TYLENOL ACUTE LIVER FAILURE LITIGATION

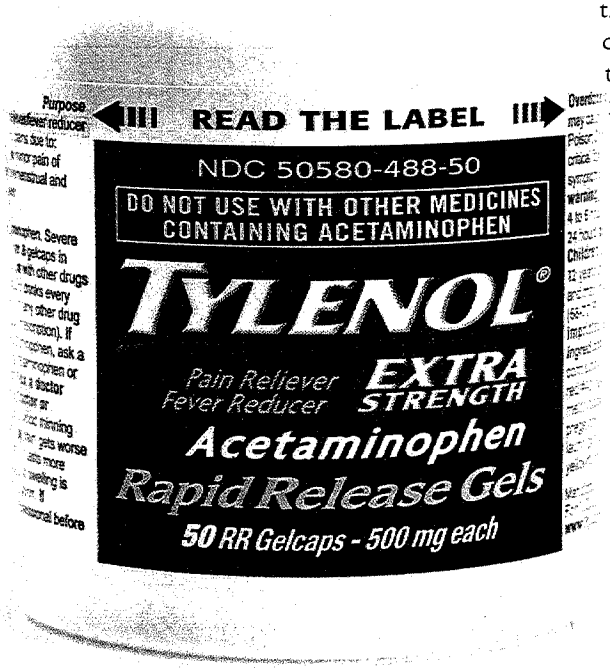
Hidden Danger & Misplaced Trust

By: Troy Rafferty and Brandon Bogle

Introduction

The public has been told for decades that Tylenol is the "safest" and "most trusted" pain reliever on the market. A prescription isn't needed to buy it. No doctor has to monitor someone while taking it. For years, people have bought Tylenol thinking it was "safe". This is exactly what the manufacturer of Tylenol, McNeil-PPC, Inc. ("McNeil"), wanted you to think. Unfortunately, the reality is much different and the danger is hidden right there in your medicine cabinet.

McNeil has known of the risks of Tylenol for decades and has chosen to keep them hidden from the public. This article will debunk many myths involving Tylenol and its active ingredient, acetaminophen. It will explore the science behind the risk of acute liver failure linked to Tylenol as well as the intense marketing campaign McNeil has undertaken to perpetuate these myths and the efforts it has undergone to mislead the public and protect its lucrative product line at all costs.



Tylenol: A Brief Overview

Before delving deeper, it is necessary to begin with a brief explanation of Tylenol's history and the various Tylenol products available today. Acetaminophen has been available as an over-the-counter pain reliever since the 1950s and was first marketed in the United States under the trademarked name Tylenol in 1955.[1] [2] Given Tylenol's early entry into the U.S. marketplace, it was not subject to the FDA's current approval process for over-the-counter medications, which requires various levels of proof of both safety and efficacy.

Tylenol is manufactured by McNeil, a subsidiary of Johnson & Johnson. There are currently 23 different types of over-the-counter Tylenol products available for purchase in the United States.[3] Tylenol is available in three different dosages for use by adults: regular strength (325 mg of acetaminophen per dose), extra strength (500 mg of acetaminophen per dose), and extended release (650 mg of acetaminophen per dose).[4] Today, acetaminophen is the most commonly used over-the-counter product in the U.S. with "19 percent of adults reporting taking the drug in a given week."[5]

Acetaminophen & Acute Liver Failure

Acetaminophen is a well-established liver toxin, and the mechanism by which acetaminophen can cause acute liver failure has been thoroughly studied over the past few decades. Acetaminophen is metabolized in the liver and as it is processed; approximately 5 percent - 6 percent of the acetaminophen is turned into a liver toxin referred to by the acronym "NAPQI". In order for NAPQI not to destroy one's liver it must bind with a substance called glutathione. When glutathione binds with the NAPQI, the NAPQI is detoxified and excreted out of the body through urine. However, if there are either inadequate amounts of glutathione present in the liver or too much NAPQI present, then NAPQI attacks the liver, which results in acute liver failure.[6]

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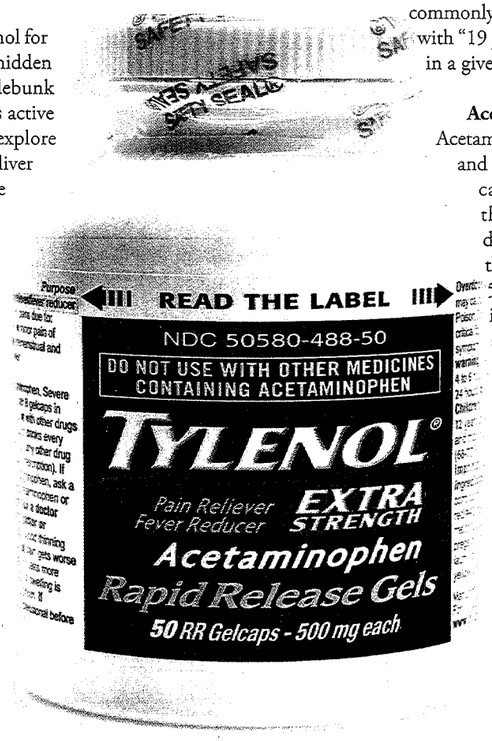

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The link between Tylenol and acute liver failure is undeniable. Beginning in the late 1990s, research began to emerge indicating that "acetaminophen hepatotoxicity was a major cause of acute liver failure (ALF) in the United States", accounting for approximately 40% of acute liver failure hospitalizations.[7] Acetaminophen-related hepatotoxicity remains the "leading cause of acute liver failure (ALF) in the United States, Great Britain and most of Europe."[8] In fact, the "incidence of acetaminophen-related ALF exceeds by at least three-fold that due to all other idiosyncratic drug reactions combined."[9]

There can also be no doubt that acetaminophen-induced acute liver failure is a serious and potentially life-threatening medical condition. The condition carries with it a 30 percent mortality rate.[10] Additionally, more than "100,000 calls to Poison Control Centers, 56,000 emergency room visits, 2,600 hospitalizations and nearly 500 deaths are attributed to acetaminophen in this country annually."[11] Data further show that the number of acetaminophen-related acute liver failure cases has increased considerably since 1998.[12]

The notion that Tylenol can cause acute liver failure is nothing new. In 1975, an editorial article in *The Lancet* included the following statement:

> The hepatotoxicity of paracetamol [acetaminophen] remains a serious problem, and liver damage has been observed after absorption of as little as 6.2 G. – not much more than the recommended dosage. … Surely the time has come to replace paracetamol with an effective analogue that cannot cause liver damage.[13]

Scores of additional articles followed in the decades thereafter, which sufficiently established Tylenol's propensity to cause acute liver failure. By 2002, the FDA found it necessary to convene an Advisory Committee meeting to discuss this growing epidemic.[14] The action ultimately recommended by the FDA prompted public comment by numerous interested parties, including the hepatic experts at the American Association for the Study of Liver Diseases ("AASLD"). Taking an unprecedented step, the AASLD recommended sweeping label changes to acetaminophen-containing OTC products, including Tylenol. Among other recommendations, the following specific language was proposed by the AASLD:

> This product can **cause** severe or even **fatal** liver injury. The chance is higher if you:
>
> - Use this drug at the maximum recommended dose (4 grams/day) for 5 or more consecutive days
> - Use this drug at the maximum recommended dose (4 grams/day) when food intake is restricted or prohibited[15]
>
> (emphasis added).

The AASLD further voiced concerns that "acetaminophen has a narrow therapeutic-to-toxic window", which simply means that exceeding the recommended daily dose of Tylenol by even a small amount can expose one to a substantial increased risk of acute liver failure.[16] The AASLD's discussion of the narrow therapeutic-to-toxic window with acetaminophen is certainly alarming, given that Tylenol is available for use without a prescription and without physician supervision. This concern was echoed by the FDA Acetaminophen Hepatotoxicity Working Group:

> The working group was also impressed with the fact that current dosing recommendations and tablet sizes of acetaminophen leave little room for error. The 4 gram per day recommended dose is also the maximum safe dose, one that must not be exceeded, an unusual situation for any drug, particularly an OTC drug, one placing a large fraction of users close to a toxic dose in the ordinary course of use.[17]

Moreover, McNeil was keenly aware that patients taking Tylenol routinely and unintentionally ingested more than the recommended dose. Some of McNeil's own studies show that many people taking Tylenol used more than the recommended daily dose. Similar findings have been seen in other published studies.[18] In fact, widespread unintentional misuse of Tylenol has been cited as a "serious public health threat requiring urgent attention."[19] Despite possessing this information, McNeil has done little to ensure that people taking Tylenol did so without exceeding the recommended daily dose.

Unfortunately, many people who have suffered acetaminophen-induced acute liver failure have not exceeded the recommended daily dose of Tylenol. While the exact number is unclear, some in the medical community have estimated that approximately 10% of the acetaminophen-induced acute liver failure cases have occurred in patients that have not exceeded the recommended daily dose.[20] What is clear is that the exact dose of acetaminophen that will lead to acute liver failure is so "highly variable and unpredictable" that it is difficult to ascertain "what is a perfectly safe dose of acetaminophen, especially when taken for more than a day or two."[21]

As noted above, the AASLD, as part of its 2007 recommendation for updated labeling for acetaminophen containing products, urged manufacturers to include warnings that the risk of acute liver failure increased "when food intake is restricted or prohibited."[22] This increased risk involves those taking Tylenol in situations where they are fasting, usually because they are suffering from the flu, migraine, recovering from dental surgery, or some other similar pain causing condition, which necessitates Tylenol use, but which prevents the consumption of food. Of course, these people are taking Tylenol for the very reason it is intended to be used; as a pain reliever. Once again, the data supporting this proposed label change were available long before 2007.

It cannot be questioned that the FDA and medical researchers alike have consistently concluded that the problem of acute liver failure among patients taking acetaminophen products, including Tylenol, is a serious problem requiring immediate attention. In fact, the FDA cited the "significant public health problem" of the continued

occurrence of acetaminophen hepatotoxicity as being the driving force for the formation of the FDA Acetaminophen Hepatotoxicity Working Group.[23]

Given the urgency and severity of this issue, one could only expect that McNeil would do anything possible to prevent further Tylenol-induced liver injuries and deaths. Unfortunately, as is discussed below, McNeil's actions indicate it is more interested in protecting its bottom line than the health of those taking Tylenol.

McNeil's Marketing of Tylenol

McNeil has spent countless millions on various marketing campaigns to support the Tylenol brand. Several phrases and buzz words have appeared repeatedly in these campaigns and still appear in Tylenol advertising today. Phrases appearing frequently in Tylenol advertising and repeatedly seen by most Americans include references to Tylenol as the "most trusted", "the #1 choice of doctors", and "recommended the most by people who know the most."

However, perhaps most prominent among the buzz words used in Tylenol advertising is the reference to Tylenol as the "safest" pain reliever on the market.[24] As noted by one author and medical researcher, this is a "claim most hepatologists might dispute."[25] By way of comparison as to safety, many have expressed concerns about statin toxicity, however, "more patients die of acetaminophen poisoning in one year than can be attributed to all the statins combined over all the years that these drugs have been in use."[26] Other advertisements tout Tylenol as having an "exceptional safety profile" when used as directed.[27] This claim is highly questionable given the large number of reports of acute liver failure in patients taking Tylenol at or below recommended daily dosages.[28]

McNeil has shown a clear desire to posture Tylenol to the public as a product that provides trusted safety. However, instead of taking the lead on advising the public about the risk of liver failure with Tylenol use, McNeil has taken every opportunity to prevent the public from gaining this information from trusted sources. As an example, in 2004 when the FDA chose to embark on a public education campaign focusing on the concerns about liver failure caused by Tylenol, McNeil moved quickly asking the FDA to cease the campaign or take other corrective action. The FDA rejected McNeil's request stating "we do not believe the education campaign taken as a whole, or in any of its parts", were false or misleading.[29]

Similarly, McNeil has taken no action to inform the public through its advertising that fasting while taking Tylenol can increase a user's risk of acute liver failure. Shockingly, McNeil has also not used its seemingly unending advertising budget to warn the public not to exceed the daily recommended dose under any circumstances. This is especially egregious given the paper thin therapeutic-to-toxic window for Tylenol and McNeil's knowledge that many people routinely exceed the recommended daily dose when using Tylenol.

Tylenol's Inadequate Warnings

Product labeling for over-the-counter (OTC) products, like Tylenol, plays an invaluable role in a user's understanding of the product's safety profile. In fact, other than direct-to-consumer advertising, a patient's understanding of an OTC product's safety profile comes almost exclusively from the product's warnings. This is necessarily the case because there is generally no physician overseeing the use of the product. Despite this fact, McNeil waited much too long to add any warning about liver damage to its Tylenol packaging and the warnings in place even today are woefully inadequate.

It was not until 2005 that McNeil first added a warning in its Tylenol packaging concerning liver damage occurring in patients taking Tylenol. At that point, the warning merely told the user that "taking more than the recommended dose of Tylenol may lead to liver damage." In 2010, McNeil slightly modified this warning to provide the language available today. The warning, as taken from the regular strength Tylenol packaging, states:

> **Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if
>
> - adult takes more than 4,000 mg of acetaminophen in 24 hours
> - child takes more than 5 doses in 24 hours, which is the maximum daily amount
> - taken with other drugs containing acetaminophen
> - adult has 3 or more alcoholic drinks every day while using this product[30] [31]

Again, this "warning" is woefully inadequate. For example, noticeably absent is any reference to Tylenol "causing" acute liver failure. In fact, the term "liver failure" does not even appear in the label. Moreover, missing is any mention that this potential "severe liver damage" can be fatal. The label is also silent on the increased risk of acute liver failure when taking Tylenol while fasting, an unequivocal and clear recommendation made by the AASLD in 2007. The inadequacies of this warning are rendered more egregious in light of McNeil's relentless marketing campaigns touting the unmatched safety of Tylenol.

"Project Protect"

It is not just McNeil's failure to warn that is alarming. Incredibly, McNeil knew of and even studied a second compound that could be added to Tylenol that would counter Tylenol's toxic effect on the liver. As early as 1991, McNeil began an investigation known as "Project Protect", which was aimed at finding a compound that could be added to Tylenol that could reduce its liver toxicity.

McNeil began studying compounds as part of "Project Protect" and ultimately did discover a compound that potentially delivered promising results. However, in 1995, McNeil abruptly pulled the plug on the project because they were concerned that if they added the compound, it would be admitting that Tylenol was in fact a dangerous liver toxin - contrary to their long standing massive marketing claims.

This is a startling revelation for multiple reasons. First, McNeil could potentially have minimized the toxic effects of Tylenol on the liver,

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This is a startling revelation for multiple reasons. First, McNeil could potentially have minimized the toxic effects of Tylenol on the liver, but chose to abandon these efforts. Second, the FDA was not notified by McNeil that "Project Protect" was ever being considered, much less that it was undertaken and a promising protective compound was discovered.

Status of Litigation

On April 1, 2013, the United States Judicial Panel on Multidistrict Litigation established MDL No. 2436, which centralized the Tylenol litigation in the United States District Court for the Eastern District of Pennsylvania with the Honorable Lawrence F. Stengel presiding over the litigation.[33] There are currently 80 actions pending in MDL No. 2436.[34] In the few months since the MDL was created, discovery has begun at a feverish pace and negotiations are ongoing regarding a bellwether trial selection plan. There are also 16 cases currently pending in state court with 15 filed in the Superior Court of the State of New Jersey in Atlantic County and one case pending in the Philadelphia Court of Common Pleas.

Conclusion

Countless Americans and people around the world reach for a bottle of Tylenol every day in their local pharmacy or supermarket. What they think when they pick up that bottle is probably what you thought before you read this article: Tylenol is a harmless over-the-counter product that I can trust. The truth, however, is much different and certainly more frightening.

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[1] William M. Lee, Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, 46(4) Hepatology 966, 966 (2007).
[2] Acetaminophen is referred to in many countries outside the United States as paracetamol.
[3] http://www.tylenol.com/products.
[4] *Id.* Tylenol is also available in various children's formulations.
[5] Michael S. Wolf, Risk of Unintentional Overdose with Non-Prescription Acetaminophen Products, 27(12) J. Gen. Intern. Med. 1587, 1587 (2012).
[6] *See* JR Mitchell et al., Acetaminophen-induced hepatic injury: protective role of glutathione in man and rationale for therapy, 16(4) Clin. Pharmacol. Ther., 676-84 (1974); Paracetamol Hepatotoxicity, 2 (7946)The Lancet 1189-91 (1975).
[7] The Acetaminophen Hepatotoxicity Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity, at 3 (Feb. 26, 2008).
[8] William M. Lee, Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, 46(4) Hepatology 966, 966 (2007).
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] Paracetamol Hepatotoxicity, 2(7946) The Lancet 1189-91, 1191 (1975).
[14] The Acetaminophen Hepatotoxicity Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity, at 3 (Feb. 26, 2008).
[15] American Association for the Study of Liver Diseases (AASLD), Public Comment Regarding the Proposed Amendment of the Tentative Final Monograph of Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use, at 2 (Apr. 27, 2007).
[16] *Id.*
[17] The Acetaminophen Hepatotoxicity Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity, at 5 (Feb. 26, 2008).
[18] Michael S. Wolf, Risk of Unintentional Overdose with Non-Prescription Acetaminophen Products, 27(12) J. Gen. Intern. Med. 1587 (2012).
[19] *Id.* at 1590.
[20] William M. Lee, Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, 46(4) Hepatology 966, 967 (2007).
[21] Neil Kaplowitz, Acetaminophen Hepatotoxicity: What Do We Know, What Don't We Know, and What Do We Do Next?, 40(1) Hepatology 23, 23, 25 (2004).
[22] American Association for the Study of Liver Diseases (AASLD), Public Comment Regarding the Proposed Amendment of the Tentative Final Monograph of Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use, at 2 (Apr. 27, 2007).
[23] The Acetaminophen Hepatotoxicity Working Group, Recommendations for FDA Interventions to Decrease the Occurrence of Acetaminophen Hepatotoxicity, at 4 (Feb. 26, 2008).
[24] William M. Lee, Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, 46(4) Hepatology 966, 967 (2007).
[25] *Id.*
[26] *Id.*
[27] http://www.tylenol.com/head-body/extra-strength-tylenol.
[28] *See e.g.,* J. Kurtovic et al., Paracetamol-induced hepatotoxicity at recommended dosage, 253 J. Intern. Med. 240, (2003); LS Eriksson et al., Hepatotoxicity due to repeated intake of low doses of paracetamol, 231 J. Intern. Med. 567 (1992).
[29] Letter from Department of Health & Human Services to Ms. Nancy L. Buc and Ms. Kate C. Beardsley, (Aug. 25, 2004).
[30] http://www.tylenol.com/head-body/regular-strength-tylenol#.
[31] The only difference in the "warnings" among the various forms of Tylenol is the maximum daily dose for each.
[33] United States Judicial Panel on Multidistrict Litigation, In Re: Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liability Litigation, Transfer Order (Apr. 1, 2013).
[34] United States Judicial Panel on Multidistrict Litigation, MDL Statistics Report (July 10, 2013).

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