BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: VIAGRA® PRODUCTS LIABILITY LITIGATION	MDL No. _____

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

Pursuant to 28 U.S.C. § 1407(c)(ii) and Rule 6.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiffs respectfully submit this brief in support of their consolidated motion to transfer all cases currently filed against Defendant Pfizer, Inc. ("Defendant") involving the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the pharmaceutical drug, Viagra®, to the United States District Court for the Northern District of California. A number of actions have already been filed nationwide, and Plaintiffs anticipate that many more will be filed in the future. Factors such as the need for judicial economy, consistency in rulings, and the commonality present among Plaintiffs' claims all merit consolidation. Plaintiffs submit that the Northern District of California would offer a logical and convenient venue for Plaintiffs' claims to be consolidated and adjudicated.

Consent and cooperation of counsel should factor into the Panel's selection of the appropriate transferee court. "As a general rule, the Panel likes to accommodate the parties in selecting an appropriate transferee district. Consequently, if the parties or a group of them can make a joint recommendation, the Panel may be favorably impressed." Judge John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tulane L. Rev. Vol. 2225 (2008); *see, e.g., In re Am. Honda Motor Co., Oil Filter Prods. Liab. Litig.*, 416 F. Supp. 2d 1368, 1369 (J.P.M.L. 2006)

("We are persuaded that the Central District of California is an appropriate transferee forum for this docket, in accordance with the unanimous support of the parties."). Defendant agrees that consolidating all currently filed federal cases in this litigation, and any subsequent "tag along" cases involving similar claims, is necessary to promote the just and efficient adjudication of these actions. Likewise, Defendant agrees that the Northern District of California is the most logical and convenient venue for these proceedings.[1]

I. BACKGROUND RE: LITIGATION STATUS AND SCOPE

A. Viagra®/Sildenafil Citrate

Since 1998, when the U.S. Food and Drug Administration approved its new drug application ("NDA") for the drug, Defendant has been manufacturing and selling sildenafil citrate under the brand name Viagra®. Viagra® treats erectile dysfunction by inhibiting the secretion of phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of cyclic guanosine monophosphate ("cGMP"). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection. Over the past few years, however, several studies have linked this same mechanism of action to cell mutation cultivating melanomagenesis. For example, a study published in 2011 found that Viagra® treatment can promote melanoma cell invasion.[2] Specifically, by inhibiting PDE5, Viagra® mimics an effect of gene activation and therefore may potentially function as a trigger for the creation of melanoma cells. Similarly, a 2012 study published in the *Journal of Cell Biochemistry* also found that PDE5 inhibitors were shown to

[1] Defendant agrees that consolidation is appropriate and venue is acceptable; however, Defendant does not agree with facts and allegations set forth more fully below.

[2] I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A*, 19 CANCER CELL 45 (2011).

promote melanin synthesis,[3] which may exacerbate melanoma development.[4]

In June of 2014, scientists building upon the knowledge set forth in these previous studies published a study in the *Journal of the American Medical Association Internal Medicine* ("the JAMA study") which examined the direct relationship between sildenafil use and melanoma development in men in the United States.[5] Among 25,848 participants, the JAMA study reported that recent sildenafil users at baseline had a significantly elevated risk of developing invasive melanoma, with a "hazard ratio" of 1.84; in other words, the JAMA study participants who had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging invasive melanoma.[6]

Rather than making any label changes or otherwise adapting their marketing strategies to convey the information published in these studies, Defendant continued a longstanding and aggressive marketing campaign to pursue profits over patient safety and market share over medication efficacy. Defendant estimates that Viagra® has been prescribed to more than 35 million men worldwide.[7] In 2012 alone, physicians wrote approximately eight million prescriptions for Viagra®.[8] Viagra® holds approximately 45% of the U.S. market share for erectile dysfunction medications,[9] and in its 2013 Annual Report, Defendant states that it accumulated

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[3] X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).
[4] F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).
[5] Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA INTERNAL MEDICINE 964 (2014).
[6] *Id.*
[7] Hilary Stout, *Viagra: The Thrill That Was*, N.Y. TIMES, June 5, 2011, *available at*: http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63.
[8] Wilson, *supra* note 4.
[9] Jacque Wilson, *Viagra: The Little Blue Pill That Could*, CNN, Mar. 27, 2013, *available at*: http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html.

revenue exceeding $1,800,000,000 from worldwide Viagra® sales.[10]

B. Viagra® Litigation

To date, multiple individuals have filed similar suits against Defendant. Each of these actions assert virtually identical claims against the same Defendant, for the same injury, caused by the same drug, i.e. Viagra®. There are currently 15 claims pending against Defendant in several different federal jurisdictions, all making similar claims and allegations. *See* Schedule of Actions.

C. Many More Claims Anticipated

Significantly, these filed cases represent only a small sample of the cases that are expected to be filed against Defendant by individuals who have developed melanoma subsequent to taking Viagra®. For example, the undersigned counsel for Plaintiffs has received more than 1,000 inquiries from various Viagra® users that have developed melanoma and their families. Melanoma is widely considered "the most serious type of skin cancer"[11] because it is more likely than other skin cancers to spread to other parts of the body, thereby causing further tissue damage and complicating the potential for effective treatment and eradication of the cancerous cells.[12] Given the widespread sale and use of Viagra® over the past 17 years, numerous additional inquiries are expected.

II. ARGUMENT

Title 28, Section 1407 of the United States Code provides: "When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. §

[10] http://www.pfizer.com/files/investors/presentations/FinancialReport2013.pdf
[11] American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, *available at*: http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts.
[12] National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, *available at*: http://www.cancer.gov/cancertopics/wyntk/skin/page4.

1407(a). The presence of common factual questions necessitates transfer under § 1407 in order to prevent duplication of discovery and eliminate the possibility of inconsistent pretrial rulings. *In re Eastern Airlines, Inc. Flight Attendant Weight Program Litig.*, 391 F. Supp. 763, 764 (J.P.M.L. 1975). Transfer under § 1407, however, does not require complete identity or even majority of common factual or legal issues as a prerequisite to transfer. *In re Rembrandt Techs., L.P.*, 493 F. Supp. 2d 1367, 1369 (J.P.M.L. 2007); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379 (J.P.M.L. 2001).

A. Plaintiffs' Claims Involve Common Questions of Law and Fact with the Same Dangerous Drug Defendant.

Plaintiffs all assert that they suffered injuries and damages as a result of using Viagra®, a drug designed, manufactured, advertised, and distributed by Defendant. All of Plaintiffs' lawsuits name Pfizer, Inc. as the singular defendant. Questions common to all suits arise from the underlying facts and course of conduct alleged in each complaint; specifically, Defendant's actions relating to the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of Viagra®. Such common questions include:

1) Whether Defendant failed to warn and/or adequately warned innocent consumers and physicians about the risks of serious injury caused by Viagra®;

2) Whether Defendant intentionally, deliberately, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed, or suppressed material and important information regarding the true and known risks of Viagra® use from physicians and Plaintiffs;

3) Whether Defendant's conduct in marketing, advertising, and/or promoting Viagra® was negligent;

4) Whether Defendant's conduct was negligent and/or intentional in failing to properly, fully, and/or thoroughly study and test Viagra®;

5) Whether Defendant's misconduct constitutes a breach of any warranty or warranties recognized by law;

6) Whether Defendant's misconduct constitutes a violation of any applicable

consumer protection and/or fair trade practices laws;

7) Whether Plaintiffs are entitled to recover damages from Defendant, including compensatory damages and/or punitive or exemplary damages; and

8) If damages are available to Plaintiffs, the method or methods by which such relief should be determined.

Coordination is therefore appropriate and necessary given the significant number of common questions of law and fact present in this potential litigation. This necessity is particularly clear because all actions relate to the same Defendant and the same pharmaceutical product.

B. Consolidation Serves the Best Economic and Equitable Interests of the Parties, Counsel, and Judiciary.

Here, coordination serves the best interests of the parties, parties' counsel, and the judiciary by conserving economic resources and equitably preventing inconsistent rulings. Unless Plaintiffs' claims are centralized and coordinated, the parties and courts will be forced to spend a great deal of time, effort, and money litigating common issues of both fact and law. Furthermore, the parties may be prejudiced by various courts entering contradictory orders ruling on discovery and evidentiary issues common to all claims. Such disparate rulings will lead to more litigation and, ultimately, to incongruous results and bad precedent. In contrast, coordination avoids the pitfalls of piecemeal litigation by resolving disputes related to common issues in one singular ruling. *In re StarLink Corn Products Liability Lit.*, 152 F.Supp.2d 1378, 1380 (J.P.M.L. 2001).

Centralized pretrial proceedings work to conserve the time, effort, and financial resources of the judiciary and the parties, while simultaneously eliminating the possibility of inconsistent rulings from sister courts in parallel proceedings that might impair the equitable and orderly administration of justice. *See, e.g., In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012) ("Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and

the judiciary"); *In re DePuy Orthopaedics, Inc.*, 753 F. Supp. 2d 1378, 1379 (J.P.M.L. 2010) ("Centralization under Section 1407 will eliminate duplicate discovery, prevent inconsistent trial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary").

Moreover, in litigation bearing both common and unique issues of fact, it is important that the actions be allowed to go forward before a single judge who can establish a pretrial program under which pretrial proceedings with respect to any non-common issues proceed concurrently with pretrial proceedings on common issues. *In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976). *See also In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 908 F. Supp. 2d 1362, 1363 (J.P.M.L. 2012) (stating that "[t]he transferee court can employ any number of pretrial techniques – such as establishing separate discovery and/or motion tracks" to manage individual questions of fact). In addition, if the actions are not centralized in one location, counsel for both parties will be forced to litigate actions in several different courts concurrently, and scheduling conflicts will likely result and potentially cause delay for multiple courts. Finally, it is essential to ensure that all parties have access to the same essential documents and discovery without concerns over duplication of costs and effort or inconsistencies in document production.

C. <u>The Northern District of California is the Proper Transferee Forum.</u>

The criteria used by the Judicial Panel on Multidistrict Litigation in determining the most appropriate transferee forum under 28 U.S.C. § 1407 include the convenience of the parties and witnesses; the relative degree of progress achieved in pending actions; the location of parties, witnesses, and documents; the likelihood that a given district's location would enhance the prospects for cooperation among the federal and state courts; and, when no clear choice emerges from these factors, the preference of the majority of the parties. *In re Factor VIII or IX Concentrate*

Blood Prods. Liab. Litig., 853 F. Supp. 454, 455 (J.P.M.L. 1993); *In re New Mexico Natural Gas Antitrust Litig.*, 482 F. Supp. 333, 337 (J.P.M.L. 1979). For example, in the phenylpropanolamine (PPA) MDL, the Panel selected a transferee court based in part on the fact that it was "a major metropolitan court that (i) is not currently overtaxed with other multidistrict dockets, and (ii) possesses the necessary resources to be able to devote the substantial time and effort to pretrial matters that this complex docket is likely to require." *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379-80 (J.P.M.L. 2001). Therefore, under the § 1407 criteria, the Northern District of California is the best location for the transferee court because the judiciary has experience with complex litigation; the judiciary is efficient; and the location is convenient for the parties.

1. The Northern District of California has the Experience and Resources to Properly Conduct this Litigation.

The Northern District of California has significant experience handling multidistrict litigation involving pharmaceutical products liability actions as well as sales and marketing practices. *See, e.g. In Re: Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation*, MDL Docket No. 1699, (N.D.Ca. 2005). Currently, five of the 15 underlying actions pending before the Panel are located in the Northern District of California. Specifically, Plaintiffs request transfer to the Honorable Richard G. Seeborg. Judge Seeborg is presently presiding over three of Plaintiffs' five cases in the Northern District of California. Thus, the Northern District of California, and particularly Judge Seeborg's docket, is the appropriate forum for this multidistrict litigation.

2. The Northern District of California is Efficient.

The Northern District of California has an efficient civil docket. The median time from filing to disposition for civil cases was 7.9 months in 2014 and 7.8 months in 2013. The median

time from filing to trial was 31 months in 2014 and 26.2 months in 2013.[13] Additionally, the Northern District of California offers an Alternative Dispute Resolution program to further expedite litigation.

3. The Northern District of California Best Serves the Convenience of Parties and Witnesses.

"[T]ransfers shall be made by the judicial panel on the multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a).

Convenience of parties and witnesses includes consideration of the accessibility to the transferee jurisdiction to counsel from multiple jurisdictions. *E.g., In re High Pressure Laminate Antitrust Litig.,* 2000 US Dist. LEXIS 14849; *In re Polyester Staple Antitrust Litig.,* 259 F.Supp 2d. at 1376; *See also* Gregory Hansel, *Extreme Litigation: An Interview with Judge Wm. Terrell Hodges, Chairman of the Judicial Panel on Multidistrict Litigation*, 19 Me. B.J. 16, 19 (2004) ("[W]e take into account…the accessibility of the court, particularly air travel in selecting a transferee district.").

4. San Francisco is a Convenient Location.

San Francisco is the fourth largest city in California with an estimated metro population of 4,594,060.[14] San Francisco International Airport, ranked 2015 Best Airport in the Americas by *Frequent Business Traveler*, makes the city easily accessible by connecting non-stop with more than 75 United States airports through 15 domestic airlines.[15] According to 2010 census data, San

[13] http://www.uscourts.gov/statistics-reports/analysis-reports/statistical-tables-federal-judiciary
[14] http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk
[15] http://www.flysfo.com/about-sfo

Francisco has 39.3 restaurants per 10,000 households, more than any city in the United States.[16] Additionally, the city conveniently provides more than 200 hotel options.[17]

Weather related travel delays thwart efficiency and interfere with timely hearings and deposition. Such inefficiency and waste of resources can be minimized if not avoided altogether by locating the MDL in the Northern District of California. San Francisco has a mild year-round climate with an average a high temperature of approximately 64 degrees and an average low temperature of approximately 51 degrees.[18]

III. CONCLUSION

Plaintiffs respectfully move this Panel for expedited consideration of their motion for transfer and coordination and accompanying brief and, pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, accordingly transfer all related Viagra® product liability claims to the United States District Court for the Northern District of California for the commencement of pretrial proceedings.

[16] http://www.huffingtonpost.com/2012/08/02/san-francisco-restaurants_n_1735091.html
[17] http://www.sanfrancisco.travel/san-francisco-visitor-industry-statistics
[18] http://www.usclimatedata.com/climate/san-francisco/california/united-states/usca0987

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Respectfully submitted,

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