UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

IN RE: ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE XR (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION	Master File No. 5:18-md-2809-KKC **MDL No. 2809** **ALL CASES**

DEFENDANTS' RESPONSE TO PLAINTIFFS' BRIEF REGARDING SCHEDULING OF PRE-TRIAL PROCEEDINGS IN THIS MDL

Plaintiffs in this multi-district litigation propose that the MDL should proceed in a fashion that gives them disproportionate, unfettered discovery of Defendants, requires the parties to conduct case-specific fact and expert discovery for an unspecified number of bellwether cases selected without sufficient case-specific information, and forces the Court to consider numerous general and case-specific motions—all activities lasting nearly two years—before the Court determines whether Plaintiffs can support the most basic tenet of their claims: that, based on a single secondary finding in a single study, an expert can reliably opine that Onglyza and Kombiglyze XR can cause heart failure or myriad other alleged injuries. As set forth in their previous submission to this Court, *see* Initial Conference Submission (Aug. 24, 2018), Defendants Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals LP, and McKesson Corporation (together, "Defendants"), respectfully oppose this schedule and request that the Court institute a phased schedule that prioritizes discovery on the issue of general causation.

PROCEDURAL HISTORY

Lead Plaintiffs' counsel filed the first suit in this litigation in the Superior Court of the State of California in April 2016. Federal cases began to be filed later in 2016. Not until October 2017, however, did Plaintiffs file a motion to centralize the federal actions. *See* Pls.' Mot. for Transfer of Actions, *In re Onglyza and Kombiglyze Prods. Liab. Litig.*, MDL No. 2809, ECF No.

1 (J.P.M.L. Oct. 11, 2017), attached to the Declaration of Emily S. Ullman in Supp. of Defs.' Resp. to Pls.' Br. Regarding Scheduling of Pre-Trial Procs. in this MDL ("Ullman Decl."), as Ex. A. Although Plaintiffs' counsel represented then that it was likely that "hundreds of other actions will be filed in jurisdictions throughout the United States," Mem. in Support of Pls.' Mot. for Transfer at 1, MDL No. 2809, ECF No. 1 (J.P.M.L. Oct. 11, 2017), Ullman Decl., Ex. B, of the 170 cases filed since that time, over 120 of those cases were not filed until after this MDL was created. Counsel now asserts that "there are a thousand cases" still to be filed. *See* Tr. of Status Conf. at 22:15-25, ECF No. 167 (Sept. 19, 2018), Ullman Decl., Ex. C.

With respect to the parallel consolidated Superior Court proceeding in California, instituted on April 19, 2017, the claims of 68 plaintiffs have been dismissed on the basis of *forum non conveniens* to be refiled elsewhere. No scheduling order has yet been entered in that proceeding, nor have any other substantive case management orders.

ARGUMENT

I. PHASED DISCOVERY ADDRESSING GENERAL CAUSATION FIRST IS THE MOST EFFICIENT MEANS OF MANAGING THESE PROCEEDINGS.

The Court should prioritize general causation because it is pivotal to every case in this proceeding and because Plaintiffs' allegations on their face fail to support many of their causation claims.[1] "For effective discovery control, initial discovery should focus on matters—

[1] As set forth in Defendants' Initial Conference Submission, phased discovery is common when it addresses a pivotal issue such as general causation. *See, e.g.*, *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1139 (9th Cir. 2002) (remanding "for resolution of generic causation issues before determining individual causation issues."); *Rizzo v. Applied Materials, Inc.*, No. 15-cv-00557, 2017 WL 4005625, at *17 (N.D.N.Y. Sept. 11, 2017) (holding, after nine months of phased general causation discovery, that "since Plaintiff has failed to raise any genuine issue of material fact regarding general causation with respect to GPA, Defendants are entitled to summary judgment"); *Giglio v. Monsanto Co.*, No. 15-CV-2279-BTM (WVG), 2016 WL 4098285, at *1 (S.D. Cal. Aug. 2, 2016) ("Proceeding immediately on all issues would subject the parties to highly extensive discovery that may ultimately be unnecessary if defendant

witnesses, documents, information—that appear pivotal." Manual for Complex Litigation ("MCL") § 11.422 (Fed. Jud. Ctr. 2004). Plaintiffs agree that this issue is important. Indeed, the first common issue that Plaintiffs raised in arguing that this litigation should be centralized was "whether and to what extent Onglyza caused or can cause, heart failure, congestive heart failure, cardiac failure, and death from heart failure." Mem. in Support of Pls.' Mot. for Transfer at 8, Ullman Decl., Ex. B; *see also* Interested Party Resp. and Mem. of Law in Support of Moving Pls.' Mot. for Centralization at 7, MDL No. 2809, ECF No. 20 (J.P.M.L. Oct. 31, 2017), Ullman Decl., Ex. D. General causation is pivotal and can be addressed independently of other issues, and resolving it first will lead to significant efficiencies in this litigation.

1. General Causation Discovery Is Distinct from Other Issues Plaintiffs Identify.

Plaintiffs demand immediate discovery on all issues by asserting that general causation discovery is "inextricably interwoven" with discovery about what Defendants knew and when they knew it. Pls.' Br. Regarding Pre-Trial Phases of this MDL ("Pls. Br.") at 3, ECF No. 168 (Sept. 21, 2018). It is not. "General causation is whether a substance is capable of causing a particular injury or condition in the general population[.]" *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007). "General causation is established by demonstrating, often through a review of ***scientific and medical literature***, that exposure to a substance can cause a particular disease[.]" *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 402 (S.D.N.Y. 2005)

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prevails on its *Daubert* motion. Limiting phase one to general causation, on the other hand, will enable the parties and the Court to arrive expeditiously at a potentially dispositive issue that the Court firmly believes can be separated from other liability and damages issues."); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 15-md-2657, ECF No. 458 (D. Mass Nov. 10, 2016), Ullman Decl., Ex. E; *Vallejo v. Amgen, Inc.*, No. 14-cv-0050, ECF No. 63, slip op. at 2 (D. Neb. Aug. 26, 2015) ("General causation is a 'pivotal' issue that may 'provide the foundation for a dispositive motion.' The staged discovery ordered by the court allows for early resolution of this threshold issue, before the parties engage in expensive, expansive, and potentially unnecessary discovery. Early resolution of the general causation issue promotes judicial efficiency and prevents the potential waste of the parties' and the Court's resources."), Ullman Decl., Ex. F.

(emphasis added). Internal company documents are generally not relevant to an inquiry into general causation. *See, e.g.*, *In re Zoloft (Sertralinehydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 497 (E.D. Pa. 2016), *aff'd*, 858 F.3d 787 (3d Cir. 2017) ("[I]nternal Pfizer documents, including discussions among Pfizer's own epidemiologists and other scientists analyzing certain epidemiological studies . . . may be relevant to questions of Pfizer's knowledge and actions if Zoloft were found to cause birth defects, but do not raise a genuine issue of material fact as to causation."). That Defendants' knowledge and internal documents are relevant to one element of Plaintiffs' claims does not render general causation inseparable.

Plaintiffs point to *In re Incretin Mimetics Prods. Liab. Litig.*, No. 13-md-2452, 2014 WL 2532315 (S.D. Cal. June 5, 2014) as an example that "perfectly illustrates the impracticality of bifurcation." Pls.' Br. at 4-5. They highlight "a dispute as to the scope of [the limitation to general causation] as well as issues regarding the timely and complete production of discovery" to suggest that the court was forced to "grant 'additional discovery and expand[] the scope of inquiry.'" Pls.' Br. at 5 (quoting *Incretin*, 2014 WL 2532315, at *2). In fact, however, the *Incretin* court refused to "open[] the door to generalized discovery." *Incretin*, 2014 WL 2532315, at *3. Instead, Judge Battaglia allowed a targeted expansion of discovery only in a response to a motion filed by defendants: "Following Defendants' motion for summary judgment based on preemption, the Court granted additional discovery and expanded the scope of inquiry to include facts relevant to preemption." *In re Incretin*, 2014 WL 4987877, at *1 (Oct. 6, 2014). With respect to a general causation discovery dispute, the court wrote:

> [T]he Court agrees with Defendants that general causation—whether the pharmaceuticals at issue cause pancreatic cancer—is a matter of science, and therefore, scientific documents and/or scientific evidence frame the universe of contemplated discovery. Without a scientific basis for the claims that the pharmaceuticals at issue cause pancreatic cancer there is no other way to prove or disprove Plaintiffs' claims. As a result, permitted discovery includes actual

> scientific evidence such as animal studies, clinical trials, epidemiologic data, adverse event reports, and submittal documents to scientific and government organizations including the FDA and EMA with regard to the causal link in dispute in this case.
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> Any such documents, which would appear in the files in other departments of the Defendant organizations (i.e., marketing, sales, etc), would be discoverable, but general marketing, sales, licenses, consulting agreements, market share, third-party contracts, advertising, promotions, marketing, sales and/or public relations efforts or campaigns, as well as training documents for sales forces would not. There will be a time and place for more generalized discovery on these issues, but it is not now.

In re Incretin Mimetics Prods. Liab. Litig., No. 13-md-2452, ECF No. 377, at 2-3 (S.D. Cal. Mar. 25, 2014), Ullman Decl., Ex. G. Although Plaintiffs can generate a discovery dispute by making overbroad requests, such requests do not render a bifurcated scheduling order impractical. Rather, as Judge Battaglia recognized, the proper scope of general causation discovery is well defined.

Plaintiffs further justify their request for early discovery relating to "research and development, regulatory and approval, corporate structure and organization, including personnel and practices, clinical and other trials, marketing and sales, electronically stored information ('ESI'), and general liability and causation, as well as identifying custodians and ESI search terms" by contending that such discovery is "necessary for Plaintiffs' experts to review in preparation for *Daubert* challenges." Pls.' Br. at 10. With the exception of information about clinical trials, however, these other topics—which are so broad as to be limitless—do not address whether reliable scientific evidence demonstrates that Onglyza can cause the injuries at issue here.[2] Plaintiffs offer no meaningful support for their claim that this discovery is necessary for their experts or would help resolve general causation motions.

[2] ESI is not a separate category in which discovery may be sought but rather simply a method of storing information. Defendants have already produced millions of pages of ESI.

2. Phasing Discovery is Likely to Create Significant Efficiencies Because Plaintiffs Lack Evidence of General Causation.

Plaintiffs seek broad discovery because the relevant science in this case shows that their claims are lacking. Contrary to their assertion that this is "not a case involving speculative scientific evidence," Pls.' Br. at 9, Plaintiffs' allegations that Onglyza causes heart failure are explicitly based on a single secondary finding in a single study, SAVOR (Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus). Benjamin M. Scirica, et al., *Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus*, 369 New Eng. J. Med. 1317 (Sept. 2013), attached to the Decl. of Emily S. Ullman in Supp. of Defs.' Initial Conference Submission (Aug. 24, 2018), as Ex. I. Moreover, that finding "was not observed in subsequent trials." Kristian B. Filion & Samy Suissa, *DPP-4 Inhibitors and Heart Failure: Some Reassurance, Some Uncertainty*, 39 Diabetes Care 735, 735 (2016), Ullman Decl., Ex. H. This limited evidence cannot serve as the basis for a reliable causation opinion.

Furthermore, Plaintiffs fail to cite *any* evidence to support a causal link between saxagliptin and heart failure distant in time from treatment or between the medication and injuries other than heart failure. SAVOR, Plaintiffs' lone scientific support, found that saxagliptin treatment neither reduced nor increased overall cardiovascular risk, risk of death, risk of myocardial infarction, or risk of ischemic stroke. *See* Scirica, 369 New End. J. Med at 1322 tbl.2. The finding regarding hospitalization for heart failure "subsided at 10 to 11 months." Benjamin M. Scirica, et al., *Heart Failure, Saxagliptin, and Diabetes Mellitus: Observations from the SAVOR-TIMI 53 Randomized Trial*, 130 Circ. 1579, 1581 (Oct. 2014), Ullman Decl., Ex. I; *see also* Filion & Suissa at 735 ("This increased risk was clustered in the first year of follow-up . . . with no increase thereafter."). Yet Plaintiffs have filed numerous complaints alleging heart failure after well over a year of treatment as well as injuries for which SAVOR

explicitly found no increased risk or did not address at all. *See, e.g.*, Compl., *Butler v. Bristol-Myers Squibb Co.*, No. 18-cv-00375 (Apr. 2, 2018) (41 months between ingestion and heart failure); *Rouse v. Bristol-Myers Squibb Co.*, No. 18-cv-00250 (Mar. 30, 2018) (108 months); Compl., *Binns v. Bristol-Myers Squibb Co.*, No. 18-cv-00083 (May 2, 2017) (alleging myocardial infarction); Compl., *Brown v. Bristol-Myers Squibb Co.*, No. 18-cv-00071 (Jan. 18, 2017) (same); Compl., *Sechler v. Bristol-Myers Squibb Co.*, No. 18-cv-00092 (May 2, 2018) (alleging coronary artery disease); Compl., *Barner v. Bristol-Myers Squibb Co.*, No 18-cv-00098 (Nov. 21, 2017) (alleging cardiomyopathy); Compl., *Davila v. Bristol-Myers Squibb Co.*, No. 18-cv-00068 (Apr. 27, 2017) (alleging acute hypoxic respiratory failure). There is no reliable basis for an expert to opine that saxagliptin caused these Plaintiffs' injuries.

Plaintiffs cannot remedy these scientific deficiencies by relying on Onglyza's FDA-approved labeling, in part because their assertions regarding FDA's actions with respect to Onglyza's labeling are incorrect. Most significantly, FDA did not "order[] the Defendants to change their label to warn consumers that the drug significantly increased the user's risk of heart failure" in 2016. Pls.' Br. at 9. As explicitly noted in the very letter from FDA cited by Plaintiffs, AstraZeneca submitted an application to FDA seeking to incorporate the results of SAVOR into the Onglyza label in February 2014, only a few months after the publication of that study. Discussions between FDA and the company continued for two years while FDA further analyzed the SAVOR data. *See* Pls.' Ex. E at 1. Nor did the agreed-upon label state that the medication "significantly increased" the risk of hospitalization for heart failure. Onglyza's label reads:

> In a cardiovascular outcomes trial enrolling participants with established ASCVD or multiple risk factors for ASCVD (SAVOR trial), more patients randomized to ONGLYZA (289/8280, 3.5%) were hospitalized for heart failure compared to patients randomized to placebo (228/8212, 2.8%). In a time-to-first-event analysis the risk of hospitalization for heart failure was higher in the ONGLYZA group (estimated Hazard Radio: 1.27; 95% CI: 1.07, 1.51). Subjects with a prior history

> of heart failure and subjects with renal impairment had a higher risk for hospitalization for heart failure, irrespective of treatment assignment.

§ 5.2, Ullman Decl., Ex. J. The label does not even mention the other injuries asserted by Plaintiffs. Finally, this label change is not reliable evidence on which Plaintiffs' experts may opine that Onglyza causes heart failure because of FDA's regulatory standards. "Changes to drug packaging inserts and letters from drug manufacturers that report possible adverse drug reactions are required by the FDA regardless of whether a causal relationship has been established. Information that Defendants were required to provide without regard to causation cannot be used as a basis for causation." *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000); *accord Lopez v. Wyeth-Ayerst Labs., Inc.*, 139 F.3d 905 (9th Cir. 1998). That Defendant AstraZeneca, with FDA's approval, incorporated SAVOR's results into Onglyza's labeling cannot demonstrate a causal relationship between the medication and Plaintiffs' alleged injuries.

3. Addressing General Causation First Is Efficient Even if Defendants Do Not Prevail.

Plaintiffs complain that a phased discovery schedule will ultimately be inefficient if Defendants do not prevail on their summary judgment motions. However, addressing general causation first will inform case-specific discovery and the selection of bellwether trials even if the Court does not grant Defendants' motions in their entirety, and the difference in timing between the proposed schedules is relatively small.

Plaintiffs' proposed schedule renders the parties likely to conduct unnecessary case-specific discovery and bellwether selection by placing *Daubert* hearings at the conclusion of case-specific discovery. *See* Pls.' Proposed Scheduling Order at 2 ("Pls.' Order"), ECF No. 168-1 (Sept. 21, 2018) (*Daubert* hearings in July 2020). As described above, Plaintiffs in this MDL allege not merely hospitalization for heart failure but also injuries including coronary artery disease, cardiomyopathy, myocardial infarction, and acute hypoxic respiratory failure, as well as

the catch-all term of "cardiovascular injury." If, for some or all categories of injuries, "a plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation." *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 676 (M.D.N.C. 2003); *see also Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005) ("[W]ithout general causation, there can be no specific causation."). Given the complete lack of any evidence linking most of Plaintiffs' alleged injuries to saxagliptin, Plaintiffs in those cases are very unlikely to be able to demonstrate general causation. But under Plaintiffs' proposed schedule, cases alleging such injuries might have already been selected as bellwethers, and case-specific discovery performed, by the time they were dismissed under *Daubert*. The parties would then need to pick new bellwether cases and conduct new case-specific discovery. By contrast, Defendants' proposal mitigates this concern by postponing case-specific discovery and bellwether selection until after the resolution of general causation.

In addition, the difference between the start of bellwether trials in the parties' currently proposed schedules is a mere ten months, not "years." *See* Pls.' Br. at 8; Defs.' Initial Conf. Submission at 9 (bellwether trials in August 2021); Pls.' Order at 2 (bellwether trials in October 2020). Defendants believe a faster time to trial is possible while retaining a phased discovery process if the Court wishes. The cases Plaintiffs cite are not to the contrary. For example, the *Roundup* court ruled on July 10, 2018 that the litigation could proceed past *Daubert* hearings on general causation. PTO 45, *In re Roundup Prods. Liab. Litig.*, No. 16-md-2741, ECF No. 1596 (N.D. Cal. July 10, 2018), Ullman Decl., Ex. K. The first bellwether trial is set for February 2019. *See* Letter from Pls., *In re Roundup Prods. Liab. Litig.*, No. 16-md-2741, ECF No. 1905 (Sept. 28, 2018), Ullman Decl. Ex. L. The *Roundup* litigation is proceeding swiftly towards trial,

not "back to square one starting discovery." In sum, phased discovery will not significantly delay the progress of this litigation and may drastically shorten it.

4. Defendants' Proposal Would Allow Coordination with State Court Proceedings.

Defendants' proposal also allows "opportunities to coordinate scheduling with state courts handling parallel cases." MCL § 22.87. Although discovery is open in California, the parties have not yet submitted a discovery plan to the court. The judge handling the state court proceedings in California, Judge Karnow, has stated that "[c]oordination with the MDL is highly preferred" in developing that discovery plan. Case Mgmt. Order No. 3, *Onglyza Product Cases*, JCCP No. 4909 (Cal. Super. Ct. June 20, 2018), Ullman Decl., Ex. M; *see also* Case Mgmt. Order No. 4 (Oct. 3, 2018), Ullman Decl., Ex N. And despite Plaintiffs' assertions that "Defendants are already under a legal obligation for full discovery in the state coordinated proceeding," Pls.' Br. at 4, Judge Karnow has explicitly noted that he is willing to consider early hearings to address a *Sargon* motion, which is the California equivalent of *Daubert*:

> [I]f the central issue in the case is general causation, the first thing we'd want to do is identify the minimum amount of discovery needed to have . . . those issues heard. It may not require a lot of work. It may require some underlying discovery, but then it's going to really be a question of expert discovery and getting those things teed up so we can handle those and we can come up with some early 402 hearing. We're not going to wait until trial, but we will come up with a hearing date so that those issues can be tested under *Sargon* here; and presumably the MDL judge may do an early *Daubert* hearing in the MDL case.

See Tr. of Proceedings at 7:12-24, *Onglyza Product Cases*, JCCP No. 4909 (June 20, 2018), Ullman Decl., Ex. O. Both fora will be well served by this Court instituting a phased discovery plan that addresses significant common issues early on the path to trial.

II. PLAINTIFFS' CASE-SPECIFIC DISCOVERY AND BELLWETHER PROPOSAL IS INEFFICIENT.

Plaintiffs' proposal places the selection of bellwether cases prior to the completion of detailed Plaintiff Fact Sheets, arguing that Defendants should not be permitted "to do full blown

case specific discovery on each individual case immediately." Pls.' Br. at 3. Completing a Plaintiff Fact Sheet is not equivalent to "full blown case specific discovery," which would involve at a minimum fact witness depositions as well as case-specific expert reports. As noted in their prior submission, Defendants propose to defer in-depth case-specific discovery until the resolution of the issue of general causation. However, in order to pick bellwether cases—a litigation stage that Plaintiffs want to prioritize—both parties must have sufficient information to determine whether particular cases are representative of the total MDL and suitable for trial. The parties will not be equipped to make those decisions before seeing Plaintiff Fact Sheets.

The parties are continuing to negotiate what should be contained in an initial Plaintiff Fact Sheet. Both parties agree that some form of disclosure by Plaintiffs early on in the litigation is appropriate; indeed, Plaintiffs have repeatedly asserted their willingness to provide key information about their individual cases in order to screen out cases in which plaintiffs' claims cannot be substantiated. *See* Pls.' Br. at 10-11. Yet they propose to bifurcate the process of submitting Plaintiff Fact Sheets by requiring only limited information at an initial stage. In the *Ethicon* case cited by Plaintiffs, Pls.' Br. at 11, an initial abbreviated fact sheet required information relating to the implantation of the device, outcomes attributed to the device, and limited other medical conditions. *See* Ex. 1, *In Re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 12-md-2327, ECF No. 281-1 (S.D. W. Va. Oct. 4, 2012), Ullman Decl., Ex. P. But it did not touch on other issues that are critically important in a drug ingestion case, including pre-existing conditions, other medications ingested by the plaintiff, and the temporal relationship between the plaintiff's symptoms and her ingestion. While such a system may have been appropriate for that particular device MDL, it would be inefficient in these proceedings where issues of causation are highly complex because cardiovascular conditions are known to be

related to diabetes. Although the parties will work to agree upon a PFS, it is important that it include all the information that will help the parties take advantage of the Court's rulings during the initial phase of discovery.

Critically, representative bellwether cases cannot be selected without Plaintiff Fact Sheets. Even aside from the fact that Plaintiffs have represented that only 20% of their projected cases have been filed, without detailed information about individual plaintiffs it is impossible to know whether the bellwether cases are representative of the entire pool of cases in this litigation. Plaintiffs propose that the parties rely on Plaintiffs' Short Form Complaints and an abbreviated Profile Form to assess the characteristics of individual cases. But these materials are unlikely to provide sufficient detail about important characteristics of Plaintiffs' cases, including pre-existing medical conditions, co-morbidities, and the severity of alleged injuries. Proof of use and injury alone are the bare minimum to sustain a case, not to determine whether it is representative for bellwether purposes. Obtaining the detailed information contained in a Plaintiff Fact Sheet in parallel with proceedings on general causation would allow the litigation to proceed promptly with case-specific discovery should the Court find reliable evidence of general causation.

CONCLUSION

Defendants respectfully request that the Court enter a phased scheduling order consistent with Defendants' proposal in their Initial Conference Submission.

DATED: October 5, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2018, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system. All attorneys appearing on the attorney service list for this multi-district litigation will be served by the CM/ECF system.

By: /s/ Emily S. Ullman
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