BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE VIAGRA PRODUCTS LIABILITY LITIGATION	)	MDL Docket No. 2691

DEFENDANT PFIZER INC.'S RESPONSE IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER TO THE NORTHERN DISTRICT OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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Plaintiffs have moved pursuant to 28 U.S.C. § 1407 for coordination or consolidation in the Northern District of California of a number of product liability actions involving Viagra, a prescription medication manufactured by Defendant Pfizer. Pfizer agrees these matters should be coordinated for pretrial purposes and thus does not oppose Plaintiffs' motion to transfer, and agrees that the Northern District of California is the most appropriate transferee forum.

BACKGROUND

The Food and Drug Administration approved Viagra in 1998 for the treatment of erectile dysfunction in men, and declared it was "safe and effective for use as recommended" in the product label. Viagra was the first oral treatment developed for erectile dysfunction, and its efficacy, safety, and ease of use surpassed any prior treatment. Since its approval, Viagra has been prescribed to millions of men in the United States and worldwide.[1]

This litigation was prompted by the publication of a single observational study in April 2014. *See* Wen-Qin Li et al., *Sildenafil Use and Increased Risk of Incident Melanoma in US Men, A Prospective Cohort Study*, JAMA Intern. Med. (April 7, 2014) ("the Li study"). The study itself was not a randomized, controlled clinical trial, but rather was based on a post-hoc analysis of observational data from surveys of Massachusetts healthcare professionals; the authors reported that the study "suggested" an increased risk of melanoma in men who had used Viagra at least once within the three months preceding the baseline survey date. The study had significant limitations. The authors themselves, in fact, "acknowledge[d] limitations" in their

[1] Plaintiffs' brief contains a number of allegations regarding Viagra and Pfizer that are not supported by the record or by science, and have nothing to do with the transfer decision before the Panel. *See* Pls.' Br. at 2-4. Pfizer will not burden the Panel with an extended response to those allegations—suffice it to say that Pfizer disagrees with the allegations and will address them at the appropriate time and in the appropriate forum.

study, and advised that their "results should be interpreted cautiously and are insufficient to alter current clinical recommendations." *Id.* at 969. They expressly stated, without any ambiguity, that "[o]ur study cannot prove cause and effect." *Id.*

Notwithstanding these limitations, Plaintiffs began filing lawsuits soon after the Li study was published, claiming their melanoma was caused by their use of Viagra. In doing so, Plaintiffs ignored the Li study's disclaimer regarding "cause and effect," the 136 clinical trials in which Viagra has been studied and determined to be safe and effective, and the demonstrated safety of the product in its fifteen years on the market. There is no reliable scientific evidence—in the Li study or anywhere else—that Viagra causes melanoma. Indeed, an observational study subsequent to the Li study has called into question any association between melanoma and Viagra, and to this day the medication continues to be used safely and effectively in accordance with its FDA-approved label.

As of this submission, Pfizer is aware of 24 federal cases pending in 11 federal districts around the country. None of the cases has advanced to any material degree (as Pfizer has not yet answered any of the complaints), although The Honorable Richard G. Seeborg in the Northern District of California has scheduled initial conferences in the related cases there.

ARGUMENT

I. COORDINATION IS APPROPRIATE AND WOULD PERMIT EARLY CONSIDERATION OF THE COMMON ISSUE OF GENERAL CAUSATION.

Plaintiffs are correct that Pfizer does not oppose the transfer of these matters to a single district for coordinated pretrial proceedings, *see* Pls.' Br. at 2, and that such coordination is in the best interests of the parties and judiciary and would prevent duplication of discovery, eliminate the potential for inconsistent pretrial rulings, and conserve resources, *id.* at 4, 6-7. *See, e.g., In re*

Bayer Healthcare LLC & Merial Ltd. Flea Control Prods. Mktg. Sales Pracs. Litig., 844 F. Supp. 2d 1369, 1370 (J.P.M.L. 2012) ("[c]entralization under Section 1407" appropriate where it would eliminate duplicative discovery, prevent inconsistent rulings, and conserve resources "of the parties, their counsel and the judiciary").

One common issue not identified by Plaintiffs in support of their motion, *see* Pls.' Br. at 5-6, is the issue of general causation. "'General causation' refers to whether the substance at issue had the capacity to cause the harm alleged, that is, could the substance at issue cause the type of harm complained about." *O'Neill v. Sherwin-Williams Co.*, 2009 WL 2997026, at *2 (C.D. Cal. 2009); *see In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 1166, 1175 (N.D. Cal. 2007) ("general causation inquiry is whether exposure to the challenged substance 'at the level of exposure alleged by the plaintiffs is capable of causing the alleged injuries'") (quoting *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002)). To establish general causation, Plaintiffs accordingly must prove—with expert testimony that satisfies the *Daubert* standard—that Viagra is capable of causing melanoma. *See, e.g.*, *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1381 (N.D. Cal. 1995) (noting plaintiffs must establish "general causation; . . . whether halothane *can* cause chronic active hepatitis," and ruling "opinion on general causation [was] not sufficiently based on scientific reliability and methodology to be admitted into evidence"); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996) ("expert opinion on . . . 'general causation' must be derived from scientifically valid methodology").

General causation is not just another common issue here. Given the absence of any scientifically reliable evidence that Viagra can cause melanoma, it is the pivotal common issue,

and it further justifies transfer of these cases. *See In re Fluoroquinolone Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2015 WL 4885571, at *1 (J.P.M.L. 2015) ("[A]ll fluoroquinolone actions . . . will share factual questions regarding general causation"); *In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014) ("All testosterone replacement therapy actions will share factual questions regarding general causation"). Indeed, because the general causation inquiry is dispositive of all claims, it warrants consideration early in a coordinated proceeding, as contemplated in the Manual for Complex Litigation and implemented in practice in other products liability MDLs. *See* Manual for Complex Lit. (4th ed. 2004) § 22.634 at 519 (identifying as worthy of being "taken up early in the litigation" the issue of "whether the facts and expert evidence support a finding that the products or acts in question have the capacity to cause the type of injuries alleged"); *see also In re Bextra & Celebrex Mktg. Sales Pracs. & Prods. Liab. Litig.*, MDL No. 1699 (N.D. Cal. March 16, 2007) (Pretrial Order No. 21); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, MDL No. 1407 (W.D. Wash. Dec. 23, 2002) (Case Management Order No. 12).

Should the Panel grant Plaintiffs' motion to transfer, Pfizer accordingly will seek in the transferee forum early consideration of the common issue of general causation, which would further conserve—and be the most efficient use of—the resources of the parties and the Court.

II. THE NORTHERN DISTRICT OF CALIFORNIA IS THE MOST APPROPRIATE TRANSFEREE FORUM.

Plaintiffs are further correct that, in the parties' judgment, the Northern District of California is the most appropriate transferee district here (and that Judge Seeborg is an appropriate transferee judge). *See* Pls.' Br. at 1-2, 7-10. An appropriate transferee district is one that will best "serve the convenience of the parties" and "promote the just and efficient conduct

of the litigation." *In re AOL Time Warner, Inc.*, 235 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002). The Northern District of California achieves these objectives in abundance.

Concentration of Cases. Of the 24 cases pending in federal courts, five are pending in the Northern District of California. *Cf. In re Wells Fargo Mortg. Lending Pracs. Lit.*, 545 F. Supp. 2d 1371, 1372 (J.P.M.L. 2008) (transferring to Northern District of California where "three of the five known actions . . . are pending"); *In re Rail Freight Surcharge Antitrust Litig.*, 528 F. Supp. 2d 1358, 1359 (J.P.M.L. 2007) ("District of Columbia is an appropriate transferee forum" where "[s]everal actions are already pending there"). Of those five cases, three have been deemed related and assigned to Judge Seeborg, and it is expected that the remaining two cases will receive similar treatment. At this point, Judge Seeborg is the only Judge presiding over three or more cases.

District and Judicial Experience. The Northern District and its judges have substantial experience in successfully managing complex, multidistrict litigation. *See, e.g.*, *In re Int'l Air Transp. Surcharge Antitrust Litig.*, 460 F. Supp. 2d 1377, 1379 (J.P.M.L. 2006) (identifying Northern District of California as "well equipped with the resources" that a "complex . . . docket is likely to require"). Through December 15, 2015, 90 MDL dockets had been transferred and successfully brought to completion in the district. *See* J.P.M.L. Statistics, Multidistrict Litig. Terminated Through Sept. 30, 2015, at 34-35 (available at http://tinyurl.com/z73lfra); J.P.M.L. Pending MDLs, MDLs Terminated Between Jan. 1, 2015, and Dec. 15, 2015 (available at http://tinyurl.com/pd68qg7).[2] The efficiency of the Northern District in managing litigation

[2] Judge Seeborg has considerable MDL experience. *See In re Optical Disk Drive Prods. Antitrust Litig.*, MDL No. 2143; *In re Webkinz Antitrust Lit.*, MDL No. 1987; *In re Cintas Corp. Overtime Pay Arbitration*, MDL No. 1781. The Panel has cited such experience approvingly.

generally is evidenced by the fact that for the 12-month period ending June 30, 2015, the median time for a civil case to reach disposition after filing was only 7.8 months. *See* Table C-5, U.S. District Courts Median Time Intervals from Filing to Disposition of Civil Cases (available at http://tinyurl.com/otkoyfk). The Northern District thus has the demonstrated capability, experience, and "resources this complex products liability litigation is likely to require." *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 398 F. Supp. 2d 1371, 1372 (J.P.M.L. 2005); *see In re Baycol Prods. Liab. Litig.*, 180 F. Supp. 2d 1378, 1380 (2001) (district has "resources, facilities, and technology . . . that this complex docket is likely to require").

Convenience. The Northern District is convenient—a particularly significant fact given that Plaintiffs' counsel anticipates bringing "many more claims." *See* Pls.' Br. at 4. San Francisco is a major metropolitan area that offers accessibility to all parties, counsel, and potential witnesses. *See In re Educ. Testing Serv. PLT 7-12 Test Scoring Litig.*, 350 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004) ("We note that this district, where four actions are already pending, provides an accessible, metropolitan location"); *In re Baycol Prods. Liab. Litig.*, 180 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001) (assignment to a "major metropolitan court"). The three major airports serving the area—San Francisco, Oakland, and San Jose—offer hundreds of daily flights to cities throughout the United States and internationally and provide easy accessibility to the forum from any place where a party, attorney, or witness is now or might later be located. In

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See In re Collecto, Inc., Tel. Consumer Protection Act (TCPA) Litig., 999 F. Supp. 2d 1373, 1374 (J.P.M.L. 2014) (transferring to "experienced transferee judge"); *In re Vision Serv. Plan Tax Litig.*, 484 F. Supp. 2d 1356, 1357 (J.P.M.L. 2007) ("assigning this litigation to an experienced jurist"); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) ("assigning this litigation to a jurist experienced in complex multidistrict products liability litigation"); *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1382 (J.P.M.L. 2004) ("centralization . . . permits the Panel to effect the Section 1407 assignment to an experienced transferee judge").

short, the Northern District is "well served by major airlines, provides ample hotel and office accommodations, and offers a well-developed support system for legal services." *In re WorldCom, Inc., Secs. & ERISA Litig.*, 226 F. Supp. 2d 1352, 1355 (J.P.M.L. 2002).

Agreement of the Parties. The Northern District is the most suitable transferee jurisdiction not only for these stated reasons, but also because the parties agree upon such transfer. This Panel frequently has cited the parties' agreement as the reason that a district "stands out" as an appropriate forum, favoring its selection. *See, e.g.*, *In re CertainTeed Corp. Roofing Shingle Prods. Liab. Litig.*, 474 F. Supp. 2d 1357, 1358 (J.P.M.L. 2007) ("Given the agreement of all moving and responding parties . . . this district stands out as an appropriate transferee forum for this litigation."); *In re Novartis Wage and Hour Litig.*, 460 F. Supp. 2d 1382, 1383 (J.P.M.L. 2006) ("Given the agreement of all parties . . . this district stands out as an appropriate transferee forum").[3]

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Panel grant Plaintiffs' motion and transfer the related actions to the Northern District of California.

[3] *Accord In re Jiffy Lube Int'l Inc., Text Spam Litig.*, 802 F. Supp. 2d 1367, 1368 (J.P.M.L. 2011) ("All parties now agree that this district is an appropriate forum"); *In re Aqua Dots Prods. Liab. Litig.*, 545 F. Supp. 2d 1369, 1370 (J.P.M.L. 2008) ("all parties now agree upon centralization in this district"); *In re High Sulfur Content Gasoline Prods. Liab. Litig.*, 344 F. Supp. 2d 755, 757 (J.P.M.L. 2004) ("[W]e note that all parties are in agreement upon selection of that district.").

Dated: December 22, 2015

Respectfully submitted,

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PROOF OF SERVICE

I hereby certify that a copy of the foregoing Defendant Pfizer Inc.'s Response in Support of Plaintiffs' Motion for Transfer to the Northern District of California Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings and this Proof of Service were filed electronically on December 22, 2015. Notice of this filing will be electronically mailed to all parties registered with the Panel's electronic filing system. I also caused a copy of the foregoing to be served upon the following counsel by first class mail on the same date.

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