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BEFORE THE JUDICIAL PANEL

ON MULTIDISTRICT LITIGATION

IN RE: ESSURE PERMANENT BIRTH CONTROL LITIGATION

MDL No. ____

BRIEF IN SUPPORT OF PLAINTIFFS' JOINT MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

ORAL ARGUMENT REQUESTED

INTRODUCTION AND SUMMARY OF ARGUMENT

Recently a number of lawsuits have been filed, and many more are anticipated to be filed against Defendants Bayer Corporation, Bayer HealthCare, LLC, Bayer Essure, Inc., Conceptus, Inc., dba Bayer Essure, Inc., Bayer Healthcare Pharmaceuticals, and Bayer A.G. ("Defendants") in the coming days and weeks.[1] Each of these lawsuits arise from injuries sustained by Plaintiffs as a result of being implanted with the defective and unreasonably dangerous permanent birth control device Essure®.

Plaintiffs in each of these lawsuits seek redress for physical injuries, pain and suffering, and, in most cases, the need for subsequent surgical intervention to remove Essure® from Plaintiffs' bodies. Plaintiffs assert claims for damages caused by Defendants' breach of express warranties, misrepresentations, and negligence, among other causes of action. These lawsuits all arise from the same medical device, assert the same or similar claims, and cause the same or similar injuries. As a result, these actions should be consolidated and coordinated for pretrial proceedings.

[1] A Schedule of Actions is filed concurrently with this Brief.

In bringing this Motion, Plaintiffs respectfully request that these cases be transferred to the Eastern District of Pennsylvania, and assigned to the Honorable Gerald A. McHugh, who is currently overseeing *Bailey (Yolonda), et al v. Bayer Corp, et al*, Case No. 2:16-cv-02154, *Bailey (Bradley), et al v. Bayer Corp., et al*, Case No. 2:16-cv-02166, and *Tulgetske, et al v. Bayer Corp., et al*, Case No. 2:16-cv-03049. Judge McHugh has the experience necessary to manage proceedings of this scope involving defective medical devices.

FACTUAL BACKGROUND

Each of these lawsuits arise from injuries Plaintiffs sustained after being implanted with Essure®, which is a permanent birth control device that is manufactured and distributed by Defendants. As part of its placement procedure, Essure® is threaded through the vaginal canal and inserted into a patient's fallopian tubes. As a permanent birth control method, Essure® is intended to cause bilateral occlusion of the patient's fallopian tubes, which creates a blockage that serves to prevent sperm from fertilizing the patient's eggs. Essure® consists of an introducer, delivery catheter, and two micro-inserts. The Essure® micro-inserts are small spring-like devices composed of a stainless steel inner coil, a nickel titanium (Nitinol) expanding outer coil, and polyethylene terephthalate (PET) fibers, which are wound in and around the inner coil.

The Moving Parties' Complaints, which are attached to the Schedule of Actions, allege that Essure® is defective and unreasonably dangerous and as a result has caused patients that have been implanted with Essure® to suffer a variety of severe side effects and complications. Plaintiffs have sustained physical injuries, including but not limited to, severe abdominal pain, severe menstrual pain, severe back pain, weight fluctuations, migraines, depression, fatigue, boils, rashes, autoimmune disorders, pain during intercourse, irregular menstrual periods, uterine

fibroids, complex ovarian cysts, dysfunctional uterine bleeding, ectopic pregnancy, unexpected pregnancy, and blood clotting. As a result of these injuries, many Plaintiffs have been forced to undergo additional surgical procedures in order to have their Essure® devices removed, including but not limited to, surgical removal of Essure®, tubal ligation, cystectomy, hysterectomy, endometrial ablation, and dilation and curettage, all with the attendant risks of complications from such surgical intervention.

Plaintiffs allege that for years Defendants have known about the harmful effects of Essure® and have actively concealed such information from the FDA, Plaintiffs, and their respective implanting physicians. Further, Plaintiffs allege that Defendants failed to notify the FDA of several adverse reactions caused by Essure®, including several incidents of perforation, pregnancies, fetal deaths, and plaintiff deaths. Plaintiffs claim that Defendants erroneously used non-conforming material in manufacturing Essure®, manufactured Essure® for years at an unlicensed manufacturing facility, and failed to notify the FDA of their internal records of over 16,000 complaints regarding Essure®. Plaintiffs also allege that Defendants failed to adequately train implanting physicians on how to implant the device and created an unreasonable distribution plan, aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiffs' safety and well-being.

In September 2015, the FDA convened an Advisory Committee Meeting to discuss the many complaints about Essure®. This meeting resulted in the FDA announcing in February 2016, that Bayer had to conduct additional post-market surveillance and draft an updated boxed warning as well as a Patient Decision Checklist to ensure that future patients understand the risks involved with undergoing the Essure® procedure.

In November 2015, Representative Michael Fitzpatrick of the 8th District of Pennsylvania introduced the E-Free Act, H.R. 3920, which would require the FDA to withdraw its approval of Essure®. Further, in February 2016, Representative Fitzpatrick drafted a letter to Jeffrey Shuren, of the FDA, in which he reported that "FDA's public materials related to Essure® have cited five reports of fetal deaths," and his office was in receipt of an independent report counting 303 fetal deaths.

As of July 14, 2016, there have been 30 lawsuits filed on behalf of over 1,000 Plaintiffs in 5 districts across the country, and even more expected to be filed in the near future. These lawsuits have been filed in the following districts: Eastern District of Pennsylvania, Northern District of California, District of Connecticut, Eastern District of Missouri, and District of Idaho. Considering that hundreds of thousands of Essure® procedures have been performed in this country, Plaintiffs expect thousands more lawsuits to follow in additional districts.

ARGUMENT

A. STANDARD FOR COORDINATION UNDER § 1407

The main purpose of Multidistrict litigation is "to 'promote the just and efficient conduct' of 'civil actions involving one or more common questions of fact" that are pending in different districts.'" *In re Phenylepropanolamine (PPA) Products Liability Litigation*, 460 F.3d 1217, 1229 (9th Cir. 2006) (quoting 28 U.S.C. § 1407(a)). In determining whether coordination under section 1407 is warranted the Judicial Panel on Multidistrict Litigation (the "Panel") considers whether it is necessary in order to "eliminate duplicative discovery, avoid inconsistent pretrial rules, and conserve the resources of the parties, their counsel, and the judiciary." *In re Vioxx*

Products Liability Litigation, 360 F.Supp.2d 1352, 1353 (J.P.M.L. 2005); Multidistrict Litigation Manual § 5.16 (noting that factors considered by the Panel also include the progress of discovery, docket conditions, familiarity of the transferee judge with the relevant issues, and the size of litigation).

With that said, promoting "the just and efficient conduct of such actions," however, is not such an easy task, when, as here, MDLs involve many independent actions brought by hundreds of plaintiffs. *In re PPA*, 460 F.3d at 1231. "[M]ultidistrict litigation assumes cooperation by counsel and macro-, rather than micro-, judicial management because otherwise, it would be an impossible task for a single district judge to accomplish." *Id.* In order for this to be accomplished, a district court must be afforded "broad discretion to administer the [MDL] proceeding as a whole," because "multidistrict litigation is a special breed of complex litigation where the whole is bigger than the sum of its parts." *Id.* at 1232. If this indeed is accomplished and these cases are coordinated, they will be able to proceed toward a resolution with less burden and expense overall than if each case were litigated through pretrial individually.

B. COORDINATION UNDER § 1407 IS APPROPRIATE IN THIS MATTER

Transfer and consolidation of these cases to the Eastern District of Pennsylvania, 24 of which are already pending in the District, is appropriate because these cases (a) involves common questions of fact; (b) will promote the just and efficient conduct of this litigation; (c) will eliminate duplicative discovery; (d) will prevent inconsistent pretrial rulings; and (5) will conserve judicial resources.

1. This Litigation Involves Common Questions of Fact

The defective and unreasonably dangerous nature of Essure® and the FDA's recent inquiry into the disproportionate number of adverse event reports it has received as to injuries

caused by the device has given rise to a plethora of "civil actions involving one or more common questions of fact." 28 U.S.C. § 1407(a). The common questions of fact involved in this litigation include the following:

a) Whether and to what extent Plaintiffs' injuries were caused by Essure®, including, but not limited to, severe abdominal pain, severe menstrual pain, severe back pain, heavy bleeding, weight fluctuations, migraines, depression, fatigue, boils, rashes, autoimmune disorders, pain during intercourse, and irregular menstrual periods;

b) Whether and to what extent Plaintiffs' need for further surgical intervention, including surgical removal of the device, was caused by Essure®;

c) Whether Defendants defectively designed and/or manufactured Essure®;

d) When Defendants first became aware of the possible connection between Essure® and the physical injuries suffered by patients who were implanted with the device;

e) Whether, and for how long, Defendants negligently and/or actively concealed knowledge of the connection between Essure® and physical injuries from Plaintiffs, implanting physicians and the FDA;

f) Whether Defendants failed to comply with the conditions of its premarket approval as required by the FDA;

g) Whether Essure® is an adulterated medical device;

h) Whether in independently undertaking a duty to train physicians to perform the Essure® procedure Defendants negligently failed to adequately train implanting physicians as to safely implanting and removing the device;

i) Whether in independently undertaking a duty to train implanting physicians Defendants devised an unreasonably dangerous distribution plan, which was aimed at capitalizing on the birth control market at the expense of patients' safety and well-being;

j) Whether Defendants failed to provide adequate warnings as to the safety and effectiveness of Essure®;

k) Whether Defendants breached their express warranties to Plaintiffs as to the safety and effectiveness of Essure®;

l) Whether Defendants falsely and misleadingly advertised Essure®, including but not limited to, inaccurately reporting clinical trial results in brochures and other advertising materials;

m) The nature and extent of damages suffered by Plaintiffs as a result of being implanted with Essure®.[2]

There exists many common questions of fact in these cases. Plaintiffs acknowledge that while these cases may have individualized fact issues such as injuries sustained, such issues should not impede the consolidation and coordination of this litigation as section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization. *In re: Darvocet, Darvon and Propoxyphene Products Liability Litigation*, 780 F.Supp.2d 1379, 1381 (J.P.M.L. 2011); *see also In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F.Supp.2d 1376, 1378 (J.P.M.L. 2010).

If these cases are not coordinated then individual pretrial proceedings in each of these cases will continue to substantially increase the costs of litigation to all parties, create significant risk of inconsistent pretrial rulings on these common questions of fact and drain already precious judicial resources. Accordingly, the common questions of fact in these cases warrant coordination.

2. Coordination Will Eliminate Duplicative Discovery

Given the substantially similar nature of each of these cases in that they assert many of the same causes of action, regarding similar injuries resulting from use of the same device, it is more than likely that the parties will face duplicative discovery if this litigation is not

[2] Indeed the Panel may decide that common and individual discovery tracks are necessary in this case, as it has previously decided in other product liability cases. *See, e.g., In re Darvocet*, 780 F.Supp. at 1381; *In re: Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, 655 F.Supp.2d 1343 (J.P.M.L. 2009).

coordinated. *See Resource Exploration Inc. Securities Litigation*, 483 F.Supp. 817, 821 (J.P.M.L. 1980) (reasoning that one of the goals of Section 1407 is to avoid duplicative discovery). Here, Plaintiffs in each of these cases will most likely seek the same documents from the same Defendants and depose the same witnesses. Additionally, Defendants will certainly raise the same objections, assert the same privileges, and seek the same protective orders in each of these actions. Coordination of this litigation will allow the parties to avoid unnecessarily duplicative discovery.

3. Coordination Will Prevent Inconsistent Pretrial Rulings

As discussed above, it is likely that Defendants will assert the same objections, raise the same privileges, and seek the same protective orders in response to Plaintiffs' discovery requests in these cases. Given the substantial risk of issue and claim preclusion in these cases, the Panel considers the effects that inconsistent pretrial rulings can have when presented with a motion made pursuant to 28 U.S.C. § 1407. *See In re: Nexium (Esomeprazole) Products Liability Litigation*, 908 F.Supp.2d 1362, 1364 (J.P.M.L. 2012). Coordination of this litigation will prevent inconsistent pretrial rulings.

The coordination and consolidation of these cases will promote the just and efficient conduct of theses common questions of fact by avoiding duplicative discovery, and preventing inconsistent pretrial rulings.

C. THIS LITIGATION SHOULD BE CENTRALIZED IN THE EASTERN DISTRICT OF PENNSYLVANIA

While some cases are currently pending in other Districts, the vast majority of these cases have been filed in the Eastern District of Pennsylvania. Currently, 24 of 30 cases are currently

pending in the Eastern District of Pennsylvania. Additionally, the Eastern District of Pennsylvania is experienced in handling mass tort multidistrict litigation, specifically, in handling multidistrict litigation of medical device and pharmaceutical cases.

For example, the Eastern District of Pennsylvania has recently presided over the *In re: Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liability Litigation*, *In re: Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, *In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation*, and *In re: Avandia Marketing, Sales Practices and Product Liability Litigation*, among others.

There are currently 15 MDL's pending in the Eastern District of Pennsylvania, with many of those actions winding down, and none pending in front of the Honorable Gerald A. McHugh. Judge McHugh took the bench in March 2014. Prior to becoming a district judge he handled complex civil litigation cases for over 30 years. Judge McHugh is eminently qualified to handle the coordination and consolidation of the Essure cases.

In addition to the Eastern District being the venue where the first and most Essure cases have been filed, Defendant Bayer Corporation has its principal place of business in Pittsburgh, which is located in the Western District of Pennsylvania. As such, much of the pertinent evidence, relevant documents and corporate officers are likely located in or near this District. Holding pretrial proceedings in the Eastern District of Pennsylvania will serve the convenience of the parties as well as conserve judicial resources.

CONCLUSION

For the foregoing reasons, Plaintiffs' Joint Motion for Transfer of Actions to the Eastern District of Pennsylvania Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial

Proceedings should be granted. Additionally, Plaintiffs respectfully request that all related actions and any subsequently filed actions against Defendants containing similar causes of action be transferred to the United States District Court for the Eastern District of Pennsylvania, and assigned to Judge Gerald McHugh.

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