Tylenol.[64] Since that time, Extra Strength Tylenol has been marketed pursuant to the monograph system only.[65]

The monograph system is essentially an expanded version of administrative notice-and-comment rulemaking, which required two rounds of proposals and comments

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[61] E.g., "How Drugs are Developed and Approved – OTC (Nonprescription) Drugs," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209647.htm; "How Drugs are Developed and Approved – Over-the-Counter (OTC) Drug Monograph Process," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm.

[62] FDA Approval letter (Hewes Decl. at Ex. 1)(Doc. No. 49-6, Ex. F). See also Defendants' Statement of Material Facts, Material Fact No. 10; Plaintiff's Statement admitting fact.

[63] FDA Approval letter (Hewes Decl. at Ex. 1)(Doc. No. 49-6, Ex. F).

[64] Doc. No. 49, Ex. T-U attached to Jones Decl., Ex. S (May 1998 communications from McNeil requesting withdrawal of approved NDA, and FDA letter in response acknowledging withdrawal).

[65] Doc. No. 49, Ex. S and Ex. T attached to Jones Decl. (McNeil letter withdrawing NDA)("We intend to continue to market Extra Strength TYLENOL® Tablets as an OTC monograph product and will continue to submit acetaminophen Adverse Drug Experience reports under NDA 19-872.").

as opposed to just one. The monograph process includes four main steps: 1) a review by a panel of qualified experts which then recommend the conditions under which the drug can be used, 2) publication of the expert panel's recommendations in the form of a proposed rule in the Federal Register for public comment, 3) FDA review of the comments on the experts' proposed rule and publication of a tentative final monograph (TFM) with a second opportunity for comments on the TFM, and 4) publication of the final monograph which includes the FDA's findings on when a drug is considered to be generally safe and effective for use.[66] See 21 C.F.R. § 330.10. A drug is considered "safe" under the monograph system when it has "a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability." 21 C.F.R. § 330.10(a)(4).

ii. Regulation of Acetaminophen Under the Monograph System

In 1972, acetaminophen was listed as "an effective analgesic" under the Drug Efficacy Study Implementation program implemented by the FDA, which was the first phase of what would become the monograph process.[67] In 1977, the FDA published a Proposed Rule for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Products reflecting the Advisory Panel's report on this category of ingredients.[68] This Rule

[66] See also Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

[67] Fed. Reg. 7820 (Apr. 20, 1972)(Doc. No. 49, Ex. T).

[68] 42 Fed. Reg. 35346 (July 8, 1977)(Pl. Ex. B attached to Ex. 3 (Affidavit of Gerald Rachanow, Esq.)) and (Def. Ex. I attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.)).

categorized acetaminophen as a Category I active ingredient, meaning that it was "generally recognized as safe and effective" or GRASE. That proposed rule made clear that warnings on products containing those ingredients were still important: "[b]ecause OTC products can be purchased by anyone [and] the public generally does not regard those products as medicines which, if used improperly, can result in injurious or potentially serious consequences."[69] The rule explained: "The consumer should be informed of any possible signs of known toxicity or any indication requiring discontinuation of the use of the drug so that appropriate steps may be taken before more severe symptoms become apparent."[70] Specifically, the Proposed Rule noted: "acetaminophen has no [] sign of toxicity or 'safety valve' to alert the consumer [to the development of ALF]."[71] For this reason, the Proposed Rule recommended that all products containing acetaminophen contain the warning, "Do not exceed recommended dosage because severe liver damage may occur."[72] The Proposed Rule also stated that a single dose of acetaminophen (2 tablets) containing 500 mg—i.e., Extra Strength

[69] 42 Fed. Reg. 35355 (July 8, 1977).

[70] 42 Fed. Reg. 35355 (July 8, 1977).

[71] 42 Fed. Reg. 35356 (July 8, 1977). See also CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8)("The symptoms of acetaminophen overdose may not appear for up to three days, so people may continue to take acetaminophen and increase the damage. The symptoms of liver injury may mimic the condition that they are treating (e.g., flu symptoms)."); FDA, Some Drugs and the Liver Don't Mix, May 2014 (Doc. No. 49-5, Ex. E)(describing symptoms of liver problems as fatigue, jaundice, and itchiness of the skin).

[72] 42 Fed. Reg. 35356, 35447 (July 8, 1977). The Proposed Rule also noted that acetaminophen advertising may indicate that it is a safer product, when in fact, it may not be under certain circumstances. See id. The Rule went further: "Because the consumer needs to be correctly and fully informed, the Panel recommends that the advertising in any medium for these drugs that in any way uses the labeling, package or container not be inconsistent, even in subtle implication through mood, focus or innuendo, with the applicable labeling in the OTC internal analgesic monograph." Id. Though the Proposed Rule recognized that the FTC regulated commercial advertising, it "strongly urge[d] the [FTC] to require that the cautionary language and warnings developed by the Panel be given emphasis in commercial advertising more so than is currently being done…" Id.

Tylenol—should be taken every 6 hours while a single dose of 325 mg tablets could be taken every 4 hours.[73]

On November 16, 1988, the FDA issued a Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) products, including acetaminophen.[74] In the TFM, the FDA reviewed comments on the 1977 Proposed Rule and determined which parts remained valid and which it declined to adopt. Though the FDA made its recommendations for regulating IAAA products, the TFM was still considered proposed regulation subject to additional comments.[75] In the TFM, the FDA continued to categorize acetaminophen under Category I: GRASE.[76] It adopted the Panel's recommended dosing as well.[77] Specifically, products containing acetaminophen were expected to have the following dosing instructions for adults: "325 to 650 milligrams every 4 hours or 325 to 650 milligrams every 3 hours or 650 to 1,000 milligrams every 6 hours, while symptoms persist, not to exceed 4,000 milligrams in 24 hours or as directed by a doctor."[78] It also "tentatively decided not to adopt the liver

[73] See 42 Fed. Reg. 35358 (July 8, 1977)(chart).

[74] 53 Fed. Reg. 46204, 46248 (Nov. 16, 1988).

[75] See 21 C.F.R. §§ 310, 343, 369, 53 Fed. Reg. 46204, 46248, 46254 (Nov. 16, 1988)(TFM)(Doc. No. 95, Ex. 48; Ex. C attached to Ex. 3 (Affidavit of Gerald Rachanow, Esq.)) or (Def. Ex. J attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.)); FDA Letter re: FOIA request, Nov. 17, 2011 (Doc. No. 95, Ex. 4).

[76] 53 Fed. Reg. 46249 (Nov. 16, 1988).

[77] 53 Fed. Reg. 46251 (Nov. 16, 1988).

[78] 53 Fed. Reg. 46257 (Nov. 16, 1988).

warning recommended by the Panel" though the FDA was "aware that liver damage can occur from acetaminophen overdosage."[79]

The FDA has not yet issued a Final Monograph for IAAA products. These products, including those containing acetaminophen, continue to operate under the Tentative Final Monograph (TFM). During the relevant timeframe of this case, Extra Strength Tylenol was only regulated by the TFM.[80] The FDA has explained: "Under a TFM, manufacturers market products at their own risk and are able to make voluntary adjustments [to their product's dosing] taking into account the information presented in the proposed TFM."[81] Until that final regulatory determination is made—if it ever is—the defendants remain responsible for all aspects of the Tylenol label.[82]

c. CHANGES IN EXTRA STRENGTH TYLENOL DOSING

From 1977 until 2011, Extra Strength Tylenol was marketed with dosing instructions that differed from what was prescribed by the TFM. Extra Strength Tylenol bottles instructed consumers to take two tablets every 4 to 6 hours.[83] The TFM

[79] 53 Fed. Reg. 46214, 46252 (Nov. 16, 1988).

[80] See FDA Letter re: FOIA request, Nov. 17, 2011 (Doc. No. 95, Ex. 4).

[81] See FDA Letter re: FOIA Request, Nov. 17, 2011 (Doc. No. 95, Ex. 4). See also E. Kuffner Dep., Mar. 18, 2011 at 8-10 (Doc. No. 95, Ex. 5)(explaining what duties a drug manufacturer has when new risks come to light in post-market surveillance); Wyeth v. Levine, 555 U.S. 555, 570-71 (2009)("[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.")(discussed further below).

[82] See McNeil letter to the FDA re: label change, Jan. 27, 1995 (Doc. No. 49, Ex. Q attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("We believe that the language we are using in the Directions section of our labeling is acceptable since the issue has not yet been finalized in the final monograph for Internal Analgesic Products.") (debating FDA's recommendation that language in McNeil's label be changed to conform with the TFM language on dosing).

[83] See 2007 Extra Strength Tylenol label (Doc. No. 90, Ex. 11).

recommended consumers take two tablets every 6 hours. In 1994, when McNeil sought approval from the FDA to add an alcohol warning to the Extra Strength Tylenol label, the FDA informed McNeil that the Extra Strength Tylenol label was not in conformity with the TFM because it instructed consumers to take 2 caplets "every 4-6 hours" as opposed to every 6 hours.[84] McNeil objected to the claimed deficiency in the instructions. McNeil continued to recommend consumers dose every 4 to 6 hours, as opposed to every 6 hours in accord with the TFM.[85]

In July 2011, McNeil voluntarily changed the dosing instructions on Extra Strength Tylenol.[86] McNeil had previously opposed reducing the daily dose when the change was recommended years before.[87] This change was made to "lessen the

[84] See FDA Letter/Fax to McNeil, Nov. 23, 1994 (Doc. No. 95, Ex. E attached to Ex. 3 (Affidavit of Gerard Rachanow, Esq.)); FDA Letter to McNeil, Mar. 31, 1997 (Doc. No. 95, Ex. F attached to Ex. 3 (Affidavit of Gerard Rachanow, Esq.)). McNeil did not agree with the FDA's determination. See McNeil letter to the FDA re: label change , Jan. 27, 1995 (Doc. No. 49, Ex. Q attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("We believe that the language we are using in the Directions section of our labeling is acceptable since the issue has not yet been finalized in the final monograph for Internal Analgesic Products.").

The FDA again sent a letter stating that the label dosing at 4 to 6 hours was not in compliance with the TFM. See FDA Letter to McNeil, Mar. 31, 1997 (Doc. No. 49, Ex. R attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("The dosage recommendations are not consistent with the tentative final monograph or supported in the application. The second sentence should be revised to read, "Take two tablets every 6 hours."). On July 21, 1997, the FDA then did send a letter to McNeil not to implement any of the changes in the previous two letters until the FDA has instructed them to. See Def. Ex. S attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.)).

Because the TFM is only a proposed rule not a final one, McNeil's decision to provide different dosing instruction would not be *per se* negligence. However, McNeil's decision to intentionally label Extra Strength Tylenol with instructions that could cause a person to consume more than the TFM's daily recommended dose is evidence that could lead a reasonable jury to believe that McNeil breached its duty to market a safe product.

[85] See 2007 Extra Strength Tylenol label (Doc. No. 90, Ex. 11).

[86] See Dear Doctor Letter (Doc. No. 90, Ex. 8). While this evidence would typically be excluded under the Federal Rules of Evidence as a subsequent remedial measure, this information can be used to rebut the defendants' defense of impossibility. See FED. R. EVID. 407.

[87] See E. Kuffner, McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29. 2009 (Doc. No. 95, Ex. 50)("We disagree with FDA's options to completely eliminate over-the-counter access to the 1,000-milligram single adult dose and the 4,000-milligram maximum daily dose.").

possibility of accidental acetaminophen overdose."[88] McNeil changed dosing from "4 to 6 hours" to "6 hours" as outlined in the TFM.[89] McNeil also changed the maximum daily dose from 8 caplets to 6 caplets, lowering the maximum daily recommended dose from 4 grams to 3 grams.[90] In a letter to doctors about the dosing change, McNeil explained that "1,000 mg has been demonstrated to provide effective relief at 6 hours."[91]

In order to implement that change, McNeil worked with "other manufacturers of acetaminophen products to help ensure consistency in dosing instructions."[92] According to McNeil, the change was not a response to the FDA's decision in January 2011 to limit the amount of acetaminophen in prescription combination products.[93] As the FDA explained, "McNeil's voluntary act to reduce the maximum daily dose for Extra Strength Tylenol® is a measure that can be commonly taken under the over-the-counter TFM and is in accordance with the provisions of the IAAA TFM."[94]

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[88] See Dear Doctor Letter (Doc. No. 90, Ex. 8).

[89] See Dear Doctor Letter (Doc. No. 90, Ex. 8).

[90] See Dear Doctor Letter (Doc. No. 90, Ex. 8).

[91] See Dear Doctor Letter (Doc. No. 90, Ex. 8). See also Christina Chang, M.D., M.P.H., Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products, of the FDA, Powerpoint, Jun 29, 2009 (Doc. No. 95, Ex. 21)(questioning whether 1000 mg is much more effective than 650 mg); Jane Filie, M.D., Medical Officer, Div. of Analgesia and Rheumatology Products of the FDA, Powerpoint, Jun. 29, 2009 at 120 (Doc. No. 95, Ex. 21)("Little data to support value of using products with 500 mg (1000 mg dose) over products with 325 mg (650 mg dose."). But see McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29-20, 2009, Powerpoint (Doc. No. 95, Ex. 22)("Clinical trial data confirms that 1000 mg is more efficacious than 650 mg"); Transcript of Comments from Kuffner related to Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 50).

[92] See Dear Doctor Letter (Doc. No. 90, Ex. 8).

[93] See Dear Doctor Letter (Doc. No. 90, Ex. 8).

[94] FDA Letter re: FOIA Request, Nov. 17, 2011 (Doc. No. 95, Ex. 4).

II. OVERVIEW OF PLAINTIFF'S CLAIMS

a. FACTS REGARDING DENICE HAYES'S DEATH

Plaintiff Rana Terry brings this wrongful death and products liability action on behalf of her deceased sister's estate.[95] Her sister Denice Hayes died on August 31, 2010.[96] Denice was a single woman living with another sister Rebecca Hayes; the two had lived together for most of her life, up until the time of Denice's death.[97] Denice was not working at the time of her death due to health problems. Prior to leaving the workforce in 2008 for health reasons, she was employed as a teacher for several years.[98]

Denice's medical history included weight issues, back and leg pain, high blood pressure, and type II diabetes.[99] Denice had taken Extra Strength Tylenol periodically for years to treat some of these health conditions with no adverse effects.[100] She allegedly preferred Extra Strength Tylenol to Regular Strength Tylenol.[101] Rebecca typically did the shopping for both she and her sister. Rebecca was unaware of the difference between

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[95] See Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G).

[96] See Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G).

[97] See R. Hayes Dep. at 191 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[98] See Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G.).

[99] R. Hayes Dep. at 201 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[100] Defendants' Statement of Facts, Material Fact No. 3; Plaintiff's Response admitting this fact. R. Hayes Dep. at 120-123 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1)(agreeing that Ms. Hayes used Tylenol without any adverse effects for pain relief for at least 20 years before her death because it was safe and did not upset her stomach). In addition, Dr. Rex Sherer, who performed Ms. Hayes's 2009 gastric bypass surgery, testified to Ms. Hayes's chronic use of acetaminophen without incident. See R. Sherer, M.D. Dep., Mar. 23, 2015 at 76 (Doc. No. 49, Ex. O). See also A. Anantharaju, M.D. Dep., Oct. 15, 2014 at 23-27, 28-30, 32, 37-39, 65-66, 71 (Doc. No. 49, Ex. P).

[101] See R. Hayes Dep. at 39 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

Extra Strength Tylenol's dosage and that of Regular Strength.[102] However, she purchased Tylenol over its generic version because she and her sister thought Tylenol was a better, safer product.[103] The two sisters often watched television together and viewed ads for Tylenol.[104] According to Rebecca, Denice believed Tylenol was easier on the stomach based on advertising about the product.[105]

In August 2009, Denice underwent gastric bypass surgery to rectify her ongoing health problems.[106] After the surgery, she lost 180 pounds; she was able to stop taking her medications for high blood pressure and diabetes.[107] She used painkillers less than before because her back and leg pain had lessened.[108] In June 2010, she had a fall which exacerbated her back pain.[109]

In mid-August 2010, Denice underwent lumbar laminectomy surgery.[110] She was instructed by her doctor to take Regular Strength Tylenol in conjunction with Lorcet, a prescription drug containing acetaminophen, and was not to exceed 4 grams of

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[102] R Hayes Dep. at 114 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[103] R. Hayes Dep. at 127, 130 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[104] R. Hayes Dep. at 191-193, 199-200 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[105] R Hayes Dep. at 129-31 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[106] See R. Hayes Dep. at 50-53 (Doc. No. 49-9, Ex. I)(explaining how decedent was about 400 pounds at time of surgery and over 200 pounds at time of death), 200-201 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[107] See R. Hayes Dep. at 201, 229(Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1); R. Sherer, M.D. Dep. at 74-75 (Doc. No. 49-15, Ex. O)(explaining Denice's conditions post gastric surgery).

[108] R. Hayes Dep. at 201, 229 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[109] R. Hayes Dep. at 201-202 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1); R. Terry Dep. at 53 (Doc. No. 49-9, Ex. I).

[110] See R. Hayes Dep. at 156-57 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

acetaminophen in a 24-hour period.[111] Denice took Extra Strength Tylenol from August 12, 2010 to August 29, 2010 at "appropriate times and in appropriate amounts."[112] She allegedly took tablets from a medium-sized bottle Rebecca had purchased the previous August to treat Denice's gastric bypass surgery pain.[113] That bottle was shared by the two sisters during that year.[114] Denice allegedly used that bottle until it ran out. Rebecca purchased another bottle of Extra Strength Tylenol for her sister on August 28, 2010.[115]

After her surgery, Ms. Hayes also began taking Lorcet as instructed by her doctor. However, she allegedly stopped taking Lorcet at some point before her death because she didn't like its side effects.[116] She continued to only take Extra Strength Tylenol because she thought it was gentler on her stomach.[117]

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[111] See R. Hayes Dep. at 156-57, 159-160 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[112] Doc. No. 28 (Short Form Compl. ¶10); Plaintiff Fact Sheet at 11-12 (redacted)(Doc. No. 49, Ex. H); Defendants' Statement of Facts, Material Fact No. 5; Plaintiff's Statement admitting this fact (as quoted from the plaintiff's complaint). However, plaintiff also admits that no fact witness has personal knowledge that Ms. Hayes took her Extra Strength Tylenol as directed. See Defendants' Statement of Material Facts, Material Fact No. 4; Plaintiff's Statement admitting this fact.

[113] R. Hayes Dep. at 189, 229 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1). According to Rebecca, she had purchased a medium-sized bottle of about 100 to 120 caplets of Extra Strength Tylenol in August 2009. Id.

[114] R. Hayes Dep. at 122, 189 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[115] R. Hayes Dep. at 147, 230 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1). According to Rebecca, Extra Strength Tylenol was all that was available; Regular Strength Tylenol was not being sold at the WalMart where she purchased the product. R. Hayes Dep. at 207 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1). See also R. Terry Dep. at 38 (Doc. No. 49-9, Ex. I).

[116] See R. Hayes Dep. at 34-36, 60, 67, 203-205 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1). Denice also was prescribed hydrocodone with acetaminophen which she took right after she was discharged from her back surgery on August 12, 2010. See R. Hayes Dep. at 156 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1). At what point between August 12th and 29th Denice stopped taking Lorcet is in dispute.

[117] R. Hayes Dep. at 34-36, 60, 67, 203-205 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

Between August 12, 2010 and August 31, 2010, Denice was in and out of the hospital.[118] She was admitted to the hospital overnight on August 20, 2010 for "nausea, vomiting, and impending dehydration."[119] She was experiencing back and rectal pain.[120] She was released on August 23, 2010.[121] During the week of August 23, 2010, Denice continued to experience symptoms of nausea and vomiting.[122] She was having trouble eating solid foods.[123] She allegedly took three to four doses of Extra Strength Tylenol each day during that week.[124] During this timeframe, Denice was cared for by several members of her family.[125]

Denice was again admitted to the hospital on August 29, 2010.[126] The doctor diagnosed her with acute liver failure "most likely [from] accidental Tylenol overuse" and treated her with the acetaminophen antidote.[127] Denice died in the hospital two days

[118] See R. Terry Dep. at 38 (Doc. No. 49-9, Ex. I); R. Hayes Dep. at 38-41 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[119] See R. Terry Dep. at 38 (Doc. No. 49-9, Ex. I); R. Hayes Dep. at 38-41, 58-61, 76, 162, 205 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[120] See R. Hayes Dep. at 38 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[121] See R. Hayes Dep. at 162-163 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[122] See R. Hayes Dep. at 56-57 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[123] See R. Hayes Dep. at 46, 56, 66-67, 237-238 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[124] R. Hayes Dep. at 209-210, 226-227 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[125] See R. Terry Dep. at 38-40 (Doc. No. 49-9, Ex. I); R. Hayes Dep. at 34-35, 39-40, 46, 56-57, 74; Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G).

[126] See R. Hayes Dep. at 38-41, 58-61, 76 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[127] R. Hayes Dep. at 76, 171 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

later. Her cause of death is listed as "liver failure" caused by "acetaminophen intoxication."[128]

b. PLAINTIFF'S CLAIMS

In January 2012, Ms. Terry filed suit against Johnson & Johnson and McNeil asserting, *inter alia*, a design defect claim. According to the plaintiff, the defendants knew that Tylenol could cause liver damage at or just above the recommended dose, especially when a person has been fasting or malnourished. The plaintiff claims the defendants are liable for Denice's death because they failed to design Extra Strength Tylenol in such a way to reduce or eliminate the risk of liver damage to consumers. The plaintiff offers several alternative designs that the defendants could have implemented.

The defendants move for summary judgment, arguing that the plaintiff cannot offer sufficient evidence at trial to support her design defect claim. The defendants also argue that the plaintiff's design defect claim is impliedly preempted by Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S.Ct. 2466 (2013).

III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A dispute is "genuine" when "a reasonable jury could return a verdict for the nonmoving party" based on the evidence in the record. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is "material" when it "might affect the outcome of the suit under the governing law." Id.

[128] See Denice Hayes Death Certificate (Doc. No. 45, Ex. A).

A party seeking summary judgment initially bears responsibility for informing the court of the basis for its motion and identifying those portions of the record that "it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial Celotex burden can be met simply by demonstrating to the district court that "there is an absence of evidence to support the non-moving party's case." Id. at 325. After the moving party has met its initial burden, the adverse party's response must cite "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." FED. R. CIV. P. 56(c)(1). Summary judgment is therefore appropriate when the non-moving party fails to rebut by making a factual showing that is "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322. [129]

[129] Alabama law governs the plaintiff's design defect claim. This standard is the same as the summary judgment standard found in Alabama law. Alabama law requires that "proof by substantial evidence shall be required to submit an issue of fact to the trier of the facts [for motions for summary judgment in all civil actions]."Ala.Code 1975 § 12-21-12. "'Substantial evidence' has been defined as 'evidence of such weight and quality that fair-minded persons in the exercise of impartial judgment can reasonably infer the existence of the fact sought to be proved.'" Mixon By and Through Mixon v. Houston County, 598 So.2d 1317, 1318 (Ala. 1992)(quoting West v. Founders Life Assurance Co. of Florida, 547 So.2d 870, 871 (Ala. 1989)).

The moving party has the burden to make a prima facie case that no genuine dispute of material fact exists. When the burden of proof at trial is on the non-moving party at the summary judgment stage—as is the case here—the moving party "may satisfy the Rule 56 burden of production either by submitting affirmative evidence that *negates an essential element* in the nonmovant's claim or, assuming discovery has been completed, by demonstrating to the trial court that the nonmovant's evidence is insufficient to establish an essential element of the nonmovant's claim." Verchot v. General Motors Corp., 812 So.2d 296, 300 (Ala. 2001)(quoting Ex parte General Motors Corp., 769 So.2d 903, 909 (Ala.1999)(citations and quotation marks omitted))(emphasis in original). The non-movant then has the burden to put forth sufficient evidence to prove each element of her claims. Id. This evidence is then considered

Under Rule 56 of the Federal Rules of Civil Procedure, the court must draw "all justifiable inferences" in favor of the non-moving party. Anderson, 477 U.S. at 255. The court must decide "not whether . . . the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." Id. at 252. If the non-moving party has produced more than a "mere scintilla of evidence" demonstrating a genuine issue of material fact, then the court may not credit the moving party's "version of events against the opponent, even if the quantity of the [moving party's] evidence far outweighs that of its opponent." Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

IV. The Plaintiff Has Offered Sufficient Evidence of Her Design Defect Claim

Alabama law governs all of the plaintiff's claims. See Choice of Law Decision, May 20, 2015 (Doc. No. 41, 42).

a. Alabama Products Liability Law (AEMLD)

Alabama's products liability doctrine is known as Alabama Extended Manufacturer's Liability Doctrine (AEMLD). The AEMLD is a hybrid liability doctrine which follows the tenets of Restatement 402A but allows defendants to show fault

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in the light most favorable to the non-movant and all reasonable doubts resolved against the moving party. See id. In other words, if the plaintiff as the non-movant cannot produce sufficient evidence to show her claim could be successfully established at trial, the defendants are entitled to summary judgment. See Verchot v. General Motors Corp., 812 So.2d 296, 300 (Ala. 2001)("If the nonmovant cannot produce sufficient evidence to prove each element of its claim, the movant is entitled to a summary judgment, for a trial would be useless.")(citations and quotation marks omitted)).

This standard is slightly different than if the party moving for summary judgment is also the party with the burden of proof at trial. If the movant were the plaintiff, she would be expected to put forth "credible evidence" to support her motion. See Verchot v. General Motors Corp., 812 So.2d 296, 300 (Ala. 2001)("If the movant has the burden of proof at trial, the movant must support his motion with credible evidence, using any of the materials specified in Rule 56(c), [Ala.]R.Civ.P. ('pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits')."(citations and quotation marks omitted)).

through traditional tort defenses like assumption of the risk, lack of causation, or contributory negligence. See Casrell v. Altec Indus., Inc., 335 So.2d 128, 131-34 (Ala. 1976); Atkins v. Am. Motors Corp., 335 So.2d 134, 137-43 (Ala.1976). The AEMLD may be applied to wrongful death cases. Casrell, 335 So.2d at 134; Atkins, 335 So.2d at 144.

"Under the AEMLD, a manufacturer has the duty to design and manufacture a product that is reasonably safe for its intended purpose and use." Townsend v. Gen. Motors Corp., 642 So.2d 411, 415 (Ala. 1994). This does not mean that the manufacturer is expected to insure against all harm or "to produce an accident-proof or injury-proof product." Id. "Proof of an accident and injury is not in itself sufficient to establish liability under the AEMLD; a defect in the product must be affirmatively shown." Id. (citing Casrell, 335 So.2d 128; Atkins, 335 So.2d 134. See also Sears, Roebuck & Co. v. Haven Hills Farm, Inc., 395 So.2d 991, 994-95 (Ala. 1981); Thompson v. Lee, 439 So.2d 113, 115 (Ala.1983); Brooks v. Colonial Chevrolet–Buick, Inc., 579 So.2d 1328, 1332 (Ala.1991); Verchot v. Gen. Motors Corp., 812 So.2d 296, 301 (Ala. 2001)."Whether a product is 'unreasonably dangerous' is for the trier of fact, just as negligence, vel non, is in a traditional negligence case." Casrell, 335 So.2d at 133.

Under the AEMLD, "the important factor is whether [the product] is safe or dangerous when the product is used as it was intended to be used." Yarbrough v. Sears, Roebuck and Co., 628 So.2d 478, 481 (Ala. 1993)(quoting Casrell, 335 So.2d at 133); Atkins, 335 So.2d 134 (quotation marks omitted)). A product is considered "defective" when "the product does not meet the reasonable expectations of an ordinary consumer as

to its safety." Casrell, 335 So.2d at 133. "[I]t makes no difference whether it is dangerous by design or defect." Id. at 133.

b. Elements of a Design Defect Claim

To establish liability under the AEMLD, the plaintiff must show that her sister was injured by the defendants' product sold to her "in a defective condition unreasonably dangerous…as the ultimate user or consumer." Casrell, 335 So.2d at 132-33. "Showing these elements, the plaintiff has proved a prima facie case although [the defendants have] exercised all possible care in the preparation and sale of [their] product, and [the decedent had] not bought the product from, or entered into any contractual relation with, the seller." Id. The plaintiff has offered evidence that the decedent died of acetaminophen-induced liver failure after taking Extra Strength Tylenol as directed.[130] Viewing the evidence in the light most favorable to the plaintiff, a jury could find that Extra Strength Tylenol was defective.[131]

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[130] See Denice Hayes Death Certificate (Doc. No. 45, Ex. A); Expert Report of T. Davern M.D. (Doc. No. 95, Ex. 20)(discussing how Ms. Hayes' liver was "normal in size" at the time of her gastric bypass surgery in August 2009 and how a colonoscopy in June 2010 produced benign results); R. Terry Dep. at 38-40 (Doc. No. 49-9, Ex. I); R. Hayes Dep. at 34-35, 38-41, 46, 56-61, 74, 76, 171 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1); Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G).

[131] There is no debate about whether the defendants produce Extra Strength Tylenol or whether the product was altered because it was sold to the decedent.

The plaintiff offers evidence from her own experts to show that Extra Strength Tylenol was unsafe at the recommended dose. See N. Kaplowitz Dep., Apr. 21, 2015 at 271-73 (Doc. No. 90, Ex. 31)("Q: "…you limit your Tylenol recommendations to patients with liver injury to two gram maximum? A: Correct. Q: Why two grams? A: Because I think that people with liver disease can't tolerate an insult, and two grams is what I would consider to be -- I consider the – the literature to -- and my personal experience to be such that I don't think I've -- you know, it's exceedingly rare. There may be a couple of cases in the literature where somebody described patients who were taking two grams or less as having liver injury. But my feeling is that it's -- you know, it's not a dangerous dose for somebody with liver disease. Q: You're testifying in this lawsuit and in the prior case that four grams can put somebody into acute liver failure? A: Right….Q: So you're giving them two grams with people with liver injury? A: Yeah. And that's exactly why the FDA lowered the dose from four grams to three grams; the recommended dose."); N. Kaplowitz, M.D. Expert Report (May 5, 2014)(Doc. No. 90, Ex. 37); L. Plunkett, M.D. Expert Report (May 2, 2014)(Doc. No. 90, Ex. 38). See also Neil Kaplowitz, M.D., Acetaminophen Hepatoxicity: What Do We Know,

For a design defect claim, "[t]he scope of a manufacturer's legal duty…depends upon two factors: (1) the foreseeability of the danger; and (2) the feasibility of an alternative design that averts that danger." Bean v. BIC Corp., 597 So.2d 1350, 1352 (Ala. 1992). There is evidence that the defendants knew or should have known that Extra Strength Tylenol could cause liver damage either because consumers took the OTC drug at or just above the recommended dose or that consumers unintentionally took too much.[132] In fact, the defendants were actively working to find an acetaminophen substitute that could provide its same benefits without its hepatotoxicity risks.[133] Furthermore, the FDA was considering whether to remove Extra Strength Tylenol from

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What Don't We Know, and What Do We Do Next?, Hepatology, Jul. 2004 at 23-26 (Doc. No. 90, Ex. 39); William Lee, Acetaminophen and the U.S. Acute Liver Failure Study Group: Lowering the Risks of Hepatic Failure, Hepatology, Vol. 40, No. 1, 6-9 (2004)(Doc. No. 90, Ex. 40).

She also offers evidence from the defendants' experts, questioning the safety of Extra Strength Tylenol at the recommended dose. See R. Brown Dep. at 72-73 (Apr. 30, 2015)(Doc. No. 95, Ex. 32)("I tell them to take no more than six or eight regular-strength tablets in a day, knowing that they'll take more….It's neigh on 2 grams [daily]."); S. Flamm Dep. at 168-73 (May 5, 2015)(Doc. No. 95, Ex. 33)(explaining why he only recommends that patients take a maximum of 3 or 4 grams of Tylenol a day but advises them that this is the upper limit on what should be taken because he recognizes the likely risk of patients taking too much).

[132] See, e.g., Erikkson, L.S., et al., Hepatotoxicity due to repeated intake of low doses of paracetamol, J Intern Med, 1992: 231:567-570 (Doc. No. 95, Ex. 16). There is also evidence the McNeil executives were aware of this medical literature. See McNeil Memorandum Nov. 19, 1987 (Doc. No. 95, Ex. 14); P. Gussin Dep., Dec. 12, 2013 at 198 (Doc. No. 95, Ex. 15); FDA Safety Analysis Power Point, Sept. 19, 2002 (Doc. No. 95, Ex. 11); FDA Memorandum, Aug. 15, 2002 (Doc. No. 95, Ex. 17); Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8).

[133] See E. Kuffner Dep. at 29-30, 32-36, 54-55 (Mar. 5, 2014)(Doc. No. 90, Ex. 3); E. Codd, Acetaminophen Analogs: Project Update and Request for Support, Powerpoint, June 17, 2010 (Doc. No. 90, Ex. 5); Internal Emails, Nov. 14, 2011 (Doc. No. 90, Ex. 6).

The plaintiff offers this possible analog as an alternative design; however, that design was not available at the time of Denice's death. The plaintiff argues that the analog could have been available at the time of her death if the defendants had continued researching and developing the analog through the later 1990s and early 2000s. Whether this is true is highly speculative. The plaintiff may offer evidence that the defendants were working to find an analog, to show knowledge of a defect and/or defendants' state of mind. However, the research and development project for the analog cannot in itself be used to show an "alternative design."

OTC status because of the risks it posed to uninformed consumers.[134] Liver injury at or just above the recommended dose was foreseeable.

c. Feasible Alternative Designs

To establish that a feasible alternative design existed, "a plaintiff must prove that 'a safer, practical, alternative design was available to the manufacturer at the time it manufactured the [product]." Hannah v. Gregg, Bland & Berry, Inc., 840 So.2d 839, 858 (Ala. 2002)(quoting Beech v. Outboard Marine Corp., 584 So.2d 447, 450 (Ala. 1991))(citations and quotation marks omitted)).[135] To establish that an alternative design was "safer" and "practical" the plaintiff must offer evidence that the plaintiff's injuries would have been prevented or reduced if the alternative design were used and that the alternative design would have been safer than the design actually used. Id. See also Richards v. Michelin Tire Corp., 21 F.3d 1048, 1057 (11th Cir. 1994).

Once a plaintiff proves the existence of an alternative safer, practical design, a defendant manufacturer cannot assert compliance with industry standards as an absolute defense. See Elliot v. Brunswick Corp., 903 F.2d 1505, 1508 (11th Cir. 1990); General Motors Corp. v. Edwards, 482 So. 2d 1176, 1198 (Ala. 1985)(overruled on other grounds). The existence of an alternative safer, practical design may indicate failure on the part of the entire industry. Elliot, 903 F.2d at 1508. A manufacturer can, however, offer proof that the design was "state of the art." See Frantz v. Brunswick, 866 F. Supp.

[134] See FDA, CDER, Joint Meeting of the Drug Safety and Risk Management Advisory Committee, NDAC, and the Anesthetic and Life Support Drugs Advisory Committee, Questionnaire (Doc. No. 90, Ex. 14).

[135] See also McMahon v. Yamaha Motor Corp., U.S.A., 95 So.3d 769, 772 (Ala. 2012)("In an AEMLD case, this is done by proving that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the allegedly defective product.").

527, 534 (S.D. Ala. 1994); Springer v. Jefferson County, 595 So.2d 1381, 1385 (Ala. 1992); Jones v. General Motors Corp., 557 So.2d 1259, 1261, 1265 (Ala. 1990). Compliance with industry standards and proof of "state of the art" design are factors a jury can consider when determining if the product was defective. See, e.g., General Motors Corp., 482 So. 2d at 1198; Caterpillar Tractor Co. v. Ford, 406 So.2d 854, 858 (Ala. 1981).

i. Antidote combinations

The plaintiff points to several alternative designs to establish her claim. First, she offers the acetaminophen/antidote combinations researched and developed by the defendants in the 1990s. The acetaminophen/methionine combination was sold in other countries.[136] The acetaminophen/diallyl-sulfone combination was covered by a patent funded by the defendants.[137] Both combinations were alternative designs available at the time of the Denice's death; they were not simply hypothetical in nature. The defendants claim that these alternative designs would not be "safer" or "practical." Whether these alternative designs were safer or more practical than Extra Strength Tylenol in its current form is a question of fact. Viewing the facts in the light most favorable to the plaintiff, a reasonable jury could find that one or both of these combinations was safer and more practical.

[136] See A. Temple Dep., Feb. 18, 2014 at 225 (Doc. No. 90, Ex. 1); McNeil Memo re: Acetaminophen Plus Methionine, Jun. 3, 1994 (Doc. No. 90, Ex. 20); Letter re: Methinione Combination, Feb. 17, 1999 (Doc. No. 90, Ex. 18).

[137] See McNeil Memo re: Acetaminophen Plus Methionine, Jun. 3, 1994 (Doc. No. 90, Ex. 20); Patent application, Dec. 12, 1995 (Doc. No. 90, Ex. 17).

ii. Lowering the Dosage

The plaintiff also claims that Extra Strength Tylenol could easily have been re-designed to be safer by changing the dosing instructions for the drug, as the defendants did after Denice's death. The defendants claim this argument is not appropriate for a design defect claim but, instead, relates to a failure-to-warn claim. I disagree.

If manufacturers are aware of a known defect, they expected to do one of two things: warn of the unknown dangers or design the product to reduce potential harm. See Casrell v. Altec Industries, Inc., 335 So.2d 128, 133 (Ala. 1976).[138] The plaintiff brings a separate failure-to-warn claim. I addressed the validity of that claim in a separate memorandum. At issue here is whether the defendants could have designed Extra Strength Tylenol differently so as to prevent liver injury in consumers.

Dosing instructions and warnings are two different parts of a label. A change in a dosing instruction could have reduced the potential danger inherent in Extra Strength Tylenol; this is an element of design for an OTC monograph product like Extra Strength Tylenol. In the case of acetaminophen, dosing *is* what makes the product. The only difference between Regular Strength Tylenol and Extra Strength Tylenol is the amount of acetaminophen or the dose provided by each caplet. This is presumably why the defendants filed a separate NDA for Extra Strength Tylenol initially.

Warnings, on the other hand, are used to reduce dangers that could not be designed out of a useful product. It is possible that the defendants could have both changed the

[138] See also Mutual Pharmaceuticals, Inc. v. Bartlett, 133 S.Ct. 2466, 2470 (2013)("Because Mutual was unable to change sulindac's composition as a matter of both federal law and basic chemistry, New Hampshire's design-defect cause of action effectively required Mutual to change sulindac's labeling to provide stronger warnings.").

dosage to reduce risk of liver injury *and* added better warnings to inform consumers about the risk of liver injury that may never be designed out of acetaminophen. For this reason, the plaintiff can assert both a failure-to-warn claim and a design defect claim. It is the jury's task to determine if the defendants are liable under one or both claims.[139]

Acetaminophen is a "dose-related toxin"—it's safe at certain doses but unsafe at higher doses.[140] Dosing is what makes acetaminophen *both* effective *and* safe. Several years before the decedent's death, the defendants were made aware that Extra Strength Tylenol could have a "narrow therapeutic margin"—i.e., the difference between its current maximum recommended dose could be very little compared to the dose that could cause liver injury.[141] Yet, the defendants only lowered the maximum daily dose in 2011 to build in a wider margin of safety. By instructing consumers to take less, the defendants lowered the risk that consumers would take too much acetaminophen, intentionally or unintentionally. Consumers would have to take much more than directed in order to "overdose" and put themselves at risk of liver damage.[142]

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[139] See Torkie-Tork v. Wyeth, 739 F.Supp.2d 895, 900 (E.D. Va. 2010)("[I]t may well be that the dosage of a drug is a fundamental characteristic of the drug, since a lower dosage may well alter or affect the positive impact the drug is designed to have on the human body.…[T]he decision properly rests with a jury to determine whether an alternative dosage of [the drug] would so fundamentally alter the drug as to render it an entirely different product.").

[140] Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6).

[141] See, e.g., CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 13)("Acetaminophen has a narrow therapeutic margin, that is, there is little difference between the current maximum recommended dose of acetaminophen and the doses that are associated with a potentially elevated risk of hepatotoxicity."); AASLD Public Comment, Apr. 27, 2007 (Doc. No. 95, Ex. 19); Christina Chang, M.D., M.P.H., Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products, of the FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

[142] See CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8)("Acetaminophen is different from other OTC pain relievers in that the maximum total daily dose limit for acetaminophen is the same for OTC and prescription products. For NSAIDs, the total daily OTC dose is

As evidenced by the defendants' 2011 change, the defendants have control of dosing instructions. The defendants could have instructed consumers to take two tablets of Extra Strength Tylenol every 6 hours, as recommended by the TFM, to ensure that consumers were taking no more than 3 grams a day. McNeil admitted that the change in dosing would be no less effective than the 4 to 6 hour dosing. The defendants were aware of this option but decided not to offer this dosing instruction. They were not in compliance with industry standards for dosing 500 mg acetaminophen, as prescribed in the TFM. This information alone could lead a jury to find that Extra Strength Tylenol was defective as designed.

iii. Dose Titration

Lastly, the plaintiff claims the defendants could have offered instructions with dose titration, as were included in their Motrin products. These instructions would encourage consumers to take the least amount of Extra Strength Tylenol to treat their condition and build in a wider margin of safety. Though the defendants proposed adding dose titration to the Extra Strength Tylenol instruction in 2009, they never actually implemented it.[143] Whether the defendants should have changed the dosing sooner to

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considerably less than the prescription dose. Doubling the maximum daily dose of OTC acetaminophen for several days presents significant risk of developing liver toxicity. In contrast, doubling the maximum OTC dose of NSAIDs for several days exposes consumers to a prescription-level dose, which only slightly increases the risk of gastrointestinal bleeding and 'is not even close to the seriousness presented by doubling the dose of acetaminophen.'… Lowering the total daily dose will increase the margin of safety of acetaminophen."), ("[L]imiting both the tablet strength and single dose should provide a wider safety margin and should reduce the incidence of hepatotoxicity."), ("Lowering the dose will increase the margin of safety."), and ("A wider safety margin is needed for acetaminophen.").

[143] See McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29-20, 2009, Powerpoint at C-8, C-63 (Doc. No. 95, Ex. 22)("Clinical trial data confirms that 1000 mg is more efficacious than 650 mg"). See also McNeil Powerpoint Response regarding Advisory Committee Meeting on Jun.

build more of a safety margin into Extra Strength Tylenol's design is a question for the jury to answer.[144] See Torkie-Tork v. Wyeth, 739 F.Supp.2d 895, 900 (E.D. Va. 2010)("[I]t may well be that the dosage of a drug is a fundamental characteristic of the drug, since a lower dosage may well alter or affect the positive impact the drug is designed to have on the human body. …[T]he decision properly rests with a jury to determine whether an alternative dosage of [the drug] would so fundamentally alter the drug as to render it an entirely different product.").

Viewing all the facts in the light most favorable to the plaintiff, a reasonable jury could find that a feasible design existed at the time of Denice's death and the defendants breached their duty to market a safe product.[145]

29-30, 2009 (Doc. No. 95, Ex. 23); E. Kuffner, McNeil's Presentation to Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee and the Anesthetic and Life Support Drugs Advisory Committee, Jun. 29. 2009 (Doc. No. 95, Ex. 50)(" McNeil is recommending changing the current dosing directions on both the 325-milligram and 500-milligram formulations, seen here on your left, from take two tablets every four to six hours while symptoms last, to the proposed directions shown on the right, take one tablet, and if pain or fever does not respond to one tablet, two tablets may be needed. This dose titration model is identical to the directions on the current over-the-counter ibuprofen label. This significant change will encourage patients to use the lowest effective dose and should, therefore, decrease overall acetaminophen exposure within the general population."); Letter from FDA to McNeil re: Proposed Dose Titration Instructions, Jun. 10, 2010 (Pl. Ex. 51)("The proposed maximum dose of no more than 3000 mg acetaminophen per 24 hours is allowed the tentative final monograph (TFM)…. The doses and dosing intervals in the proposed titration directions, to take 500 mg every 4 to 6 hours while symptoms persist and a maximum of 1000 mg every 4 to 6 hours if pain or fever does not respond to 500 mg, are all at levels allowable under the TFM.").

[144] The defendants also could have limited the amount of caplets available in each package. Legislation in the United Kingdom required acetaminophen manufacturers to limit the size of packages, resulting in a decrease of acetaminophen related hospital admissions. See Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9). Members of the medical community also recommended this change prior to the decedent's death. See Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(. No. 95, Ex. 9). Though the Acetaminophen Hepatotoxicity Working Group did not recommend that the package size be limited, there were no regulations in place to prevent the defendants from changing the packaging to prevent liability, as they had done in other countries for this same reason. See CDER Working Group Executive Summary and Recommendations, Feb. 26, 2008 (Doc. No. 95, Ex. 8).

[145] The defendants offer Yarbrough v. Sears, Roebuck and Co., 628 So.2d 478, 482 (Ala. 1993), to support their argument that the plaintiff has not offered sufficient evidence to present the design defect claim to a jury. In Yarbrough, the court found that the plaintiffs had only offered a "general statement" by their expert that a "simple

V. Genuine Disputes of Material Fact Remain

Several facts remain in dispute about whether it was feasible for the defendants to implement a safer design of Extra Strength Tylenol.[146] How these facts are resolved affects the outcome of the plaintiff's design defect claim, making them genuine disputes of material fact. The plaintiff has offered evidence that these safer designs could have been implemented prior to the decedent's death. The defendants counter with reasons why the alternative designs would not have been better (i.e., diallyl sulfone was found to evaporate after a month making it no more effective after a month's time, the methionine combination would have had other side effects).

These disputes center on whether the proffered alternative designs would have been safer than the Extra Strength Tylenol already on the market. To determine if the alternative design was safer and more practical, a jury should consider the following factors: styling, cost, desirability, safety, the foreseeability of the particular accident, the

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design modification" would have prevented their injuries, caused by their own misuse of the product. Id. Yarbrough is factually distinguishable. The plaintiff here offers more than general expert statements that Extra Strength Tylenol could have been re-designed. The plaintiff, instead, offers actual alternative designs which were possible at the time of the decedent's death. She relies on more than general statements by her experts. Yarbrough is not helpful.

In the same way, Smith v. Louisville Ladder Co., 237 F.3d 515, 519-20 (5th Cir. 2001), is not helpful. In Smith, the plaintiff relied completely on his expert's testimony to show a safer, alternative design. Id. at 519. Smith's expert offered only a "preliminary concept," which was not market-ready, may be "awkward," and might have safety issues of its own. Id. The plaintiff here offers alternative designs that were either developed by the defendants (to the point of applying for a patent), implemented by the defendants after the decedent's death (i.e., dosage change), or were available in other countries. For these reasons, Smith, and other analogous cases cited by the defendants, are distinguishable. See Elliott v. Brunswick Corp., 903 F.2d 1505, 1508 (11th Cir. 1990)("In short, although Elliott's experts promoted the use of propeller guards, they agreed that companies could not yet market them for general use. Both sets of experts, moreover, discussed the problems that these devices engender."); Beech v. Outboard Marion Corp., 584 So. 2d 447, 450 (Ala. 1991)("We decline to hold, as a matter of law, that simply because 'a feasible propeller guard *could* have been designed by a proper use of the manufacturer's resources' that an 'alternative design' existed. Furthermore, a propeller guard that 'arguably creat[es] other dangers' is not a 'safer' design within the meaning of General Motors Corp. v. Edwards." (emphasis added)).

[146] See Defendants' Statement of Facts, Doc. No. 50; Plaintiff's Response to Defendants' Statement of Facts, Doc. No. 95 (disputing ¶¶ 3-19).

likelihood of injury from that accident, the probable seriousness of the injury, the obviousness of the defect, and the manufacturer's ability to eliminate the defect. Hannah v. Gregg, Bland & Berry, Inc., 840 So.2d 839, 858 (Ala. 2002)(quoting Beech v. Outboard Marine Corp., 584 So.2d 447, 450 (Ala. 1991))(citations and quotation marks omitted)).[147]

The plaintiff also offers evidence that the defendants' real reasons for not implementing the alternative designs were profit-driven. For example, the plaintiff points to evidence that the defendants only seriously started investing in research and development on an acetaminophen-like analog devoid of hepatotoxic effects *after* the FDA committees recommended that Extra Strength Tylenol be available only by prescription. Determinations about what the defendants' real motives for not implementing available alternative designs involve credibility judgments.[148] They are for a jury to decide, not the court.

For these reasons, the plaintiff's design defect claim cannot be decided on summary judgment.

VI. Plaintiff's Design Defect Claim is Not Preempted

The defendants also argue that the plaintiff's design defect claim is impliedly preempted under Mutual Pharmaceuticals, Inc. v. Bartlett, 133 S.Ct. 2466 (2013). Preemption is a concept based on the Supremacy Clause of the U.S. Constitution that

[147] See also Richards v. Michelin Tire Corp., 21 F.3d 1048, 1057 (11th Cir. 1994).

[148] Defenses like compliance with industry standards and proof of "state of the art" design are also factors a jury can consider when determining if the product was defective. See General Motors Corp. v. Edwards, 482 So. 2d 1176, 1198 (Ala. 1985)(overruled on other grounds); Caterpillar Tractor Co. v. Ford, 406 So.2d 854, 858 (Ala. 1981).

provides a conflicting state law will be trumped by its federal counterpart. See Bartlett, 133 S. Ct. at 2472-73 (citing U.S. Const., Art. VI, cl. 2). Even if a federal statute does not expressly preempt a state law, the state law may be impliedly pre-empted where it is "impossible for a private party to comply with both state and federal requirements." Id. at 2473 (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)(quotation marks omitted)).[149] There is a general presumption against preemption. See, e.g., Deweese v. Nat'l R.R. Passenger Corp. (Amtrak), 590 F.3d 239, 246 (3d Cir. 2009)(citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).

"Impossibility pre-emption is a demanding defense." Wyeth v. Levine, 555 U.S. 555, 573 (2009). The Third Circuit has cautioned against "lightly infer[ring]" preemption where "state compensatory regimes have traditionally played an important role." Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 249 (3d Cir. 2008). Whenever possible, preemption analysis should attempt to reconcile the state law and federal law with one another. See Deweese, 590 F.3d at 248. "[S]tate tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes" and fall "squarely within the realm of traditional state regulation." Fellner, 539 F.3d at 248-49.

a. Bartlett Does Not Require a Finding of Preemption

Mutual Pharmaceuticals, Inc. v. Bartlett, 133 S.Ct. 2466 (2013), was a New Hampshire drug products liability action involving a generic drug manufacturer brought

[149] See also Deweese v. Nat'l R.R. Passenger Corp. (Amtrak), 590 F.3d 239, 246 (3d Cir. 2009)("[I]mplied conflict preemption exists when, 'under the circumstances of [a] particular case, [the state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'")(quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–143 (1963)("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce").

under both failure-to-warn and design defect theories. 133 S.Ct. 2466, 2470 (2013). New Hampshire law requires drug manufacturers to ensure that their products are not unreasonably unsafe, either because of inadequate warnings or inadequate design. Id. Under federal law, however, generic manufacturers are unable to change their drug labels or the composition of their drug products without prior FDA approval. Id. at 2741. For this reason, the Court found that the plaintiff could not comply with both state and federal law and the plaintiff's claims were impliedly preempted under federal law. Id. at 2479. In making its decision, the Court relied on PLIVA v. Mensing, 131 S.Ct. 2567 (2011). PLIVA, decided shortly before, held that failure-to-warn claims against generic drug manufacturers were preempted because "federal law prohibits generic drug manufacturers from independently changing their drugs' labels." Id. at 2470, 2472. Their products are expected to be identical to brand-name products. See Bartlett, 133 S.Ct. at 2475.

This case involves a brand-name drug manufacturer, not a generic manufacturer. The Supreme Court has not addressed whether a design defect claim brought against a brand-name OTC drug manufacturer is preempted. See Brown v. Johnson & Johnson, 64 F.Supp.3d 717, 721 (E.D. Pa. 2014). However, Supreme Court precedent on when failure-to-warn claims are impliedly preempted offers some insight on how the Court might rule if faced with this question.

As explained in PLIVA, the same federal regulations that apply to generic manufacturers do not necessarily apply to brand-name manufacturers, such as the defendants. "[B]rand-name and generic drug manufacturers have different federal drug

labeling duties." PLIVA, 131 S.Ct. at 2574. While a brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label based on 21 U.S.C. §§ 355(b)(1), (d), a generic manufacturer is only responsible for "ensuring that its warning label is the same as the brand name's" under § 355(j)(2)(A)(v), § 355(j)(4)(G), and 21 CFR §§ 314.94(a)(8), 314.127(a)(7). Id. This explains why the failure-to-warn claim brought against a generic drug manufacturer in PLIVA was preempted but failure-to-warn claim brought against the brand-name manufacturer in Wyeth v. Levine was not.[150] See PLIVA, 131 S.Ct. at 2581; Wyeth v. Levine, 555 U.S. 555, 581 (2009)("We conclude that it is not impossible for Wyeth to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.").[151] In the same way, generic manufacturers cannot change the design of their products because their products have to be the same as the brand-name manufacturer's. See Bartlett, 133 S.Ct. at 2475 ("[T]he

[150] PLIVA explained why Wyeth was distinguishable:

> Wyeth is not to the contrary. In that case, as here, the plaintiff contended that a drug manufacturer had breached a state tortlaw duty to provide an adequate warning label. 555 U.S., at 559–560, 129 S.Ct. 1187. The Court held that the lawsuit was not pre-empted because it was possible for Wyeth, a brand-name drug manufacturer, to comply with both state and federal law. Id., at 572–573, 129 S.Ct. 1187. Specifically, the CBE regulation, 21 CFR § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval. 555 U.S., at 573, 129 S.Ct. 1187; cf. supra, at 2575 – 2576. Thus, the federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.…Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted.

PLIVA, 131 S.Ct. at 2581.

[151] See also Wyeth, Inc. v. Weeks, 159 So.3d 649 (Ala. 2014)("It is beyond dispute that the federal statutes and regulations that apply to brand name manufacturers are meaningfully different than those that apply to generic drug manufacturers. ... But different federal statutes and regulations may, as here, lead to different pre-emption results." (quoting PLIVA, 131 at 2582)).

FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based."). Brand-name manufacturers, however, can petition the FDA to change their drug's dosing, strength, etc. if the design poses a risk to consumers. See Wyeth, 555 U.S. 568-576. This is especially true in the context of acetaminophen which still operates under a TFM and not a final monograph.[152]

Following from this logic, I find that Bartlett—a case involving a generic manufacturer and following PLIVA v. Messing—does not apply to the plaintiff's design defect claim against a brand-name manufacturer. Under the dictates of Wyeth v. Levine, preemption is not warranted.

b. It Was Not Impossible for the Defendants to Re-Design Extra Strength Tylenol

Furthermore, I find no reason here why the defendants could not comply with both their state and federal obligations.[153] In terms of changing the dose of Extra Strength Tylenol, the defendants could and did lower the dose after the decedent's death. In fact, the new dosage directions the defendants offered were *more in line* with FDA guidance because they followed the TFM dosing instructions for 500 mg caplets. Operating under

[152] "Under a TFM, manufacturers market products at their own risk and are able to make voluntary adjustments taking into account the information presented in the proposed TFM." See FDA Letter re: FOIA Request, Nov. 17, 2011 (Doc. No. 95, Ex. 4). See also E. Kuffner Dep., Mar. 18, 2011 at 8-10 (Doc. No. 95, Ex. 5)(explaining what duties a drug manufacturer has when new risks come to light in post-market surveillance); Wyeth v. Levine, 555 U.S. 555, 570-71 (2009)("[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.")(discussed further below).

[153] See Brown v. Johnson & Johnson, 64 F.Supp.3d 717, 721 (E.D. Pa. 2014)("The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products.")(citing Wyeth and Bartlett as distinguishable).

the TFM—a proposed rule—the defendants could have changed the dosing instructions prior to 2011. The FDA even advised them in the 1990s that they should change their dosing instructions to adhere to the TFM.[154] McNeil determined this was unnecessary.[155] The FDA also had approved the defendants' proposal to add dose titration instructions to Extra Strength Tylenol. Yet, the defendants never implemented these dose titration instructions. It was the defendants, not the FDA, which prevented those instructions from changing.

As for the alternative designs related to acetaminophen/antidote combinations, the defendants put forth no evidence that the FDA would not have allowed those drugs on the market in the United States. Impossibility preemption is a defense; the defendants bear the burden of showing it. See Wyeth v. Levine, 555 U.S. 555, 573 (2009)("Impossibility pre-emption is a demanding *defense*. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements." (emphasis added)). They have not made such a showing to require preemption. The plaintiff's design defect claims are not impliedly preempted. See

[154] See FDA Letter/Fax to McNeil, Nov. 23, 1994 (Doc. No. 95, Ex. E attached to Ex. 3 (Affidavit of Gerald Rachanow, Esq.)); FDA Letter to McNeil, Mar. 31, 1997 (Doc. No. 95, Ex. F attached to Ex. 3 (Affidavit of Gerald Rachanow, Esq.)). The FDA again sent a letter stating that the label dosing at 4 to 6 hours was not in compliance with the TFM. See FDA Letter to McNeil, Mar. 31, 1997 (Doc. No. 49, Ex. R attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("The dosage recommendations are not consistent with the tentative final monograph or supported in the application. The second sentence should be revised to read, "Take two tablets every 6 hours."). On Jul. 21, 1997, the FDA then did send a letter to McNeil not to implement any of the changes in the previous two letters until the FDA has instructed them to. See Doc. No. 49, Ex. S attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.)). Because the TFM is only a proposed rule not a final one, McNeil's decision to provide different dosing instruction would not be *per se* negligence. McNeil's decision to intentionally instruct consumers to take a dose which was higher than that prescribed by the TFM could lead a reasonable jury to believe that McNeil breached its duty to adequately prevent potential risks.

[155] See McNeil letter to the FDA re: label change , Jan. 27, 1995 (Doc. No. 49, Ex. Q attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("We believe that the language we are using in the Directions section of our labeling is acceptable since the issue has not yet been finalized in the final monograph for Internal Analgesic Products."); 2007 Extra Strength Tylenol label (Doc. No. 90, Ex. 11)(with 4 to 6 hour language).

Brown v. Johnson & Johnson, 64 F.Supp.3d 717, 721-22 (E.D. Pa. 2014)(finding that the "[d]efendants have not made out federal preemption" on the design defect claim because the "[d]efendants have also failed to demonstrate that the FDA would have rejected a proposed change to Children's Motrin's chemical composition…Defendants have failed to meet their 'exacting burden.'").

VII. CONCLUSION

For the foregoing reasons, I will deny the defendants' motion for summary judgment on the plaintiff's design defect claim.

An appropriate Order follows.