BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITIGATION	* * * *	MDL Docket No. 2452

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DEFENDANT MERCK SHARP & DOHME CORP'S RESPONSE TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS TO THE SOUTHERN DISTRICT OF CALIFORNIA FOR COORDINATED PRETRIAL PROCEEDINGS

Merck Sharp & Dohme Corp. ("Merck") agrees with plaintiffs Moses Scott and Rosalie Duhon that the 53 actions (and any subsequently-filed, related actions) should be centralized before a single judge, and that Judge Anthony Battaglia from the United States District Court for the Southern District of California would be an appropriate choice to manage the coordinated pretrial proceedings.[1]

All of the identified actions are product liability suits in which plaintiffs assert claims against four manufacturers of incretin-based therapies for the treatment of type 2 diabetes. All plaintiffs allege that these medications cause pancreatic cancer. The medications at issue differ in pharmacology and mechanism of actions, but each is an incretin-based therapy, designed to normalize insulin levels. Sufficient common and overlapping issues exist generally to warrant centralized coordination, including that a substantial number of plaintiffs allege the use of more than one of the incretin-based therapies.

[1] Plaintiffs make numerous unsupported and inaccurate representations regarding Merck and its prescription medications Januvia and Janumet. Merck will reserve its substantive response to those allegations for a forum in which such matters would be relevant.

FACTUAL BACKGROUND

Diabetes and Incretin-Based Therapies

Diabetes is a metabolic disease that adversely affects the way the body processes insulin and blood glucose. Insulin is a hormone that helps glucose enter cells and reduces glucose levels in the blood. In type 1 diabetes, the body does not produce insulin. In type 2 diabetes—the most common form of diabetes, which comprises approximately 90% of the diabetic population—the body does not produce enough insulin, or the cells in the body do not react properly to the insulin that the body is able to produce. Without sufficient insulin, too much glucose remains in the blood. Over time, excess blood glucose causes serious problems, including serious damage to eyes, kidneys, and nerves. Diabetes can also cause heart disease, stroke, and lead to limb amputation.

In managing glucose levels in the body, the human digestive system releases incretin hormones. The incretin hormone called GLP-1 (glucagon-like peptide-1) signals the pancreas to release insulin. An enzyme called DPP-4 (dipeptidyl peptidase-4) helps regulate the GLP-1 hormone by degrading the hormone over a short period of time. In type 2 diabetes, there is a progressive decline of incretin levels, including GLP-1, which results in an impaired ability to manage blood sugar levels. The incretin-based therapies counteract this decline of incretin levels in diabetics in one of two ways: (i) by supplementing the body's natural incretins with incretin analogues ("incretin mimetics") that are resistant to DPP-4; or (ii) by slowing down the elimination of the body's natural incretins by inhibiting the enzyme DPP-4 ("DPP-4

inhibitors").[2] In other words, both types of therapies increase, or prolong, blood levels of active incretins, thereby improving insulin secretion and lowering high blood glucose levels.

The Litigation

Starting in the fall of 2012, plaintiffs began filing lawsuits against the manufacturers of incretin-based therapies alleging that those medicines caused the development of pancreatic cancer.[3] Lawsuits were brought against Eli Lilly ("Lilly") and Amylin Pharmaceuticals ("Amylin") which jointly manufacture and/or market the incretin mimetic exenatide (Byetta); Merck, which manufactures the DPP-4 inhibitor sitagliptin (Januvia) and sitagliptin combined with metformin (Janumet); and Novo Nordisk, which manufactures the incretin mimetic liraglutide (Victoza). The first federal court case commenced when the defendants in October 2012 removed to the United States District Court for the Southern District of California a complaint filed by Plaintiff Moses Scott.

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[2] Although plaintiffs refer to all of these medications collectively as "incretin mimetics," that reference is a misnomer. *See, e.g.,* Molitch and Umpierrez, "Diabetes and Incretin-based Therapy," J. of Clin. Endocrinology & Metabolism (April 2007) (*available at* http://jcem.endojournals.org/content/92/4/0.1.full). Thus, this potential MDL should be retitled. A title such as *In re GLP-1/DPP-4 Products Liability Litigation* would use more appropriate terminology.

[3] Notably, pancreatic cancer occurs more frequently in the population of diabetics than the population at large. The incidence rate in the general population is 12.1 cases per 100,000 people per year, (*see* SEER Cancer Statistics Review, 1975-2009, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2009_pops09/) whereas the incidence rate in people with type 2 diabetes is much higher – 78.76 cases per 100,000 people per year. Brodovicz KG, et al. Impact of Diabetes Duration and Chronic Pancreatitis on the Association Between Type 2 Diabetes and Pancreatic Cancer Risk, *Diabetes, Obesity and Metabolism*, 14: 1123–1128 (*abstract available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1463-1326.2012.01667.x/abstract)).

Between October 2012 and February 2013, fifteen additional cases were either filed in, or removed, to the Southern District of California. On February 4, the Court (through Magistrate Judge Dembin) entered an Order consolidating for purposes of discovery all then-pending cases and any other related cases subsequently filed in that District. Over the next two months, additional cases were filed in, or removed to, other District Courts including the District of Arizona, the District of Colorado, the District of Kansas, the Eastern District of Missouri, the Western District of Oklahoma, and the Middle District of Pennsylvania. On April 5, 2013, Plaintiffs Moses and Duhon filed their petition for creation of an MDL, at which time there were 53 cases pending in federal courts in seven Districts.[4]

According to the plaintiffs, this litigation is expected to grow. Plaintiffs' lawyers around the country have been advertising for potential plaintiffs who have taken an incretin-based therapy medication and have been diagnosed with pancreatic cancer. Thus, it is likely that additional cases will be filed in or removed to, federal courts in the future.[5]

ARGUMENT

I. CREATION OF AN MDL FOR PRODUCT LIABILITY ACTIONS INVOLVING INCRETIN-BASED THERAPIES PROMOTES THE GOALS OF 28 U.S.C. § 1407.

The MDL requested by Plaintiffs meets all of the criteria of 28 U.S.C. § 1407. Transfer under Section 1407 requires: (i) that "civil actions involving one or more common questions of

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[4] Of the 53 cases, 11 assert claims based solely on the use of Merck's products (Januvia and/or Janumet) and 31 assert claims based on the use of Byetta and/or Victoza as well as one of Merck's products. Since then, plaintiffs have filed an additional 3 cases based solely on the use of Merck's products, all in the Southern District of California.

[5] Plaintiffs state that "counsel herein is personally aware of over 500 related cases that are currently under contract with various law firms across the United States of America." Pl. Br. at 2.

fact are pending in different districts"; (ii) that MDL coordination "will promote the just and efficient conduct of such actions"; and (iii) that MDL coordination will serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a).

Applying these criteria, the request for MDL coordination should be granted because: (i) the complaints all assert product liability claims against one or more manufacturers of incretin-based therapies based on allegations that such therapies can and did cause pancreatic cancer and, as a result, the actions involve certain common questions of fact, including whether plaintiffs can proffer reliable scientific evidence on critical issues of general causation—i.e., whether each of the incretin-based therapies are capable of causing the injury alleged; (ii) transfer to a single court will be convenient for the parties and the witnesses, and will promote the just and efficient conduct of the litigation; and (iii) absent transfer and coordination, the parties and courts will face a needless increase in burden and expense due to multiplicative discovery and pretrial proceedings with inconsistent pretrial rulings more likely.

A. All of These Actions Involve Similar Scientific Issues.

These actions raise certain common scientific issues. Each plaintiff alleges that one or more of the incretin-based therapy medications was used to treat diabetes, and that he or she was subsequently diagnosed with pancreatic cancer. Thus, all of these cases involve a well-defined plaintiff population (diabetic patients) asserting a discrete injury (pancreatic cancer). Scientific issues relating to diabetes, pancreatic cancer and the potential role incretins may have played in the alleged injury will be present in each case. Coordination of the cases before one court for purposes of pre-trial proceedings will promote the uniform consideration of such issues.

In similar circumstances, the Panel has found that centralization was warranted where multiple products were involved. For instance, in *In re Gadolinium Contrast Dyes,* the

defendants were five manufacturers of contrast agents that were chemically and pharmacologically different. The Panel concluded that MDL treatment was warranted nevertheless because all of the actions shared some common questions of fact arising out of the allegation that gadolinium-based contrast dyes may cause nephrogenic systemic fibrosis in patients with impaired renal function. *In re Gadolinium Contrast Dyes Prods. Liab. Litig.,* 536 F.Supp.2d 1380 (J.P.M.L. 2008). *See also In re: Avaulta Pelvic Support Sys. Prods. Liab. Litig.,* 746 F.Supp.2d 1362, 1364 (J.P.M.L. 2010). As the Panel noted in the *Avaulta Pelvic Support Sys.* cases, "[i]n our experience, centralized proceedings in such dockets have worked well." *Id.*

It is Merck's position—and that of the other defendants, respectively—that there is no reliable scientific basis for asserting a causal connection between the incretin-based therapy medication that each manufactures and pancreatic cancer. That said, discovery relating to general causation will have some overlap across cases, as will challenges involving plaintiffs' ability to satisfy the requirements of *Daubert v. Merrell Dow Pharmaceuticals, Inc.* Plaintiffs state that their experts, and perhaps their causation theories, will likely relate to all types of incretin-based therapies, Pl. Br. at 9, and they assert that "it would be an unnecessary expense and burden to have expert witnesses vetted in multiple federal district courts on the same injuries, studies, evidence and opinions." *Id.* Replicating these inquiries dozens of times across the country could result in inconsistent and conflicting rulings, and potentially lead to multiple appellate courts devoting resources to repeated review of what could essentially be the same issues. This potential chaos and gross redundancy could be substantially reduced, if not eliminated, by coordinating the proceedings in a single court.

B. **A Significant Percentage of Cases Involve More Than One Product.**

Beyond the threshold issue of general causation, these cases will also involve overlapping questions of fact and law. A number of plaintiffs assert claims against *multiple* manufacturers. Of the 53 cases listed in Plaintiffs' Motion, 20 allege the use of more than one incretin-based therapy. *See* Pl. Br. at 9 ("at least 20 of the 53 plaintiffs … have ingested various combinations of one or more of Byetta, Januvia, Janumet, and Victoza"). Because the same plaintiffs took more than one incretin-based medication, discovery specific to the plaintiff in those cases will involve many of the same or substantially similar documents and witnesses. Concerns regarding increased and unnecessary burden and expense and the potential for inconsistent rulings are particularly true if 30-40 percent of the litigants, based on current filings, could have consumed multiple products and will be attributing their alleged injuries to each of them.

While it is true that these actions will also involve factual issues that are specific to each manufacturer and each individual plaintiff, this is true in almost all products liability litigation, as this Panel has frequently noted. The existence of some disparate fact and issues is not a bar to MDL coordination, for Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization. *See*, e.g., *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011) (citing cases). *See also In re Mirena IUD* (MDL No. 2434) J.P.M.L. Transfer Order 4/8/13 ("While we agree that these actions present a number of individualized factual issues, the existence of such issues does not negate the common ones . . . . Almost all injury litigation involves questions of causation that are case-and plaintiff-specific.") This Panel has consistently found that such differences can be addressed by an MDL judge by establishing separate tracks for issues or cases and/or other relevant pre-trial procedures.

Centralization benefits the overall litigation because it places all of the related actions before a single judge who can formulate a cohesive pretrial program that: "(1) allows discovery with respect to any non-common issues to proceed concurrently with discovery on common issues; and (2) ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties." *In re Denture Creams Prods. Liab. Litig.*, 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009) (internal citation omitted).

Allowing a single judge to coordinate these proceedings will provide the most efficient approach to managing the current cases and the growing litigation. A single judge can more efficiently evaluate the needs of all parties, address overlapping discovery in an organized manner, and set priorities as needed.

II. The MDL Should Be Coordinated in the Southern District of California (San Diego) By Judge Battaglia.

Plaintiffs have requested that all of these actions and any tag-along cases be transferred and consolidated before Judge Anthony J. Battaglia in the Southern District of California. Merck joins in the plaintiffs' request. Plaintiffs have set forth numerous valid reasons supporting the Southern District of California as a forum and Judge Battaglia as the presiding judge. *See* Pl. Br. at 12-16. In this brief, Merck will only highlight some of the more compelling reasons.[6]

First, the overwhelming majority of the federal cases are currently pending in the Southern District of California—45 of 53 filed cases, or almost 85 percent of the cases. This factor heavily favors this District for the MDL coordination. *See, e.g., In re Fosamax Prods.*

[6] Plaintiffs also provide a detailed discussion of the favorable attributes that San Diego has for hosting large-scale multi-party litigation, and the background of Judge Battaglia. *Id.*

Liab. Litig., 787 F. Supp. 2d 1355, 1357 (J.P.M.L. 2011) (MDL assigned to District of New Jersey where two-thirds of the pending actions already docketed); *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp.2d 1376, 1377-78 (J.P.M.L. 2010) (transferring litigation to the district where "substantial majority" of actions—33 of 45—were pending).

Moreover, the earliest filed case subject to this motion, *Moses Scott v. Merck, et al.,* 3:12-cv-02549, was filed in state court in San Diego and removed to this District. This Panel often views the location of the first-filed action as a favorable factor in deciding where to assign an MDL proceeding. *See, e.g., In re DirecTV Early Cancellation Fee Mktg. & Sales Practices Litig.*, 655 F. Supp. 2d 1369, 1370 (J.P.M.L. 2009); *In re Airline Baggage Fee Antitrust Litig.,* 655 F. Supp. 2d 1362, 1363 (J.P.M.L. 2009) (choosing transferee court where 10 of the 11 pending cases were filed, including the first-filed action); *In re Sepracor, Inc. Fair Labor Standards Act Litig.*, 629 F. Supp. 2d 1356, 1356 (J.P.M.L. 2009) (designating the District of Arizona "because the first-filed action is pending there and discovery is well underway").

Second, there is a consensus that the Southern District of California is an appropriate forum for a MDL.[7] All of the defendants have agreed that the Southern District would be appropriate for the centralization of the actions for pretrial purposes and a majority of the plaintiffs—45 of 53—filed their cases in California. Consensus among a substantial number of the adverse parties is a factor that the Panel has previously considered in its analysis. *See, e.g., In re Polyurethane Foam Antitrust Litig.,* 753 F. Supp. 2d 1376, 1377-78 (J.P.M.L. 2010) (selecting transfer court where defendants, as well as responding plaintiffs from chosen district supported centralization); *In re Vytorin/Zetia Marketing, Sales Practices & Prods. Liab. Litig.,*

[7] As of this time, Merck is unaware of any party who objects to San Diego as a venue for this litigation or to Judge Battaglia as the presiding judge for this litigation.

543 F. Supp. 2d 1378, 1380 (J.P.M.L. 2008) (noting that "transfer to this district [New Jersey] enjoys the support of defendants and several plaintiffs").[8]

Third, the parties have made substantial progress in Judge Battaglia's court (with the assistance of Magistrate Judge Dembin). A mechanism for certain case-specific discovery is nearly complete and generic discovery is underway.

III. Alternatively, Coordination in the Western District of Oklahoma or District of Colorado Would Be Appropriate.

As an alternative to the Southern District of California, Merck submits that the Western District of Oklahoma or the District of Colorado would also be appropriate.

Each of those jurisdictions currently has at least one case pending involving incretin-based therapy. In the Western District of Oklahoma, the *Wickware* case is before Judge Heaton

[8] As previously noted, there is ample precedent for multi-product, multi-defendant litigation to be handled in one MDL. *See* § I(A), *supra. See also In re: American Med. Sys., Inc., Pelvic Repair Sys. Prods. Liab. Litig.,* 844 F. Supp. 2d 1359 (J.P.M.L.2012) (centralization in one court "will allow for coordination of any overlapping issues of fact in such multi-product, multi-defendant actions.") A single MDL judge could employ numerous pretrial techniques to manage the litigation efficiently. *Avaulta Pelvic Support Sys.,* 746 F.Supp.2d at 1364. Based on his experience in managing the litigation as it evolves, the presiding judge could create different discovery and/or motions tracks (sequenced as appropriate) to deal with separate manufacturers, types of medications and/or the usage of multiple products as necessary. And, the judge would have the flexibility to alter or modify the structural procedures as new developments might require. If the Panel, however, were to decide to create separate MDLs here, Merck requests that the Panel adopt the litigation structure it employed in the vaginal mesh litigation. There, the Panel created three MDLs (MDL Nos. 2325, 2326 and 2327), and assigned all three MDLs to Judge Goodwin in West Virginia who was presiding over similar litigation involving other manufacturers in MDL No. 2187. As true here, in the vaginal mesh litigation, a significant number of plaintiffs had used more than one mesh product and were asserting claims against multiple manufacturers. Similarly, the Panel could establish separate MDLs for the two types of incretin-based therapy medications and assign both to Judge Battaglia. Claims in cases that allege use of more than product could be severed, by product, and the claims could then be assigned to the respective MDL. *See, e.g., In re Vioxx Mkt., Sales Practices & Prods. Liab. Litig.*, 416 F. Supp. 2d 1354 1355-56 (J.P.M.L. 2006) (severing plaintiff's individual Vioxx and Celebrex claims and assigning them to MDL No. 1657 (Vioxx) and MDL No. 1699 (Celebrex)).

who has served for more than 11 years, presided over numerous products liability cases, and previously served as an MDL Judge (*In re General Motors "Piston Slap" Products Liability Litigation,* MDL No. 1600). In the District of Colorado, the *Graham* case is before Judge Krieger (now Chief Judge) who has been on the bench for more than ten years, and also has substantial experience with products liability cases.

These alternative districts are centrally located. Each is easily accessible to plaintiffs and plaintiffs' counsel, who are geographically dispersed. The Western District of Oklahoma courthouse is in Oklahoma City and only 10 miles from the main airport, which has approximately 20 nonstop flights daily to 18 major cities. The District of Colorado courthouse is located in Denver and is a 30 minute drive to the Denver International Airport, one of the largest and busiest airports in the world.

Finally, each court has the capacity and resources to handle this litigation in an efficient and expeditious manner. The Western District of Oklahoma currently has only two MDL proceedings pending (both before a different judge) while the District of Colorado currently has one MDL proceeding pending (also before a different judge).[9] As of fiscal year ending September 30, 2012, the Western District of Oklahoma had 1,461 cases pending, or an average of 244 actions per judge. This caseload placed the District as No. 87 out of 94 U.S. District Courts nationally (with No. 94 having the least number of cases). The median time between filing a case and disposition was a speedy 8.3 months, and the median time between filing and trial was 20.8 months (ranking as No. 24 out of 94 with 1 being the fastest). The District of Colorado had 3,229 pending cases. The median time between filing and disposition was 5.5

[9] JPML Litigation Statistics by MDL (Report Date 3/5/2013) (*available at* http://www.jpml.uscourts.gov/pending-mdls-0)

months (No. 5 out of 94) and the median time to trial was 23.6 months (No. 32 out of 94).[10] In sum, centralization in either of these districts would make prudent use of available judicial resources and "permits the Panel to assign the litigation to a less-utilized district with an experienced judge who is not presently overseeing a multidistrict litigation." *In re E.I. Du Pont De Nemours and Company C-8 Personal Injury Litigation* (MDL No. 2433) (4/8/13).

IV. THE MDL SHOULD BE LIMITED TO PANCREATIC CANCER CASES.

In establishing an MDL, the Panel should define the injury for which the proceeding has been established. All of the plaintiffs in the cases filed in the federal courts allege that they developed pancreatic cancer as a result of the use of one (or more) of the incretin-based therapies. Accordingly, any MDL should be limited to that injury.

[10] *See* Federal Judicial Caseload Statistics 2012, *available at* http://www.uscourts.gov/Statistics/FederalJudicialCaseloadStatistics/FederalJudicialCaseloadStatistics2012.aspx.

CONCLUSION

For the foregoing reasons, Merck respectfully requests that the Panel transfer the actions identified in Plaintiffs' Schedule of Actions to the U.S. District Court for the Southern District of California, or, in the alternative, to the U.S. District Court for the District of Colorado or the U.S. District Court for the Western District of Oklahoma, for coordinated pretrial proceedings.

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Respectfully submitted,

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