

BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: TYLENOL (ACETAMINOPHEN)
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 2436
Oral Argument Requested

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR
TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407**

Defendants McNEIL-PPC, Inc., McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. and Johnson & Johnson ("Defendants" or "McNeil") request that the Panel deny Plaintiffs' Motion for Transfer and Coordination Under 28 U.S.C. § 1407 ("Plaintiffs' Motion").

I. INTRODUCTION

It is undisputed that acetaminophen, the active ingredient in Tylenol, can lead to liver damage when taken in excess of the recommended dosage. McNeil has, in fact, warned of the risks of liver damage associated with overdose. A telling illustration of these warnings is found in the following excerpts of a 2005 label on Extra Strength Tylenol:

Warnings

Acetaminophen may cause liver damage.

Do not use with any other product containing acetaminophen.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**



This is just one portion of just one product label (from 2005) that unequivocally warned—*years before* Plaintiffs’ alleged dates of ingestion/injury—that **acetaminophen may cause liver damage** and that **overdosing on acetaminophen leads to liver damage**. In the face of these long-standing, FDA-approved warnings, and the common knowledge that taking excessive amounts of acetaminophen can harm a person’s liver or cause other problems, an alliance of plaintiffs’ firms seeks an MDL here. Their attempt is a thinly veiled effort to manipulate and aggrandize into a “mass tort” what are otherwise simply individual cases involving patient overdose. Plaintiffs’ request violates the very principles of MDL centralization. It also ignores the fact that **a unified proceeding—involving the vast majority of cases, the same Plaintiffs’ counsel and the same counsel for the common Defendants—is already in place before Judge Lawrence Stengel in the Eastern District of Pennsylvania.**

There is no valid basis to create an MDL here. Plaintiffs’ Motion should be denied.

II. FACTUAL BACKGROUND

A. **The risk of liver damage associated with acetaminophen overdosage has been known for decades.**

Acetaminophen is one of the most commonly used drugs in the United States for treating pain and fever. Kaufman et al. *Recent Patterns of Medication Use in the Ambulatory Adult Population of the United States: the Slone Survey* JAMA 2002; 287(3): 337, 340. In 2005, the Federal Food and Drug Administration (“FDA”) estimated that consumers purchased more than 28 billion doses of products containing acetaminophen.¹

Tylenol has been available as an over-the counter (“OTC”) analgesic since 1960, and the risk of liver damage associated with massive acetaminophen overdose has been known for decades. In 1977, the FDA cited studies concluding that liver damage is a toxic effect present in

¹ www.fda.gov/downloads/AdvisoryCommittees/.../UCM164897.pdf

most patients who ingest more than 15 grams of acetaminophen (23 times the usual recommended dose of regular strength acetaminophen, 15 times the usual recommended dose of extra strength acetaminophen and 4 times the maximum recommended daily intake). 43 Fed. Reg. 35346, 35413 (July 8, 1977). Therefore, any allegation that liver damage can result from acetaminophen overdosage is not, by any stretch, a recently discovered (or unknown) “risk.”²

B. The FDA has consistently deemed Tylenol safe and effective when used in accordance with the label—and McNeil has included pertinent liver damage warnings on its labels.

Since 1977, the FDA has convened several Advisory Committee Panels to assess the safety and efficacy of acetaminophen—and ultimately promulgated several proposed and final regulations regarding acetaminophen warnings. Throughout this time, the FDA consistently found acetaminophen to be safe and effective when labeled appropriately and used as directed. *See, e.g.*, 43 Fed. Reg. 35346, 35412 (July 8, 1977); 71 Fed. Reg. 77314, 77331 (Dec. 26, 2006); Gerald Dal Pan, M.D., MHS, Director, FDA Office of Surveillance and Epidemiology, CDER, Address Before the FDA Advisory Panel (June 29, 2009) at 2.³

In 2005, McNeil warned that taking more than the recommended dose of acetaminophen may cause liver damage. McNeil’s inclusion of this warning came *four years before the FDA issued its Final Rule, in 2009*, mandating that all acetaminophen manufacturers include a liver-specific overdose warning on OTC products. *See* 74 Fed. Reg. 19385 (Apr. 29, 2009). And as recently as February 5, 2013, FDA has affirmed (again) that acetaminophen is safe when used according to the label directions:

Acetaminophen is one of the most commonly used medicines in the United States. When used according to the label directions, it has a well-established

² To this point, individual lawsuits alleging liver damage from acetaminophen have been making the rounds in federal and state courts since the early 1990s.

³ www.fda.gov/downloads/AdvisoryCommittees/.../UCM164897.pdf

record of safety and efficacy. Although acetaminophen overdose is very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.⁴

As a result, not only has the FDA continually found Tylenol products safe and effective when a patient uses the product as directed—but McNeil has also addressed the very risks alleged here (i.e., liver damage associated with overdosage) and placed these warnings on package labels.

C. These cases will turn on Plaintiff-specific facts, not common discovery.

In light of the above brief history of Tylenol and liver damage warnings, it is important to note from the outset that all of Plaintiffs' cases allege liver damage secondary to acetaminophen ingestion. Yet, again, it is undisputed that acetaminophen can lead to liver damage when taken in excess of the recommended dosage, and McNeil has warned of the risk of liver damage associated with overdose.

Significantly, McNeil's 2005 liver damage warning (excerpts reproduced above) predates Plaintiffs' alleged dates of ingestion/injury in this litigation—in some instances by as much as six years.⁵ The cases filed by these Plaintiffs, therefore, will not benefit from MDL centralization on "common issues" of fact because, stated simply, causation for each case will *not* turn on whether acetaminophen can cause liver damage. Instead, the cases will turn on individualized facts about each Plaintiff, including (but not limited to) the following:

⁴ <http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm230396.htm> (last visited Feb. 7, 2013).

⁵ See Appendix A (listing the 27 cases in Plaintiffs' Schedule of Actions and identifying the alleged product(s) in question, dates of ingestion and/or injury, and the purported injury). If new cases are filed and/or removed, and are designated as Related Actions (e.g., ECF Nos. 20, 26), such circumstances emphasize that the liver damage warning predates Plaintiffs' claims by an even greater number of years.

1. whether the individual plaintiff can show proof of ingestion of a Tylenol product;
2. how much acetaminophen the individual plaintiff ingested;
3. how long the individual plaintiff ingested the acetaminophen;
4. whether the individual plaintiff ingested the product with suicidal intentions;
5. whether the individual plaintiff read the label;
6. whether the individual plaintiff ingested acetaminophen according to the label;
7. whether the individual plaintiff relied on any advertisements;
8. whether the individual plaintiff ingested other medications that caused his/her liver injury;
9. whether the individual plaintiff suffered from a virus or condition that damaged the liver;
10. whether the individual plaintiff's liver was damaged;
11. whether the individual plaintiff's liver was damaged due to drug or alcohol abuse; and/or
12. whether the case actually is a liver damage case versus injury due to some other variable.

For these reasons, and as explained below, centralization in an MDL is improper.

III. SECTION 1407 ANALYSIS

A. Applicable Standard

MDLs are authorized by 28 U.S.C. § 1407, which provides in relevant part as follows:

When civil actions involving one or more **common questions of fact** are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the **convenience of parties and witnesses** and will promote the **just and efficient conduct** of such actions.

28 U.S.C. § 1407(a) (emphasis added). The key criterion for transfer to an MDL is, therefore, the presence of common questions of fact. *See id.* In addition, Section 1407 explains the overarching purposes in centralizing cases in an MDL: convenience of parties and witnesses and the promotion of judicial efficiency. *See id.*

B. An MDL is not warranted in these cases.⁶

An MDL is not appropriate where (1) individual issues predominate over common questions of fact, (2) most of the actions are already being handled by the same judge, (3) most of the plaintiffs are being represented by the same counsel, (4) most of the defendants are being represented by the same defense counsel, or (5) most of the actions are already being handled in a coordinated fashion. *See, e.g., In re: Droplets, Inc. Patent Litig.*, MDL 2403, 2012 U.S. Dist. LEXIS 177688 (J.P.M.L. Dec. 12, 2012); *In re: Chase Investment Servs. Corp. Fair Labor Standards Act (FLSA) and Wage & Hour Litig.*, MDL 2412, 2012 U.S. Dist. LEXIS 177689 (J.P.M.L. Dec. 11, 2012); *In re: Plavix Prods. Liab. Litig.*, MDL 2300, 829 F. Supp.2d 1378 (J.P.M.L. 2011). These factors counsel against an MDL in this litigation.

1. These cases involve highly individualized, product-specific inquiries about patient overdose—not common questions of fact.

MDL centralization should be denied where, as here, individual issues of causation and liability will predominate. Under such circumstances, individualized issues are “likely to overwhelm any efficiencies” that might otherwise be gained by centralization. *See, e.g., In re: Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp.2d 1375, 1377 (J.P.M.L. 2010); *see also In re: Watson Fentanyl Patch Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 112485 (J.P.M.L. Aug. 7, 2012) (citing *In re: Yellow Brass Plumbing Component Prods. Liab. Litig.*,

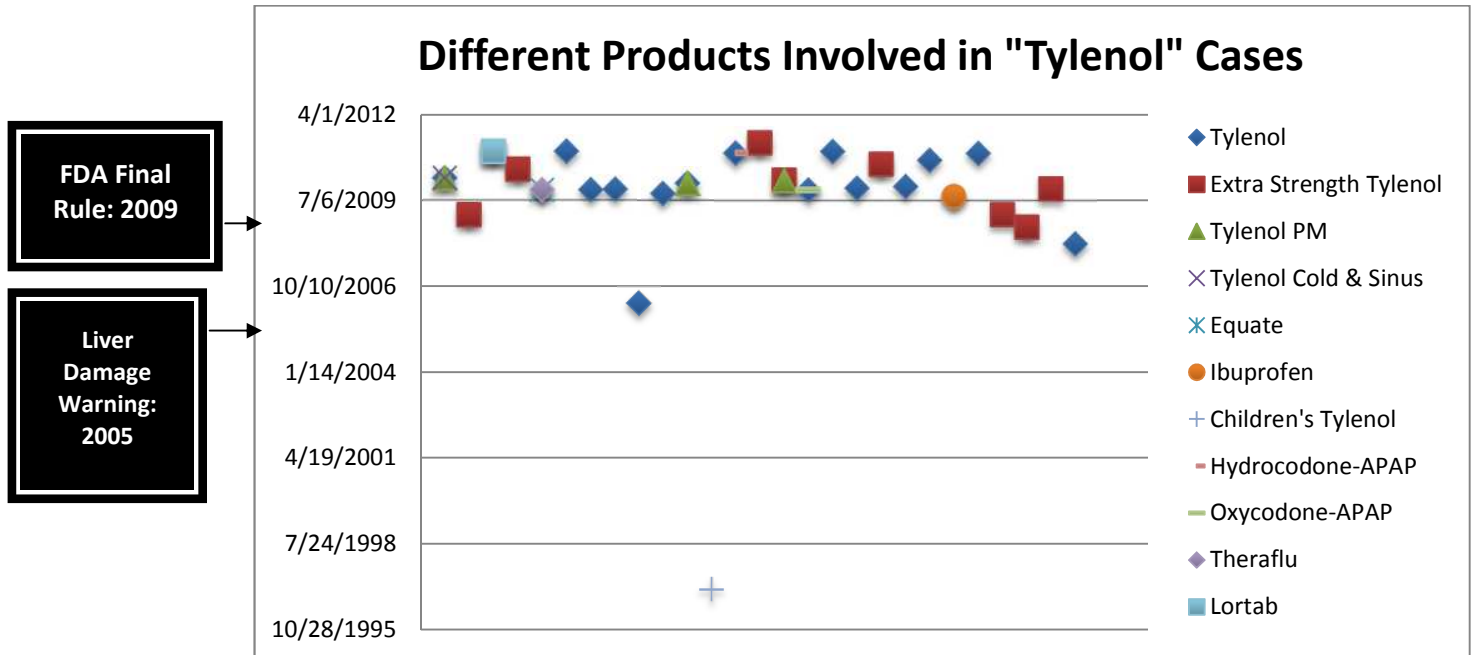
⁶ Plaintiffs’ Motion originally included 28 related actions. However, on February 4, 2013, the Eastern District of California ordered remand of Plaintiffs’ case in *Oliver v. McNEIL-PPC, Inc. et al.*, No. 1:12-cv-1865. Accordingly, *Oliver* is no longer in issue for MDL centralization.

844 F. Supp.2d 1377 (J.P.M.L. 2012)). Plaintiffs ignore this principle when considering the vast distinctions in the personal injury actions involved here. Instead, they maintain that the legal theories and facts asserted in all the cases “are virtually identical and arise from [] identical conduct” of Defendants. (Pl. Mem., ECF No. 7, at 2). In so arguing, Plaintiffs improperly refer to all of the products as simply involving “OTC Tylenol.” (E.g., Pl. Mot., ECF No. 7, at 2)

Review of the Complaints paints a much different picture. Each of these cases, at its core, alleges an inadequate warning products liability claim, whereby Plaintiffs contend that the product(s) did not contain an adequate warning of the risks of liver damage associated with a patient’s ingestion of an excessive dosage of the “Tylenol”—or whatever product(s) are in question in any particular case. Plaintiffs thus must prove, for each individual plaintiff under each applicable state’s substantive law, that the label was “defective and unreasonably dangerous” and that the alleged inadequacies in the labeling were the direct and proximate cause of the individual patient’s liver injuries.⁷ This scenario necessitates a particularly individualized inquiry for each Plaintiff.

Of the 27 cases identified in Plaintiffs’ Schedule of Actions, there are myriad combinations of over-the-counter and prescription pain relievers and/or cold medicines, sometimes taken singly and sometimes in combination:

⁷ Such labeling claims are also subject federal preemption of individual state law claims, in light of the liver damage warning and the FDA Final Rule, discussed above.



As the graph shows, these cases involve no fewer than 11 different products: Tylenol, Extra Strength Tylenol, Tylenol PM, Tylenol Cold and Sinus, Children's Tylenol, Hydrocodone-APAP, "Equate" Pain Relief (generic), Oxycodone-APAP, Ibuprofen, Theraflu, and Lortab.⁸ This variety of products will most certainly expand once plaintiff-specific discovery is obtained. Next, several of the products, sometimes used in combination with others, are not even manufactured by Defendants.⁹ Each case will thus involve one (or even as many as three or more) different products' warning labels—subject to the liver damage warnings and the 2009 FDA Final Rule and its corresponding preemptive force.

⁸ To this point, 13 matters were recently removed to the Eastern District of Pennsylvania, of which 12 have been designated as Related Actions. (ECF Nos. 20, 26, 2/6/2013). These cases, like the 27 matters identified in Plaintiffs' Schedule of Actions, include a variety of products, such as Tylenol, Extra Strength Tylenol, Tylenol PM, Generic Vicodin, Hydrocodone-APAP, Oxycodone-APAP, Tylenol Cold, and Infants' Tylenol.

⁹ See Appendix A.

In addition, given that these are personal injury actions, each patient's medical history, dosage (and usage or abuse) of the product(s) in question involve highly individualized undertakings. Consider, for instance, the variations as alleged in Plaintiffs' Complaints, which are provided in Appendix A. Despite the vast distinctions in the Plaintiffs (and the product(s) ingested), the mantra of almost every single case is that the Plaintiff or Decedent ingested the product(s) at "appropriate times" and in "appropriate amounts." Otherwise, the Complaints are carbon copies of one another with boilerplate, non-specific (and incorrect) assertions.

As a result, the key inquiry in each of these cases is *not* Defendants' "conduct" in labeling. Quite the opposite is true—the fundamental issue is patient-specific: what product(s) did the patient take, how much did the patient take, and for how long? It is not an overstatement to say that this single factual issue will overwhelmingly control the disposition of these cases. Further pointing to the individualized inquiry in these matters are the significant distinctions in the alleged timespan between purported ingestion and injury; in some cases, there is an assertion of almost-immediate liver injury, whereas in other cases, as much as a year purportedly lapsed before injury. This, again, demonstrates the highly patient-specific/product-specific inquiry about what products were ingested, how much was ingested and for how long, as well as the other idiosyncratic medical conditions of each individual plaintiff. These factors do not lend themselves to common methods of discovery.¹⁰ Instead, with this many different product combinations, different dates of ingestion, and different dates of injury, the great variety in

¹⁰ Further, as explained below, counsel for these Plaintiffs have, in fact, already received millions of pages of documents from Defendants, thus negating any "need" for them to obtain defense-oriented discovery as a matter of common questions of fact. *See Plavix*, 829 F. Supp.2d at 1378 (denying centralization where, inter alia, defendants had already "completed all document production" in the constituent action (approximately 3.5 million pages); the parties had served and responded to other written discovery; and most, if not all, depositions of the plaintiffs had been completed).

warning labels and causation issues that will govern the cases will predominate any “common questions.”

Given the nature of these claims, this is not a traditional “mass tort” with a common exposure and a large number of similar injuries. Quite to the contrary, these cases involve 27 individual matters that do not lend themselves to MDL centralization; rather, discrete issues of product identification, causation and liability predominate. *See, e.g., In re: Watson Fentanyl*, 2012 U.S. Dist. LEXIS 112485 (in the context of a request for industry-wide centralization, rejecting MDL transfer as lacking sufficient commonalities: “[e]ach group of cases against each manufacturer will involve unique product- and defendant-specific issues (such as the different product designs, manufacturing processes, [and] regulatory histories” that will ‘overwhelm the few common issues. . . .’”). As the Panel stated in its Order denying centralization in *In re: Shoulder Pain Pump-Chondrolysis Products Liability Litigation*:

Although these personal injury actions have some commonality as to whether shoulder pain pumps and/or the anesthetic drugs used in those pumps cause glenohumeral chondrolysis, **an indeterminate number of different pain pumps made by different manufacturers are at issue, as are different anesthetic drugs made by different pharmaceutical companies. . . .** The proponents of centralization have not convinced us that the efficiencies that might be gained by centralization would not be overwhelmed by the multiple individualized issues (including ones of liability and causation) that these actions appear to present.

In re: Shoulder Pain Pump - Chondrolysis Prods. Liab. Litig., 571 F. Supp. 2d 1367, 368 (J.P.M.L. 2008). In these cases, individualized issues will undoubtedly overwhelm any efficiencies that might be gained by centralization of cases involving acetaminophen, thus demonstrating the absence of sufficient commonality to merit MDL treatment.

2. *An MDL will not enhance convenience or promote efficiency.*

Not only do these 27 cases inherently turn upon facts about each particular patient’s ingestion/overdose, the critical consideration of convenience/efficiency is altogether lacking. To

this point, and as discussed in greater detail below, a “de facto” MDL is already in place—with the **same plaintiffs’ firms and common defense counsel**—thus demonstrating that there is no basis to create yet another procedural framework to manage these individualized matters.

a. *The overwhelming majority of these cases are already being handled in a coordinated fashion by Judge Stengel in the Eastern District of Pennsylvania.*

As the Panel has recognized, transfer may be inappropriate where there are other options in place that can minimize duplicative discovery and/or inconsistent pretrial rulings. *See, e.g., In re: Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litigation*, 446 F. Supp. 242, 244 (J.P.M.L. 1978), *cited in In re: Orthalliance, Inc.*, 350 F. Supp.2d 1354, 1355 (J.P.M.L. 2004); *see also* Manual for Complex Litigation, Fourth, § 20.14 (2004). For instance, the Panel has endorsed the utilization of voluntary cooperation among the few involved counsel and courts, *In re: Droplets*, 2012 U.S. Dist. LEXIS 177688, at *4, and has noted that parties “can avail themselves of alternatives to Section 1407 transfer to minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings.” *In re: Ambulatory Pain Pump*, 709 F. Supp.2d at 1377 (citing *In re: Shoulder Pain Pump*, 571 F. Supp.2d at 1368). Here, MDL centralization is unnecessary because existing coordination efforts are already under way.

As Plaintiffs themselves emphasize, 21 of the 27 matters are now pending in the Eastern District of Pennsylvania and have been assigned to Judge Lawrence Stengel.¹¹ (Pl. Mot. at 3; Pl. Mem. at 1-3, 11-12; *see also Speal v. McNEIL-PPC, Inc. et al.*, No. 2:12-cv-5997, Order

¹¹ On January 30, 2013, an additional 13 cases were removed to the Eastern District of Pennsylvania; as noted above, 12 of these have been designated as Related Actions. (ECF Nos. 20, 26). Presumably these cases will also be assigned to Judge Stengel. The inclusion of those (and potentially additional) cases in the proceedings before Judge Stengel, if ordered, strengthens Defendants’ position here. I.e., there is no basis to create an additional MDL on top of the existing structure, especially when the matters involve no common questions of fact and the same counsel for Plaintiffs and common Defendants are involved in all of the cases.

Assigning Cases to Hon. Lawrence Stengel, ECF No. 9, 11/21/2012). Since the assignment of the cases to Judge Stengel over the past few months, the parties have worked together to develop a proposed Joint Case Management Statement. On January 30, 2013, Judge Stengel postponed a previously scheduled in-person Case Management Conference, ordered the parties to exchange Rule 26(a) initial disclosures, postponed the submission of the parties' Joint Case Management Statement, and conducted a telephone conference on February 7, 2013. In short, the existing cases are already proceeding before Judge Stengel in an organized and coordinated matter.

Further, although the opportunity is not yet ripe, the cases before Judge Stengel are amenable to various procedural measures, under Rule 16, to simplify issues and eliminate frivolous claims or defenses. Fed.R.Civ.P. 16(c)(2)(A). For example, the court may order the parties to obtain admissions and stipulations of facts and documents to avoid unnecessary proof or cumulative evidence. Fed.R.Civ.P. 16(c)(2)(C)-(D). Rule 16 also allows the court to adopt "special procedures" to manage complex actions. Fed.R.Civ.P. 16(c)(2)(L). For instance, a "pure" or modified *Lone Pine* Order could be entered.¹² Judge Stengel could require the Plaintiffs to provide, by a date early in the litigation, items such as all medical records; identification of the treating physician(s) who prescribed Tylenol and/or other products; as appropriate, a declaration of the treating physician(s) stating that s/he was unaware that

¹² A "*Lone Pine* Order" requires the plaintiffs to provide basic facts in the form of expert reports or other proof early in the case—or run the risk of dismissal. *See, e.g., In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008). This concept originated from a New Jersey state court case, *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super. Ct. Law Civ. Nov. 18, 1986), which involved property damage and personal injury claims arising out of exposure to polluted waters from the Lone Pine Landfill. For personal injury claims, the court required plaintiffs to provide (1) facts of each individual plaintiff's exposure to alleged toxic substances from the site and (2) reports from treating physicians or other experts to support the individual's claim of injury and causation. *See, e.g., In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 250 n.1 (S.D. W.Va. 2010) (explaining *Lone Pine*). Because *Lone Pine* orders are designed to identify and cull potentially meritless claims and streamline litigation in complex cases, *see In re Vioxx*, 557 F. Supp. 2d at 743, implementation may be particularly suitable in these cases.

“Tylenol” contained a risk of liver damage; that s/he did not see any warning/labels (such as the approved label, PDR or other warnings); that s/he would not have recommended Tylenol if aware of the risk of liver damage; and/or that the lack of an adequate warning proximately caused the alleged liver damage. Alternatively, the Court could stay all discovery or other pretrial matters until the Plaintiffs submit to a medical examination (if feasible, given that some cases involve a decedent; if not feasible, a review of medical records could be ordered). Another option would include modified/detailed interrogatories, tracking case-specific information from physicians or other medical personnel, to be answered early in the case; and the failure of Plaintiffs to provide this information by the court-ordered deadline would result in dismissal.

Whether some or all of the above options are utilized by Judge Stengel rests, of course, in the Court’s inherent discretion in managing its docket. The point, here, is that Judge Stengel is already proceeding over an ostensibly centralized set of cases and there are many tools at his disposal—without requiring creation of an MDL—to efficiently manage the litigation, promote efficiency, and enhance convenience for the Court, parties, witnesses and counsel alike. *See, e.g., In re: Droplets, Inc.*, 2012 U.S. Dist. LEXIS 177688, at *3-4 (denying centralization where six actions were pending in just three districts, and two of the cases were before the same judge and being handled in a coordinated manner).

b. The same plaintiffs’ firms are involved in these actions (and the state court actions), and the same defense counsel represent all of the common defendants.

Closely related to the above discussion is the near unanimity of counsel for Plaintiffs and Defendants. As Plaintiffs themselves tout in their motion, the same law firms represent the overwhelming majority of Plaintiffs. (Pl. Mot. at 8). These are the very same attorneys who are representing other plaintiffs in pending state court cases, most notably in New Jersey. Only the few, non-Eastern District of Pennsylvania cases include different counsel for Plaintiffs.

Moreover, Defendants—who are the only *common* defendants across all of the cases—are represented by the undersigned counsel, thus demonstrating common defense counsel. These circumstances weigh against the need for MDL centralization. As the Panel recently ruled:

[I]nformal coordination among the three involved courts seems practicable — just as it does among the parties, given that Droplets is **represented in all actions by the same law firm and defense counsel overlap**, at least to some extent, in four actions (the three Northern District of California actions and the Eastern District of Texas Target action). *See In re: Boehringer Ingelheim Pharms., Inc., Fair Labor Standards Act (FLSA) Litig.*, 763 F. Supp. 2d 1377, 1378 (J.P.M.L. 2011) (denying centralization of four actions in which **plaintiffs in three actions shared counsel and the common defendant was represented by the same counsel in all actions, concluding that “alternatives to formal centralization, such as voluntary cooperation among the few involved counsel and courts, appear[ed] viable”**).

In re Droplets, Inc., 2012 U.S. Dist. LEXIS 177688, at *4 (emphasis added). In like fashion, the existing coordinated proceedings—involving the same Plaintiffs’ firms, common defense counsel, and the same judge—are preferable to creation of another, new framework via MDL.

c. The small number of other pending cases involve many of the same Plaintiffs’ firms and the same defense counsel.

Beyond the cases pending before Judge Stengel, the other six related actions (pending in different federal district courts) are not all in their infancy. *See In re: Droplets, Inc.*, 2012 U.S. Dist. LEXIS 177688, at *4-5 (denying MDL centralization where at least one of the actions had been on file since 2011).¹³ Further, the other federal actions share significant overlap in terms of Plaintiffs’ firms, and all of the cases involve the same common Defendants and undersigned

¹³ One example is *Murphy v. McNEIL-PPC et al.*, Case No. 2:10-cv-5967 (E.D. N.Y.), which has been pending since December 22, 2010.

counsel for those Defendants.¹⁴ *See In re: Droplets, Inc.*, 2012 U.S. Dist. LEXIS 177688, at *4. Each of these cases can benefit from informal coordination of proceedings among the same Plaintiffs' counsel and defense counsel—as is already in place. *See id.* Moreover, deposition notices could be filed in other cases for enhanced cooperation and coordination. *See Manual for Complex Litigation* § 20.14. And if deemed preferable and in the interest of efficiency, the district courts in any of the related actions could enter a stay of proceedings until one or more cases has been determined. *Id.* This would be particularly appropriate if, for instance, federal preemption is found to bar some or all of Plaintiffs' state law claims, as Defendants believe will occur. In sum, there are numerous case management alternatives at the courts' disposal without the need to create an additional MDL proceeding.

IV. CONCLUSION

Given the foregoing, an MDL is not appropriate here and Defendants request that Plaintiffs' Motion be denied. If the Panel determines that the Section 1407 criteria have been satisfied, Defendants strongly urge that the cases be assigned to the Eastern District of Pennsylvania before the Honorable Lawrence Stengel, given that he already has proceedings in place for the vast majority of cases, with near unanimity in Plaintiffs' counsel, and common defense counsel. Defendants pray for all other relief to which they are entitled.

¹⁴ Several state cases are significantly advanced—again, with the same Plaintiffs' firms and defense counsel—in New Jersey Superior Court, where plaintiff-specific discovery is nearly complete and the cases will be identified and set for trial in the near term. *See In re Plavix*, 829 F. Supp.2d at 1378 (denying centralization and explaining that an MDL would delay the progress of long-pending actions while providing little benefit to the plaintiffs).

Respectfully submitted,

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¹⁵ McNEIL-PPC, Inc. submits this Response on its own behalf and on behalf of McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., an unincorporated division of McNEIL-PPC that is not separately amenable to suit. To this point, Plaintiffs' repeated references in their motion and memorandum to McNeil Consumer Healthcare Division's "headquarters" is misplaced. Further, one related action names McNeil Consumer & Specialty Pharmaceuticals as a defendant, but that entity is no longer active; its name has been changed to McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

APPENDIX A:
DISTINCT ISSUES IN 27 CASES IDENTIFIED IN PLAINTIFFS' SCHEDULE OF ACTIONS

Plaintiff/State	Products in Question	Date(s) Ingestion/Injury	Dosage History
Kaitlyn Allen (GA)	Tylenol, "including Tylenol Cold and Sinus and Tylenol PM"	Ingestion/purchase "prior to March 11, 2010" and injury "on or about March 20, 2010"	Plaintiff "took these products on a daily basis for approximately one week before experiencing liver failure"
Angela Altimus (MI)	Tylenol, "including Tylenol Extra Strength"	Ingestion "prior to December 1, 2008" and injury "on or about January 13, 2009"	Plaintiff "took these products on a daily basis for approximately one month before experiencing liver failure"
Betty Barnes (TN)	"Tylenol and/or Tylenol Extra Strength and generic Lortab" ¹⁶	Ingestion "prior to January 18, 2011" and injury "on or about January 18, 2011" (same date)	Plaintiff "ingested doses of Tylenol and Lortab at appropriate times and in appropriate amounts for therapeutic purposes and within the recommended daily doses for the products and as prescribed by her physician"
Lia Barney (Justin Barney, Deceased) (OR)	Tylenol, "including Tylenol Extra Strength"	Ingestion "prior to June 2010" and death "on or about June 26, 2010"	Decedent "took doses of Tylenol at appropriate times and in appropriate amounts" which resulted in his death on June 26, 2010
Laura Becker (IL)	Tylenol, Equate Pain Reliever Acetaminophen, and Theraflu ¹⁷	Ingestion of all three products "from approximately 10/20/2009 through 10/29/2009" and injury on November 1, 2009	Plaintiff took doses of Tylenol, Equate Pain Reliever Acetaminophen and Theraflu during an approximate 9-day timeframe "at appropriate times and in appropriate amounts"
Marilyn Seaboch Blake (Clifford Wesley Blake, Deceased) (TN)	Tylenol	Ingestion "prior to January 17, 2011," injury "on or about January 17, 2011" and death on January 21, 2011	Decedent "took doses of Tylenol at appropriate times and in appropriate amounts"

¹⁶ Plaintiff alleges the generic Lortab was manufactured by Watson Pharmaceuticals.

¹⁷ Plaintiff asserts that Equate Pain Reliever was manufactured by L. Perrigo Co. and Perrigo Co., and that Theraflu was manufactured by Novartis Corp. and Novartis Consumer Health, Inc.

Plaintiff/State	Products in Question	Date(s) Ingestion/Injury	Dosage History
Linda Jean Davidson (Kristin Davidson, Deceased) (KY)	Tylenol	Ingestion “prior to October 29, 2009,” injury “on or about October 29, 2009” and death on October 31, 2009	Decedent “took doses of Tylenol at appropriate times and in appropriate amounts”
Hope Fleischer (Scott Fleischer, Deceased) (VA)	Tylenol	Ingestion “prior to November 8, 2009” with injury “on or about November 8, 2009” and death on November 10, 2009	Decedent “took doses of Tylenol at appropriate times and in appropriate amounts”
Maria Guadagno (Katilyn Guadagno, a Minor) (CA)	Tylenol	Ingestion “prior to March 1, 2006” and injury “on or about March 26, 2006”	Minor “took these products on a daily basis for approximately three days before experiencing liver failure”
August Jiminez (CO)	Tylenol	Ingestion “prior to September 22, 2009” and injury “on or about September 22, 2009”	Plaintiff “took these products on a daily basis for approximately one (1) month before experiencing liver failure”
Aleisha Osborne (VA)	Tylenol, “including Tylenol PM”	Ingestion “prior to January 18, 2010” and injury “on or about January 20, 2010”	Plaintiff “took these products on a daily basis for approximately one day before experiencing liver failure”
Lucky Pettersen (CA)	Children’s Tylenol	Ingestion “prior to February 7, 1997” and injury “on or about February 7, 1997”	Plaintiff’s mother “gave doses of Children’s Tylenol to her son at appropriate times and in appropriate amounts”
Phillip Pewitt (Kimberly Terry, Deceased) (TN)	“Tylenol and Hydrocodone-APAP”	Ingestion “prior to January 8, 2011,” injury “on or about December 29, 2010” and death January 8, 2011	Decedent “ingested doses of Tylenol and Hydrocodone-APAP at appropriate times and in appropriate amounts for therapeutic purposes and within the recommended daily doses for the products and as prescribed by her physician”
Jordan Rutkowski (Torri Rutkowski, Deceased) (FL)	Tylenol “including Tylenol Extra Strength”	Ingestion “prior to May 2, 2011,” injury “on or about April 22, 2011” and death on May 2, 2011	Decedent “took doses of Tylenol at appropriate times and in appropriate amounts”
Lori Sears (CO)	Tylenol, “including Tylenol PM and	Ingestion “prior to February 2010” and injury “on or about February 24,	Plaintiff “took these products on a daily basis for approximately one week before

Plaintiff/State	Products in Question	Date(s) Ingestion/Injury	Dosage History
	Tylenol Extra Strength”	2010”	experiencing liver failure”
Sharyn Skursha (PA)	Tylenol and “prescription products that contained acetaminophen,” identified as “Oxycodone-APAP” ¹⁸	Ingestion “prior to . . . November 6, 2009,” and/or “during the calendar year 2009,” and injury on or about November 6, 2009	Plaintiff “ingested at appropriate times and in appropriate amounts for therapeutic purposes Tylenol and Oxycodone-APAP,” Plaintiff ingested Oxycodone-APAP in therapeutic doses as prescribed during the calendar year 2009,” and between November 1-5, 2009, “supplemented her ingestion with Tylenol for therapeutic purposes and within the recommended daily dose for the product”
Jason Snyder (Karissa Snyder, Deceased) (PA)	Tylenol	Ingestion “prior to January 26, 2011,” injury “on or about January 7, 2011” and death on January 26, 2011	Decedent “took doses of Tylenol at appropriate times and in appropriate amounts”
Madeline Speal (PA)	Tylenol	Ingestion “prior to November 28, 2009” and injury on or about November 28, 2009	Plaintiff “took doses of Tylenol from approximately 11/25/2009 through 11/28/2009, at appropriate times and in appropriate amounts”
Rana Terry (Denice Hayes, Deceased) (AL)	Tylenol, “including Tylenol Extra Strength”	Ingestion “prior to August 31, 2010,” injury on or about August 23, 2010, and death on August 31, 2010	Decedent “took doses of Tylenol at appropriate times and in appropriate amounts”
Petru Ursoi (PA)	Tylenol	Ingestion “prior to 12/15/2009” and injury on or about 12/15/2009	Plaintiff “took these products on a daily basis from December 1 through December 15, 2009 before experiencing liver failure”
Herbert Why (Anne Why, Deceased) (PA)	Tylenol	Ingestion “prior to October 2, 2010,” injury “on or about October 2, 2010”	Decedent “took doses of Tylenol at appropriate times and in appropriate

¹⁸ Plaintiff asserts that the Oxycodone-APAP was manufactured by Vintage Pharmaceuticals d/b/a Qualitest Pharmaceuticals.

Plaintiff/State	Products in Question	Date(s) Ingestion/Injury	Dosage History
		and death on October 14, 2010	amounts”
Tommie Coleman (Robert Coleman, Deceased) (MS)	Tylenol and Ibuprofen	Ingestion “prior to August 21, 2009,” and death on August 21, 2009	Decedent “was using and administered Tylenol following a knee surgery for several months prior to experiencing liver failure which resulted in his death. During this time, Decedent was also taking Ibuprofen.”
Lilowtie Hardine (NY)	Tylenol	Ingestion “prior to January 5, 2011” and injury “on or about January 5, 2011”	Plaintiff “took Tylenol on a daily basis for approximately three days before experiencing liver failure. Plaintiff was mindful of the recommended dose limits of Tylenol and always took the medication accordingly.”
Cathleen Murphy (Michael Murphy, Deceased) (NY)	Extra Strength Tylenol	Ingestion on or about “April and May 2008 to May 9, 2008” and injury/death on January 23, 2009	Decedent “ingested a dosage of Extra Strength Tylenol” “from April and May 2008 to May 9, 2008”
Sandra Rudd (FL)	Tylenol and/or Extra Strength Tylenol	Ingestion “prior to August 29, 2008;” no date specified for injury	Plaintiff “reviewed the product label, and took the drug several times daily for approximately one to two days before feeling ill, ultimately leading to a diagnosis of acute liver failure and hepatotoxicity”
Kayleigh Sechi (MA)	Tylenol and/or Extra Strength Tylenol	Ingestion “prior to mid November 2009;” no date specified for injury	Plaintiff “reviewed the product label, and took the drug several times daily for approximately two weeks before feeling ill, ultimately leading to a diagnosis of acute liver failure and hepatotoxicity”
Charlotte Thompson (FL)	Tylenol	Ingestion “prior to February 18, 2008” and injury “on or about February 2008”	Plaintiff “took Tylenol for several days before experiencing liver failure” and “was mindful of the recommended dose limits of Tylenol and always took the medication accordingly”

CERTIFICATE OF SERVICE

Pursuant to Rule 4.1(a) of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, I hereby certify that the foregoing document was served on February 8, 2013, via CM/ECF. The JPML's Notice of Electronic (NEF) filing shall constitute service of pleadings on registered counsel.

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Further, under Rule 4.1(a), counsel or parties who are identified by NEF as having no email address will be mailed hard copies via first-class United States mail.

Finally, a Courtesy Copy of the foregoing shall be delivered to the Clerk of the Panel within one business day, in accordance with Rule 3.2(d).

/s/Christy D. Jones

Christy D. Jones