BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: DEPO-PROVERA (DEPOT MEDROXYPROGESTERONE ACETATE) PRODUCTS LIABILITY LITIGATION	**MDL No. 3140**

RESPONSE OF DEFENDANTS PFIZER INC., PHARMACIA & UPJOHN CO. LLC, AND PHARMACIA LLC TO MOTIONS FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

INTRODUCTION

For 65 years, Depo-Provera has been an FDA-approved medication, used by millions of patients worldwide, for treatment of cancers and other serious diseases and for contraception. This litigation pits those decades of safe and effective use against a small fraction of patients in two recently published studies who developed meningioma at some point after taking the medication. Dozens of lawsuits have been filed, with more to follow.

Pfizer agrees that these cases should be centralized into an MDL; the question is the location of the transferee court. The litigation is almost certain to be complex and hard-fought—Pfizer (the parent company of Pharmacia and Pharmacia & Upjohn) and the other defendants will vigorously defend the medicine's safety and efficacy. Under these circumstances, the Southern District of New York is the most appropriate forum for centralization. Pfizer is the only defendant that is named in every case, and as the innovator of the product, appears to be the main defendant in the litigation. Pfizer is headquartered in New York City, and at least one other defendant is close by. The Panel should therefore centralize these cases in the Southern District of New York before one of that District's experienced MDL judges.

FACTUAL BACKGROUND

The Food and Drug Administration ("FDA") first approved Depo-Provera for use in the United States to treat endometrial and renal cancers in 1959, and its list of FDA-approved therapeutic uses has only expanded over time. In 1992, FDA approved Depo-Provera for the prevention of pregnancy. Over these many decades, the medication has been used by millions of women in the United States and in other countries around the world. Depo-Provera contains a progestin called medroxyprogesterone acetate or "MPA," which is a derivative of the naturally occurring hormone progesterone. Progestin prevents pregnancy by stopping ovulation and by

making fertilization less likely to occur. In its injectable form, Depo-Provera is administered every three months by a healthcare provider and, when used as directed, is more than 99% effective at preventing pregnancy.

Depo-Provera remains an important treatment option for women seeking to manage their fertility. Because Depo-Provera does not contain estrogen—only progestin—it is an appropriate contraceptive choice for postpartum and lactating women, as well as those who cannot use estrogen, like those with increased thromboembolism risk, women with cardiovascular or liver disease, certain migraine sufferers, and women over age 35 who smoke.[1] Many women prefer Depo-Provera because of the convenience of once-quarterly injections.

Like all medications, Depo-Provera carries a risk of certain side effects. Common side effects include irregular or missed periods, weight gain, headaches, weakness, and fatigue.[2] Since 2004, Depo-Provera has carried FDA's most prominent warning, a boxed warning relating to the potential for loss of bone mineral density in some patients. The boxed warning advises healthcare practitioners against long-term use of more than two years, "unless other options are considered inadequate."[3]

In 2023, Pfizer learned of a forthcoming observational study in France that suggested an increased risk of meningioma in patients using various contraceptives, including Depo-Provera.[4]

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[1] Kaunitz AM. Injectable depot medroxyprogesterone acetate contraception: an update for U.S. clinicians. Int J Fertil Womens Med. 1998 Mar-Apr;43(2):73-83, available at https://pubmed.ncbi.nlm.nih.gov/9609206/ (last visited Dec. 23, 2024).

[2] *See* Depo-Provera CI (medroxyprogesterone acetate) Label, dated July 11, 2024, available at labeling.pfizer.com/Show Labeling.aspx?id=522.

[3] *Id.* at 1 (*see* WARNING: LOSS OF BONE MINERAL DENSITY).

[4] Roland M, Neumann A, Hoisnard L, Duranteau L, Froelich S, Zureik M, Weill A. Use of progestogens and the risk of intracranial meningioma: national case-control study. *BMJ*

That study of 18,000 women included only 9 who had taken Depo-Provera and at some point later developed meningioma. In a response to the study's publisher, researchers at Albert Einstein College of Medicine in New York urged "caution" in interpreting the study's finding, advising that "[t]o draw a conclusion of disease causation from the observation of nine patients is premature."[5] They further warned that "using such decisive language is potentially more detrimental to the ability of patients to access contraception and providers to confidently prescribe."[6] Just last month, the premier medical association of obstetrician-gynecologists, the American College of Obstetricians and Gynecologists (ACOG), addressed the issue in its *Guide for Ob-Gyns for Patient Counseling on Birth Control Injection and Meningioma*.[7] ACOG noted that the French study had a number of limitations, and similarly advised its physician members that "[i]t is important to interpret the results of this study with caution . . . because this study has several limitations and warrants further research."[8]

Following a review of this new study and all available data, and as a matter of caution, Pfizer submitted proposed Depo-Provera label changes to regulators in both the United States

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2024;384:e078078, available at https://www.bmj.com/content/384/bmj-2023-078078 (last visited Dec. 23, 2024).

[5] Smith EM, Atrio JM, Pesci SE. Rapid Response: Re: Use of progestogens and the risk of intracranial meningioma: national case-control study. *BMJ* 2024;384:e078078, available at https://www.bmj.com/content/384/bmj-2023-078078/rr-2 (last visited Dec. 23, 2024).

[6] *Id.*

[7] ACOG, *Guide for Ob-Gyns for Patient Counseling on Birth Control Injection and Meningioma* (November 20, 2024), available at https://www.acog.org/news/news-articles/2024/11/guide-for-ob-gyns-for-patient-counseling-on-birth-control-injection-and-meningioma (last visited Dec. 23, 2024).

[8] *Id.*

(FDA) and European Union (European Medicines Agency, "EMA"). The proposed changes included language stating that meningioma had been reported following long-term use of MPA-containing products, and that patients should stop using Depo-Provera if they suspected meningioma. On November 1, 2024, FDA rejected Pfizer's requested label change in a Complete Response Letter. FDA concluded that, "[t]he findings of the available observational studies alone do not support the addition of a warning on Meningioma risk to medroxyprogesterone acetate (MPA)-containing products." EMA, operating under a different regulatory framework, provided recommended labeling changes to certain MPA-containing products, including-Depo Provera, in September 2024.

These recent developments are expected to raise important and threshold federal preemption and general causation issues in any prospective MDL.

LITIGATION BACKGROUND

I. Filings to Date.

Since October 1, 2024 (including after the initial MDL petition was filed on November 26), plaintiffs have filed at least 47 actions in 15 U.S. District Courts across the country alleging development of meningioma associated with Depo-Provera. These actions involve 57 plaintiffs (including loss of consortium plaintiffs), 6 Defendants, and 23 sets of plaintiffs' counsel. Most of the initial filings were in federal courts in California, but there are now 11 other jurisdictions scattered across the country where cases have been filed, and patients nationwide used Depo-Provera.

II. The Parties.

The 57 Plaintiffs with currently-filed federal cases reside in nine states: California, Florida, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Jersey, and Pennsylvania.

Plaintiffs' counsel are scattered throughout the country. Counsel for the plaintiffs who filed the first two petitions, Weitz & Luxenberg and Anapol Weiss, are headquartered in New York City and Philadelphia, respectively. These two firms collectively brought 16 of the 47 pending cases.

Plaintiffs have named Pfizer as a defendant in all 47 actions. Pfizer, through its subsidiaries Pharmacia and Pharmacia & Upjohn, is the innovator, manufacturer, and distributor of branded Depo-Provera. Pfizer and Pharmacia are headquartered in New York City, and Pharmacia & Upjohn is located in Kalamazoo, Michigan. Lead counsel for the Pfizer and Pharmacia entities are located in New York and Washington, D.C.

All remaining defendants are in the eastern part of the country. Defendant Greenstone, LLC sold the authorized generic version of Depo-Provera. It is currently headquartered in Morgantown, West Virginia, but during the time it sold the authorized generic version of Depo-Provera, it was located in New Jersey. Its counsel is in Pittsburgh, Pennsylvania. Defendant Prasco, LLC currently sells the authorized generic version of Depo-Provera. It is located in Mason, Ohio and its counsel is in Cincinnati, Ohio. While it is unclear if Defendant Viatris, Inc. is even a proper defendant, it is located in Canonsburg, Pennsylvania with its counsel located in Pittsburgh.

In short, all defendants and all key witnesses central to all cases are in the eastern part of the country, thousands of miles from California, where Moving Plaintiffs' counsel have chosen to file their first bolus of cases.

ARGUMENT

The Pfizer Defendants agree that these cases should be centralized, but disagree with Moving Plaintiffs' assertion that the Northern District of California, Central District of California, or District of Massachusetts are the most appropriate venues for transfer. The

Southern District of New York is the most appropriate transfer venue based on convenience to the major parties and counsel and the District's capacity and expertise to handle this complex products liability litigation. The Southern District of New York is the location of Pfizer's headquarters—and therefore key witnesses and evidence—and is convenient to lead counsel for both Plaintiffs and Defendants, who are largely on the east coast. It is home to experienced judges who have presided over MDLs related to female contraceptive products dealing with similar questions of fact and law. Because the Northern District of California, Central District of California, and the District of Massachusetts lack any meaningful tie to the litigation or its major parties, these districts would undermine the convenience and efficiency of coordinated litigation.

I. The Actions Should be Centralized.

The Pfizer Defendants agree that these cases should be centralized for pretrial proceedings. Centralization is appropriate where there are common questions of fact pending in different districts and the coordination of pretrial proceedings will serve the convenience of the parties and witnesses and promote the just and efficient conduct of litigation. 28 U.S.C. § 1407(a). The Pfizer Defendants agree those criteria are met here.

II. The Southern District of New York is the Most Appropriate Venue for Transfer.

This will be a nationwide litigation, which will include (as is already true) cases filed by plaintiffs from states across the country, whose home federal courts are scattered across those states. Nothing about the plaintiffs, their claims, or their alleged injuries is or will be tied to one specific geographic location. In these circumstances, the related cases should be centralized in a court that best serves the convenience and efficiency of the litigation and has the capacity and expertise to efficiently manage claims concerning this important woman's health medication.

Because Pfizer, the inventor and long-time manufacturer of Depo-Provera, is located in New York City, the Southern District of New York is the most appropriate transferee court.

A. The Southern District of New York is the Most Convenient Venue.

Pfizer (and its predecessors) discovered Depo-Provera, conducted clinical trials of the product, and manufactured it for over 30 years. Pfizer (and in some instances, its subsidiaries) is the only defendant named in every related complaint. It is headquartered in New York City, making the Southern District of New York the home of many employees who will serve as key witnesses and other evidence related to Depo-Provera. Defendant Greenstone, a prior seller of the authorized generic version of Depo-Provera that is named in 35 related suits, was headquartered nearby in northern New Jersey during the events relevant to this litigation. *See In Re: Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1382 (J.P.M.L. 2011) (granting transfer to the district of defendant's headquarters because it was the likely location of "[r]elevant documents and witnesses"); *In Re Johnson & Johnson Talcum Powder*, 220 F. Supp. 3d 1356, 1359 (J.P.M.L. 2016) (granting transfer to the District of New Jersey in part because defendant was headquartered in New Jersey and relevant witnesses and evidence were likely located there); *In re: Biomet Magnum Hip Implant Prods. Liab. Litig.*, 896 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (transferring to Northern District of Indiana despite no case being filed there yet because the defendant company and many of the relevant documents and witnesses were located nearby). Transfer to the Southern District of New York would reduce (if not eliminate) the need for lengthy travel for witnesses and evidence that will be relevant to all related cases.

The Weitz & Luxenberg Plaintiffs' petition claims that discovery related to the merger between Defendants Upjohn, Mylan, and Greenstone to form Defendant Viatris will be

important. Weitz Pls.' MDL Pet. at 12-13. The Pfizer Defendants do not believe that is likely to be true, and Moving Plaintiffs identify no specific reason to believe as much. But even if it is true, like Pfizer and Greenstone, Upjohn, Mylan, and Viatris are located in the eastern part of the country—in Pennsylvania and Michigan—making the Southern District of New York a sensible location.

The Southern District of New York would also be convenient for lead counsel for both Plaintiffs and Defendants. Counsel for the Moving Plaintiffs named in the first two petitions, Weitz & Luxenberg P.C., which has filed many of the lawsuits to date, and Anapol Weiss, are headquartered in New York City and Philadelphia, respectively. Lead counsel for Pfizer are located in Washington, D.C. and New York City. New York City has three major airports nearby and a major train hub with plenty of public transit options, making it accessible to parties throughout the country and internationally.

B. The Southern District of New York has the Capacity and Expertise to Handle this Litigation.

The Southern District of New York has multiple judges with experience in presiding over large, pharmaceutical products MDLs. Judges Seibel and Engelmayer each presided over MDLs related to Mirena, another female contraceptive product with a synthetic hormone, and the Southern District was chosen as the transferee court in those MDLs in part because the defendant was headquartered in nearby New Jersey. *In re Mirena IUD Prods. Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013) (selecting the Southern District of New York as the transferee district for Mirena litigation based in part on proximity to defendant's corporate headquarters in New York, overall accessibility of the district, and because Judge Seibel is "an experienced transferee judge"); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 249 F. Supp. 3d 1357, 1361 (J.P.M.L. 2017) (selecting the Southern District of New York as the

transferee district for Mirena litigation based in part on its proximity to defendant's corporate headquarters in New Jersey, overall geographic convenience, and because Judge Engelmayer is "an experienced transferee judge with the willingness and ability to manage this litigation"). The judges presiding over the Mirena MDLs had to navigate issues similar to those in Plaintiffs' claims, including whether there was reliable evidence under Rule 702 of general causation between the contraceptive and alleged injuries, the background science, and the product's extensive labeling and regulatory history. *In re Mirena IUD*, 938 F. Supp at 1357-58; *In re Mirena IUS (No. II)*, 249 F. Supp. 3d at 1361. Experience navigating these related issues makes Judges Seibel or Engelmayer well equipped to oversee this litigation. *See, e.g.*, *In re Bard Implanted Port Catheter Prods. Liab. Litig.*, 698 F. Supp. 3d 1381, 1383 (J.P.M.L. 2023) (selecting a judge to preside over an MDL in part because of his experience presiding over an MDL involving a different medical device manufactured by defendant); *In re: Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378, 1381 (J.P.M.L. 2015) (selecting a judge to preside over an MDL in part because of his familiarity with the scientific and regulatory background gained from presiding over a related MDL).

III. In the Alternative, the Litigation Should be Transferred to a Judge with Experience Overseeing and Considering Early Dispositive Issues in Pharmaceutical Products MDLs.

Because (other than New York) there is no geographic center of gravity underlying the facts in this litigation, if the Panel decides not to centralize in the Southern District of New York, Pfizer suggests a judge in any court in the eastern part of the country with experience deciding important threshold issues in a large pharmaceutical MDL. This litigation will involve substantial motions practice regarding threshold legal issues common in pharmaceutical products MDLs, including preemption (as noted above, the FDA rejected Pfizer's proposed precautionary

warning regarding meningioma), Rule 702/*Daubert* general causation challenges, and the viability of so-called "innovator liability" claims. The Panel at times centralizes large MDLs in courts or before judges with no currently-filed cases pending before them, *see In re Aqueous Film-Forming Foams Prods. Liab. Litig.*, 357 F. Supp. 3d 1391, 1396 (J.P.M.L. 2018), and there is no reason why that could not occur here. The efficiency and effective resolution of the litigation would be well served by placing it in front of a judge with experience managing a similarly expansive and complex pharmaceutical MDL and, particularly, one with experience deciding threshold issues related to preemption, the reliability of scientific evidence, and general causation.

IV. The Northern District of California, Central District of California, and District of Massachusetts are Not the Most Appropriate Venues.

Neither the Northern or Central Districts of California nor the District of Massachusetts has any genuine connection to this litigation and its underlying facts, apart from the fact that Moving Plaintiffs' counsel apparently prefer the California courts and therefore have artificially filed the most cases there (for now).

A. The Northern District of California, Central District of California, and District of Massachusetts Would be Less Convenient for Litigation.

Transfer to the Northern or Central Districts of California would be inconvenient for major parties to the litigation. For New York-based Pfizer, the defendant with the most significant role in the litigation, transfer to California would require significant cross-country travel for the company's witnesses and counsel. Further, the Northern District of California is already replete with MDLs; the district has eighteen pending MDLs—more than any other district in the country. *See MDL Statistics Report – Distribution of MDL Dockets by District,* JUDICIAL PANEL ON MULTIDISTRICT LITIGATION (DEC. 2, 2024).

That most of the cases Plaintiffs' counsel have filed so far (31 out of 47) are pending in one of the California federal courts is irrelevant. Patients from across the country have used Depo-Provera for decades; there is no basis to believe (as Moving Plaintiffs contend) that most of the cases that ultimately will be filed will involve California residents. Rather, as the Panel knows, plaintiffs' counsel seeking an MDL often file an initial wave of cases only (or mostly) in the jurisdiction that, for whatever strategic reasons, they prefer to have the MDL—and then argue to the Panel that the MDL should be sent to that jurisdiction because most of the current cases are pending there. That is exactly what is happening here. The Northern and Central Districts of California have no *genuine* connection to the litigation and certainly nothing like the connection of the Southern District of New York. Indeed, the Panel frequently has selected transferee districts without pending actions based on factors of convenience and judicial expertise and capacity. *See, e.g.*, *In re: Biomet M2a*, 896 F. Supp. 2d at 1340 (transferring to Northern District of Indiana despite no actions pending there because the defendant company and many of the relevant documents and witnesses were located nearby); *In re: Webvention LLC ('294) Patent Litig.*, 831 F. Supp. 2d 1366, 1367 (J.P.M.L. 2011) (transferring to District of Maryland despite no actions pending there because it was a convenient forum for the parties and had a judge "well-versed in multidistrict litigation''); *In re: GAF Elk Cross Timbers Decking Mktg., Sales Practices & Prods. Liab. Litig.*, 65 F. Supp. 3d 1407, 1408 (J.P.M.L. 2014) (transferring to the District of New Jersey despite no actions pending there because defendant headquarters and relevant documents and witness were located in the district).

The District of Massachusetts likewise lacks any connection to the litigation or the geographical location of major parties, and there is currently only one case that has been filed there. Although a recently-filed joinder claims that Pfizer has employees and facilities in

Massachusetts, there is no suggestion that any of those employees or facilities had or have any involvement with Depo-Provera. *See* Dkt. 58 at 5.

B. The Existence of Innovator Liability Claims Does Not Make These Jurisdictions More Appropriate.

Moving Plaintiffs argue that because California and Massachusetts are the only states that recognize an "innovator liability" theory – the minority legal theory under which brand-name manufacturers of medications can be held liable for failure-to-warn claims of patients who used only generic versions of the product – these cases should be centralized in a federal court in one of those two jurisdictions. *E.g.*, Weitz Pls.' MDL Pet. at 7. This is entirely mistaken and makes no sense.

First, although MDLs centralize pretrial proceedings, the law applicable to each plaintiff's claim does not change based on the venue selected. *In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) ("When considering questions of state law . . . the [MDL] transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation"—i.e., the "transferee court must apply the 'choice-of-law rules of the states where the actions were originally filed.'"). Thus, wherever these cases are centralized, for any claims brought by individual plaintiffs, the MDL judge will apply the law that would have applied if the case were pending in the transferor court—so plaintiffs who were entitled to assert innovator liability claims under California or Massachusetts law are not prohibited from bringing such claims simply because the MDL is not pending in those jurisdictions. And judges in any district are qualified to make determinations about the application of California and Massachusetts state law; it is "within the very nature of coordinated or consolidated pretrial proceedings in multidistrict litigation for the transferee judge to be called upon to apply the law of more than one state." *In re*

Air Crash Disaster at John F. Kennedy Int'l Airport on June 24, 1975, 407 F. Supp. 244, 246-47 (J.P.M.L. 1976); *Utts v. Bristol-Myers Squibb Company*, 251 F. Supp. 3d 644, 662, 682 (S.D.N.Y. 2017) (applying California law to an MDL case in the Southern District of New York) (Cote, J.).

Second, in pharmaceutical MDLs involving branded and generic products, plaintiffs from outside California and Massachusetts often file claims and argue that because the highest courts of some states have not explicitly rejected an innovator liability theory, the MDL court should predict (under *Erie*) that the theory would be viable in these states, and allow innovator liability claims to proceed in the MDL. For that reason, an MDL judge's analysis of innovator liability claims may not be limited to California and Massachusetts law. For example, in the recent *In re Zantac* MDL, this is exactly the position plaintiffs took, and Judge Rosenberg issued an opinion reviewing the law in almost all 50 states, finding that those states do not and would not recognize innovator liability claims. *In re Zantac (Ranitidine) Products Liab. Litig.*, 510 F. Supp. 3d 1175, 1195-97 (S.D. Fla. 2020). There is nothing about potential innovator liability claims that favors transfer of this litigation to courts in California or Massachusetts.

C. The Possible Need for *Lexecon* Waivers for Trials is Hypothetical and Not a Relevant Barrier.

Moving Plaintiffs' concern that an MDL court outside of the Northern District of California would not be able to oversee a bellwether trial is unsupported, and in any event easily addressed. Weitz Pls.' MDL Pet. at 16-18.

As noted above, there is no basis to believe this litigation ultimately will be dominated by California plaintiffs. To the contrary, with a product that has been widely used by millions of patients across the country for over 30 years, there is every reason to believe that, as with all such MDLs, there will be plaintiffs from almost every state. So, a transferee court in almost any

state will be able to try some number of cases as a matter of right, without the need for *Lexecon* waivers.

Moreover, *Lexecon* waivers in personal injury products liability MDLs are commonplace—they are the norm, not the exception. *See In re Biomet M2A Magnum Hip Implant Prods. Liab. Litig.*, 357 F. Supp. 3d 1389,1390 (J.P.M.L. 2018) ("parties often waive *Lexecon* rights for a given case to remain in the transferee court for trial"). At this stage, there is no basis to believe this litigation, if it ever gets to a bellwether trial phase, would be any different.

Finally, in almost any MDL, there will be plaintiffs who reside outside the transferee district whose cases cannot be tried in the MDL court without a *Lexecon* waiver. The same will be true here, no matter where the MDL is situated. There already are many non-California plaintiffs who have filed cases, and even if some of the law firms that have filed cases to date choose to focus on California plaintiffs, that will not bind any other plaintiff or firm. And if some large number of plaintiffs in an MDL refuse to waive *Lexecon* and the transferee judge believes it is important for him or her to preside over initial bellwether trials, under 28 U.S.C. § 292(d) the transferee judge can seek an intercircuit assignment, allowing the judge to oversee litigation in a different district.

In short, whether or not *Lexecon* waivers will be required for the transferee court to preside over bellwether trials should not be a factor in deciding where this particular litigation should be centralized.

CONCLUSION

For these reasons, the related actions should be centralized for pretrial proceedings in the Southern District of New York.

Dated: December 23, 2024

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: Depo-Provera (Depot Medroxyprogesterone Acetate) Products Liability Litigation	**MDL Docket No. 3140**

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that copies of the foregoing Response of Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, and Pharmacia LLC to Motion for Transfer and Schedule of Actions were served on all parties by email or U.S. Postal Service on December 23, 2024.

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