BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Effexor (Venlafaxine Hydrochloride) Products Liability Litigation MDL Docket No. 2458

DEFENDANTS PFIZER INC., PFIZER INTERNATIONAL LLC, WYETH LLC, AND WYETH PHARMACEUTICALS INC.'S RESPONSE TO THE *BOYER* PLAINTIFFS' MOTION TO TRANSFER RELATED ACTIONS TO THE EASTERN DISTRICT OF PENNSYLVANIA FOR COORDINATED PRETRIAL PROCEEDINGS

Pfizer Inc., Pfizer International LLC (together, "Pfizer"), Wyeth LLC ("Wyeth"), and Wyeth Pharmaceuticals Inc. ("Wyeth Pharmaceuticals") (collectively, the "Defendants") respectfully submit this memorandum of law in response to the motion by the plaintiffs in *Boyer v. Wyeth Pharmaceuticals Inc., et al.*, No. 2:12-cv-00739 (E.D. Pa.) (the "*Boyer* plaintiffs") to create a coordinated pretrial multidistrict litigation ("MDL") pursuant to 28 U.S.C. § 1407 for fourteen cases pending before more than ten different judges in seven different federal courts around the country that allege birth defects due to maternal use of Effexor. *See* Dkt. 1 (the "Effexor MDL Petition"). The *Boyer* plaintiffs requested that the fourteen related federal actions, and any subsequently filed related actions, be centralized before District Judge Cynthia M. Rufe of the United States District Court for the Eastern District of Pennsylvania. As explained below, Defendants support centralization of these actions before Judge Rufe, to the extent that her schedule and docket can accommodate the Effexor MDL.

PRELIMINARY STATEMENT AND BACKGROUND

Effexor (venlafaxine hydrochloride) is a serotonin-norepinephrine reuptake inhibitor approved by the FDA in 1993 for the treatment of major depressive disorder.[1] Effexor XR, the extended-release version of Effexor, is also indicated for the treatment of generalized anxiety disorder, social anxiety disorder, and panic disorder.[2] Effexor was originally developed and

[1] *See* Effexor Prescribing Information (Dec. 2012), at 4-5, *available at* http://labeling.pfizer.com/showlabeling.aspx?id=99.

[2] *See* Effexor XR Prescribing Information (Dec. 2012), at 6-8, *available at* http://labeling.pfizer.com/showlabeling.aspx?id=100.

manufactured by Wyeth but is now manufactured by Pfizer, through its subsidiaries, following Pfizer's 2009 acquisition of Wyeth. Generic versions of venlafaxine became available in 2006. Effexor and venlafaxine have provided safe and effective relief from symptoms of major depression and other psychiatric conditions to millions of patients for 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. Animal studies with Effexor have not demonstrated the existence of any teratogenic effects, even at several multiples of the normal human dose. The Effexor label accordingly has always contained a "Category C" pregnancy warning, disclosing that "[b]ecause animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."[3]

Between December 2011 and the time the Effexor MDL Petition was filed, fourteen lawsuits against Defendants alleging that exposure to Effexor in utero caused birth defects had been filed in or removed to federal courts.[4] In each case, the plaintiffs claim that Defendants failed to adequately warn that the use of Effexor during pregnancy could cause birth defects and that the plaintiff mothers and exposed children were injured as a result. Five of the fourteen Effexor cases are currently pending in the Eastern District of Pennsylvania,[5] three in the Central

[3] *See* Effexor Prescribing Information (Dec. 2012), at 19.

[4] Since the Effexor MDL Petition was filed, at least three additional cases alleging birth defects due to maternal use of Effexor have been filed in, or removed to, federal court. On April 25, 2013, Wyeth, Wyeth Pharmaceuticals, and Pfizer removed *Beaver v. Wyeth Pharmaceuticals, Inc., et al.*, No. 2:13-cv-02220-EL (E.D. Pa.) and *Simnitt v. Wyeth Pharmaceuticals, Inc., et al.*, No. 2:13-cv-02226-EL (E.D. Pa.) to the Eastern District of Pennsylvania. On April 30, 2013, *Wharton v. Wyeth Pharmaceuticals, Inc., et al.*, No. 1:13-cv-00067 (D. Utah) was filed in the District of Utah. Defendants intend to file a Notice of Related Action for each case, identifying each as appropriate for inclusion in the Effexor MDL.

[5] *Adamczyk v. Wyeth*, No. 12-5058; *Boyer v. Wyeth*, No. 12-739; *Decker v. Wyeth*, No. 12-2052; *Demastus v. Wyeth*, No. 12-5057; *Johnson v. Wyeth*, No. 12-6366. Defendants have also moved to transfer four of the cases pending before Judge Ludwig in the Eastern District of Pennsylvania to each Plaintiff's home jurisdiction pursuant to 28 U.S.C. § 1404(a). These motions remain pending, and discovery has commenced in the interim. Defendants note that their position in favor of transferring these cases to their home jurisdictions for trial is fully consistent with their position supporting centralization of *(cont'd)*

District of California,[6] two in the Eastern District of California,[7] and one each in the Southern District of California,[8] Northern District of Mississippi,[9] Northern District of Illinois,[10] and Northern District of Ohio.[11] Of these fourteen actions, only the California actions involve a co-defendant other than Defendants. The California actions also name McKesson Corp. ("McKesson"), a distributor of prescription medications. Pfizer removed the California actions to federal court based on the assertion that McKesson, a California citizen, is a fraudulently joined defendant whose citizenship need not be considered for purposes of evaluating diversity jurisdiction.[12]

For the reasons discussed below, Defendants agree that centralization of the federal Effexor actions in an MDL is appropriate. Defendants further agree that the Effexor MDL should be assigned to Judge Rufe in the Eastern District of Pennsylvania, to the extent that her

---

(cont'd from previous page)
the Effexor litigation before Judge Rufe in the Eastern District of Pennsylvania for coordinated pretrial proceedings. While coordinated handling of discovery and pretrial motions in the Eastern District of Pennsylvania will result in efficiencies, Defendants do not waive their right to, upon the conclusion of pretrial proceedings, seek transfer of these cases to the jurisdictions where Plaintiffs reside for trial, where Defendants can obtain compulsory process over key third-party witnesses, such as Plaintiffs' prescribing and treating physicians.

[6] *Lara v. Pfizer Inc.*, No. 13-2578; *Reid v. Pfizer Inc.*, No. 13-591; *Taha v. Pfizer Inc.*, No. 13-2577.

[7] *Hatherley v. Pfizer Inc.*, No. 13-719; *Scusa v. Pfizer Inc.*, No. 13-524.

[8] *Huntington v. Pfizer Inc.*, No. 13-879.

[9] *Miles v. Wyeth, Inc.*, No. 12-41. Defendants have moved for summary judgment in *Miles* due to the Plaintiffs' failure to disclose expert testimony in accordance with the Court's scheduling order, and the Plaintiffs have cross-moved for voluntary dismissal without prejudice. To the extent Plaintiffs' motion is granted, any refiling is expected to be in federal court and would therefore be subject to transfer to an MDL proceeding.

[10] *Sitkowski v. Wyeth*, No. 12-8326.

[11] *Beatty v. Wyeth*, No. 13-677.

[12] The *Boyer* and *Decker* actions pending in the Eastern District of Pennsylvania originally named defendants Wolters Kluwer Health, Inc. and Wolters Kluwer United States, Inc., two entities allegedly involved in the publication of an Effexor monograph distributed by certain pharmacies. Those entities have since been voluntarily dismissed from those cases.

schedule and docket permit. Judge Rufe currently presides over the Zoloft MDL, which involves claims alleging birth defects due to Zoloft, another prescription antidepressant medication manufactured by Pfizer. Further, Judge Rufe has substantial MDL experience and has expertise in many of the procedural and substantive issues that will exist in the Effexor litigation, including the scientific issues concerning antidepressant medications and birth defects. The Eastern District of Pennsylvania is also a convenient forum for the parties and is where the greatest number of federal Effexor cases are currently pending, and additional efficiencies could be gained because the Zoloft and Effexor cases involve many of the same counsel. In the alternative, if the Panel were to determine that it would not be appropriate to transfer the Effexor cases to Judge Rufe, Defendants request centralization before Judge Joel A. Pisano of the District of New Jersey based on his MDL experience and his experience presiding over other actions involving Effexor.

ARGUMENT

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

Transfer and coordination of the related Effexor 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). Defendants agree that these criteria are satisfied here. *See, e.g., In re Zoloft (Sertraline Hydrochloride) Products Liab. Litig.*, 856 F. Supp. 2d 1347, 1348 (J.P.M.L. 2012) (finding that centralization will "conserve the resources of the parties, their counsel and the judiciary").

II. The Actions Should Be Centralized in the Eastern District of Pennsylvania Before Judge Rufe

Defendants also agree that centralization of the Effexor actions before Judge Rufe in the Eastern District of Pennsylvania is appropriate. Judge Rufe is gaining expertise from the Zoloft

MDL in some of the same issues that have been raised in this litigation, including substantive issues involving anti-depressants and birth defects and jurisdictional issues such as the fraudulent joinder of McKesson. To date, the parties in the Zoloft MDL have worked closely with Judge Rufe and a recently assigned discovery master to adopt an organized and realistic schedule for discovery and other pretrial proceedings, including case-specific discovery in an initial discovery group of 25 cases and the filing of expert disclosures and motions over the next nine months. Defendants believe that similar efforts could proceed on a separate track in the Effexor litigation, with the potential to gain efficiencies and conserve resources in both litigations. Therefore, to the extent that Judge Rufe's schedule and docket can accommodate the Effexor MDL, Defendants agree that Judge Rufe would be an excellent choice.

Alternatively, to the extent that the Panel determines that it would not be appropriate to transfer the Effexor actions to Judge Rufe, Defendants would suggest centralization before Judge Joel A. Pisano of the District of New Jersey. Judge Pisano has significant relevant MDL experience as the judge presiding over MDL No. 2243, *In re Fosamax Products Liability Litigation (II)*, a personal injury pharmaceutical litigation with over 1,000 actions that has now advanced through discovery and expert phases to the trial stage. In addition, Judge Pisano has experience with respect to complex Effexor litigation. Specifically, Judge Pisano has presided over Effexor patent litigation and continues to preside over Effexor antitrust litigation, including consolidated class and individual actions that remain pending. While the claims in such litigation differ from the cases that are the subject of the instant motion, the familiarity that Judge Pisano has gained and will gain with the product, its history, and the Defendants has the potential to create synergies with the Effexor products litigation. In addition, Judge Pisano's location in Trenton, New Jersey would be convenient for the parties. It is readily accessible by air and train transportation and is nearly equidistant, and less than an hour away, from both New York City, where Pfizer has its main offices, and Wyeth's location in Collegeville, Pennsylvania.

CONCLUSION

For the foregoing reasons, Defendants support the *Boyer* plaintiffs' request for an Order transferring the Effexor actions to Judge Rufe in the Eastern District of Pennsylvania for pretrial coordination and granting such other and further relief as the Panel may deem just and proper. If the Panel determines not to transfer the Effexor actions to Judge Rufe, Defendants respectfully request that the Panel consider transfer to Judge Pisano in the District of New Jersey based on his relevant experience and expertise.

Dated: New York, New York
May 21, 2013

Respectfully submitted,

/s/ Mark S. Cheffo
Mark S. Cheffo
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
markcheffo@quinnemanuel.com
Telephone: (212) 849-7000
Facsimile: (212) 849-7100
Attorneys for Defendants Pfizer Inc., Pfizer International LLC, Wyeth LLC, and Wyeth Pharmaceuticals Inc.