BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: AMIODARONE TOXICITY LITIGATION

MDL Docket No.:

PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION PURSUANT TO 28 U.S.C. §1407

INTRODUCTION

Plaintiff Heather Moore Cook, as Executor of the Estate of Mal M. Moore, deceased, has moved the Judicial Panel on Multidistrict Litigation (hereinafter "Panel" or "JPML") for an order, pursuant to 28 U.S.C. § 1407 transferring virtually identical actions pending in multiple district courts throughout the United States (hereinafter the "Amiodarone Toxicity Actions") to a single district court, and coordinating those actions for pretrial proceedings (hereinafter "Motion for Transfer and Coordination" or "Movant's Motion"). All of the Amiodarone Toxicity Actions allege injuries following the improper and unreasonable distribution, marketing, promotion, sale, labeling, and design of amiodarone throughout the United States, which caused injuries to the plaintiffs.

Each of the Amiodarone Toxicity Actions puts at issue the defendants' liability for the improper and unreasonable distribution, marketing, promotion, sale, labeling, and design of amiodarone throughout the United States, which caused injuries to the plaintiffs. As such, the common questions of fact among these actions—*i.e.,* whether the defendants engaged in the illegal actions alleged—warrant the transfer of these cases to one court to allow the resolution of all threshold matters in the most efficient manner for the courts and the parties.

These cases fall squarely within the requirements of Section 1407. All of the actions arise from plaintiffs' injuries resulting from the defendants' improper and unreasonable distribution, marketing, promotion, sale, labeling, and design of amiodarone throughout the United States. It is beyond dispute that all of the Amiodarone Toxicity Actions share common questions of fact, including the same causes of actions and defendants. Transferring all of these cases to one court for pretrial proceedings will be more convenient for the parties, will not prejudice any party's interests, and will conserve judicial resources.

BACKGROUND

All prescription drugs require approval by the Food and Drug Administration (hereinafter "FDA") before the drug may be marketed. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's safety

and efficiency gleaned from clinical trials. It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions.

In 1985, Defendant Wyeth received FDA approval to market and sell the anti-arrhythmic heart medication Cordarone® (amiodarone hydrochloride is the generic formulation) under a rare "special needs" approval, granted without the usually mandated rigorous and FDA-approved double-blind, randomized clinical trials. Although the FDA has urged Wyeth to conduct such trials, they have not been conducted. The FDA's approval for the marketing of Cordarone® remains a "special needs" approval. The customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for amiodarone. Defendant Wyeth was the initial manufacturer, promoter and distributor or "brand manufacturer" of Cordarone® in the United States.

Amiodarone went "off patent" in or around 1998 and the other noted defendants entered the market with a generic formulation of amiodarone that is a bioequivalent of Wyeth's brand product. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (hereinafter "FDCA") and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers. Generic manufacturers are not

required to repeat the clinical trials conducted by name brand manufacturers. ANDA's are approved based on the initial safety profile of the name brand drug and are subject to sameness in labeling and warnings and all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug.

Defendant Wyeth's Cordarone® was approved by the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia, and only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Defendant Wyeth nevertheless aggressively and successfully marketed Cordarone® for inappropriate "off-label" uses as a "first line anti-arrhythmic therapy." Defendant Wyeth instituted and maintained an active promotional campaign to physicians touting the anti-arrhythmic benefits of amiodarone. The campaigns were aggressive and in many situations, focused on the use of the drug for atrial fibrillation and failed to warn prescribing physicians of the potential dangers associated with amiodarone toxicity and dangers to atrial fibrillation patients. Defendant Wyeth's campaigns were so pervasive and effective that for an entire generation of physicians, the drug wrongfully became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug.

Defendant Wyeth's fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop the false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy. The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. The purpose of this federal requirement is to protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomize and well-controlled clinical trials to determine whether the drug is safe and effective for such uses. This requirement is meant to ensure that drug companies like Defendant Wyeth will give physicians and medical personnel trustworthy information so that medications are prescribed appropriately.

Physicians may still prescribe drugs for unapproved uses. These uses are deemed "off-label" because they have not been approved by the FDA. Pharmaceutical companies are permitted to disseminate certain information about off-label uses, but such dissemination must adhere to strict requirements. For instance, these manufacturers must: (1) submit an application to the FDA seeking approval of the drug for off-label use; (2) provide its unabridged marketing materials to the FDA prior to dissemination; and (3) include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . .

necessary to provide objectivity and balance." The dissemination of information in violation of these provisions violates the FDCA.

For certain prescription drugs, the FDA mandates that manufacturers provide each patient who receives those drugs a medication guide ("Medication Guide"). Medication Guides are short documents in large print that explain medication risks in plain language. The Medication Guides are to be provided in lieu of the manufacturer's standard drug label. The FDA required the provision of a Medication Guide to each patient who was prescribed amiodarone. The failure of the various manufacturer Defendants to provide the FDA approved Medication Guides results in the drug being sold "mislabeled" and "illegal" and is a common element in each Amiodarone Toxicity suit.

Each manufacturer that ships a container of an FDA-approved drug product for which a Medication Guide is required to ensure that Medication Guides are available for distribution to patients. The FDA has recognized that "it is important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications." The Medication Guides are to specifically provide information directly to the patient outside of the interaction with the physician. The FDA has mandated that the warnings included in the Medication Guides go directly to the distributor and via the distributor and pharmacists directly to the patient as an important notification

distributed outside and in addition to any warning or information that is provided by the physician. Drugs identified by the FDA for the Medication Guide procedure are significantly dangerous to such a degree that the FDA desires a warning outside of information provided directly by the physician. The FDA has expressed concern at the failure of drug manufacturers in the distribution of the Medication Guides to the distributors and that "the current Medication Guide program is too cumbersome and that it lacks a standard distribution system." Failure to provide the Medication Guide results in the distribution of a mislabeled and illegal drug.

The National Consumer Pharmacy Association has also identified the failure of manufacturers to ensure the distribution of Medication Guides to distributors and thus to the patients as a significant safety issue and called on the FDA in a recent publication to "enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product."

Each defendant manufacturer was required by federal regulation to ensure that the appropriate warning labels and Medication Guides were provided to the plaintiffs. The serious side effects outlined in the Medication Guide included lung

damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. Because distributors and pharmacists were not provided Medication Guides to distribute by the Defendant manufacturers, the plaintiffs did not know that amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then when "other treatments did not work or were not tolerated." The plaintiffs did not know that any other use such as the use for atrial fibrillation was considered to be "off-label" and did not know of the corresponding dangers associated with such uses.

Millions of atrial fibrillation heart patients, including each of the plaintiffs, have received amiodarone without the benefit of the Medication Guides and for off label purposes other than ventricular tachycardia. The facts associated with the defendants' off label marketing and the defendants' failure to distribute the Medication Guides are common to all currently filed and to be filed amiodarone lawsuits.

C. Pending Lawsuits Against the Defendants

Presently, Movant is Plaintiff in a lawsuit pending in the Northern District of Alabama. Additionally, other lawsuits are pending in different federal jurisdictions regarding similar claims and allegations of injury. All of the actions share substantial commonalities regarding the named defendants, factual allegations, and

claims. All of the plaintiffs complain that they were injured following the improper and unreasonable distribution, marketing, promotion, sale, labeling, and design, of amiodarone throughout the United States, which caused them injury.

ARGUMENT

This Panel is authorized under 28 U.S.C. § 1407 to centralize and transfer "civil actions involving one or more common questions of fact" to a single district court for coordination or consolidated pretrial proceedings upon the Panel's "determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). The purpose of this transfer procedure is to conserve judicial resources and to avoid the delays that are bound to result if all aspects of pretrial proceedings were conducted separately. *See* Moore's Federal Practice – Civil, Chapter 112 Multidistrict Litigation § 112.02.

All of the Amiodarone Toxicity Actions fall squarely within the requirements of 28 U.S.C. § 1407(a). They all involve virtually identical causes of action against virtually identical defendants, and important considerations warrant transferring all these cases to one district court for coordination/consolidation and pretrial proceedings.

I. The Amiodarone Toxicity Actions Satisfy All of the Requirements of Section 1407(a).

The Amiodarone Toxicity Actions satisfy the requirements of section 1407(a), *i.e.,* they "involve[] one or more common questions of fact" and transfer for consolidated or coordinated pretrial proceedings "will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a).

A. All of the Actions Share One or More Common Questions of Fact

It is without doubt that all of the Amiodarone Toxicity Actions share "one or more common questions of fact." *See* 28 U.S.C. § 1407(a). All of these actions put at issue the defendants' liability for the improper and unreasonable distribution, marketing, promotion, sale, labeling, and design, of amiodarone throughout the United States, which caused injuries to the plaintiffs. The factual allegations in each of these complaints are virtually identical. As a result, they are highly likely to involve duplicative discovery, including shared witnesses and documents. On these bases alone, the MDL Panel has repeatedly recognized that creation of a centralized forum is highly appropriate. *See In re Merscorp, Inc., Real Estate Settlement Procedures*, No. 1810, --- F. Supp. 2d ---, 2007 WL 128792, at *1 (J.P.M.L. Jan. 10, 2007) (holding that centralization under Section 1407 was warranted since all actions involved common questions of fact and centralization would promote just and efficient conduct of the litigation, and was necessary in

order to eliminate duplicative discovery); *In re NSA Telecomms. Records Litig.*, 444 F. Supp. 2d 1332, 1334 (J.P.M.L. 2006); *In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006); *In re Cobra Tax Shelters Litig.*, 408 F. Supp. 2d 1348, 1349 (J.P.M.L. 2005); *In re Capital One Bank Credit Card Terms Litig.*, 201 F. Supp. 2d 1377, 1378 (J.P.M.L. 2002) ("[T]hese actions share sufficient complex common questions of fact . . . ."). In addition, these actions generally bring the same claims—namely products liability and the common law. There cannot be any dispute that all of these actions share "one or more common questions of fact."

B. Transfer of These Cases Promotes Just and Efficient Conduct of These Actions and Serves the Convenience of the Parties and Witnesses

Because all of the Amiodarone Toxicity Actions are factually similar, and advance similar causes of actions, pretrial proceedings in all these actions will virtually be the same. Transfer and coordination to one district court will preclude inconsistent rulings relating to pretrial proceedings by different district courts on similar issues. Accordingly, the transfer and coordination of these actions will promote the just and efficient conduct of these actions. *See, e.g., In re NSA Telecomms. Records Litig.*, 444 F. Supp. 2d at 1334 (centralization for pretrial proceedings was warranted to "prevent inconsistent pretrial rulings" and "conserve the resources of the parties, their counsel and the judiciary."); *In re Seroquel*

Prods. Liab. Litig., 447 F. Supp. 2d at 1378; *In re Banc of America Inv. Services, Inc.*, No. 1803, 2006 U.S. Dist. LEXIS 94113, at *4 (J.P.M.L. Dec. 19, 2006) ("Transfer under Section 1407 will have the salutary effect of assigning the present actions and any future tag-along action to a single judge who can formulate a pretrial program . . . that ensures that pretrial proceedings will be conducted in a streamlined manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties and the courts."); *In re Prempro Products Liability Lit.*, 254 F.Supp.2d 1366, 1367 (J.P.M.L. 2003) ("Centralization under Section 1407 is necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings . . ., and conserve the resources of the parties, their counsel and the judiciary"); *In re Cobra Tax Shelters Litig.*, 408 F. Supp. 2d at 1349 ("Transfer under Section 1407 will offer the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to accommodate all parties' legitimate discovery needs."). Most fundamentally, transfer of these actions to a single district will permit the formulation of a rational, sequenced pretrial program that will streamline discovery, minimize witness inconvenience and overall discovery expenses and permit parties, through cooperation and pooling of resources, to benefit from the "economies of scale" that MDL pre-trial proceedings uniquely facilitate.

The resolution of the defendants' purported affirmative defenses by a single district court, moreover, further supports the judicial economy of centralization of these actions. Pretrial motions, such as motions to dismiss or for summary judgment, are the types of pretrial proceedings that are appropriate for the transferee court to consider. *See, e.g., U.S. v. Baxter Inter., Inc.*, 345 F.3d 866 (11th Cir. 2003), *cert. denied*, 542 U.S. 946 (2004)(court affirmed in part and reversed in part district court's granting of defendants' motion to dismiss in multidistrict litigation actions). Centralization of these actions in one district court will facilitate the prompt resolution of the defendants' intended assertions and preclude any potential inconsistent rulings in similar cases.

The statutory requirement that transfer and coordination of the Amiodarone Toxicity Actions serve the convenience of the parties and witnesses is also met here. Litigating these cases in multiple courts across the country will cause substantial inconvenience to representatives of the defendants, who would be required to appear and sit for deposition in each action. Given the significant day-to-day responsibilities of the defendants' representatives, the need for them to personally participate in discovery for separate lawsuits will impose a substantial and unwarranted distraction for an extended period of time.

It would serve the convenience of all parties, moreover, to have such similar matters resolved in one forum. As noted, these cases assert the same factual

allegations, bring similar causes of actions, and seek similar relief. Resolving the pretrial proceedings in one court would facilitate resolution of all claims in a timely manner without the risk of inconsistent rulings.

II. The Western District of Texas is an Appropriate Forum

In light of the substantial progress that has been made in the cases filed in the Western District of Texas, the number of Amiodarone Toxicity Actions filed in the Western District of Texas, and the residence in the Western District of Texas of plaintiffs with actions subject to the Motion for Transfer, that district would be a logical and convenient forum.

The Western District of Texas is unquestionably the geographic "center of gravity" and focal point of this litigation due to that jurisdiction's prompt and efficient manage of the cases currently before the court and the trial schedule that is in place in that court. As the MDL Panel has repeatedly indicated, the geographic locus of duplicative litigation is the preferred forum for centralization of duplicative multi-district litigation. *See In re Merscorp, Inc.*, 2007 WL 1287921, at *1 (holding that the Eastern District of Texas was the appropriate transferee forum in this docket since "one of the eleven actions is already pending in that district . . ."); *In re Commer, Money Ctr., Inc. Equip. Lease Litig.*, 22*9 F. Supp. 2d 1379, 1380 (J.P.M.L. 2002) (centralizing litigation in the district "where almost half of the constituent actions are already pending."); *In re Lupron Mktg &*

Sales Practices Litig., 180 F. Supp. 2d at 1378) (holding that the District of Massachusetts was the most appropriate transferee district for this litigations since "three of the four actions now before the Panel are already pending there.").

Moreover, since actions against a number of the Defendants have been filed in the Western District of Texas, transfer of all the Amiodarone Toxicity Actions to that court can conserve judicial resources and minimize any inconvenience to the parties and the court. *See In re Asbestos Prods. Liab. Litig. (No. VI)*, 771 F. Supp. 415, 422 (J.P.M.L. 1991) (transfer of actions to the district with the greatest number of pending actions is the most likely to effectuate "an overall savings of cost and a reduction of inconvenience to all concerned.")

Additionally, the Judges in the Western District of Texas have particular experience with complex multi-party products liability litigation, such as presented here. *See In RE: Whole Foods Market, Inc., Greek Yogurt Marketing and Sales Practices Litigation,* 1:14-mc-02588-SS (transferred to W.D. Texas. December 10, 2014).

CONCLUSION

Accordingly, Plaintiff respectfully requests that this Panel grant Plaintiff's Motion for Transfer and Coordination of all the Amiodarone Toxicity Actions to one district court for pretrial proceedings.

/s/ E. Kirk Wood
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CERTIFICATE OF SERVICE

This is to certify that on this 3rd day of March, 2016, a copy of Plaintiffs' Memorandum of Law in Support of Plaintiffs' Motion for Transfer and Coordination or Consolidation Pursuant to 28 U.S.C. § 1407 was served on the following:

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