BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: **ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE XR (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION**	)	**MDL DOCKET NO. 2809**

DEFENDANTS ASTRAZENECA PHARMACEUTICALS LP, BRISTOL-MYERS SQUIBB COMPANY, AND MCKESSON CORPORATION'S RESPONSE TO PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS

Nearly two years after these Onglyza lawsuits began, fewer than 40 active cases are currently pending in federal court. A single plaintiffs' law firm is counsel of record in the vast majority of these cases (30) and works closely with the four law firms handling the remaining suits. Given the limited number of suits and firms, coupled with the lack of evidence that the volume of cases will grow materially in the absence of an MDL, there is no need for centralization when the parties can readily coordinate, as they already have, across the litigation.

At the same time, an MDL could frustrate resolution of these cases. Determinative merits issues will overwhelmingly focus on varying plaintiff-specific facts. For example, unlike other MDLs that focus exclusively on a narrowly-defined injury type, these cases involve a range of claimed injuries not well suited for consolidation, including heart failure, unrelated forms of cardiovascular injury, and a form of lung injury. In fact, one case has already been resolved after discovery confirmed that the claimed injury, placement of coronary stents, had no relationship to Onglyza. Creating an MDL could slow resolution of these dispositive case-specific issues. The Onglyza lawsuits filed to date also include a significant percentage of cases that the plaintiffs have filed and then elected not to pursue — or simply failed to litigate meaningfully over the span of nearly two years. Rather than encourage focused prosecution of these suits, an MDL

might simply attract additional filings that the history of these cases shows may be either wholly meritless or not worth pursuing as independent matters.

A litigation of this limited scale presenting distinct individualized causation questions does not require the resources of an MDL. Nor should a federal MDL be a vector to expand a litigation that has gone unattended by plaintiffs' counsel and otherwise shown no signs of materially expanding. The Panel should deny Plaintiff's motion.[1]

I. BACKGROUND

A. Overview of Onglyza and Alleged Cardiac Risks

The active ingredient in Onglyza and Kombiglyze XR is saxagliptin, which helps adults with type 2 diabetes mellitus lower their blood sugar levels. Type 2 diabetes mellitus is a chronic condition that affects tens of millions of Americans and, if not properly controlled, can lead to a host of serious conditions including kidney disease, high blood pressure, stroke, and heart disease. *See Nat'l Diabetes Statistics Report, 2017*, Center for Disease Control 2, 9–10 http://www.diabetes.org/assets/pdfs/basics/cdc-statistics-report-2017.pdf.

Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca") and Bristol-Myers Squibb Company ("BMS") jointly marketed Onglyza and Kombiglyze XR, and Defendant McKesson Corporation ("McKesson") is one of several wholesalers of these medicines.[2] The FDA approved Onglyza on July 31, 2009, on the basis of eight Phase 3 clinical studies in over 4,600 patients. *See* Ex. 1, Onglyza Approval Letter (July 31, 2009). The FDA later approved

[1] The follow-on arguments asserted by the Johnson Becker firm in their October 31 Interested Party submission (which merely paraphrases Plaintiff's motion) suffer these same shortcomings.

[2] In 2014, AstraZeneca acquired BMS's interest in Onglyza and Kombiglyze XR. *See* Press Release, AstraZeneca (Feb. 3, 2014), https://www.astrazeneca.com/media-centre/press-releases/2014/astrazeneca-aquisition-bristol-myers-squibb-global-diabetes-alliance-03022014.html#.

Kombiglyze XR, an extended-release formulation of Onglyza, on November 5, 2010. *See* Ex. 2, Kombiglyze XR Approval Letter.

Plaintiffs' claims in this litigation rest upon a single finding from one study — the "SAVOR" study. In 2009, AstraZeneca and BMS began the SAVOR study to evaluate whether saxagliptin is associated with cardiovascular events. In June 2013, the results of this study were published in the *New England Journal of Medicine*. Ex. 3, Benjamin M. Scirica et al., *Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus*, 369 New Eng. J. Med. 1317 (Sept. 2013). The study showed that saxagliptin did not increase the risk of a range of cardiovascular events, including myocardial infarction, ischemic stroke, or death from cardiovascular causes. *See id.* at 1322. However, the rate for "hospitalization for heart failure" — a single specific event — was modestly higher in saxagliptin than placebo patients: 3.5% versus 2.8%. *Id.* at 1317. The single finding regarding heart failure in SAVOR is at odds with both previous and subsequent studies demonstrating either no increased risk of cardiovascular outcomes or even a protective effect. *See, e.g.*, Sengwee Toh et al., *Risk for Hospitalized Heart Failure Among New Users of Saxagliptin, Sitagliptin, and Other Antihyperglycemic Drugs*, 164 Annals Internal Med. 705 (June 7, 2016).

Upon learning of the SAVOR results, AstraZeneca and BMS re-examined the body of available scientific evidence and promptly pursued action with the FDA, including a request in February 2014 that information about SAVOR's findings be included in the labels for Onglyza and Kombiglyze XR. In April 2016, the FDA announced a change to include that information. *See* Ex. 4, Onglyza Apr. 2016 label, at § 5.2; Ex. 5, Kombiglyze XR Apr. 2016 label, at § 5.3.

B. Status of the Litigation

The Sanders Phillips Grossman, LLC law firm ("the Sanders Firm") began filing Onglyza lawsuits in February 2016. Nearly two years later, only a small number of federal cases are

pending, brought by counsel from a small number of plaintiffs' law firms. *See* Pl.'s Mem. in Supp. of Pl's Mot. for Transfer of Actions, dkt. 1-1, at 1 (Oct. 11, 2017); Pl.'s Notice of Related Action, dkt. 5 (Oct. 17, 2017). Two law firms jointly represent all defendants.

Plaintiff represents that there are currently 45 cases pending in federal court. But only 31 of these cases are not subject to immediate dismissal: Two cases (*Thomas*, D.N.J., and *Seabrian*, N.D. Ga.) have agreements to dismiss pending; one case (*Cortina*, E.D.N.Y.) plainly lacks federal subject matter jurisdiction because the plaintiff and Defendants do not have diversity of citizenship; and an additional 11 cases, brought by Napoli Shkolnik PLLC, are subject to immediate dismissal because they were never served on Defendants and the deadline for service expired months ago. In addition to the 31 cases Plaintiff identifies that are not subject to immediate dismissal, Defendants are aware of 8 additional federal cases: 1 in New Jersey, 1 in Texas, and 6 in Georgia.[3]

The Sanders Firm controls most of the 39 cases not subject to immediate dismissal, and it is closely coordinating with the four firms in the remaining cases. According to its own on-the-record statements, the Sanders Firm controls 80% of the filed cases.[4] It serves as counsel of record in 30 of the 39 active cases and has partnered with the four firms that are counsel of

[3] *Diaz v. Bristol-Myers Squibb Co.*, No. 1:17-cv-04345 (N.D. Ga.); *Green v. Bristol-Myers Squibb Co.*, No. 1:17-cv-04342 (N.D. Ga.); *Hayes v. Bristol-Myers Squibb Co.*, 3:17-cv-00157 (N.D. Ga.); *Merritt v. Bristol-Myers Squibb Co.*, 3:17-cv-00156 (N.D. Ga.); *Nance v. Bristol-Myers Squibb Co.*, 3:17-cv-00155 (N.D. Ga.); *Hunt v. Bristol-Myers Squibb Co.*, 5:17-cv-00419-CAR (M.D. Ga.); *Johnson v. Bristol-Myers Squibb Co.*, 3:17-cv-04533-PGS-LHG (D.N.J.); *Slaughter v. Bristol-Myers Squibb Co*, 4:17-cv-03321 (S.D. Tex.). There is also a California consolidated state court proceeding that includes 6 cases involving 11 plaintiffs.

[4] Ex. 6, Hr'g Tr., *Williams v. AstraZeneca Pharms. LP*, No. CV 16-071152, at 34:12-14 (July 12, 2017). Notably, in the wake of filing its MDL petition, the Sanders Firm withdrew as counsel in *Campbell v. Bristol-Myers Squibb Co.* Order Granting Pl.'s Mot. to Withdraw as Counsel of Record, *Campbell v. Bristol-Myers Squibb Co.*, No. 1:17-cv-00219-JRG-CHS, dkt. 67 (E.D. Tenn. Oct. 27, 2017).

record in the remaining 9 cases.[5] Thus, the suggestion of unwieldiness implied by Plaintiff's claim that this litigation involves "over a dozen different plaintiffs' law firms" is simply not accurate.

The suits allege a broad range of injuries from Onglyza. Most allege some form of heart failure, invoking the single elevated risk of "hospitalization for heart failure" suggested by the SAVOR study. But the cases also allege a range of other dissimilar conditions, including injuries like "cardiovascular injury" (a broad umbrella term that encompasses a range of problems related to the heart and blood vessels), myocardial infarction, and acute hypoxic respiratory failure (a lung condition). These conditions are distinct from heart failure in terms of their causes and symptoms.[6] This is reflected by the SAVOR findings, which showed no increased risk of the other heart conditions occurring, and which did not even evaluate the alleged lung injury. Plaintiffs also vary widely in the length of time during which they ingested Onglyza, with some taking the medicine for a few months and others taking it for years.

Although many of these cases have been on file for some time, the plaintiffs have shown little inclination to prosecute them. The plaintiffs have sought limited document discovery from Defendants and have taken no depositions. Plaintiffs' counsel have actively avoided investing effort in a number of their cases, resulting in 5 federal cases that will have been dismissed either

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[5] *See* Ex. 7, Docket, *Vallentine v. Bristol-Myers Squibb Co.*, 3:17-cv-00265-WKW-GMB (M.D. Ala.) (Aylstock Witkin Kreis & Overholtz PLLC and Sanders as co-counsel); Ex. 8, Docket, *Martin v. Bristol-Myers Squibb Co.*, 3:17-cv-00661-JST (N.D. Cal.) (Johnson Becker, PLLC and Sanders as co-counsel); Ex. 9, Docket, *Barnes v. Bristol-Myers Squibb Co.*, 2:17-cv-00124-DLB-CJS (E.D. Ky.) (Jones Ward PLC and Sanders as co-counsel); Ex. 10, Case Mgmt. Order No. 1, *Onglyza Products Cases*, at 1–2 (Cal. Super. Ct. June 2, 2017) (naming Sanders Firm attorneys as lead and liaison counsel in proceeding involving both Sanders and Napoli Shkolnik).

[6] *See What is Cardiovascular Disease?*, American Heart Association (May 2017), http://www.heart.org/HEARTORG/Support/What-is-Cardiovascular-Disease_UCM_301852_Article.jsp#.WfDzA-SQy70/.

at a plaintiff's request or for failure to prosecute. *Seabrian v. Bristol-Myers Squibb Co.*, No. 1:17-cv-00648-RWS (N.D. Ga.); Ex. 11, Order, *Eldridge v. Bristol-Myers Squibb Co.*, No. 3:16-cv-00296-DJH-DW, dkt. 38 (W.D. Ky. Sept. 19, 2017); Ex. 12; Order, *Savoie v. Bristol-Myers Squibb Co.*, No. 6:17-cv-00586-RGJ-CBW, dkt. 4 (W.D. La. Sept. 25, 2017); Ex. 13, *Sua Sponte* Mem. Ruling, *Guidry v. Bristol Myers Squibb Co.*, No. 2:16-cv-609, dkt. 28 (W.D. La. July 12, 2017); Ex 14, Stip. of Dismissal, *Thomas v. Bristol-Myers Squibb Co.*, No. 3:17-cv-04532, dkt. 15 (D.N.J. Oct. 27, 2017). Indeed, in the most advanced case of the litigation to date, *Eldridge*, plaintiff-specific discovery sought by Defendants yielded dispositive evidence that ultimately led to the parties stipulating to a consent judgment in Defendants' favor. *See* Ex. 15, Proposed Consent J., *Eldridge*, dkt. 37 (Sept. 18, 2017). Counting the 11 pending cases discussed above that are subject to dismissal for failure to serve, the plaintiffs have elected not to pursue nearly a third of the filed federal cases.[7]

That said, the parties have worked together in an orderly, coordinated fashion to make progress on procedural matters governing the litigation and on discovery where that is underway. For example, similar joint reports have been submitted in 23 cases and scheduling orders have been entered in 13 cases. Substantively identical protective orders, privilege log orders, and electronically-stored information orders have been agreed upon and submitted in 14 cases; Defendants expect that similar orders will be submitted in the additional cases.

[7] The same pattern has played out in the state court consolidated action, where 77 non-resident cases were dismissed from California JCCP 4909 on *forum non conveniens* grounds. *See* Ex. 16, Order of Dismissal of Causes of Action by Non-Cal. Resident Pls., *Williams v. Bristol-Myers Squibb Co.*, Case No. CGC-16-550418 (Cal. Super. Ct. Oct. 21, 2016); Order of Dismissal of Causes of Action by Non-Cal. Resident Pls., *Leedy v. Bristol-Myers Squibb Co.*, Case No. CGC-16-552157 (Cal. Super. Ct. Oct. 21, 2016); Order of Dismissal of Non-Cal.-Resident Pls., *Okoye v. Bristol-Myers Squibb Co.*, Case No. CGC-16-553662 (Cal .Super. Ct. Jan. 30, 2017); Order Granting Dismissal of Non-Resident Pls., *Onglyza Product Cases*, Case No. CJC-16-004909 (Cal. Super. Ct. Oct. 4, 2017). Of the 50 cases in which the time for refiling has passed, 14 were never refiled.

For their part, Defendants have worked to coordinate discovery matters across the litigation. Defendants have served standardized written discovery in 17 of the pending cases. At the request of the Sanders Firm, Defendants also made a coordinated reproduction of the documents produced in separate litigation alleging that Onglyza and Kombiglyze XR are linked to pancreatic cancer. Those cases were litigated before the Honorable Anthony Battaglia of the Southern District of California in concert with the *In re Incretin-Based Therapies Product Liability Litigation*, MDL No. 2452 (S.D. Cal). That pancreatic cancer litigation production is approximately 7 million pages and includes the regulatory files (IND/NDA submissions, periodic reports submitted to FDA, and FDA correspondence, including labeling) for these medications through February 2014, as well as documents from the files of eight key custodians. Defendants anticipate that this production will serve as the basis for further discussions on discovery across all of the pending Onglyza actions and will work with all plaintiffs' counsel to coordinate that discovery.

II. ARGUMENT

A. The Panel Should Not Centralize These Actions.

1. Centralization is inappropriate because there is a relatively small number of actions.

Centralization is not warranted here because of the relatively small number of actions. The Panel has noted that where a small number of actions are involved, "the proponent of centralization bears a heavier burden to demonstrate that centralization is appropriate." *In re Colgate Optic White Toothpaste Mktg. and Sales Practices Litig.*, 232 F. Supp. 3d 1346, 1347 (J.P.M.L. 2016). Despite nearly two years of litigation, Plaintiff identifies only 45 related cases, many of which are either inactive, subject to dismissal, or both. Seven more cases were filed only post-petition.

Recognizing that this volume of cases (with coordinated counsel) does not justify MDL treatment, *see In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1375 (J.P.M.L. 2015) (holding that centralization of forty-one actions was not warranted), Plaintiff argues that "it is likely that hundreds of other actions will be filed in jurisdictions across the United States." Pl.'s Mem. at 1. The Panel has consistently rejected such unsupported promises of additional filings as insufficient justification for centralization. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013) (declining to consider "the mere possibility of future filings in our centralization calculus").

That caution is well-placed on these facts. The relatively slow growth of the volume of suits in the wake of the FDA label change nearly 18 months ago materially differs from the situation where hundreds of suits are filed within months of a label change. *See id.* (denying transfer where "more than a year" after label change cited in complaints "only a relative handful of actions have been brought"). Indeed, despite Plaintiff counsel's months-old stated intent to seek an MDL, only 5 new cases — that is, not previously brought in the California state proceeding — have been filed since June 1, 2017. Coupled with the ongoing dismissals, the volume of cases in this litigation is currently *decreasing* — confirmation that this litigation is not likely to grow materially in the absence of an MDL. That plaintiffs have not refiled many of the cases dismissed from the consolidated California state court proceeding reinforces the likely trajectory of this litigation if centralization does not occur. Indeed, an MDL may simply serve as a vehicle to incubate claims that would not on their own warrant prosecution.

2. Centralization is not necessary because informal cooperation between the small number of counsel will realize the same efficiencies as an MDL, if not greater.

Centralization is not necessary because the plaintiffs in this litigation are represented by a small number of counsel, and the parties have already, over the course of nearly two years, informally coordinated across the cases without centralization.

Plaintiff's implication that coordination will be difficult because there are "over a dozen different plaintiffs' law firms" is misleading and fundamentally at odds with the nearly two-year history of the litigation. The Sanders Firm and its four co-counsel firms are involved in every case,[8] appearing at court conferences, filing complaints, and negotiating stipulations. Where counsel from firms other than the Sanders Firm have appeared as lead counsel, they have agreed to the discovery orders first negotiated with the Sanders Firm. The complaints filed by each firm are virtually identical. And the firms have been serving as each other's co-counsel and, indeed, passing responsibility for particular cases and plaintiffs back and forth where desired. *See, e.g.*, Ex. 9, Docket, *Barnes* (identifying both Sanders Phillips Grossman and Jones Ward as counsel for Plaintiff Kathy Barnes); Ex. 17, Email from T. Clark to W. Steimle (Sept. 5, 2017) (identifying Amy German of the Michael Brady Lynch firm as co-counsel for Ms. Barnes).

Defense and plaintiffs' counsel have also successfully coordinated. The Panel has held that where there are "few involved counsel and [a] limited number of actions, informal cooperation among the involved attorneys is both practicable and preferable to centralization." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014); *see also In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, 223 F. Supp. 3d

[8] A fifth firm, the Michael Brady Lynch Firm, has participated in negotiations but shares all of its cases with Sanders Phillips Grossman.

1351, 1353 (J.P.M.L. 2016) (noting that informal coordination is feasible without centralization where plaintiffs are "represented by only three groups of plaintiffs' counsel"). Here, coordination among counsel for the parties is not only practicable, it has been the reality of this litigation for nearly two years.[9] In fact, in joint filings with district courts around the country, including as recently as one week ago, plaintiffs' counsel committed to "actively work[with Defendants] to foster efficiency by aligning certain orders governing litigation in these cases" and agreed that they are "confident that . . . discovery protocols and materials from prior actions can be leveraged to avoid excessive costs" *see* Ex. 18, Am. Joint Rule 26(f) Report, *Holland v. Bristol-Myers Squibb Co.*, Case No. 1:17-cv-00710-CCE, dkt. 52, at 2 (M.D.N.C. Oct. 26, 2017); Ex. 19, Joint Case Mgmt. Statement & Proposed Order, *Martin v. Bristol-Myers Squibb Co.*, Case No. 3:17-cv-00661-JST, dkt. 30 (N.D. Cal. May 15, 2017). Plaintiff points to no reason that counsel cannot continue to fulfill those commitments.

To the contrary, coordinated discovery efforts have already begun. The parties have reached agreement on a number of threshold procedural and discovery issues, including the terms of a protective order and ESI protocol. In addition, AstraZeneca and BMS have made a document production across 30 cases of roughly 7 million pages containing information on the regulatory history of Onglyza and Kombiglyze XR and several different custodial files from key custodians. Defendants will also cross-notice the depositions of any company witnesses across

[9] This analysis remains unchanged in the unlikely event that "hundreds" of new actions materialize, as the Panel has repeatedly declined to "take into account the mere possibility of future filings in [its] centralization calculus," particularly where the additional "potential plaintiffs would be represented by movants' counsel" and the number of involved law firms would remain limited. *In re Qualitest Birth Control Prod. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014) (citation and quotation omitted).

the cases in the litigation and will work with plaintiffs' counsel to ensure participation by counsel of record for all plaintiffs.

In short, the benefits of centralization are already being achieved informally, and Defendants are fully willing to continue cooperation across the cases. The Panel has repeatedly demonstrated its reluctance to centralize cases where the parties have already begun to informally and effectively coordinate discovery. *See In re OxyElite Pro & Jack3d Prod. Liab. Litig. (No. II)*, 65 F. Supp. 3d 1412, 1413–14 (J.P.M.L. 2014) (re-denying centralization where the parties had "made substantial efforts to informally coordinate discovery in all actions" since the Panel's first denial); *see also In re Cordarone (Amiodarone Hydrochloride) Mktg., Sales Practices & Prods. Liab. Litig.*, 190 F. Supp. 3d 1346, 1348 (J.P.M.L. 2016) (where "[m]ost plaintiffs in the constituent actions are represented by either or both of two law firms" and counsel for two of the defendants "have represented that they stand ready and willing to cooperate and coordinate to avoid unnecessary duplication of discovery and other pretrial matters . . . such cooperation and coordination are preferable to the creation of an MDL"). So too, here, the Panel should deny centralization and allow informal coordination to continue.

3. Centralization will not further the goals of 28 U.S.C. § 1407.

Pursuant to § 1407(a), centralization is appropriate where (1) the cases involve "one or more common questions of fact," (2) centralization would serve "the convenience of parties and witnesses," and (3) transfer would "promote the just and efficient conduct of" the litigation. Here, centralization will satisfy none of these criteria.

First, centralization will not meaningfully advance the litigation of "one or more common questions of fact." Insofar as there are common questions of fact, including the adequacy of the warnings for Onglyza and Kombiglyze XR as to the risk of heart failure, those questions have already begun to be addressed through informal cooperation as detailed above,

including through AstraZeneca and BMS's large common production of regulatory files. The Panel has recognized that where "plaintiffs in actions that are concluded or well advanced have conducted extensive discovery of defendant . . . in areas of common factual inquiry" and defense counsel is, as it is here, "willing[] to make this common discovery applicable in those actions that are not far advanced," centralization is unnecessary. *In re Eli Lilly & Co. Oraflex Prods. Liab. Litig.*, 578 F. Supp. 422, 423 (J.P.M.L. 1984). This being the case, centralization offers little benefit.

But even these areas of common factual inquiry will vary meaningfully across plaintiffs, given the various conditions at issue and the timeframes in which different plaintiffs used the medicine (whether before or after the label change). *See In re Mirena IUS*, 38 F. Supp. 3d at 1381 (declining to centralize actions where plaintiffs' failure-to-warn claims involved injuries that "[gave] rise to a fact-intensive inquiry," such that "individualized causation disputes [were] likely to predominate").

More significantly, although Plaintiff asserts in her brief that there are many common questions related to the risk of heart failure, *see* Pl.'s Mem. at 8, in fact the cases filed by all 45 plaintiffs listed on the Schedule of Actions encompass significantly more alleged injuries. Specifically, in addition to alleging heart failure, a large number of plaintiffs allege highly dissimilar conditions: 8 plaintiffs allege acute hypoxic respiratory failure, a lung injury, and a host of other plaintiffs alleged heart injuries that are causally distinct from heart failure, including coronary artery disease (11 plaintiffs), myocardial infarction (6 plaintiffs), and unspecified "cardiovascular injury" (13 plaintiffs). But SAVOR did not find an increased risk of any cardiovascular injury other than hospitalization for heart failure; for example, there was no increased risk of myocardial infarction identified in the study. *See* Ex. 3, Scirica et al., at 1322–

23. And plaintiffs have no support at all for their assertions that acute hypoxic respiratory failure — a lung condition with a wide range of causes — is caused by saxagliptin. Thus, although Plaintiff attempts to justify creation of this MDL by reference to the SAVOR heart failure findings, the actual injuries alleged by the various plaintiffs present a range of dissimilar questions regarding general and specific causation. Moreover, these disparate claims will present a wide array of warning adequacy issues that will be either wholly plaintiff-specific or common only to a much smaller set of plaintiffs.

Given the scattershot of largely unsupported allegations present in plaintiffs' complaints and preliminary discovery, centralization would not advance the litigation of a common question of fact in a manner that would most efficiently lead to resolution of these suits. The plaintiffs' alleged injuries are varied, and in some cases bear no resemblance to the single study on which the plaintiffs' central allegations rely. This suggests that resolution of the cases may turn heavily on case-specific issues. Indeed, the only case that has proceeded to judgment was dismissed on case-specific evidence, including the plaintiff's medical records and his treating physician's deposition testimony, both of which failed to demonstrate a diagnosis of the alleged injury. *See* Ex. 15, Proposed Consent J., *Eldridge*, dkt. 37. Centralization would delay reaching and resolving such issues.

Second, centralization would not serve "the convenience of the parties and witnesses." Because the parties have already agreed upon a significant portion of general discovery, future discovery efforts will necessarily focus on individual plaintiffs. Centralization will thus do little to minimize travel and other expenses associated with case-specific discovery efforts.

Finally, centralization would not "promote the just and efficient conduct of" the litigation Instead, the centralization process may result in "the unintended consequence of producing more

new case filings of marginal merit in federal court, many of which would not have been filed otherwise." *See In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, MDL No. 2004, 2016 WL 4705827, at *2 (M.D. Ga. Sept. 7, 2016). The history of this litigation bears out this concern, with a national trend toward a decrease in the rate of new filings after nearly two years of litigation, nearly a third of federal cases dismissed or unserved by plaintiffs, and relative inactivity in the remaining suits. Against this backdrop, Plaintiff's promise of "hundreds" of new filings suggests an intent to use a federal MDL as an accelerant for a wave of filings that may not ultimately withstand individual scrutiny. But this "warehousing" strategy does not promote the "just and efficient conduct of litigation" called for under § 1407.

B. If the Panel Determines That an MDL Is Warranted, the Cases Should Be Sent to the Southern District of California.

Should the Panel conclude that centralization is warranted, any proceeding should be centralized in the Southern District of California, where Judge Battaglia has ably managed the diabetes medicine litigation, *In re Incretin-Based Therapies Products Liability Litigation*, and its companion Onglyza-related cases. Judge Battaglia in particular has developed substantial experience with both the basic scientific aspects of these types of diabetes medicines generally and with the discovery record to date relating to both Onglyza and Kombiglyze XR.

1. Centralization before Judge Battaglia is most appropriate.

The Southern District of California would be the most sensible assignment should the Panel find centralization appropriate, as it is the court most familiar with the scientific and factual issues implicated in this litigation. The Southern District of California also provides a convenient forum whose docket can accommodate this MDL.

Within the Southern District of California, Judge Battaglia has presided over consolidated litigation involving 13 plaintiffs who had taken Onglyza and Kombiglyze XR and alleged that

Onglyza and Kombiglyze caused them to develop pancreatic cancer. In granting defendants' motion for summary judgment, Judge Battaglia reviewed and cited the clinical trials for Onglyza, including SAVOR, and the FDA's assessment of the SAVOR data as it related to pancreatic cancer, evidencing the court's understanding of the study. *See Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1167, 1177–78 & n.18 (S.D. Cal. 2016); *see also* Ex. 20; Def.'s Mem. of P. & A. in Supp. of Mot. for Summ. J. Based on Preemption, *Seufert*, No. 3:13-cv-02169-AJB-MDD, dkt. 119-1, at 1–2, 18–19 (S.D. Cal. Feb. 4, 2016) (citing SAVOR results in support of summary judgment motion). Many of the same counsel present in this litigation — including counsel from the Sanders Firm — appeared before Judge Battaglia in those cases.

By necessity, therefore, Judge Battaglia is already familiar with many of the critical scientific and regulatory issues surrounding the development of Onglyza, including the results and implications of the SAVOR trial. Indeed, at the request of the Sanders Firm, AstraZeneca and BMS have reproduced their production from that litigation as the starting point for common discovery in the present cases. The Panel regularly considers whether a particular judge "already has relevant experience with some issues likely involved in th[e] litigation," making Judge Battaglia an appropriate judge to oversee follow-on litigation regarding these products. *See In re Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378, 1381 (J.P.M.L. 2015) (the JPML transferred an MDL to a judge, stating that the judge's "familiar[ity] with the scientific and regulatory background of Levaquin in his capacity as transferee judge for a separate Levaquin MDL" involving a different injury would "benefit the parties and facilitate the just and efficient conduct of th[e] litigation"); *In re Effexor (Venlafaxine Hydrochloride) Prods. Liab. Litig.*, 959 F. Supp. 2d 1359, 1360 (J.P.M.L. 2013); *In re Wireless Tel. Radio Frequency Emissions Prods. Liab. Litig.*, 170 F. Supp. 2d 1356, 1358 (J.P.M.L. 2001); *see also In re Sony Corp. SXRD Rear*

Projection Television Mktg., Sales Practices & Prods. Liab. Litig., 655 F. Supp. 2d 1367, 1367 (J.P.M.L. 2009) (emphasizing that the transferee judge was "already familiar with the contours of th[e] litigation by virtue of presiding over similar litigation" in the past); *In re "Factor VIII or IX Concentrate Blood Products" Prods. Liab. Litig.*, 853 F. Supp. 454, 455 (J.P.M.L. 1993) (highlighting that the transferee judge had gained "familiarity with the issues . . . by presiding at [a] recent trial" involving the product at issue); *In re Cutter Labs., Inc. "Braunwald-Cutter" Aortic Heart Valve Prods. Liab. Litig.*, 465 F. Supp. 1295, 1298 (J.P.M.L. 1979) (transferring the litigation to a judge who had presided over trials that shared many of the same "complex technical and medical questions").

Judge Battaglia and the Southern District of California's dockets are also well-equipped to handle a centralized action. The *In re Incretin-Based Therapies Products Liability Litigation* MDL remains pending before Judge Battaglia while on appeal following a grant of summary judgment. Assignment of this MDL would not overwhelm Judge Battaglia's docket, particularly in light of the efficiencies to be achieved through his prior experience with that MDL. Similarly, the Southern District of California has only five pending MDLs among its 13 judges. *See* Pending MDL Dockets by District, http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-October-16-2017.pdf; *see also In re ClassicStar Mare Lease Litig.*, 528 F. Supp. 2d 1345, 1347 (J.P.M.L. 2007) ("[T]he district's general docket conditions permit us to make the Section 1407 assignment knowing that the court has the resources available to manage the litigation."). Further, the Southern District of California processes a civil matter from filing to disposition in an average of 6.6 month, making it the 10th fastest judicial district in a nationwide ranking. *See* Federal Court Management Statistics Report 2017 at 69, *available at* http://www.uscourts.gov/sites/default/files/data_tables/fcms_na_appprofile0630.2017.pdf.

Lastly, the Southern District of California is easily accessible. Both Plaintiff's counsel and counsel for Defendants are in California. Moreover, the San Diego International Airport is only three miles, and a short drive, from Judge Battaglia's chambers; it offers nearly 500 daily flights, with more than 60 nonstop markets domestically and abroad. The courthouse is also easily accessible by the judge overseeing the consolidated proceeding pending in San Francisco in the event there is a need for joint activities.

2. Other Potential Jurisdictions.

To the extent that Judge Battaglia is unavailable, the Northern District of Georgia, the Western District of Kentucky, or the Eastern District of Kentucky are also appropriate jurisdictions given the number of actions pending there and their more advanced procedural stages.

Most Active Plaintiffs: Northern District of Georgia. The Northern District of Georgia is currently home to ten pending lawsuits, with Judge Story presiding over six of these actions. The Panel has often favored sending MDLs to districts where a significant number of actions are pending, and the Northern District of Georgia is such a district. *See In re FieldTurf Artificial Turf Mktg. & Sales Practices Litig.*, MDL No. 2779, 2017 WL 2391963, at *1 (J.P.M.L. June 1, 2017) (ordering transfer to a district where five out of fourteen actions were pending); *In re Daily Fantasy Sports Mktg. & Sales Practices Litig.*, 158 F. Supp. 3d 1375, 1380 (J.P.M.L. 2016) (selecting a district because it was where a "significant number of related actions . . . are pending"). Additionally, many plaintiffs are Georgia residents, making the Northern District of Georgia a convenient forum for witnesses and trials.

Judge Story is currently assigned one MDL, *In re Ethicon Physiomesh Flexible Composite Mesh Products Liability Litigation*, and the Northern District of Georgia is home to four MDLs. The Northern District of Georgia ranks fifth among district courts nationwide in the

median time from filing to disposition for civil cases, at an average of 5.8 months. *See* Federal Court Management Statistics Report 2017 at 93. This efficiency makes Judge Story and the Northern District of Georgia sound assignments.

The Northern District of Georgia is also easily accessible. The courthouse is located in downtown Atlanta, ten miles from Hartsfield-Jackson International Airport, the largest airport in the world, with nonstop travel to every major city in the country.

Most Advanced Cases: Eastern or Western District of Kentucky. The Panel has expressed a preference for assigning centralized actions to judges who have procedurally-advanced cases on their dockets. *See In re Johnson & Johnson Talcum Power Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1359 (J.P.M.L. 2016) (transferring to the judge "presiding over the most procedurally-advanced action"). Judge Caldwell (Eastern District of Kentucky) presides over *Taylor*, one of the most advanced actions. The plaintiff in *Taylor* has served responses to the Defendants' Interrogatories and Requests for Production and has himself served an initial set of discovery requests, negotiations over which are ongoing. Plaintiff Taylor would also support consolidation in this district. *See* Pl. David Taylor's Resp. Supp. Transfer to the N.D. Cal., dkt. 13, at 4 (Oct. 26, 2017). Judge Hale (Western District of Kentucky) also presided over one of the most advanced actions, *Eldridge*. Discovery was taken in this case, which was dismissed following the deposition of the treating physician.

Neither the Eastern District of Kentucky nor the Western District of Kentucky would be overburdened by this assignment. Judge Caldwell does not have any MDLs on her docket, and the Eastern District of Kentucky only has one MDL on its docket. Judge Hale is currently assigned one MDL, *In re Amazon.com Inc., Fulfillment Center Fair Labor Standards Act (FLSA) and Wage and Hour Litigation*, but summary judgment has been granted against the sole

remaining plaintiff in that litigation. Aside from this largely completed action, the Western District of Kentucky is home to only one other MDL.

Both the Eastern District of Kentucky and Western District of Kentucky are convenient jurisdictions. The courthouse in Lexington, Kentucky, home of the Eastern District of Kentucky, is an accessible location seven miles from the Lexington Blue Grass Airport and 75 minutes from each of the Cincinnati and Louisville International Airports. The Western District of Kentucky is conveniently accessible by the Louisville International Airport, which is six miles from downtown Louisville and the courthouse. *See In re Ameriquest Mortg. Co. Lending Practices. Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L 2005) (centralizing actions in a "geographically central district [that] will be a convenient location for a litigation already nationwide in scope").

Northern District of California. The Northern District of California, as proposed by Plaintiff, does not have the most cases (it has only two) or the most advanced cases. It similarly does not offer the same advantages as the Southern District of California. Although Judge Tigar is an able jurist, the Northern District of California is not a natural home for these cases, as both plaintiffs in the cases pending there reside in the Eastern District of California.

Plaintiff argues that the Northern District of California will be a convenient forum because "[o]ne of the three defendants named in the suit is based in San Francisco." Pl.'s Mem. at 13. But this defendant, McKesson, has been fraudulently joined as a defendant and has no involvement with Onglyza that bears on plaintiffs' claims. Proving this, the plaintiffs have already dismissed McKesson in the two actions before Judge Tigar to maintain a federal forum. The dismissal of San Francisco-based McKesson severs any ties these two cases had to the Northern District of California.

Additionally, contrary to Plaintiff's assertion, the two Northern District of California cases remain in preliminary stages. Motion practice in those cases has been limited to threshold motions to transfer the suits of non-resident plaintiffs to their home states pursuant to 28 U.S.C. § 1404. No motions have addressed the merits of the claims and no written discovery has been exchanged, in contrast to the cases in Kentucky and Georgia.

The Northern District of California is also home to a significant number of pending MDLs. The Northern District of California has twenty-three MDLs, including *In re Volkswagen "Clean Diesel" Marketing, Sales Practices, and Products Liability Litigation*, which has 1,662 pending actions, and *In re Viagra and Cialis Products Litigation*, which has 571 pending actions.

III. CONCLUSION

For the foregoing reasons, Plaintiff's motion for transfer to the Northern District of California for coordinated and consolidated pretrial proceedings should be denied in its entirety. In the alternative, the Panel should centralize the cases before Judge Battaglia in the Southern District of California.

Respectfully submitted,

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