BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

BRIEF IN SUPPORT OF DEFENDANT PFIZER INC'S MOTION PURSUANT TO 28 U.S.C. § 1407 TO TRANSFER RELATED ACTIONS FOR COORDINATED PRETRIAL PROCEEDINGS IN THE SOUTHERN DISTRICT OF NEW YORK

Pfizer Inc ("Pfizer") respectfully submits this memorandum of law in support of its motion, pursuant to 28 U.S.C. § 1407, to centralize fifty-nine related federal actions, and any subsequently filed related actions, before a single judge in the United States District Court for the Southern District of New York for coordinated pretrial proceedings. The actions are product liability suits in which plaintiffs assert claims against Pfizer alleging that Zoloft, a Pfizer medication, caused birth defects.

PRELIMINARY STATEMENT

Pfizer requests coordination of the federal Zoloft actions in a multidistrict litigation ("MDL") because: (i) the complaints all assert product liability claims against Pfizer based on allegations that Zoloft can and did cause congenital abnormalities when taken by women during pregnancy; (ii) the actions involve common questions of fact, including whether plaintiffs can proffer reliable scientific evidence on the pivotal issue of general causation, that is, whether Zoloft is capable of causing the injuries alleged; (iii) transfer to a single district will be convenient for the parties and witnesses and will promote the just and efficient conduct of the litigation; and (iv) absent transfer and coordination, the parties and courts will face the burden and expense of needlessly duplicative discovery and pretrial proceedings and possible inconsistent pretrial rulings. The creation of an MDL at this time is appropriate because there are already fifty-nine similar actions pending before more than eleven different judges in seven different federal courts, all in the preliminary stages of litigation, and additional actions are expected to be filed in, or removed to, federal court in the future.

In addition, Pfizer requests that the MDL be assigned to a judge in the Southern District of New York, a highly accessible district in a metropolitan location where five of the actions are currently pending, Pfizer's headquarters are located, and the courts have the requisite resources and expertise, including a robust record with similar MDLs. Alternatively, Pfizer requests coordination before a judge in either the Northern District or the Southern District of Mississippi or the Northern District of Ohio.

STATEMENT OF FACTS

Zoloft (sertraline hydrochloride) is a selective serotonin reuptake inhibitor ("SSRI"), manufactured and sold by Pfizer. Zoloft was approved by the Food and Drug Administration ("FDA") for the treatment of major depressive disorder in 1991. Zoloft is also indicated for the treatment of obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder. Generic versions of sertraline became available in 2006. Zoloft and sertraline have provided safe and effective relief from symptoms of major depression and other psychiatric conditions to millions of patients for over twenty years.

The use of any prescription medicine during pregnancy is a concern for any woman and her physician. Pregnant women are almost always excluded from clinical trials and, as a result, the safety of prescription medicines during pregnancy cannot be established through double blind, randomized, controlled clinical trials. As the FDA has recognized, the risks of using an SSRI during pregnancy must be balanced against the health risks to the mother and child if the mother's depression is not properly treated. In particular, the FDA recently noted: "Untreated depression during pregnancy may lead to poor birth outcomes, including low birth weight, preterm delivery, lower Apgar Scores, poor prenatal care, failure to recognize or report signs of labor; and an increased risk of fetal abuse, neonaticide or maternal suicide."[1] Accordingly, since

[1] U.S. Food & Drug Admin., FDA Drug Safety Communication: Selective serotonin reuptake inhibitor (SSRI) antidepressant use during pregnancy and reports of a rare heart and lung condition in newborn babies (Dec. 14, 2011) ("FDA December 2011 Communication"), http://www.fda.gov/Drugs/DrugSafety/ucm283375.htm.

1995, the FDA-approved label for Zoloft has advised physicians that "[t]here are no adequate and well-controlled studies in pregnant women. Zoloft (sertraline hydrochloride) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus."[2] In addition, in 2006, the FDA requested that all SSRIs carry a warning that "[i]nfants exposed to SSRIs in pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN)."[3] In December 2011, however, the FDA updated its position on the possible association between SSRIs and PPHN. "[A]dvis[ing] health care professionals not to alter their current clinical practice of treating depression during pregnancy," the FDA explained that it had "reviewed the additional new study results and . . . concluded that, given the conflicting results from different studies, it is premature to reach any conclusion about a possible link between SSRI use in pregnancy and PPHN."[4] The FDA intends to update SSRI medication labels "to reflect the new data and the conflicting results."[5]

Between May 2011 and the present, various individual plaintiffs filed ten lawsuits against Pfizer in federal courts alleging that exposure to Zoloft in utero caused birth defects. During the same time period, forty-nine similar actions were filed in various state courts and removed to federal court on diversity grounds. In each case, the plaintiffs claim that Pfizer failed to adequately warn that the use of Zoloft during pregnancy could cause birth defects and that the plaintiff mothers and exposed children were injured as a result. Forty-eight of the cases are currently pending in the Eastern District of Pennsylvania,[6] five cases are pending in the Southern

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[2] *See, e.g.*, Zoloft prescribing information (September 2011) at 25, *available at* http://labeling.pfizer.com/ShowLabeling.aspx?id=517.

[3] *See id.*

[4] FDA December 2011 Communication.

[5] *Id.*

[6] Those cases are: *Agbaroji*, *Amadio*, *Armstrong*, *Bailey*, *Baker*, *Barnes*, *Booker*, *Byrd*, *Casl*, *Castillo*, *Christianson*, *Compton*, *Dzubin*, *Emlen*, *Fitzpatrick*, *Forrer*, *Frank*, *Gordon*, *Gully*, *Hanks*, *Hayes*, *Hays*, *Johnson*, *Johnson*, *Jones*, *Julien*, *Kiah*, *King*, *Knight*, *Long*, *Lorenze*, *M. Martinez*, *V. Martinez*, *Mapp*, *May*, *Mitchell*, *Moore*, *Parsley*, *Potts*, *Richburg-Rodriguez*, *Rosenkranz*, *Rowan*, *Tellier*, *B.A. Smith*, *C. Smith*, *Wright*, *Ybarra*, *Young*. Plaintiffs have created an artificial concentration of cases *(cont'd)*

District of New York (*Anderson*, *Hagan*, *Lewis*, *Peska*, and *Phelps*), two cases are pending in the Southern District of Illinois (*Saville* and *Wilson*), and the remaining cases are pending in the Northern District of Mississippi (*Hopkins*), the Southern District of Mississippi (*Mallory*), the Eastern District of Missouri (*Gregory*), and the Northern District of Ohio (*Hodge*).[7]

In *Hodge*, which also names Cardinal Health as a defendant, and in each of the Eastern District of Pennsylvania cases naming the Wolters Kluwer defendants, Pfizer has removed the actions to federal court on the ground that the non-Pfizer defendants were fraudulently joined to defeat diversity jurisdiction. In *Saville* and *Wilson*, Pfizer removed the actions on the ground that the numerous unrelated plaintiffs there fraudulently misjoined their claims to defeat diversity. Plaintiffs have made motions to remand in *Hodge*, *Wilson*, and *Martinez* (one of the Eastern District of Pennsylvania cases). Although the remand motions remain pending, the panel may still transfer the actions pursuant to 28 U.S.C. § 1407. *See In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) ("The pendency of a motion to remand to state court is not a sufficient basis to avoid inclusion in Section 1407 proceedings."); *see also In re Ivy*, 901

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in Pennsylvania by, in forty-six of the actions, fraudulently joining Wolters Kluwer Health ("WKH"), a Pennsylvania corporation, as a defendant, in order to defeat diversity jurisdiction. WKH is not affiliated with Pfizer and was not involved in the manufacturing or distribution of Zoloft. Instead, WKH, through its MediSpan division, published patient education monographs, protected by the First Amendment. Not only is WKH a fraudulently joined defendant, its MediSpan division is headquarted in Indiana, with offices in Missouri. None of the plaintiffs in the Pennsylvania actions are from Pennsylvania, and none of the relevant transactions took place in Pennsylvania. In short, Pennsylvania has no real nexus to the cases that have been filed there.

[7] In certain cases, plaintiffs have named defendants in addition to Pfizer: Plaintiffs in *Hodge* have named Cardinal Health, Inc., an independent distributor or wholesaler of pharmaceutical products; as noted above, plaintiffs in forty-six of the cases pending in the Eastern District of Pennsylvania have named WKH and Wolters Kluwer United States, Inc., a company that the plaintiffs also allege was involved in the publication and distribution of the Zoloft monograph (*see supra* n. 6); plaintiffs in *Hopkins* have asserted claims against New York-based Forest Pharmaceuticals, Inc., and Forest Laboratories, Inc., based on alleged injuries to the plaintiffs and their decedent as a result of the mother plaintiff's alleged use of Forest Pharmaceutical's medication, Lexapro, during pregnancy; and plaintiffs in *Long* have named GlaxoSmithKline LLC and claim injuries as a result of the mother plaintiff's alleged use of GlaxoSmithKline's medication Paxil, during pregnancy. GlaxoSmithKline has its U.S. headquarters in Philadelphia, Pennsylvania.

F.2d 7, 9 (2d Cir. 1990); *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 170 F. Supp. 2d 1346, 1347-48 (J.P.M.L. 2001).

These fifty-nine actions are all in the preliminary stages of litigation. Activity to date has been limited to initial pleadings, preliminary conferences and, in a few cases, service of written discovery requests and deposition notices. No depositions have yet taken place and no trials are scheduled for 2012. In recent months, plaintiffs' lawyers around the country have been actively soliciting, through TV and Internet advertising, additional cases involving Zoloft and congenital abnormalities, and it is likely that additional similar actions will be filed in or removed to federal courts in the future. For example, on January 17, 2011, Pfizer was served with summonses in eight additional actions in Pennsylvania state court, all of which name the Wolters Kluwer defendants, in addition to Pfizer, and which Pfizer thus expects to remove to federal court.

ARGUMENT

I. Transfer and Pretrial Coordination of These Related Actions Will Promote the Goals of 28 U.S.C. § 1407

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

A. The Actions Involve Common Issues of Fact

The Zoloft actions share a substantial overlap of factual issues. Each alleges that Zoloft can and did cause birth defects and that Pfizer failed to adequately warn of such risks. The actions involve the same categories of plaintiffs: mothers who ingested Zoloft during pregnancy and their children who were allegedly exposed and injured. Plaintiffs also assert similar causes of action, including negligence, failure to warn, breach of warranty, and fraud. Pfizer vehemently contests plaintiffs' allegations and believes that there is no reliable scientific basis

for asserting a causal connection between Zoloft and the birth defects alleged. It is clear that discovery relating to medical causation and the adequacy of product testing and warnings will overlap across the cases, as will challenges involving plaintiffs' ability to satisfy the requirements of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rules of Evidence 702 and 703, with respect to general causation.[8]

Although the actions present certain individualized factual issues, including specific causation (whether Zoloft actually caused each plaintiff's alleged injury), "Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization." *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp. 2d 1376, 1378 (J.P.M.L. 2010); *accord In re Denture Cream Prods. Liab. Litig.*, 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009). Instead, where, as here, the underlying factual and legal allegations are sufficiently similar, "[t]ransferee judges have demonstrated the ability to accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits." *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009). Courts have applied this dual discovery approach in a number of recent product liability actions involving pharmaceutical products. *See, e.g.*, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 655 F. Supp. 2d 1343, 1344 (J.P.M.L. 2009); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 655 F. Supp. 2d 1346, 1346 (J.P.M.L. 2009); *In re Vioxx*, 360 F. Supp. 2d at 1353-54.

[8] Evidence related to general causation may vary based upon the nature of the injuries alleged. In other words, evidence related to PPHN is not relevant to a limb defect such as clubfoot. Nonetheless, there is significant overlap in the injuries alleged, so that efficiencies can be achieved through an MDL.

B. Coordination Will Promote the Just and Efficient Management of Pretrial Proceedings in the Actions

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

In each of the fifty-nine pending actions, plaintiffs are seeking or will likely seek much of the same discovery from Pfizer, including documents and deposition testimony related to the testing, design, labeling, marketing, and safety of Zoloft. Coordinating the actions before one judge at this early stage will allow the parties and the court to address this overlapping discovery in an organized manner and avoid the potentially very costly duplication of efforts and judicial resources that would be required if the cases were to continue to proceed on separate schedules and in separate courts.

Indeed, this Panel has consistently recognized that Section 1407 coordination is a preferred way to manage individual lawsuits that raise similar questions regarding a defendant's development, design, and testing of a particular prescription medication or device. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381-82 (J.P.M.L. 2004); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1367 (J.P.M.L. 2003); *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 844 F. Supp. 1553, 1554 (J.P.M.L. 1994); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098, 1100 (J.P.M.L. 1992); *In re A. H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig.*, 406 F. Supp. 540, 542 (J.P.M.L. 1975).

Coordination is also appropriate here to avoid potentially inconsistent pre-trial rulings on the same or similar issues, including expert challenges under *Daubert*, and the uncertainty and confusion that would result. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, MDL No. 2272, 2011 WL 3563293, at *1 (J.P.M.L. Aug. 8, 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and] prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues . . . ."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all

three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort.").

C. Coordination Will Serve the Convenience of Witnesses and Parties

For many of the same reasons that coordination will promote the just and efficient management of the actions at this time, it will also serve the convenience of the witnesses and parties. In particular, coordinating and streamlining discovery will minimize unnecessary duplication, travel, and other expenses, and allow the parties to conserve, and more effectively focus, their resources in litigating these actions. As this Panel has noted:

> Since a Section 1407 transfer is for pretrial proceedings only, there is usually no need for the parties and witnesses to travel to the transferee district for depositions or otherwise. Furthermore, the judicious use of liaison counsel, lead counsel and steering committees will eliminate the need for most counsel ever to travel to the transferee district. And it is most logical to assume that prudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned.

In re Baldwin-United Corp. Litig., 581 F. Supp. 739, 740-41 (J.P.M.L. 1984) (citations omitted).

In sum, coordination of these actions is appropriate because it would "eliminate duplicative discovery, prevent inconsistent pretrial rulings . . . and conserve the resources of the parties, their counsel and the judiciary." *In re Temporomandibular Joint (TMJ) Implants*, 844 F. Supp. at 1554.

II. Coordination in the Southern District of New York Is Appropriate

As noted above, these fifty-nine Zoloft actions are pending before district courts in seven districts across the country. The Panel considers several key factors in selecting an appropriate MDL forum, including: (i) the location of parties, witnesses, and documents; (ii) the accessibility of the transferee district for parties and witnesses; and (iii) the respective case loads and experience of the proposed transferee district courts. *See, e.g.*, *In re Camp Lejeune, N.C. Water Contamination Litig.*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011); *In re Air Crash at Belle Harbor, N.Y. on Nov. 12, 2001*, 203 F. Supp. 2d 1379, 1380-81 (J.P.M.L. 2002); *In re Corn*

Derivatives Antitrust Litig., 486 F. Supp. 929, 931-32 (J.P.M.L. 1980). As set forth below, these factors support coordination of these actions in the Southern District of New York.

First, Pfizer, which is a defendant in all of the actions, has its corporate headquarters in the Southern District of New York. The Forest defendants in the *Hopkins* action are also located in that district. Thus, a significant number of parties, witnesses and documents are likely to be located in and immediately around the Southern District of New York. *See In re Pfizer Inc. Sec., Derivative & "ERISA" Litig.*, 374 F. Supp. 2d 1348, 1350 (J.P.M.L. 2005) (centralizing 29 actions in the Southern District of New York where "Pfizer has its headquarters and many individual defendants reside, and therefore relevant witnesses and documents will likely be found there"); *see also In re Navistar 6.0 L Diesel Engine Prods. Liab. Litig.*, 777 F. Supp. 2d 1347, 1348 (J.P.M.L. 2011) (transferring multiple actions to the Northern District of Illinois because "[d]efendants' headquarters, and therefore relevant documents and witnesses, are located in or relatively near [the] district"); *In re Canon U.S.A., Inc., Digital Cameras Prods. Liab. Litig.*, 416 F. Supp. 2d 1369, 1371 (J.P.M.L. 2006) (transferring cases to the Southern District of New York in part because it would "likely provide a source of relevant documents and witnesses, inasmuch as [defendant]'s principal place of business is located there").

Second, the Southern District of New York, and New York City in particular, is a geographically accessible and convenient forum for all parties and witnesses. Plaintiffs in these actions are geographically dispersed across the country, making no single district most convenient to plaintiffs. Plaintiffs' counsel are similarly scattered, with counsel based in cities across the country, including Birmingham, Denver, Houston, Kansas City, St. Louis, New York, and Philadelphia. Three international airports serve New York City and provide daily, non-stop service to most metropolitan areas, including each of the cities where plaintiffs' counsel reside. The federal courthouse is less than twenty miles from any of these airports. The panel has previously recognized New York City's central location and accessibility in finding that the Southern District of New York was an appropriate MDL forum. *See, e.g., In re Rhodia S.A., Sec. Litig.*, 398 F. Supp. 2d 1359, 1360 (J.P.M.L. 2005) (noting that the Southern District of New

York "provides an accessible, metropolitan location"); *accord In re Amtel, Inc. Sec. Litig.*, 447 F. Supp. 466, 468 (J.P.M.L. 1978).

Third, the Southern District of New York is well-equipped to handle and manage these actions. For the year ending September 30, 2010, the Southern District of New York had the third highest number of civil court filings and the third highest number of civil court terminations.[9] The median time from filing to disposition for all civil cases in 2010 was only 8.1 months.[10] The Southern District of New York is also one of the most experienced districts in handling product liability cases.[11] Additionally, the Southern District of New York has extensive experience handling complex multidistrict litigations: from 1977 to 2010, the panel transferred well over a hundred multidistrict litigations to the Southern District of New York, by far the largest number of MDLs of any other district.[12]

With respect to the selection of a judge, Pfizer submits that any of the judges who are currently presiding over the Zoloft actions pending in the Southern District of New York – namely, Judge Paul A. Engelmayer (*Hagan*, *Phelps*), Judge Paul A. Crotty (*Anderson*), Judge Paul J. Oetken (*Lewis*), and Judge Paul G. Gardephe (*Peska*) – would be highly capable of managing this MDL.

III. Alternatively, Coordination in the Northern District of Mississippi, the Southern District of Mississippi, or the Northern District of Ohio Would be Appropriate

As an alternative to the Southern District of New York, Pfizer submits that coordination before a court in the Northern or Southern District of Mississippi or the Northern District of Ohio would also be an appropriate choice here.

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[9] *See* Administrative Office of the United States Courts, *2010 Annual Report of the Director: Judicial Business of the United States Courts* 138-40 (2011) (Table C), *available at* http://www.uscourts.gov/uscourts/Statistics/JudicialBusiness/2010/JudicialBusinespdfversion.pdf.

[10] *See id.* at 175 (Table C-5).

[11] *See, e.g.*, *id.* at 57-59 (Table S-10).

[12] *See* J.P.M.L., Multidistrict Litigation Terminated Through September 30, 2010, at 6-9, *available at* http://www.jpml.uscourts.gov/Statistics/JPML_Terminated_Litigations-2010.pdf.

There is currently one action pending in each of those jurisdictions: *Hopkins* is pending in the Northern District of Mississippi before Judge Neil B. Biggers; *Mallory* is pending in the Southern District of Mississippi before Judge Daniel P. Jordan, III; and *Hodge* is pending in the Northern District of Ohio before Judge Christopher A. Boyko.

Each of these alternative districts is centrally located and would be accessible to plaintiffs and plaintiffs' counsel, who are geographically dispersed. The Northern District of Mississippi, in Oxford, is less than an hour and a half's drive from the Memphis International Airport; the courthouse for the Southern District of Mississippi, in Jackson, is less than ten miles from the Jackson-Evers International Airport, which provides approximately thirty-eight non-stop flights per day to nine cities; and the Northern District of Ohio in Cleveland is just twelve miles from the Cleveland-Hopkins International Airport, which serves over seventy cities with approximately 250 non-stop flights daily.

All three districts are experienced handling large volumes of cases and have experience with MDLs. The Northern District of Ohio also has significant experience with product liability actions, with nearly 700 such actions filed in the year ending September 30, 2010.[13] In addition, neither Judge Biggers, Judge Jordan, nor Judge Boyko is currently presiding over another MDL. There is currently only one MDL pending in the Southern District of Mississippi and twelve pending in the Northern District of Ohio (before other judges).[14] All of these judges have significant experience handling complex litigation, and these districts presumably have the time and resources to oversee a coordinated matter.

[13] *See* Administrative Office of the United States Courts, *2010 Annual Report of the Director: Judicial Business of the United States Courts* 57-59 (2011) (Table S-10), *available at* http://www.uscourts.gov/uscourts/Statistics/JudicialBusiness/2010/JudicialBusinespdfversion.pdf.

[14] *See* United States Judicial Panel on Multidistrict Litigation, *MDL Statistics Report – Distribution of Pending MDL Dockets* (Jan. 11, 2012), *at* http://www.jpml.uscourts.gov/Pending_MDL_Dockets-By-District-January-2012.pdf.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests an Order transferring the actions identified in the accompanying Schedule of Actions to a single judge in the Southern District of New York for pretrial coordination and granting such other and further relief as the Panel may deem just and proper. Alternatively, Pfizer requests transfer to the Northern District of Mississippi, the Southern District of Mississippi, or the Northern District of Ohio.

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Respectfully submitted,

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