BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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

DEFENDANT PRASCO, LLC'S RESPONSE TO MOTION FOR TRANSFER AND CONSOLIDATION UNDER 28 U.S.C. § 1407

Defendant Prasco, LLC d/b/a Prasco Laboratories ("Prasco") submits this Response to the *Schmidt* plaintiffs'[1] and *Fazio* plaintiffs'[2] Motions for Transfer and Consolidation Pursuant to 28 U.S.C. § 1407, and to the *Valencia* plaintiffs'[3] separate Response in Support (Dkt. 1, 12, 58). Prasco conditionally does not object to centralization in a Multidistrict Litigation ("MDL") of those cases involving use of Depo-Provera/Depot Medroxyprogesterone Acetate ("MPA") in which a plaintiff alleges a meningioma injury; however, for the reasons discussed below, Prasco's non-objection to MDL centralization is conditioned upon rejection of plaintiffs' proposed venues. Prasco also incorporates herein the Responses of its co-defendants Pfizer Inc., Viatris Inc., Greenstone LLC, Pharmacia & Upjohn Co. LLC, and Pharmacia LLC, to the extent those responses advocate for centralization in the Southern District of New York (with Judges Seibel or Engelmayer), but writes separately to underscore the inappropriateness of an MDL in plaintiffs'

[1] "*Schmidt* plaintiffs" means those plaintiffs represented by Weitz & Luxenberg and who filed the Motion for Transfer of Actions on November 26, 2024 (Dkt. 1).

[2] "*Fazio* plaintiffs" means those plaintiffs represented by Anapol Weiss and who filed a separate Motion for Transfer of Actions on December 10, 2024 (Dkt. 12.)

[3] "*Valencia* plaintiffs" means those plaintiffs represented by Nigh Goldenberg Raso & Vaughn, who filed a separate Interested Party Response and Memorandum in Support of Centralized Related Cases Pursuant to 28 U.S.C. § 1407 on December 23, 2024 (Dkt. 58).

proposed venues with respect to Prasco, specifically, and to argue further in support of the Southern District of New York.[4]

I. INTRODUCTION

Prasco is a distributor of authorized generic MPA pharmaceutical products pursuant to a licensing agreement with Pfizer. Prasco is located and has its operations in Mason, Ohio, a suburb of Cincinnati. Prasco does not manufacture MPA and does not hold (and never has held) the New Drug Application ("NDA") for MPA.[5] Although every named defendant, defendants' counsel, and the *Schmidt* and *Fazio* plaintiffs' counsel, are located in, headquartered in, or have offices east of the Mississippi River, and cases will be filed by plaintiffs across the country, plaintiffs suggest the requirements of MDL centralization are satisfied and advanced by transfer of all these nationwide pharmaceutical product liability cases to California.[6] Prasco disagrees.

Forcing Prasco and its counsel to litigate this MDL in California or Massachusetts would add tangible and demonstrable inefficiencies and undue burdens not present in the alternate proposed Southern District of New York venue. Moreover, as will be explained to any eventual MDL transferee judge, because Prasco does not hold the NDA for the authorized generic MPA it distributes, plaintiffs' claims against Prasco are preempted under *PLIVA v. Mensing*, 564 U.S. 604

[4] The *Valencia* plaintiffs filed a response ((Dkt. 58) on December 23, 2024, requesting transfer to the District of Massachusetts. It is unclear whether the *Schmidt* and *Fazio* plaintiffs are proposing the District of Massachusetts as a transfer venue. Prasco objects to centralization in Massachusetts and submits that District also is not an appropriate venue, for the reasons set forth herein and as set forth in co-Defendant Pfizer's response objecting to transfer to the District of Massachusetts.

[5] At present, there are 30 Depo-Provera/MPA cases, pending in nine Districts in six states, naming Prasco as a defendant. Prasco currently is aware of 17 additional Depo-Provera/MPA cases that do ***not*** name Prasco pending around the country. Prasco acknowledges that the number of cases is expected to increase, and cases are anticipated to be filed nationwide. Prasco also acknowledges and agrees with the *Schmidt* and *Fazio* plaintiffs' request that any order of this Panel centralizing cases into an MDL specifically limit those cases to plaintiffs who allege to have intracranial meningiomas. Prasco objects to the inclusion (or transfer) of cases alleging any other injuries. Prasco also disagrees with plaintiffs' description of literature purporting to identify an association between Depo-Provera/MPA use and development of meningioma. (*See, e.g.*, Dkt. 1-1, p. 11-12.)

[6] The *Valencia* plaintiffs' proposal for the District of Massachusetts also would lead to inefficiencies; no defendant, defendants' lead counsel, or the *Schmidt*, *Fazio*, or *Valencia* plaintiffs' lead counsel are located in Massachusetts.

(2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). Prasco should not be forced to litigate these cases at all, much less in a venue that is inconvenient, unnecessarily expensive, and unduly burdensome on it and its counsel. Pfizer, the NDA holder for Depo-Provera, and according to plaintiffs the "primary" defendant, is headquartered in New York; the remaining defendants (including Prasco) are headquartered nearby or a short, direct plane flight away in the same time zone. Thus, the Southern District of New York is undeniably more convenient, accessible, and economical for defendants, defendants' counsel, and plaintiffs' counsel to reach. The goals of MDL centralization would not be advanced by transfer of cases to California or Massachusetts.

Prasco's non-objection to centralization of these cases in an MDL therefore is conditioned upon transfer to a venue that does not *itself* make this purported nationwide litigation *more* expensive and burdensome and *less* convenient, efficient, and cognizant of any purported common issues for Prasco. As explained in greater detail below, if the Panel is inclined to centralize an MDL for these cases, it should do so in the Southern District of New York with Judge Seibel or Judge Engelmayer.

II. FACTUAL BACKGROUND

The U.S. Food and Drug Administration ("FDA") first approved Depo-Provera – the brand name version of the authorized generic MPA product Prasco distributes – for use as a contraceptive in 1992. (*See, e.g.*, *Schmidt v. Pfizer Inc., et al.*, No. 3:24-cv-06875 (N.D. Cal.), Dkt. 25, ¶ 75 ("*Schmidt* Complt.").[7]) Depo-Provera is a 150 mg/mL dosage of MPA injected intramuscularly into a patient every three months. (*Id.*, ¶ 77.) Pfizer holds the NDA for Depo-Provera. (*Id.*, ¶ 24.) In contrast, Prasco has never owned the NDA for Depo-Provera; it has never owned an

[7] Prasco cites only to the *Schmidt* amended complaint for ease of reference. There is substantial overlap in the factual allegations in each Depo-Provera/MPA complaint, including identical language.

Abbreviated New Drug Application ("ANDA") for generic MPA; and it has never owned an NDA for the authorized generic MPA. Prasco does not manufacture, or perform any manufacturing activities with respect to, MPA, and, as plaintiffs themselves allege in their complaints, Prasco simply distributes MPA authorized generic products that are manufactured, labeled, and packaged by Pfizer pursuant to Pfizer's NDA. (*Id.*, ¶¶ 35, 37.)[8] Prasco also does not hold any NDA or ANDA for, and does not have a licensing agreement to distribute, any other dosage or form of injectable MPA, including the Depo-SubQ Provera 104 drug that plaintiffs allege should have been sold or distributed in lieu of Depo-Provera/MPA. (*See, e.g.*, *id.*, ¶ 121.)

Prasco's involvement in the sale and distribution of MPA authorized generic product began no earlier than November 2020. On October 30, 2020, to address potential anticompetitive effects of a proposed merger between Pfizer and other entities, the U.S. Federal Trade Commission ("FTC") ordered Pfizer to grant an authorized generic license to Prasco because doing so would introduce a ***new*** competitor (Prasco) into the marketplace.[9] Despite this publicly-available information, various plaintiffs (and their counsel) continue naming Prasco as a defendant in cases where a plaintiff's alleged use of authorized generic MPA ended before November 2020.[10] Indeed,

[8] To the extent plaintiffs' Motion here contains statements that "Defendants" manufactured the products at issue here, those statements are demonstrably false; Prasco has never manufactured any of those products. Additionally, because Prasco is not the NDA holder of the authorized generic MPA it distributes, the label on that product must be the same as the brand-name Depo-Provera label. *See Mensing* 564 U.S. at 618 ("Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.").

[9] *FTC Imposes Conditions on Combination of Pfizer Inc.'s Upjohn and Mylan N.V.*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/news/press-releases/2020/10/ftc-imposes-conditions-combination-pfizer-incs-upjohn-mylan-nv (Oct. 30, 2020). Plaintiffs have alleged Prasco is a Pfizer "affiliate." This is not true. A corporate "affiliate" means a "corporation that is related to another corporation by shareholdings or other means of control; a subsidiary, parent, or sibling corporation." *Affiliate*, Black's Law Dictionary 69 (10th ed. 2014). Prasco is not related to Pfizer through shareholdings or any means of control. Prasco is an independent, third party business entity that simply has a contractual relationship with Pfizer to distribute and sell MPA.

[10] Prasco does not concede that product use after November 2020 necessarily implicates product distributed by Prasco.

as of the filing of this Response, approximately one quarter of the Depo-Provera/MPA cases filed against it have no merit based on alleged dates of product use alone.

It is a well-known problem in MDLs that defendants are named in cases without identification of that defendant's product and, as a result, MDL defendants often are saddled with numerous lawsuits they fundamentally do not belong in, and they incur significant time and expense to extricate themselves from those lawsuits.[11] For this reason, the Panel should, as part of any coordination order, include a directive that Prasco not be named as a defendant where the plaintiff's alleged product use ended before November 2020. Prasco respectfully submits this is necessary and appropriate to place guardrails over the improper naming of Prasco in potentially hundreds (or even thousands) of transferred cases for which there is no possibility that the plaintiff used a product distributed by Prasco.

III. ARGUMENT

A. While Prasco Should Not Be an MDL Defendant, It Recognizes the Efficiencies of MDL Coordination and *Conditionally* Does Not Object to Coordination

Because Prasco does not hold the NDA for Depo-Provera, it has no power to change the design or labeling of the authorized generic MPA it distributes; thus, plaintiffs' claims against Prasco are preempted.[12] *Mensing*, 564 U.S. at 618-619; *Bartlett*, 570 U.S. at 483-84. *See also, e.g.*, *Silver v. Bayer Healthcare Pharms., Inc.*, 2021 WL 8362387, *4 (D.S.C. May 28, 2021); *Lewis v. GE Healthcare, Inc.*, 2020 WL 1243397, *4 (W.D. La. Mar. 13, 2020); *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1170 (E.D. Cal. 2019); *In re Fosamax (No. II)*, 751 F.3d 150 (3d Cir. 2014);

[11] Both commentators and MDL judges have recognized these issues. *See, e.g.*, Alan E. Rothman & Mallika Balachandran, *Early Vetting: A Simple Plan to Shed MDL Docket Bloat*, UMKC L. REV., 89 UMKCLR 881 (2021); *In re: Prempro Prods. Liab. Litig.*, 4:03-cv-01507 (E.D. Ark.), Dkt. 840 (establishing procedure to address product identification to address "broad boilerplate language" in complaints naming every pharmaceutical company that manufactured drug at issue, but that did not allege a plaintiff took a drug manufactured by a specific defendant).

[12] With regard to the authorized generic MPA Prasco distributes, all matters related to its design, labeling, and the other relevant obligations of the NDA holder were and are controlled by Pfizer.

In re Fosamax (No. II), 2012 WL 181411, *3-4 (D.N.J. Jan. 17, 2012); *In re Yasmin & Yaz (Drosperinone) Mktg., Sales Pracs. & Prods. Liab. Litig. (Gannon)*, 2014 WL 1632149 (S.D. Ill. 2014); *Smith v. Teva Pharmaceuticals USA, Inc.*, 437 F. Supp. 3d 1159, 1165 (S.D. Fla. 2020); *Brazil v. Janssen Research & Development LLC*, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016).

No discovery, let alone the broad discovery often seen in MDLs and used as a justification for coordination, is necessary to establish what already is undisputed here: Pfizer, not Prasco, holds the NDA, and Pfizer is the "only entity legally authorized to update the label unilaterally under federal law. (*Schmidt* Complt., ¶ 147.) Nor is discovery directed toward Prasco necessary to establish that Prasco acquired rights to distribute authorized generic MPA in late 2020 pursuant to a publicly-available FTC divestiture order. The *Schmidt* plaintiffs' only mention of purported coordinated discovery of Prasco is a vague assertion that discovery "as to the due diligence" of Prasco in acquiring an authorized generic license to distribute MPA will be "important." (Dkt. 1-1, p. 13.) They do not explain why this discovery is relevant to a pled claim; nor do the *Schmidt* plaintiffs address the fact that Prasco's "acquisition" of an authorized generic license to distribute MPA was the result of a highly regulated acquisition ordered by the FTC – which plaintiffs already know about, as they reference and cite it in their respective complaints. Based on Prasco's unique position in these cases – both in terms of the timing of its distribution of authorized generic MPA and the fact that it is ***not*** the NDA-holder – centralized proceedings in an MDL, without a necessary and preliminary determination on Prasco's intended motion to dismiss based on preemption, will not make discovery of Prasco more efficient.

Prasco nonetheless recognizes that efficiencies related to coordinated proceedings will allow the MDL court to dismiss all claims against it at once. *See generally, e.g.*, *In re Fosamax*, 751 F.3d 150; *In re Fosamax*, 2012 WL 181411, *aff'd*, 751 F.3d 150; *In re Zantac (Ranitidine)*

Prods. Liab. Litig., 510 F. Supp. 3d 1234, 1250-51 (S.D. Fla. 2021). And, if necessary and appropriate, an MDL court presumably could craft mechanisms to efficiently address questions of general causation (which all plaintiffs must prove) and to assess whether reliable scientific evidence exists to support plaintiffs' claims.[13] *See, e.g.*, *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 249 F. Supp. 3d 1357, 1359 (J.P.M.L. 2017); *In re Viagra (Sildenafil Citrate) Prod. Liab. Litig.*, 176 F. Supp. 3d 1377, 1378 (J.P.M.L. 2016).

Accordingly, and as discussed further below, Prasco's conditional non-objection to an MDL here, and acknowledgment that these cases may satisfy the requirements for coordination of these cases in one venue for pre-trial purposes, is premised upon transfer to a venue that furthers the efficient treatment of these cases with respect to all parties, including all plaintiffs and all defendants – not just those with purported "connections" to California[14] or Massachusetts, or those who arguably implicate questions of California or Massachusetts law. Thus, Prasco's non-objection to an MDL is conditioned on rejection of the *Schmidt*, *Fazio*, and *Valencia* plaintiffs' proposed venues.

B. The Southern District of New York Is an Appropriate Venue Here

Given the relevant factors, if the Panel concludes centralization of these cases in an MDL is justified and beneficial to the parties, centralization in the Southern District of New York would be appropriate. Although Prasco itself has no significant connection to New York, other defendants do, and the relative convenience, expense, and burden factors associated with the Southern District

[13] Even the purported "common" meningioma injury necessarily will implicate general and plaintiff-specific causation questions because each plaintiff will allegedly have developed meningiomas in different parts of the brain at different times following different periods of use; likewise, each plaintiff will have different health histories, comorbidities, and alternative causation factors.

[14] Plaintiffs' allegation that "Defendants" have strong connections to California is based ***entirely*** on non-Prasco defendants' alleged connections to California. (*Schmidt* Complt., ¶¶ 43-55.) Plaintiffs do not identify with specificity any facts purportedly creating a "strong connection" between Prasco and California.

of New York greatly weigh in favor of that venues versus plaintiffs' proposed California venues. Thus, Prasco does not object to centralization in the Southern District of New York before either Judge Cathy Seibel or Judge Paul A. Engelmayer.

The *Schmidt* plaintiffs argue (and neither the *Fazio* nor *Valencia* plaintiffs disagree) that Pfizer is the "primary" defendant in this litigation. (Dkt. 1-1, p. 5.) Pfizer is headquartered in New York, and as such, Prasco anticipates most of the key evidence and witnesses will be located in or near New York. *See In re: Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 780 F. Supp. 2d 1379, 1382 (J.P.M.L. 2011) (ordering MDL in district where defendant's headquarters were located, as "[r]elevant documents and witnesses" were likely located there); *In re Vytorin/Zetia Mktg., Sales Practices & Prod. Liab. Litig.*, 543 F. Supp. 2d 1378, 1380 (J.P.M.L 2008) (same); *In re: Kia Hyundai Vehicle Theft Litig.*, 648 F. Supp. 1374, 1375 (J.P.M.L 2022) (same). Pharmacia, a Pfizer subsidiary, also is headquartered in New York. The remaining defendants are headquartered nearby in Pennsylvania (Viatris) or a relatively short, direct plane flight away in West Virginia (Greenstone),[15] Ohio (Prasco), or Michigan (Pharmacia & Upjohn). Because plaintiffs' "primary" defendant is located in New York, and because all other defendants are located near to or able to easily travel to New York, the convenience of the parties and witnesses plainly is served by transferring cases to an MDL in the Southern District of New York.

The Southern District of New York also would be a convenient location for defense counsel, as counsel for all defendants is based in or maintains offices in New York. Likewise, the Southern District of New York would be convenient for plaintiffs' counsel – the *Schmidt* plaintiffs' lead counsel already is located in New York, and the *Fazio* plaintiffs' lead counsel is in Philadelphia. Transfer to the Southern District of New York also would be convenient for non-

[15] Greenstone was headquartered in New Jersey until July 2021, when its operations shifted to West Virginia.

local parties and witnesses. The Southern District of New York is located with easy access to a number of airports (including John F. Kennedy International Airport, LaGuardia Airport, and Newark Liberty International Airport) and also is accessible via Amtrak for individuals residing on the east coast, including in Philadelphia or Washington, D.C.

Overall, the locations of the parties (and their counsel), the location of the anticipated relevant evidence and witnesses, and the forum's accessibility, make the Southern District of New York well suited to be the transferee district for nationwide litigation. *See In re Mirena IUD Prods. Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013) (transferring cases to MDL in Southern District of New York because primary defendant was located there, its corporate affiliates were located nearby, and the district is easily accessible for nationwide litigation); *In re Mirena (No. II)*, 249 F. Supp. 3d at 1361 (centralization case in Southern District of New York, in part because primary defendant was headquartered nearby and New York was a "geographically convenient forum for this nationwide litigation").

This MDL could become large and complex, and counsel in the plaintiffs' bar has announced this MDL as one of the "top five mass torts" in 2025, with the expectation there could be more than 10,000 cases filed.[16] The nationwide[17] advertising campaign undertaken by plaintiffs' counsel also highlights the need for an experienced MDL judge to craft methods to weed out baseless claims at an early stage. Judges Seibel and Engelmayer are well suited to handle an MDL

[16] Susan Barfield, *Joe Shares Top 5 Mass Torts to Get Involved in, Going Into 2025*, CASE WORKS, https://yourcaseworks.com/the-leverage-report/joe-shares-top-5-mass-torts-to-get-involved-in-going-into-2025/?utm_campaign=Newsletter&utm_medium=email&_hsenc=p2ANqtz-8XJW7XkqpsjtkWNdKB0p6fnDtg9kyx52AGQ-HRnx3maEqih9nKznCKLirNKGunRlhu6zFma-b-IF0fco6pP6_OvDxlOQ&_hsmi=335067428&utm_content=335067428&utm_source=hs_email (Nov. 21, 2024).

[17] Indeed, Depo-Provera litigation advertisements have appeared in Ohio markets, among others. *See, e.g.*, *Understanding Depo-Provera: The Alarming Link to Meningioma and Legal Implications*, RITTGERS RITTGERS NAKAJIMA, https://www.rittgers.com/cincinnati/personal-injury/product-liability/depo-provera-brain-tumor-lawsuit/ (last visited Dec. 13, 2024) (Cincinnati-based law firm's Depo-Provera advertisement).

of this nature. Both have extensive experience overseeing complex pharmaceutical product liability MDLs. *See In re Mirena*, 938 F. Supp. 2d at 1358 (appointing Judge Seibel to oversee pharmaceutical MDL given prior experience and expressing Panel's confidence she would "steer this litigation on a prudent course"); *In re Mirena (No. II)*, 249 F. Supp. 3d at 1361 (appointing Judge Engelmayer to oversee pharmaceutical MDL). Indeed, this Panel has recognized both Judge Engelmayer and Judge Seibel as able and experienced jurists with the ability to steer complex MDLs. *See, e.g.*, *In re Interest Rate Swaps Antitrust Litig.*, 190 F. Supp. 3d 1364, 1366 (J.P.M.L. 2016) (appointing Judge Engelmayer as MDL judge and noting the Panel's confidence in him as "an able and experienced jurist"); *In re Mirena*, 938 F. Supp. 2d at 1358; *In re Mirena (No. II)*, 249 F. Supp. 3d at 1361. And, both judges also appear to have capacity to handle a new MDL proceeding at this time – Judge Seibel is not currently overseeing an MDL, while Judge Engelmayer's current MDL appears to have resolved in total. *See generally In re: One Apus Container Ship Incident on November 30*, 2020, 22-MD-3028 (S.D.N.Y.).

These considerations weigh heavily in favor of coordinating these cases in the Southern District of New York and appointing either Judge Seibel or Judge Engelmayer to oversee them.

C. California Is Not an Appropriate Venue

As explained above, Prasco's non-objection to an MDL is conditioned upon the Panel's rejection of centralization in California. The *Schmidt* plaintiffs seek coordination in the Northern District of California before Judge Jon S. Tigar or Judge William H. Orrick, and the *Fazio* plaintiffs seek coordination before Judge Josephine L. Staton in the Central District of California. Neither of these proposed venues are appropriate, let alone more appropriate than the Southern District of New York. Prasco objects to MDL centralization if in a California venue.

A California venue is not convenient for Prasco or its counsel, and the venue itself would reduce any efficiencies gained through any pretrial coordination. The travel logistics, expense, and

cost of requiring Prasco to litigate these nationwide federal court cases in California would be extraordinary in comparison with other more convenient and accessible venues. An example is illustrative. Prasco's counsel researched flight options from Cincinnati to San Francisco assuming a hypothetical, in-person MDL status conference scheduled for two hours on the morning of Thursday, January 16, 2025. To arrive in San Francisco in time for the conference, Prasco's counsel would be required to travel for at least seven and one-half hours (depending on the airline) the day before the conference (January 15) and, best case scenario, would be required to return on a red eye flight leaving the evening of January 16 and returning to Ohio the morning of January 17.[18] In other words, Prasco's counsel would be required to travel upwards of 15 hours (counting only time on an airplane) across three days for a two-hour long status conference.[19] The same logistical problems exist in the *Fazio* plaintiffs' proposed venue of Los Angeles.

California is not a convenient venue for Prasco's co-defendants or their counsel, either. As discussed above, all defendants in this litigation are located east of the Mississippi River, and all of defendants' counsel have offices located in or near New York. The same is not true for California. Travel to California is not even convenient for plaintiffs' counsel: the *Schmidt* plaintiffs' counsel (Ellen Relkin at Weitz & Luxenberg) is located in New York, while the *Fazio* plaintiffs' (Tracy A. Finken at Anapol Weiss) counsel is based in Philadelphia. It is likely, based on filings to date and plaintiffs' law firm advertising,[20] that the attorneys on what inevitably would

[18] This, of course, assumes no delays or missed connections at any layover. A simple delay of even 30 minutes at any departure or layover destination would cause even longer travel times – and additional expense to Prasco.

[19] If any conference is scheduled for a Monday or Friday, this would necessitate travel on weekends.

[20] For example, every speaker at a recent webinar (including the *Schmidt* and *Fazio* plaintiffs' counsel) at a recent webinar reside on the east coast in New York, New Jersey, Pennsylvania, Florida, and South Carolina. *See HarrisMartin's Webinar Series: Depo-Provera CI Litigation Speaker Profiles*, HARRISMARTIN, https://www.harrismartin.com/conferences/595/Webinar_DepoProvera_Nov2024/speaker-profiles/ (lasted visited Dec. 23, 2024).

become the plaintiffs' "steering committee" or "leadership" likewise will predominantly reside on the eastern side of the U.S.

If at all, California would be a convenient venue ***only*** for the subset of individual plaintiffs themselves who reside in California and any local California lawyers. But, notably, individual plaintiffs rarely, if ever, have in person obligations in an MDL venue: they do not appear at MDL conferences; they generally appear for deposition in their "home" venue regardless of MDL location; and plaintiff-side discovery is, largely, written (i.e., "Plaintiff Fact Sheets" and medical record productions) and can be completed remotely. There simply is no burden or added inconvenience to plaintiffs themselves of coordinating this MDL outside of California. Even assuming the purported convenience to California plaintiffs, one state's plaintiffs should not be placed above those of 49 others in an MDL.

In short, plaintiffs' primary arguments for coordination in California are speculative, contrived and premised on the fact that: (1) the highest number of Depo-Provera recipients is in California because California is the largest state in the U.S.; (2) most of the Depo-Provera cases filed to date have been filed in California federal court; (3) a California-centered MDL would obviate the need for *Lexecon* waivers and increase the likelihood the MDL court would try a case; and (4) California is one of the *two* jurisdictions that recognizes so-called "innovator liability." (Dkt. 1-1, pp. 13-18.) None of those reasons carries the day.

First, if a state's population were the determining factor in MDL centralization, ***every*** MDL would be located in California. And, moreover, it is pure speculation that the highest number of Depo-Provera recipients must be located in California (let alone that the largest inventory of plaintiffs will be from California) simply by virtue of California having the largest population in the country.

Second, that a majority of the cases filed to date have been filed in California is not, as plaintiffs appear to suggest, the result of mere happenstance or what will be the actual map of cases filed. Rather, at a recent webinar, the *Schmidt* plaintiffs' lead counsel actively "encourage[d] filings in any district court in California" with a "[f]ocus[] on" filings in the Northern and Central Districts of California.[21] Concentrating initial filings in California to support a later argument for centralization in California is, simply put, a forum-shopping strategy. It would be fundamentally unfair to permit plaintiffs' counsel to coordinate early filings in their preferred venues for the very purpose of propping up a later contrived argument that the MDL should be centralized in those venues because there already are a number of filed cases in those venues, as the *Schmidt* plaintiffs' counsel encouraged.[22]

Third, the *Schmidt* plaintiffs presumptively assert that centralizing the litigation in the Northern District of California gives the "best opportunity" for the MDL court to try a bellwether case because there will be no need for a *Lexecon* waiver. (Dkt. 1-1, pp. 16-17.) This argument fails and should be rejected. Plaintiffs assume, with no evidence, the MDL court will adopt a bellwether process at all. While Prasco takes no position on that particular end-stage case management procedure for purposes of this Response, it is pure speculation that an eventual MDL court in fact will set up a bellwether process, or that potential bellwether plaintiffs will reside, for example, in the Northern District of California. Second, even assuming a bellwether procedure, any cases filed outside the Northern District of California (even cases originating from other Districts in

[21] *See* Ellen Relkin, *Parties, Authorized Generics, Failing and MDL Strategy, and Design Defect*, HARRISMARTIN'S WEBINAR SERIES: DEPO-PROVERA CI LITIGATION, at 8 (Nov. 4, 2024), available at https://harrismartin.s3.amazonaws.com/media/uploads/conf_materials/04-RelkinPresentation.pdf (attached as Ex. 1).

[22] Further, as is clear from plaintiffs' counsel's nationwide advertising efforts, and estimates that this litigation could exceed 10,000 plaintiffs, both discussed above, there can be little doubt this will be a nationwide – not California-focused – litigation. And, even assuming, for purposes of this Response, the truth or accuracy of plaintiffs' representation that an MDL would have a high number of California residents, the residence of most of a hypothetical number of plaintiffs in an MDL is not the standard this Panel applies in deciding where to centralize litigation.

California) will need to be remanded to their originating District. *See* 28 U.S.C. § 1407(a) ("Each action so transferred shall be remanded…to the district from which it was transferred."). Thus, centralizing an MDL in the Northern District of California guarantees only that plaintiffs whose claims originated in the Northern District of California would be tried there. There simply is no basis here to give preference to one state's plaintiffs above all others, in selecting an MDL venue. Further, MDL courts can (and do) apply the substantive law of a jurisdiction outside the state in which they sit, if otherwise appropriate.[23] If after a proper choice-of-law analysis, a transferee court concludes California substantive law applies to a *particular* plaintiff's claims, then California law would apply *regardless* of whether the MDL is centralized in California. Plaintiffs' argument that this MDL should be centralized in California so that California law can apply (if otherwise appropriate) is, thus, a red herring.

Finally, plaintiffs' suggestion that California's recognition of "innovator liability" should lead to an MDL in California is directed to defendant Pfizer. (*Schmidt* Complt., ¶¶ 142-51.) Prasco does not hold the Depo-Provera NDA and, therefore, is not the "innovator" who arguably may be subject to "innovator liability" in a case in which California substantive law applies. Thus, whatever reasons the *Schmidt* and *Fazio* plaintiffs may have for litigating these cases in California in order to assert "innovator liability" claims against Pfizer, those arguments do not support pulling Prasco into a California venue.

D. Massachusetts Is Not an Appropriate Venue

The *Valencia* plaintiffs filed a separate Response in Support of centralization on December 23, 2024, proposing the District of Massachusetts as the transferee court. (Dkt. 58.) Notably, the

[23] If after a proper choice-of-law analysis, a transferee court concludes California substantive law applies to a particular plaintiff's claims, then California law will apply ***regardless*** of whether the MDL is centralized in California. Plaintiffs' argument that this MDL should be centralized in California so that California law can apply is, thus, a red herring.

Valencia plaintiffs make no argument that centralization in Massachusetts would increase efficiency or further the goals of an MDL as to Prasco. For the reasons set forth above, and for those set forth in Pfizer's Response, Prasco submits the District of Massachusetts is not a more appropriate venue for an MDL than the Southern District of New York and objects to centralization of these cases in Massachusetts.

IV. CONCLUSION

Prasco does not object to centralization of these cases in an MDL, so long as the Panel rejects plaintiffs' proposed California and Massachusetts venues and centralizes this litigation in the Southern District of New York (with Judge Seibel or Judge Engelmayer).

Dated: December 23, 2024

Respectfully submitted

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EXHIBIT 1

Parties, Authorized Generics, Filing and MDL Strategy, and Design Defect

Ellen Relkin

WEITZ & LUXENBERG

Parties

Pfizer Inc.

Viatris Inc. ?

Greenstone LLC

Prasco, LLC d/b/a Prasco Labs.

Pharmacia & Upjohn Co. LLC

Pharmacia LLC

Parties

Pharmacia & Upjohn developed Depo-Provera in the ‘50s and got FDA approval in the ‘60s for other indications

Finally got approved for contraception in 1992

Pfizer bought **Pharmacia & Upjohn** in 2002 just as the patent was expiring and shortly thereafter **Greenstone** was formed to be the authorized generic

First authorized generic sales in late 2004

Parties

Pfizer owned **Greenstone** and **Pharmacia & Upjohn** until Nov 2020 when **Greenstone** and **Upjohn** were spun off to form **Viatris**

Pfizer retained **Pharmacia** which is an LLC with members

Viatris holds the rest but Defense counsel maintains that Viatris has never held the NDA or ANDA for Depo-Provera or any DMPA product, nor marketed, sold or distributed such (awaiting affidavit proof)

But **Pfizer** still owns 57% of **Viatris**

As part of that merger and a ruling by the FTC, **Pfizer/Greenstone** had to license authorized generic Depo-Provera to **Prasco**

Authorized Generic Liability

Is an Authorized Generic Drug the Same Thing as a Generic Drug?

No. The term "authorized generic" drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug.

https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs#:~:text=The%20term%20%E2%80%9Cauthorized%20generic%E2%80%9D%20drug,product%20as%20the%20branded%20product

Authorized Generic Liability

Greenstone and Prasco – the "Authorized Generics"

Really not generics at all

They just re-sell brand name Depo-Provera made by Pfizer

Therefore the *Mensing* defense should not apply, Pfizer as actual manufacturer could have changed the label

Greenstone actually operated out of "Pfizer Peapack Campus" in NJ
Basically Pfizer employees

Filing and MDL Strategy

Despite optimism that we will defeat preemption on authorized generics, nothing is certain

And, generics have been on the market since 2004 – pre-2004 exposures are Pfizer

There will be many "true" generics which will probably not be compensable
Thus, we want to have the innovator liability claims from the heavily populated states CA and MA which are compensable even if other cases elsewhere fail

Innovator liability holds the brand name manufacturer liable for failure to warn even if the plaintiff only took the generic version of the drug under the theory that the brand name knew there were generics mimicking their inadequate label and yet they did did nothing

Filing and MDL Strategy

Focusing on ND Cal and CD Cal at present

But encourage filings in any district court in California or Massachusetts

Filing and MDL Strategy

The injury is **cerebral meningioma**

Other things like pseudotumor cerebri (also known as idiopathic intracranial hypertension or IIH) is not a claim to pursue. It is NOT a tumor

The epi on spinal meningioma is not as strong as cerebral

Cases with treatment – craniotomy or radiation are clearly stronger damage wise than the “watch and wait” cases

But note a minority of meningiomas become heavily calcified making treatment less effective and that may be the reason why in some cases there has been no Sx

Warnings Claims

- No mention of meningioma in US label
- Meningioma was listed as an adverse reaction in Canadian Monograph as early as 2015
- Europe label was changed this year to add:
  - *"Meningioma:* Meningiomas have been reported following long term administration of progestogens, including medroxyprogesterone acetate. Depo-Provera should bediscontinued if a meningioma is diagnosed. Caution is advised when recommending Depo-Provera to patients with a history of meningioma"
- The issue is apparently "under discussion" now with the FDA

Bone Demineralization warning impact here?

- Concern is Black Box Warning since 2004:

"Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.

It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.

Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g. longer than 2 years) only if other birth control methods are inadequate. (See WARNINGS.)"

OBVIOUSLY BRAIN TUMOR IS MUCH SCARIER THAN BONE MASS

Design Defect is a Uniquely Strong Claim Here

Lowest Effective Dose

Typically it is very hard to point to a safer alternative in Pharma cases

But here we have Pfizer's own product - Depo-SubQ Provera 104
Approved December 2004, yet hardly used

Not only is it a much lower dose

The subcutaneous administration route provides much more gradual uptake of the drug, so you don't have the high initial spike, and it still remains at a level that is more than enough to be efficacious for contraception for at least 3 months and likely more

Mystery: naming the Safer Alternative in the US vs Europe

Proprietary Drug Name

At the time of submission of the Complete Response, the Applicant wished to use the proprietary name '
(alternative name). Neither the Division of Reproductive and Urologic Drug Products (DRUDP) nor the Division of Medication Errors and Technical Support (DMETS) supported the use of either name.

The proposed proprietary name "depo-subQ provera 104" is acceptable to DRUDP in that it does not suggest any clinical benefit and clearly differentiates this product from the intramuscular formulation by inclusion of (1) the term "subQ" within the name (rather than at the end of the name) and (2) the mg dose of MPA (104), which differs from that of the IM formulation.

← FDA response to proposed trade name in 2004 approval of the SubQ variant

- Contrast with in Europe and elsewhere, where it has a commercial name and is widely used, including by self- injection
- Persistent question: Why did Pfizer not seek to get a trade name for 20 years and encourage the US of this Safer Alternative Design??

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: DEPO-PROVERA (DEPOT MEDROXYPROGESTERONE ACETATE) PRODUCTS LIABILITY LITIGATION	**MDL 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 a copy of the foregoing document was served on all parties in the following cases electronically via ECF, or as indicated below, on December 23, 2024.

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