BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re: Cymbalta Products Liability Litigation MDL Docket No. _____

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION PURSUANT TO 28 U.S.C. § 1407 TO TRANSFER RELATED ACTIONS FOR COORDINATED PRETRIAL PROCEEDINGS IN THE SOUTHERN DISTRICT OF INDIANA

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PRELIMINARY STATEMENT

This is the second motion seeking to centralize Cymbalta withdrawal cases—personal injury lawsuits alleging that Defendant Eli Lilly and Company ("Lilly") failed to accurately warn about the risks associated with discontinuing the antidepressant Cymbalta. *In re: Cymbalta (Duloxetine) Products Liab. Litig.* ("*Cymbalta I*"), 65 F. Supp. 3d 1393 (J.P.M.L. 2014). In *Cymbalta I*, this Panel denied a petition to centralize twenty-eight (28) federal actions involving thirty-nine (39) plaintiffs. The Panel acknowledged that "these actions share factual issues concerning Cymbalta's development, marketing, labeling, and sale" but denied centralization because: (1) the "procedural posture of the actions" varied too significantly; (2) "most, if not all, of the common discovery has already taken place" notwithstanding that the "moving plaintiffs dispute[d] the adequacy of Lilly's" discovery productions; and (3) "just two firms represent plaintiffs in all the constituent actions" making "informal coordination . . . practicable." *Id.*

This petition presents a very different scenario. First, the constituent actions at issue, which include forty-four (44) related federal actions involving two-hundred and forty-nine (249) individual plaintiffs, are *all* on the *same* discovery schedule, with discovery set to close at some point in 2016 or later. Second, common discovery is *still* ongoing—Lilly's claim that common discovery was complete in *Cymbalta I* has proven to be false. *See, e.g.*, *Hexum v. Eli Lilly & Co.*, No. 2:13-CV-02701-SVW, 2015 WL 4064633, at *16 (C.D. Cal. June 19, 2015) ("[I[n light of the newly uncovered evidence, the Court finds this case distinguishable from both *McDowell* and *Carnes*."). Third, there are *at least* eight (8) separate firms actively litigating Cymbalta withdrawal cases around the country, both in state and federal court. Informal coordination is no longer practicable without some formal committee. And, as described below, since *Cymbalta I*, Lilly has opposed all good-faith efforts by plaintiffs to informally coordinate this litigation.

Most importantly, centralization pursuant to 28 U.S. C. § 1407 is warranted in that : (1) all of the actions assert product liability claims against Lilly for injuries sustained by individuals discontinuing Cymbalta; (2) the actions involve common questions of fact, including Cymbalta's capacity to cause withdrawal injuries and whether Lilly properly and adequately warned about the risks of Cymbalta withdrawal; (3) transfer to a single district will be convenient for all parties and witnesses and will allow for just and efficient pretrial proceedings; and (4) absent transfer and coordination, the parties and courts will face the burden and expense of duplicative discovery and pretrial proceedings and inconsistent pretrial rulings.

For these reasons, Plaintiffs request that the MDL be centralized in the Southern District of Indiana. The Southern District of Indiana has a robust record with MDLs, including those involving pharmaceutical drugs, has the requisite resources and expertise to manage such an MDL, and is the jurisdiction in which Defendant Lilly maintains its headquartered—indeed, the courthouse is less than a mile from Lilly's global campus.

STATEMENT OF FACTS

I. The Cymbalta Litigation: What These Cases Are About

Cymbalta is an antidepressant in a class known as selective serotonin and norepinephrine reuptake inhibitors ("SNRIs"). These lawsuits centers on a phenomenon called "withdrawal"—the physical and mental effects patients suffer when they stop taking Cymbalta. The term "withdrawal" is deliberate. The physical effects patients experience upon stopping Cymbalta mirror those that drug addicts experience when they stop a narcotic: dizziness, headaches, nausea, diarrhea, excessive sweating, sensory disturbances, nightmares, and insomnia. However, in addition to these "typical" withdrawal effects, patients stopping Cymbalta also experience side effects that are unique to antidepressants: electric shock sensations in the brain, loss of motor

functions, seizures, extreme mood swings, depression (even if the patient never previously suffered from depression), emotional outbursts, and suicidal behavior / attempts.

It is widely accepted that an antidepressant's withdrawal risk is, in large part, associated with the drug's half-life, i.e., the amount of time for half of a drug to leave a patient's system. The shorter a drug's half-life, the faster the drug leaves the patient's body. This rapid depletion, in turn, leads to more pronounced withdrawal symptoms. Much of the research about the relationship between half-life and withdrawal was conducted by Lilly as part of Lilly's efforts to bolster sales of the antidepressant Prozac in the 1980s and 1990s. Lilly wanted to position Prozac as being superior to its competitors Zoloft and Paxil by marketing Prozac's longer half-life as having a superior withdrawal profile. Prozac has a half-life of approximately 6 days. Zoloft and Paxil's are 26 and 21 hours respectively. Lilly sponsored clinical trials to measure antidepressant withdrawal in Prozac, Paxil, and Zoloft, and published these studies in medical journals.

Thus, when it came to Cymbalta, Lilly had a problem. Lilly knew the drug posed a serious withdrawal risk. Not only is Cymbalta's half-life only twelve hours—half the length of Paxil or Zoloft—Lilly's own clinical data revealed that a large percentage of Cymbalta users who stopped the medication suffered serious withdrawal symptoms. Specifically, Lilly's early clinical trial data showed that approximately 45% of patients who stopped taking Cymbalta following completion of controlled trials spontaneously reported withdrawal symptoms.

Lilly also conducted marketing studies to determine what factors influenced how doctors made prescribing decisions in the antidepressant marketplace. The studies revealed that the issue of withdrawal was one of the most important factors that physicians used to differentiate between antidepressants. Indeed, Lilly's marketing studies showed that one of the primary ways

Cymbalta could be competitive to other antidepressants was to minimize the risks of withdrawal.

Against this background, Lilly crafted a Cymbalta warning label about discontinuation minimized the risks of withdrawal. The Cymbalta label stated:

> Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate greater than or equal to 2%[1] and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.
>
> During marketing of other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional liability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Plaintiffs allege that his warning label is materially deficient and misleading.

First, the original Cymbalta label did not provide any incident rates for withdrawal, and was written in a way that suggested the risks were rare or uncommon, even though Lilly's data indicated that withdrawal was very common. The "greater than or equal to 2%" language suggests that a patient's risk of suffering from withdrawal is rare. Lilly later updated the label and actually implied the risk was even less, "greater than or equal to 1%."The true data indicates that the actual risk of suffering from withdrawal ranges between 44.3% and 78%, depending on the methodology used. Indeed, the Cymbalta label in Europe has stated since 2006 that

[1] Lilly revised the label to indicate 1% in later years, and made several changes to the various symptoms associated with withdrawal. In all material ways, however, the warning is the same on the current labeling.

withdrawal is observed in "approximately 45%" of patients. Lilly's label, thus, misleadingly minimizes the risks of withdrawal.

Second, the Cymbalta label falsely states that withdrawal was systematically studied even though Lilly deliberately avoided using its own methodology to measure withdrawal risks. Lilly developed and promoted a specific methodology for measuring discontinuation symptoms using a discontinuation checklist in its marketing of Prozac. A symptom checklist, as opposed to spontaneous reporting, collects withdrawal data by asking each clinical trial participant if they experienced a specific symptom, instead of relying on the patient to spontaneously volunteer the same symptom. Symptom checklists generally yield higher rates. Lilly's medical director specifically chose not to use checklists because "[i]f you use an elicited scale, you'll see higher rates. This WILL end up in the label." *Hexum*, 2015 WL 4064633, at *8. Although Lilly never used a checklist in a placebo-controlled trial, it did use a checklist in two active-controlled trials, comparing Cymbalta to Effexor. In those studies, 74% to 78% of Cymbalta users experienced withdrawal. None of this information ever was put into the label.

Third, the Cymbalta label does not indicate how long withdrawal symptoms can last suggesting, instead, that they are short-lived. Lilly's own clinical trials, however, show that the majority of withdrawal lasts longer than two weeks. This information was never put in the label. This is in contrast to the European label, which states that withdrawal can "resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more)." And, consistent with Lilly's efforts to avoid "bad" data, even though most withdrawal lasted longer than two weeks, Lilly *never* measured withdrawal reactions beyond two weeks. In fact, in 2003, before Cymbalta hit the market, one of Lilly's senior medical researchers expressed serious concerns about Lilly not being proactive about the withdrawal issue and that Lilly was burying

its head in the sand. He even proposed conducting clinical trials with longer observation periods, but Lilly ignored his request.

Fourth, the Cymbalta label does not indicate the likely severity of withdrawal symptoms and fails to disclose Lilly's Cymbalta-specific data on the issue. The Cymbalta label states, in reference to data about *other* SSRIs and SNRIs, i.e., not Cymbalta-specific data, that "[a]lthough these events are generally self-limiting, some have been reported to be severe." However, Lilly possessed data specific *to Cymbalta*—between 9.6% and 17.2% of withdrawal was severe. Moreover, Lilly's clinical studies showed that approximately 50% of withdrawal was moderate.

Finally, the Cymbalta label does not disclose the data Lilly possessed comparing abrupt and tapered discontinuation and contains recommendations that are "inconsistent" with Lilly's own data. According to Lilly's own Medical Director, the sentence "[a] gradual reduction in dose rather than abrupt cessation is recommended whenever possible" is "inconsistent" with Lilly's own clinical data. *Hexum*, 2015 WL 4064633, at *8. According to Lilly, "[n]one of the individual studies specifically designed to look at this (SUI or GAD)[2] have shown a benefit to tapere [sic] compare with abrupt discontinuation." *Id.* Lilly, however, elected not to change the label because "it's from previous class labeling and not worth the fight[.]" *Id.*

This lawsuit also alleges that the Cymbalta drug, itself, is defectively designed. Cymbalta comes in 20mg, 30 mg, or 60 mg capsules. Due to the short half-life of Cymbalta, the drug must be dispensed in an enteric-coated (delayed release) capsule. And, to ensure the enteric coating of the Cymbalta capsule is not compromised, the Cymbalta label instructs patients that the Cymbalta capsule is to "be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids." Thus, unlike other medications which

[2] SUI and GAD are abbreviations for studies that investigated stress urinary incontinence and general anxiety disorder.

are manufactured as scored tablets that can be easily divided to create smaller doses, the smallest possible dose for Cymbalta is 20 mg, swallowed whole. In the context of withdrawal, this poses a problem. The Cymbalta label recommends tapering off the medication gradually, but practically, the patient will eventually have to quit taking Cymbalta at a 20 mg dose, without any option for tapering. Likewise, patients prescribed the 20 mg dose are not able to taper, either. Thus, the actual design of the Cymbalta pill prevents safe discontinuation of Cymbalta.

II. Informal Coordination Efforts Since *Cymbalta I* Have Been Thwarted by Lilly

Following this Panel's ruling in *Cymbalta I* and its adopting Lilly's suggestion that informal coordination should be sufficient, the attorneys who submitted the original petition made several overtures of voluntary coordination, specifically designed to reduce the burden on the judiciary and allow the parties to resolve these cases efficiently and quickly. As described below, Lilly categorically opposed those efforts.

A. Lilly Rejects Plaintiffs' Informal Discovery Proposal

As was represented to the Panel previously, the attorneys litigating these cases have thousands of cases in the pipeline which, absent an MDL, would need to be filed prior to the expiration of various statutes of limitations. To address this large inventory through informal coordination—as advised by the Panel—Plaintiffs' counsel proposed an informal discovery process. Plaintiffs proposed entering into a tolling agreement, whereby specified plaintiffs' statute of limitations would be tolled and Lilly would be given authorization to collect medical records and conduct informal discovery about each plaintiff. After reviewing the records, counsel could informally address each case and determine whether it could be settled out-of-court or whether it would need to be litigated, avoiding the need to file thousands of cases in different federal or state courts. Lilly flatly rejected this proposal, offering no explanation.

B. Lilly Rejects Plaintiffs Informal Centralization Proposal

With the thousands of cases in the pipeline, Plaintiffs' counsel also sought to centralize the already-filed cases before a single court. Outside of an MDL, the only court that would have unquestioned jurisdiction over Lilly was the Southern District of Indiana in Indianapolis, where Lilly's global headquarters is located. Plaintiffs' counsel sent a proposal to Lilly, whereby the already-filed cases would be dismissed without prejudice and re-filed in the Southern District of Indiana provided Lilly did not raise any statute of limitation defense that did not exist prior to the dismissal. Within that court, the attorneys could work out reasonable pretrial procedures, i.e., factsheets, doctor depositions, etc., and allow all other discovery to be coordinated through a single court. As part of this proposal, Plaintiffs' counsel proposed filing future cases in the Southern District of Indiana. This proposal would allow Lilly to litigate all cases in a single court less than a mile from its global headquarters. Lilly rejected this proposal, too..

In the face of Lilly's refusal, plaintiffs in several cases filed motions to transfer to the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a), the convenience transfer statute. The plaintiffs argued for transfer to reduce the costs associated with litigating each case, reduce the burden on the judiciary, and allow for the creation of a centralized proceeding in the courthouse that was convenient for Lilly. Lilly, however, opposed these motions, arguing, among other things, that transfer to the Southern District of Indiana would undermine this Panel decision not to create an MDL. Lilly claimed that only this Panel has the authority to create or permit any centralization and that efforts to transfer all the cases to the Southern District of Indiana were inappropriate.

Lilly's arguments generally prevailed. The first court to consider the motion deferred ruling on the issue, stating that it wanted to see what, if anything developed in Indiana first. The

court acknowledged, however, that:

> Absent centralization, there will be a duplication of effort in the routine aspects of each case, resulting in a substantial increase in the per case cost of those cases not centralized because of travel and other costs that could be avoided or broadly shared were the cases included within a group of centralized cases.

Ali v. Eli Lilly and Company, 1:14-cv-1615-AJT-JFA, slip op. at 9 (E.D. Va. Mar. 4, 2015). After the first ruling, other courts considering the motion concurred, denying the motion to transfer without prejudice until some form of coordination was set up in Indiana.

Undersigned counsel, consistent with the effort to voluntarily coordinate, sought to dismiss, without prejudice, a handful of cases so they could be refiled in the Southern District of Indiana. There was no need to transfer since the statute of limitations on those cases had not yet run. Lilly opposed the voluntary dismissal, forcing plaintiffs to file a motion to dismiss their own cases. Consistent with Lilly's effort to keep these cases decentralized, at the expense of the judiciary, Lilly opposed these motions. The courts considering the issue, however, all rejected Lilly's efforts. As one court explained:

> Plaintiffs have adequately explained that they desire dismissal so that they may refile all of their Cymbalta cases in the Southern District of Indiana to better coordinate discovery, better manage protective and scheduling orders which may affect all of the Cymbalta cases, and more efficiently resolve each action. As Eli Lilly notes, Plaintiffs' counsel has moved to transfer at least ten other Cymbalta cases against Eli Lilly to the same court, demonstrating that Plaintiffs' purported reasons for desiring a voluntary dismissal are more than empty words. . . .
>
> Moreover, due to the early stage of this litigation, Eli Lilly will not be unduly prejudiced by this case being refiled in a different federal court. Indeed, the only prejudice Eli Lilly can identify is that it may be more difficult to subpoena the physicians who prescribed Cymbalta to Plaintiff Elaine Scherer, as their offices are in Missouri. However, Rule 45 gives federal courts the power to serve a subpoena "at any place within the United States." Fed. R. Civ. P. 45(b)(2). This Court declines to assume that the physicians will refuse to comply with a properly served subpoena, but even should they do so, the Indiana court may still command them to attend a deposition within 100 miles of their residences or places of business. The federal rules of procedure and evidence likewise provide avenues to use such depositions at trial.

Scherer v. Eli Lilly and Company, 4:14-CV-01484-AGF, slip op. at 4 (E.D. Mo. Mar. 17, 2015).

C. Lilly Takes Proactive Action to Decentralize Cases and Further Burden the Judiciary

Lilly has recently taken efforts to further decentralize the litigation and place additional burden on the judiciary. Specifically, Lilly moved to sever and transfer, pursuant to 28 U.S.C. § 1404(a), those cases filed in bundled complaints in Indiana; asking the court to break up consolidated complaints into twenty-eight (28) individual cases and transfer those cases to the home districts of each plaintiff, to be litigated separately in twenty-eight (28) different courts around the country.[3] These motions are under submission or are being briefed. Should Lilly's motions be granted, the plaintiffs who have filed cases in the Southern District of Indiana will have their specific case transferred to a new federal court, exponentially burdening the judiciary with even more Cymbalta withdrawal cases.

Separately, groups of plaintiffs from all over the country filed bundled complaints in the Eastern District of California.[4] These cases were filed due to statute of limitation issues and in the wake of the Panel's denial of an MDL and Lilly's rejection of a tolling agreement. Lilly has now moved to dismiss each non-California plaintiff for lack of personal jurisdiction, arguing that it is a violation of due process to subject Lilly to the jurisdiction of the Eastern District of California for claims involving non-California residents—even though those claims were filed along with several California residents and even though Lilly has conceded grounds for California personal jurisdiction for two Cymbalta Withdrawal cases filed in Los Angeles. In

[3] *See Hill v. Eli Lilly & Co.*, 15-cv-00141-JMS-DKL (S.D. Ind.), Dkt. 22 (June 23, 2015) (motion to sever complaint into six (6) different cases and transfer each case to a separate court); *Boles v. Eli Lilly & Co.*, 15-cv-00351-JMS-DKL (S.D. Ind.), Dkt. 22 (July 20, 2015) (motion to sever complaint into twenty (20) different cases and transfer each case to a separate court); DeCrane v. Eli Lilly & Co., 15-cv-00365-JMS-DKL (S.D. Ind.), Dkt. 23 (Jul. 21, 2015) (motion to sever complaint into two (2) different cases and transfer each case to a separate court).

[4] *Nelson-Devlin v. Eli Lilly &. Co.*, 14-cv-02811-KJM-EFB (E.D. Cal.) (twenty-one (21) plaintiffs); *Wolff v. Eli Lilly & Co.*, 14-cv-03004-KJM-EFB (E.D. Cal.) (thirty-one (31) plaintiffs); *Ben v. Eli Lilly & Co.*, 14-cv-02914-KJM-EFB (E.D. Cal.) (twenty-four (24) plaintiffs).

response, plaintiffs opposed the motions to dismiss and requested, in lieu of dismissal, to have their claims transferred to the Southern District of Indiana or each plaintiffs' home district pursuant to 28 U.S.C. § 1406. In other words, in the absence of an MDL, Lilly has taken every effort to destabilize and prejudice plaintiffs pursuing claims for personal injuries, leveraging the lack of a coordinated proceeding to make litigation too expensive and too spread-out to be worth pursuing, simultaneously burdening multiple federal courts around the country with duplicate litigation.

ARGUMENT

I. The Concerns that Prevented Centralization in *Cymbalta I* Do Not Apply Here and Changed Circumstances Warrant Centralization

The Panel may revisit a denied MDL petition as the litigation expands. *See, e.g.*, *In re Plavix Mktg., Sales Practices & Products Liab. Litig. (No. II)*, 923 F. Supp. 2d 1376, 1378 (J.P.M.L. 2013); *In re: Glaceau VitaminWater Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1349, 1350 (J.P.M.L. 2011); *In re Fedex Ground Package Sys., Inc., Employment Practices Litig. (No. II)*, 381 F. Supp. 2d 1380, 1381 (J.P.M.L. 2005); *In re: Lipitor II*, 997 F. Supp. 2d at 1356. The Panel, however, will only revisit an MDL petition "where a significant change in circumstances has occurred." *In re Plavix II*, 923 F. Supp. 2d at 1378.

A. The Panel's Concerns from *Cymbalta I* No Longer Militate against Centralization

There is no dispute that "[t]he actions in this docket are highly similar" and that "[u]nquestionably, these actions share factual issues concerning Cymbalta's development, marketing, labeling, and sale." *Cymbalta I*, 65 F. Supp. 3d at 1393. In *Cymbalta I*, however, the Panel expressed three concerns with centralization. Those concerns are each addressed.

First, the Panel was disinclined to transfer all the listed actions in *Cymbalta I* because "the

procedural posture of the actions varie[d] significantly." *Id.* Four of the listed cases were set to conclude discovery while the remaining cases were "still in their infancy." *Id.* Such procedural disparities create difficulties upon centralization. Here, however, there is no such procedural disparity. To be sure, there are several cases that are scheduled for trial in August, but those cases are not the subject of this motion. The constituent actions herein are all in the same procedural posture. Little, if any, discovery has transpired in the cases subject to this petition, and the cases are set to conclude discovery at some point in 2016 or later. *See In re: TR Labs Patent Litig.*, 896 F. Supp. 2d 1337, 1338 (J.P.M.L. 2012) ("[T]he record shows that the fact discovery period in the action[s] remain[] open, and little, if any, expert discovery has taken place."). In other words, the constituent actions at issue are all on similar and lengthy runways, with much of the anticipated discovery still to be conducted. Centralization of these actions would only reduce the number of courts overseeing these cases—it would not impact the pace of cases.

Second, the Panel did not believe centralization was warranted because "most, if not all, of the common discovery has already taken place[.]" *Cymbalta I*, 65 F. Supp. 3d at 1394. The Panel noted that the "moving plaintiffs dispute the adequacy of Lilly's production" but nonetheless concluded that substantial discovery had already occurred. *Id.* Since *Cymbalta I*, however, Lilly has produced an additional one million pages of documents and several additional company witnesses have been disposed. Indeed, a court recently denied two motions for summary judgment, distinguishing prior Cymbalta withdrawal rulings because "of the newly uncovered evidence[.]" *Hexum*, 2015 WL 4064633, at *16; *Herrera v. Eli Lilly & Co.*, No. 2:13-CV-02702-SVW, 2015 WL 4064639, at *13 (C.D. Cal. June 19, 2015). In three Cymbalta withdrawal cases, there are pending motions for sanctions against Lilly, alleging that Lilly

withheld the production of documents in one case, but produced responsive documents in another.[5] And, in one case in the Eastern District of Virginia, Lilly was sanctioned for withholding case-specific documents in violation of a court order.[6] Lilly's prior representations about discovery being complete were not true.

More to the point, there is still a significant amount of discovery that needs to be done. There has been no discovery related to Lilly's direct-to-consumer marketing practices or direct-to-prescriber marketing practices, i.e., sales representatives, advisory boards, continuing medical education, etc., no discovery related to the design of the Cymbalta pill, no discovery related to Cymbalta pricing, and no discovery related to post-marketing pharmacovigilance and adverse event analysis.

Notwithstanding the various broad topics that need further discovery, none of the discovery that has been conducted so far has been made available to undersigned counsel. However, even if it were, that discovery was conducted without any of undersigned counsel's input (or the input of other attorneys). The discovery conducted by other plaintiffs' counsel was done independently. Thus, depositions may need to be retaken and additional written discovery is warranted. In the absence of an MDL, undersigned counsel has a right—indeed an obligation—to re-depose Lilly's witnesses, conduct whatever additional written discovery is warranted, and focus on a theory of liability that might be different than what other attorneys pursued. An MDL militates against this issue by forcing plaintiffs' attorneys to coordinate their discovery efforts as a unified group. This is particularly true in light of the recent creation of a **Judicial Council Coordinated Proceedings** ("**JCCP"**). in the State of California—an effort spearheaded by

[5] *Herrera v. Eli Lilly & Co.*, 13-cv-02702-SVW-MAN (C.D. Cal.), Dkt. 236 (Apr. 20, 2015); *Hexum v. Eli Lilly & Co.*, 13-cv-02701-SVW-MAN (C.D. Cal.), Dkt. 265 (Apr. 21, 2015); *Saavedra v. Eli Lilly & Co.*, 12-cv-09366-SVW-MAN (C.D. Cal.), Dkt. 171 (Jul. 14, 2015).
[6] *Ali v. Eli Lilly & Co.*, 14-cv-01615-AJT-JFA (E.D. Va.), Dkt. 114 (June 24, 2015).

separate attorneys who plan to conduct new discovery.

Moreover, even if substantial common discovery was already complete—a fact that is disputed—there is still significant individual discovery required for each plaintiff. Having dozens of different courts oversee that process is inefficient and is precisely why MDL proceedings were created. MDLs create uniform and streamlined processes to allow individual claims to be resolved quickly and consistently, and not get bogged down by the different procedures and approaches used in different courts.

Third, in *Cymbalta I*, the Panel rejected centralization because "just two firms represent plaintiffs in all the constituent actions, and Lilly is represented in all actions by a single law firm. This overlap suggests that informal coordination with respect to the remaining common discovery, as well as other pretrial matters, should be practicable." *Cymbalta I*, 65 F. Supp. 3d at 1394. The Panel reasoned that the very limited number of attorneys involved permitted informal coordination and obviated the need for an MDL. That is no longer the case. Many other law firms have entered the fray and, considering Lilly's refusal to find practicable ways to reduce the need to involve hundreds of courts, involuntary coordination is simply not feasible anymore. Undersigned counsel has made several efforts to coordinate various plaintiffs' counsel and create informal coordination. Those efforts, however, have proven difficult outside the context of an MDL. Sharing work product, "hot" documents, deposition outlines, etc., is simply not feasible outside of the protections of a formal MDL proceeding.

B. Changed Circumstances Warrant Reconsideration

At base, the circumstances surrounding centralization have changed. In the Lipitor litigation, the Panel previously denied the plaintiffs' petition for centralization. *In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Products Liab. Litig. ("Lipitor I")*, 959 F.

Supp. 2d 1375, 1376 (J.P.M.L. 2013). The Panel, just like in *Cymbalta I*, held that the actions involved very similar factual issues but that "other factors weigh against centralization[.]" *Id.* The Panel reasoned that due to the limited number of claims, the limited number of plaintiffs' counsel, and the drug manufacturer's willingness to voluntarily coordinate the "creation of an MDL is [not] necessary at this time." *Id.* This holding mirrors the Panel's reasoning for initially denying an MDL in *Cymbalta I*. *Compare Cymbalta I*, 65 F. Supp. 3d at 1393-94 *with Lipitor II*, 997 F. Supp. 2d at 1355.

The plaintiffs in the Lipitor litigation, however, re-filed an MDL petition after the litigation was given time to expand. On reconsideration, the Panel elected to create an MDL because the plaintiffs had demonstrated sufficient change of circumstances. *Lipitor II*, 997 F. Supp. 2d at 1355. The Panel noted the circumstances changed with regard to: (1) "the number of involved actions, districts, and judges has grown considerably"; (2) "the number of involved plaintiffs' firms has grown as well"; and (3) the existence of "any related state court" litigation. *Id.*

Just as in *Lipitor II*, the circumstances here have changed. First, the number of constituent actions has grown considerably, from twenty-eight (28) federal actions involving thirty-nine (39) plaintiffs in *Cymbalta I* to forty-four (44) federal actions involving two-hundred and forty-nine (249) plaintiffs here.[7] *See id.* (Panel recognized that 56 constituent actions and over 170 tag-alongs was sufficient to show considerable growth). Second, the number of different law firms involved in the litigation has grown from two in *Cymbalta I* to at least eight (8) here (Lilly would have the total number). *Id.* ("[T]he increased presence of apparently unique counsel, coupled with the increased number of involved actions, districts, and judges, makes it highly difficult, if

[7] As part of plaintiffs' efforts to maintain some form of centralization, complaints have been filed in a bundled fashion, with numerous plaintiffs asserting claims within a single complaint. Thus, although the number of constituent actions has only increased by approximately twenty (20) cases, the number of actual plaintiffs seeking claims has increased by two-hundred ten (210). And this is just the tip of a large ice-berg—many thousands of cases will be filed in the coming months as statutes of limitations approach.

not impossible, to coordinate this litigation effectively on an informal basis."). Third, since *Cymbalta I*, a JCCP in California state court has been created, which involves well over 100 additional plaintiffs.[8] *See id.* ("Creation of an MDL likely will make it easier to coordinate, as needed, pretrial proceedings in both the state and federal cases, because there will now be just one judge handling the latter."). The very considerations that warranted reconsideration in *Lipitor II* apply here.

II. Transfer and Pretrial Coordination of These Related Cymbalta Withdrawal Cases Will Promote the Just and Efficient Conduct of Litigation and Further the Goals of 28 U.S.C. § 1407

Transfer and pretrial coordination of these related actions in a single court is appropriate and will promote the goals of 28 U.S.C. § 1407. Transfer is appropriate where: (A) "civil actions involving one or more common questions of fact are pending in different districts"; (B) transfer and coordination "will promote the just and efficient conduct of such actions"; and (C) transfer and coordination will serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a). As set forth below, each of these criteria is satisfied.

A. The Related Actions Involve Common Issues of Fact

These Cymbalta Withdrawal actions share many factual issues. Each alleges that Cymbalta caused withdrawal reactions and injuries to patients who ceased ingesting Cymbalta and that Lilly, through its labeling, advertising, and promotion, failed to adequately warn about the risk of withdrawal. This is why the plaintiffs all assert similar causes of action, including negligence, failure-to-warn, breach of warranty, fraud, and various state-specific consumer fraud claims. Additionally, the actions also involve the same defendant (Lilly) and the same categories of plaintiffs—patients who stopped ingesting Cymbalta and experienced withdrawal injuries as a result. Lilly has continuously taken the position that the Cymbalta warning label is adequate as it

[8] *Cymbalta Drug Cases*, Case No. JCCP 4825 (Cal. Sup. Ct. Los Angeles, Dept. 308) (J. Johnson).

currently reads,[9] which necessarily means that significant pretrial discovery is required to evaluate: (i) Cymbalta's propensity to develop withdrawal symptoms, (ii) Lilly's knowledge of Cymbalta's withdrawal risks, and (iii) any effort by Lilly to conceal those risks including Lilly's decision to implement, and its implementation of the "greater than or equal to 1%" labeling language—pretrial discovery that will apply equally to *all* plaintiffs.

Although these Cymbalta Withdrawal actions present certain individualized factual issues, (e.g., specific causation and damages), "Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization." *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp. 2d 1376, 1378; (J.P.M.L. 2010); *see In re Denture Cream Prods. Liab. Litig.*, 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009).

Instead, where, as here, the underlying factual and legal allegations are sufficiently similar, "[t]ransferee judges have demonstrated the ability to accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits." *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009); *see In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011).

Moreover, courts frequently apply a dual discovery approach in products liability actions involving pharmaceutical products. *See, e.g.*, *In re: Actos Products Liab. Litig.*, MDL 2299, 2011 WL 6889721 (Dec. 29, 2011); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 655 F. Supp. 2d 1346, 1346 (J.P.M.L. 2009); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005). "The transferee judge also can use any number of pretrial techniques, such as plaintiff fact sheets and separate motion tracks, to resolve threshold issues promptly." *In re*

[9] Indeed, Lilly recently filed a motion for summary judgment specifically arguing that the Cymbalta label is sufficient as a matter of law. See *Ali v. Eli Lilly & Co.*, 14-cv-01615-AJT-JFA (E.D. Va.), Dkt. 125 (June 29, 2015).

Darvocet, 780 F. Supp. 2d at 1381.

B. Coordination Promotes the Just and Efficient Management of Pretrial Proceedings for All Related Actions

Because these related Cymbalta Withdrawal actions share common questions of fact and implicate overlapping fact and expert discovery, coordination of these actions before a single judge will provide the most efficient approach to managing the cases at this time.

In each of the forty-four pending federal actions, the Plaintiffs are likely to seek much of the same discovery from Lilly, including documents and deposition testimony related to the testing, design, labeling, marketing, and safety of Cymbalta and Lilly's research and evaluation of antidepressant withdrawal for other Lilly products like Prozac. Coordinating the actions before one judge allows the parties and the court to address this overlapping discovery in an organized manner and avoid the costly and unnecessary duplication of efforts and judicial resources that would be required if the cases proceeded on separate schedules in separate courts.

This Panel consistently recognizes that Section 1407 coordination is a preferred way to manage individual lawsuits that raise similar questions regarding a defendant's development, design, and testing of a particular prescription medication or device. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381-82 (J.P.M.L. 2004); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1367 (J.P.M.L. 2003); *In re A. H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig.*, 406 F. Supp. 540, 542 (J.P.M.L. 1975).

Coordination is also appropriate to avoid potentially inconsistent pre-trial rulings on the same or similar issues, including expert challenges under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the uncertainty and confusion that would result. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig*., MDL No. 2272, 2011 WL 3563293, at *1 (J.P.M.L. Aug. 8, 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and]

prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues . . . ."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort."). Indeed, there is already disharmony in the law relating to Cymbalta withdrawal cases. *Compare McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014) (granting summary judgment) and *Carnes v. Eli Lilly & Co.*, No. CA 0:13-591-CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013) (same) *with Hexum*, 2015 WL 4064633, at *16 (specifically distinguishing *McDowell* and *Carnes*) and *Herrera v. Eli Lilly & Co.*, No. 2:13-CV-02702-SVW, 2015 WL 4064639, at *13 (C.D. Cal. June 19, 2015) (same) noting the substantial discovery unavailable for the earlier dismissals.

C. Coordination Will Serve the Convenience of Witnesses and Parties.

For many of the same reasons that coordination will promote the just and efficient management of the actions at this time, it will also serve the convenience of the witnesses and parties. In particular, coordinating and streamlining discovery will minimize unnecessary duplication, travel, and other expenses, and allow the parties to conserve, and more effectively focus, their resources. By allowing the centralization and coordination of pretrial proceedings for these related actions, and the anticipated flood of actions in the future, current and future plaintiffs will have a single, organized, and easily accessible forum to have the bulwark of discovery resolved. Centralization will "eliminate duplicative discovery, prevent inconsistent pretrial rulings . . . and conserve the resources of the parties, their counsel and the judiciary." *In re Temporomandibular Joint (TMJ) Implants*, 844 F. Supp. at 1554.

III. Centralization and Pretrial Coordination in the Southern District of Indiana Is Appropriate

The selection of an appropriate transferee court is based on a balancing test of several factors, no one of which is dispositive. *See* Manual For Complex Litigation (Fourth) § 20.131 (2004). These factors include "where the largest number of cases is pending, where discovery has occurred, where cases have progressed furthest, the site of the occurrence of the common facts, where the cost and inconvenience will be minimized, and the experience, skill, and caseloads of available judges." *Id*. Movants submit that coordination in any of the jurisdictions with filed cases would be an improvement over the present fragmented status, however, the Southern District of Indiana may be the most logical forum.

First, the Southern District of Indiana is the present jurisdiction with management of the largest number of Cymbalta Withdrawal cases. There are currently eight separate cases pending before Judges in the Southern District of Indiana representing 117 plaintiffs .

Second, the Southern District of Indiana is an accessible and convenient forum for all parties and witnesses. Plaintiffs in the currently pending actions—and in future cases that will be filed—are geographically dispersed across the country, making no single district *most* convenient to all plaintiffs. Indianapolis is a centralized location, which would allow disparate plaintiffs to easily access the court. More to the point, Lilly's home offices are headquartered in Indianapolis, Indiana, about a mile from the courthouse. Lilly's company witnesses, documents, and general counsel are all located in Indianapolis.

CONCLUSION

Based on the foregoing, Movants respectfully request that the Panel order coordinated pretrial proceedings for Cymbalta withdrawal injury cases and transfer all such pending and future cases to the Southern District of Indiana or to such other Court or Judge as the Panel finds appropriate under the circumstances.

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