BEFORE THE
UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: ONGLYZA® and KOMBIGLYZE® PRODUCTS LIABILITY LITIGATION	MDL No. _____

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407 AND JPML RULE 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

Pursuant to 28 USC § 1407 and Rule 7.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Moving Plaintiff respectfully submits this memorandum of law in support of her motion for transfer and coordination for pretrial purposes of all currently filed cases identified in the Schedule of Actions ("Actions"), as well as any cases subsequently filed involving similar facts or claims ("tag along cases"), to the United States District Court for the Northern District of California.

There are currently at least forty-four (44) actions pending in twenty-four (24) different judicial districts in the United States alleging similar wrongful conduct on the part of Defendants resulted in similar injuries. Likewise, because of the scope of Defendants' sales of Onglyza® and Kombiglyze® (saxagliptin) (hereinafter "Onglyza"), it is likely that hundreds of other actions will be filed in jurisdictions throughout the United States. Transfer for consolidation and coordination is proper because each of these Actions and tag along cases arise out of the same or similar nucleus of operative facts, arise out of the same or similar alleged wrongful conduct, will involve the resolution of the same or similar questions of fact and law, and discovery will be substantially similar and involve many of the same documents and witnesses.

I. FACTUAL BACKGROUND

Onglyza® was introduced to the United States market on July 31, 2009 and Kombiglyze® was introduced on November 5, 2010. Defendants developed their Onglyza drugs to market and sell them as treatments for type 2 diabetes and agents to help reduce adverse complications associated with the disease. However, the use of Onglyza carries a significant increased risk of causing heart failure, congestive heart failure, cardiac failure, and death from heart failure.

Type 2 diabetes mellitus is a chronic disease, characterized by insulin resistance and deficient insulin secretion leading to high blood sugar levels and/or hyperglycemia. Type 2 diabetics have an increased risk of cardiovascular disease, which is the leading cause of morbidity and mortality in the patient population. Therefore, it is critical that drugs developed to allegedly help prevent type 2 diabetes do not increase the risk of cardiovascular adverse events in users. With full knowledge of the susceptibility of type 2 diabetics to cardiovascular related adverse events, Defendants developed their drugs Onglyza and Kombiglyze XR to market and sell them to type 2 diabetics to allegedly lower adverse complications associated with type 2 diabetes.

Saxagliptin works by inhibiting the proteolytic activity of DPP4, thereby potentiating the action of Glucagon-like peptide-1 (GLP-1), an antihyperglycemic hormone, known as an incretin. This induces glucose-dependent stimulation of insulin secretion while suppressing glucagon secretion, which may help Saxagliptin users lower their HA1c. DPP4 inhibitors, including Saxagliptin, inhibit natural enzymes from cleaving, or stopping, the endogenous GLP-1, which enables the stimulation of insulin to continue longer than what naturally occurs after meals in the postprandial state. Endogenous GLP-1's half-life is approximately two minutes

without Saxagliptin exposure, but survives for at least three hours during Saxagliptin exposure. Therefore, Saxagliptin manipulates the natural biological incretin effect by enabling the process to continue for an exponentially greater period of time than what the human body has adapted as a sufficient and safe period of time. At no time during the development of its Saxagliptin drugs did Defendants perform adequate studies to determine if their drug, and its drastic alterations of the natural incretin hormone cycle, may cause increased risks of cardiovascular related adverse events. Such studies are essential when developing, and then marketing, diabetic drugs to individuals already at an increased cardiovascular risk.

In December 2008, with knowledge of the increased cardiovascular risk type 2 diabetics suffer from, the FDA issued important guidance regarding this topic to companies developing anti-diabetic drugs, including Defendants. The FDA's memorandum, entitled Final Guidance for Industry, *Diabetes Mellitus: Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes,* stated applicants of new anti-diabetic medications for the treatment of type 2 diabetes should demonstrate their products are not associated with an unacceptable increase in cardiovascular risk. Despite this guidance being issued during the development of Defendants' drugs, Defendants failed to perform adequate clinical trials to determine if their drugs created such an increased risk. Instead of adequately assessing the potential, and now established, significant risk of heart failure, congestive heart failure, cardiac failure, and death related to those events, prior to marketing and selling Saxagliptin nationwide to millions of type 2 diabetics, Defendants ignored patient safety and sold Saxagliptin before studying the risks. Defendants marketed and sold Saxagliptin for nearly five years before completing an adequately powered and designed study of the risks of heart failure, congestive heart failure, cardiac failure, and death related to those events.

On July 31, 2009 Defendants began marketing Onglyza. On November 5, 2010, Defendants began marketing Kombiglyze XR. Defendants marketed both drugs as treatments for type 2 diabetes and agents to help reduce adverse complications associated with the disease. At no time did Defendants perform adequate studies or adequately warn that Onglyza and Kombiglyze XR increased the risk of cardiovascular related adverse events.

After Defendants began selling and making substantial profits off their drugs Onglyza and Kombiglyze XR, Defendants finally conducted what the FDA guidance recommended back in December 2008 – a Cardiovascular Outcome Trial ("CVOT") for Saxagliptin. The CVOT for Saxagliptin entitled "Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus — Thrombolysis in Myocardial Infarction 53" (SAVOR-TIMI 53 or more simply "SAVOR") found Saxagliptin users had a statistically significant increased risk of being hospitalized due to heart failure. After receiving and reviewing the disturbing findings from the SAVOR trial, the FDA requested the raw clinical trial data, free from manipulation by Defendants, and performed its own analysis of the SAVOR data. Following the FDA's detailed analysis and review of the SAVOR safety signal for hospitalization for heart failure, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee convened and voted 14 to 1 for the FDA to order Defendants to add a heart failure warning to its Saxagliptin drugs. The single member who voted against adding the warning stated a warning was insufficient and the drug should instead be withdrawn from the US market.[1] Despite the SAVOR findings and despite the FDA Advisory Committee voting to add a warning (or remove the drugs from the market), Defendants failed to warn. Once again, Defendants place sales over patient safety. In fact, no

1 Diabetes in Control (April 17, 2015) "FDA Panel Recommends New CV Safety Warnings on Onglyza and Nesina DPP-4s," available from: http://www.diabetesincontrol.com/articles/diabetes-news/17836-fda-panel-recommends-new-cv-safety-warnings-on-onglyza-and-nesina-dpp-4s-

label change occurred until the FDA added a new warning to the drug label on April 5, 2016.[2]

In addition to Defendants refusing and failing to warn of the risks of heart failure, congestive heart failure, cardiac failure and death, Defendants' Saxagliptin drugs lack any benefit sufficient to tolerate the risks posed by its use because other anti-diabetes drugs are available that do not carry the increased cardiac risks of Saxagliptin. Defendants, with knowledge of the true relationship between use of Saxagliptin and heart failure, congestive heart failure, cardiac failure, and death related to those events, promoted and continue to promote Saxagliptin as a safe and effective treatment for type 2 diabetes mellitus.

II. ARGUMENT

A. The Standard for Transfer and Coordination

This Panel considers the following factors when determining whether to authorize transfer and consolidation of multidistrict actions: (1) one or more common questions of fact are pending in different districts; (2) a transfer would serve the convenience of parties and witnesses; and (3) a transfer would promote the just and efficient conduct of the actions. 28 U.S.C. § 1407(a). The purpose of the multidistrict litigation process is to "eliminate the potential for contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions." *In re: Multidistrict Private Civ. Treble Damages Litig.*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968). Consolidation is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *Id*. at 493.

Multidistrict litigation is designed "to 'promote the just and efficient conduct' of 'civil actions involving one or more common questions of fact' that are pending in different districts." *In re Phenylpropanolamine (PPA) Products Liability Litigation*, 460 F.3d 1217, 1229 (9th Cir.

2 *See*, https://www.fda.gov/Drugs/DrugSafety/ucm486096.htm, last visited May 17, 2017.

2006), *quoting* 28 U.S.C. § 1407(a)). Upon a motion for transfer, the Panel "analyzes each group of cases in light of the statutory criteria and the primary purposes of the MDL process to determine whether transfer is appropriate." *In re PPA Products Liability Litigation,* 460 F .3d at 1230. To that end, it considers factors including "the progress of discovery, docket conditions, familiarity of the transferee judge with the relevant issues, and the size of the litigation." *Id. citing* Multidistrict Litigation Manual § 5.16. On the specific issue of whether to centralize litigation in a single district, the Panel considers the convenience of the parties and witnesses, the number of related actions, and the complexity of common questions of fact.

In this instance, transfer, coordination and consolidation is appropriate because many common questions of fact and law exist, including but not limited to the following: whether Onglyza was marketed with an adequate label; whether Defendants conducted adequate testing of Onglyza; and whether Defendants failed to warn about various issues involving Onglyza including but not limited to, the increased risk of causing heart failure, congestive heart failure, cardiac failure, and death from heart failure.

B. Transfer and Coordination of the Actions is Appropriate and Necessary

The Onglyza cases are well suited for centralization under Section 1407. Though filed in different jurisdictions within the federal court system, these cases are closely related: they share the same Defendants, the same basic theory of liability, and the same basic factual allegations. All the cases will involve the same core discovery, fact witnesses, and experts. Moreover, none of these cases have made any substantial progress toward trial, making this the ideal time to order transfer. Discovery has not commenced in most cases however, in the cases consolidated in the Northern District of California, a protective order, privilege order and an ESI Order have been agreed to and submitted to the Court and entered, and the Court has given a discovery

deadline of one year from now with a trial date in July 2019. As such, transfer to the Northern District of California would promote efficiency and avoid duplicative and inconsistent motions and rulings and allow Judge Jon S. Tigar to continue advancing this litigation in ways that are useful and convenient to all parties.[3]

Further, the Panel has frequently recognized coordination under § 1407(a) is particularly appropriate in pharmaceutical product liability cases. *See generally In Re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, MDL No. 1203 (E.D.PA); In Re: Rezulin Products Liability Litigation, MDL No. 1348 (S.D.NY); In Re: Propulsid Products Liability Litigation, MDL No. 1355 (E.D. LA); In Re: Serzone Products Liability Litigation, MDL No. 1477 (S.D. WV); In Re: Meridia Products Liability Litigation, MDL No. 1481 (N.D. OH); In Re: Prempro Products Liability Litigation, MDL No. 1507 (E.D. AR); In Re: Viagra Products Liability Litigation, MDL No. 1727 (D. MN); In Re: Zyprexa Products Liability Litigation, MDL No. 1596 (E.D. NY); In Re: Ephedra Products Liability Litigation, MDL No. 1598 (S.D. NY); In Re: Phenylpropanolamine (PPA) Products Liability Litigation, MDL No. 1407 (W.D. WA); In Re: Accutane Products Liability Litigation, MDL No. 1626 (NJ Superior Court); In Re: Vioxx Marketing, Sales Practices and Products Liability Litigation, MDL No. 1657 (E.D. LA); In Re: Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation, MDL No. 1699 (N.D. CA); In Re: Aredia and Zometa Products Liability Litigation, MDL No. 1760 (M.D. TN); In Re: Seroquel Products Liability Litigation, MDL No. 1769 (M.D. FL); In Re: Fosamax Products Liability Litigation, MDL No. 1789 (S.D. NY); In Re: Mirapex Products Liability Litigation, MDL No. 1836 (D. MN); In Re: Levaquin*

3 While Moving Plaintiffs understand case management orders and protocols may change after consolidation and coordination, the progress made in the Northern District of California would streamline the process and result in more efficient and expedient case management and discovery.

Products Liability Litigation, MDL No. 1943 (D. MN); In Re: Darvocet, Darvon and Propoxyphene Products Liability Litigation, MDL No. 2226 (E.D. KY). These cases all share one core fact pattern: namely, a single chemical component that caused a specific type of harm. This case, like the long list of cases cited above is no different. Specifically, this case involves a similar harm predicated upon a similar mechanism of injury (i.e., heart failure resulting from the use of Onglyza).

For these reasons, transferring these cases pursuant to 28 U.S.C. § 1407 would enhance the convenience and efficiency of this litigation. Failing to transfer would almost certainly lead to inconsistent and conflicting rulings-particularly with respect to discovery and squander judicial resources in several judicial districts. Thus, the Panel should issue an order transferring all the Onglyza Cases to one judicial district for pretrial coordination or consolidation.

C. The Onglyza Cases Involve Common Questions of Fact

The threshold requirement of § 1407 is that there be questions of fact common to the cases for which MDL treatment is sought. This requirement is satisfied here. The claims in the Onglyza cases each arise from the same course of conduct. Among the numerous commons questions of fact are:

a. Whether and to what extent Onglyza caused or can cause, heart failure, congestive heart failure, cardiac failure, and death from heart failure;

b. When Defendants first learned of the connection between use of Onglyza and the increased risk of heart failure;

c. Whether Defendants failed to warn prescribers about the increased risk of heart failure, congestive heart failure, cardiac failure, and death from heart failure associated with use of Onglyza;

d. Whether Onglyza is defective in design because of its propensity to cause heart failure, congestive heart failure, cardiac failure, and death from heart failure;

e. Whether Onglyza was defective and unreasonably dangerous when taken by Plaintiffs because any benefits are significantly outweighed by the risks associated with use of Onglyza;

f. Whether Onglyza was sold without adequate warnings of the increased risk of heart failure, congestive heart failure, cardiac failure, and death from heart failure;

g. Whether Defendants negligently, recklessly or intentionally misrepresented the risk of heart failure, congestive heart failure, cardiac failure, and death from heart failure associated with Onglyza; and

h. Whether Defendants knowingly, recklessly, or negligently concealed from physicians and/or consumers the increased risk of heart failure, congestive heart failure, cardiac failure, and death from heart failure.

Given the commonality of factual issues in each of the related cases, MDL treatment is appropriate. *See e.g., In re Accutane Prods. Liab. Litig.*, 343 F.Supp. 1382, 1383 (J.P.M.L. 2004) ("The actions . . . present common questions of fact concerning, inter alia, i) the development, testing, manufacturing, and marketing of Accutane, and ii) defendants' knowledge concerning the drug's possible adverse effects.").

D. Pretrial Centralization Will Enhance the Litigation as a Whole

Transfer is appropriate when it would enhance the convenience of the litigation. *See e.g., In re Library Editions of Children's Books*, 297 F. Supp. 385, 386 (J.P.M.L. 1968) ("[T]he Panel must weigh the interests of all the plaintiffs and all the defendants, and must consider multiple litigation as a whole in the light of the purposes of the law."). Here, pretrial transfer will

undoubtedly ease the burdens on all involved – particularly if, as Moving Plaintiff requests, these cases are transferred to the Northern District of California.

As an initial matter, it is important to note all these cases are in their early stages – little motion practice has taken place and to the best of the undersigned's knowledge, very limited discovery has occurred. Therefore, it is the optimal time for transfer.

Additionally, both Defendants and Plaintiffs stand to benefit from pretrial centralization. Pretrial transfer will reduce the burdens of discovery and costs significantly for Bristol-Myers Squibb and AstraZeneca. Similarly, consolidation will permit Moving Plaintiff's counsel to coordinate their efforts and share the pretrial workload amongst various plaintiffs' counsel. The Panel has endorsed this rationale noting, "[P]rudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of case and a minimum of inconvenience to all concerned." *See e.g. In re Baldwin-United Corp. Litig.*, 581 F.Supp 739, 741 (J.P.M.L. 1984). Consolidation of these cases will effectuate this purpose.

Pretrial centralization will also allow Defendants to concentrate its attention and energy on one forum, rather than numerous federal jurisdictions throughout the country. As a result, Moving Plaintiff anticipates that Defendants will be able to move quickly and effectively to discovery and the transferee court, enhancing the overall efficiency of the litigation. *See In re Apple iPhone 3G Prod. Liab. Litig.*, 630 F. Supp. 2d 1382, 1383 (J.P.M.L. 2009) (noting efficiency obtained through MDL process). Finally, pretrial transfer will reduce the burden on witnesses – most of whom are likely Defendants' employees, by substantially cutting down costly and time-consuming travel, duplicative testimony, and discovery. *See e.g., In re Allstate Ins. Co. Underwriting and Rating Practices Litig.*, 206 F.Supp.2d 1371, 1372 (J.P.M.L. 2002).

Given that each of these cases arises from a common core set of factual allegations, counsel for plaintiffs will invariably seek discovery from the same Defendants and witnesses relating to the development, testing, manufacture, marketing, and sale of Onglyza. MDL treatment will enable a single court to establish a pretrial program that will minimize the inconvenience and expenses of redundant and duplicative discovery, which is precisely the purpose of transfer and coordination under § 1407. *See e.g., In re Accutane*, 343 F. Supp. 2d at 1383 ("Centralization under Section 1407 is necessary in order to eliminate duplicative discovery, prevent inconsistent rulings, and conserve the resources of the parties, their counsel, and the judiciary."). In short, transferring the Onglyza cases for pretrial coordination or consolidation will make this litigation far more efficient and convenient for all involved.

E. Pretrial Centralization Will Promote the Just and Efficient Conduct of These Cases

Fairness and efficiency will be furthered in this litigation by a single centralized and coordinated pretrial program, which will avoid duplicative discovery and inconsistent pretrial rulings, and will conserve the resources of the parties, their counsel and the judiciary. *See In re Levaquin Prods. Liab. Litig.*, 560 F. Supp. 2d 1384 (J.P.M.L. 2008); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 398 F. Supp. 2d 1371 (J.P.M.L. 2005). This risk is very real and will likely occur as motions are being filed and courts are setting trial and discovery schedules. There are currently 44 cases pending in 24 different district courts involving over a dozen different plaintiffs' law firms.

Coordinated discovery will benefit both Plaintiffs and Defendants. Rather than answering discovery in 44 different actions in 24 different district courts, depositions of key witnesses can be coordinated and done once. Additionally, document productions can be reduced to a single

coordinated, central location where all plaintiffs can have access. Being able to streamline the work and coordinate efforts amongst plaintiffs' counsel will serve the interests of the plaintiffs. *See In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005) ("it is most logical to assume that prudent counsel will combine their forces and apportion their workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating and overall savings of cost and minimum of inconvenience to all concerned"). And having one court oversee these actions instead of 23 different courts will allow the judiciary to preserve its resources.

Coordinated discovery will also help the plaintiffs in these cases. Instead of more than a dozen different law firms pursuing different strategies for the litigation, a coordinated team of attorneys can pursue the claims in one court, preserving the plaintiffs' resources and allowing the attorneys to work together in common to further these cases.

If transfer is denied in this litigation, these cases will proceed on independent tracks, requiring duplicative discovery, including repeated depositions of the same corporate personnel. Both Plaintiffs and Defendants would benefit from centralization and the economies of scale that it would bring. Transfer would also avoid that danger of inconsistent rulings and result in economy of judicial resources.

Should the Panel determine transfer is proper, it should centralize these cases in the Northern District of California in front of Judge Tigar.

F. The Northern District of California is the Most Suitable Venue for the MDL

Once the Panel determines that centralization is appropriate it then "looks for an available and convenient transfer forum." Federal Judicial Center, *Manual for Complex Litig.* § 22.33, at

367 (4th Ed. 2011). The Northern District of California is a suitable venue for the pretrial proceedings of the Onglyza Litigation. The Panel generally selects a forum that:

> (1) is not overtaxed with other MDL cases, (2) has a related action pending on its docket, (3) has a judge with some degree of expertise in handling the issues presented, and (4) is convenient to the parties.

Id. The Northern District of California is not overtaxed with other MDL cases. At the time of filing this Motion, there are 22 MDLs pending in the Northern District spread among the 20 District Judges housed there. There are currently two related actions filed in the Northern District pending before the Honorable Jon Tigar. Judge Tigar is an experienced jurist, having been a judge for 15 years between state and federal courts. Judge Tigar also has MDL experience, with one MDL pending in front of him, MDL 1917, *In re: Cathode Ray Tube (CRT) Antitrust Litigation*. Judge Tigar has overseen the two related Onglyza actions pending before him for the past year, overseeing the parties' agreement and entering orders on ESI, Privilege, and Protective Orders, overseen the exchange of documents, held multiple case management conferences, and set the cases on track for trial dates in 2018. And finally, in terms of convenience to the parties, the Northern District of California is certainly a convenient forum. National counsel for Defendants are based in San Francisco. More than half of the plaintiffs are represented by counsel from California. One of the three defendants named in these suits is based in San Francisco. San Francisco is one of the largest cities in the United States, is equipped with one of the busiest airports in the world, is a hub of major airlines, and there are scores of hotels nearby the courthouse. San Francisco is certainly a convenient location.

Another factor in favor of the Northern District of California is its proximity to the only other consolidated proceeding related to Onglyza and the injuries asserted here. Indeed, *In re: Onglyza Product Cases*, JCCP 4909 pending in front of Hon. Curtis E.A. Karnow in San

Francisco County, contains more than a dozen cases alleging heart failure and related injuries connected to the ingestion of Onglyza. The courthouse where Judge Karnow sits in San Francisco County is two blocks away from Judge Tigar's courthouse. The ability of the parties to conduct joint status conferences, a joint science day, and coordinate discovery between these two venues would be extremely beneficial for the parties, judges, and counsel. Indeed, Judge Karnow has already indicated a willingness to enter into some degree of coordination and cooperation with the Northern District of California.

For the above reasons, Moving Plaintiff requests the Actions and tag-along cases should be transferred and consolidated before the Honorable Jon S. Tigar, United States District Judge for the Northern District of California.

Dated: October 11, 2017 Respectfully submitted,

By: _____