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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: VIAGRA (SILDENAFIL CITRATE) PRODUCTS LIABILITY LITIGATION	Case No. 16-md-02691-RS MDL No. 2691
This Document Relates to: ALL ACTIONS	**DEFENDANT PFIZER'S POSITION STATEMENT FOR INITIAL CASE MANAGEMENT CONFERENCE**

TABLE OF CONTENTS

INTRODUCTION

In 2015—seventeen years after Viagra was approved by the Food and Drug Administration as safe and effective and became available to patients—several men began filing lawsuits alleging that they used Viagra for unspecified time periods at unspecified intervals, and that such use caused or exacerbated their melanoma. These claims lack any reliable scientific basis. Viagra has been one of the most studied medications in the past twenty years, and none of the more than 100 clinical trials involving many thousands of patients suggests a link between Viagra use and melanoma. This litigation, instead, was prompted by the April 2014 publication of a single observational study—the "Li study"—which performed a statistical analysis of responses to questionnaires and reported an association between Viagra use in 2000 and the development of melanoma at some point during the following ten years. The authors, however, "acknowledge[d]" their study had "limitations" and expressly stated the reported results could not "prove cause and effect" and should not alter the current clinical use of Viagra.

Plaintiffs' claims also find no support in the regulatory record. No regulatory agency—anywhere—has found the causal relationship now asserted by Plaintiffs or otherwise suggested it has any validity. To the contrary, the European Medicines Agency, after publication of the Li study, considered the issue at length in 2014 and concluded that "*[a] causal relationship between the use of sildenafil [Viagra] and the risk for melanoma skin cancer is not supported by the data currently available*."

In light of this record, Pfizer respectfully suggests that threshold consideration of the issue of general causation—whether Plaintiffs have reliable scientific evidence that Viagra can cause melanoma—would best serve the interests of all parties and streamline the litigation. The Manual for Complex Litigation counsels in favor of such discovery phasing in these circumstances, and numerous other MDL courts, including those in the recent *Incretin Products* MDL (C.D. Cal., Battaglia, J.), the *Bextra and Celebrex* MDL (N.D. Cal., Breyer, J.), and a prior *Viagra* MDL (D. Minn., Magnuson, J.), all structured discovery such that the issue of general causation was considered and decided early in the proceedings.

FACTUAL BACKGROUND

A. Viagra and Erectile Dysfunction.

Pfizer manufactures and distributes Viagra (sildenafil citrate), an oral medication indicated for the treatment of erectile dysfunction. Erectile dysfunction—or ED—is a serious disorder that affects approximately 30 million men in the United States, and 150 million men worldwide. ED has a number of causes. It may result from such varying physical and mental conditions as high blood pressure, heart disease, and diabetes; excessive smoking and obesity; and depression and stress. Certain medications can contribute to ED or make it worse. The impact of undiagnosed or untreated ED can be profound—ED may lead to feelings of depression, anxiety, and low self-esteem, and may strain intimate relationships.

In general terms, Viagra treats ED by increasing blood flow to the penis such that an erection can occur. It does so by selectively inhibiting an enzyme known as phosphodiesterase type 5, or PDE5 (thus making Viagra part of a class of medications known as "PDE5 inhibitors"). This selective inhibition of PDE5 allows blood vessels to dilate, increasing blood flow to the penis tissue and producing an erection.

B. Regulatory Approval.

The Food and Drug Administration approved Viagra in March 1998, after evaluating the available scientific evidence and determining that Viagra "is safe and effective for use as recommended" in the product label. Nearly ten years of study and testing by Pfizer preceded FDA's approval. During this time, Pfizer conducted 71 FDA-supervised clinical studies involving thousands of men. Eleven of these studies were double-blind, placebo-controlled trials, the "gold standard for determining the relationship of an agent to a health outcome or adverse side effect." Reference Manual on Scientific Evidence (Reference Guide to Epidemiology) (Third Ed.) at 555. None of these studies suggests any link between Viagra and melanoma. Viagra now has been approved in more than 140 countries; it has been used by more than 28 million men in the United States and more than 68 million men worldwide.[1]

[1] Sildenafil, the active ingredient in Viagra, also was approved by FDA in 2005 (under the separate brand name Revatio) as a safe and effective treatment for pulmonary arterial hypertension

C. Prior Viagra Litigation and Current Litigation Status.

This is the third "wave" of Viagra litigation. In a first wave of litigation, plaintiffs alleged that Viagra caused heart attacks, strokes, and other cardiovascular injuries. Those allegations were unsupported by the scientific record, and the courts in many of those cases accordingly excluded the proffered opinions of plaintiffs' experts as unreliable and entered judgment for Pfizer. *See, e.g.*, *Brumley v. Pfizer Inc.*, 200 F.R.D. 596 & 149 F. Supp. 2d 305 (S.D. Tex. 2001) (excluding expert testimony that Viagra causes heart attacks and granting summary judgment for Pfizer); *Selig v. Pfizer Inc.*, 735 N.Y.S.2d 549, 551 (1st Dep't), *leave to appeal denied*, 745 N.Y.S.2d 502 (N.Y. 2002) (affirming exclusion of plaintiffs' expert in three cases where no "clinical data" or "other scientific evidence" supported "causal link between . . . Viagra and heart attacks"). The remaining plaintiffs either dismissed their cases voluntarily or settled them for *de minimis* amounts.

In a second wave of litigation, plaintiffs alleged that Viagra caused an eye condition called non-arteritic anterior ischemic optic neuropathy, or NAION. In 2006, those cases were coordinated in an MDL proceeding in the District of Minnesota, *see In re Viagra Prods. Liab. Litig.*, MDL No. 1724 (Magnuson, J.), where, like the first wave of Viagra cases, they were found to be without any reliable scientific basis. The MDL court, after an initial phase of general causation discovery, excluded all of plaintiffs' experts under *Daubert*, thereby ending the litigation, *see In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071 (D. Minn. 2008) (excluding all but one of plaintiffs' experts); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936 (D. Minn. 2009) (excluding plaintiffs' remaining expert).

In this third wave of litigation, Plaintiffs now allege that Viagra caused or exacerbated their melanoma. And here too there is no reliable scientific evidence to support Plaintiffs' claims. Plaintiffs began filing their cases in early 2015, in the wake of an observational study—the Li

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(PAH), a serious and potentially fatal vascular disease. Pfizer conducted separate clinical trials of Revatio, in both men and women, which likewise did not suggest any link between sildenafil and melanoma.

study, in which the lead researchers expressly stated that the study results do not establish a cause and effect relationship between Viagra use and melanoma, *see infra* at 4-8—and the plaintiff lawyer advertising that followed the study. As of this submission, there are 109 cases pending in seven jurisdictions—102 cases in this Court, five cases in four other federal districts awaiting transfer here, and two cases in state courts. *See* Ex. 1 (List of Actions). Pfizer has not answered any of the federal complaints, and none of the cases has advanced to any material degree, with the exception of two of the earliest filed cases, which were pending before Judge Ozerden in the Southern District of Mississippi; after full briefing, Judge Ozerden dismissed both cases with prejudice on statute of limitations grounds, *see Tanner v. Pfizer, Inc.*, No. 1:15cv75-HSO-JCG, 2015 WL 6133207 (S.D. Miss. Oct. 19, 2015); *O'Neill v. Pfizer, Inc.*, No. 1:15cv76-HSO-JCG (S.D. Miss. Oct. 19, 2015), ECF No. 14. In the state court actions, Pfizer's motion to dismiss the Second Amended Petition for lack of personal jurisdiction is pending in an 89-plaintiff case filed in Missouri, *see Parker v. Pfizer, Inc.*, No. 1522-CC00318-01 (St. Louis City Cir. Ct.), and Pfizer has answered and served initial disclosures in a case filed in Arizona, *see Baggott v. Pfizer, Inc.*, No. C20153927 (Pima County Sup. Ct.), but discovery has not further progressed.

THE SCIENTIFIC RECORD

Melanoma is a form of skin cancer involving melanocytes, which are cells that color the skin. It is a disease caused by, among other things, excessive exposure to natural or artificial sunlight, exposure to certain environmental factors, and genetic factors (such as having certain changes in genes linked to melanoma). In the United States, melanoma occurs at a rate of 28.5 cases per 100,000 men, and it is estimated there will be 76,380 new cases diagnosed here in men and women in 2016. If caught early, the five-year survival rate is around 95%.

Pfizer believes an initial phase of general causation discovery would show that there is no reliable scientific evidence that Viagra causes or exacerbates melanoma. For more than fifteen years the scientific record has continued to demonstrate the safety and efficacy of Viagra that was demonstrated in pre-approval trials and studies. To date, Pfizer has conducted 136 clinical trials of Viagra, 74 of which were double-blind placebo-controlled clinical trials. Those studies do not

show any relationship between Viagra and melanoma. Many other scientists have studied Viagra (or Revatio) as well, and those studies likewise have not suggested any link between use of the medication and melanoma.

Plaintiffs base their claims on a handful of studies, none of which was a double-blind, placebo-controlled clinical trial, and only one of which involved human patients. That one study, the Li study, suggested an 84% increased risk of melanoma in men who used Viagra at least once within the three months preceding the baseline survey date (HR: 1.84; 95% CI, 1.04-3.22).[2] The Li study analyzed data from prior surveys of Massachusetts healthcare professionals, which were not specifically designed to study Viagra use or to collect data on any other PDE5 inhibitors. *See* Wen-Qin Li et al., JAMA INTERN. MED. 2014; 174(6):964-70. The study has significant limitations, which the authors themselves "acknowledge[d]." For example, because the study was not designed to evaluate PDE5 inhibitors, the study participants were asked only once, in 2000, about whether they had recently or ever used Viagra. Absent from the study—and not collected—is any information regarding the frequency and duration of use of Viagra, if any, or any other erectile dysfunction medications in the fourteen years between 2000 and the date of publication. This means that if a man took one Viagra pill on one occasion during some unidentified year before 2000, and developed melanoma in, say, 2010, he would be counted as a Viagra user, and the study authors would count his melanoma in their calculations supporting an increased risk of melanoma in Viagra users. The study's sample size, moreover, was "modest" at best—the data included only 142 total melanomas in all groups, 17 of which were in men who had ever used Viagra. And Viagra users were more likely to be older, have a higher BMI, and have a history of six or more severe or blistering sunburns, suggesting that they had a greater baseline risk of developing melanoma before ever taking Viagra.

[2] In a particular study, the ratio of an event happening in people exposed to a medication compared to those not exposed to a medication may be expressed as a "hazard ratio" (or HR), a "relative risk" (or RR), or an "odds ratio" (or OR). (The technical differences between those statistical measures are not important for present purposes.) The "confidence interval" (or CI) "is, in simple terms, the 'margin of error'" for the risk measure. *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 1166, 1172, 1174 (N.D. Cal. 2007).

In light of these and other limitations, the authors advised that their "results should be interpreted cautiously and are insufficient to alter current clinical recommendations." *Id*. at 969. They expressly stated: "Our study cannot prove cause and effect." *Id*.

Notably, a 2015 observational study (the "Loeb study") conducted in response to the Li study found a statistical 21% increased risk of melanoma in men taking all PDE5 inhibitors (OR: 1.21, 95% CI, 1.08-1.36) but concluded that the study results were inconsistent with a causal relationship. *See* Stacy Loeb et al., JAMA 2015; 313(24): 2449-55. The Loeb study, which, unlike the Li study, was based on six years of detailed prescription data, showed no relationship between the risk of melanoma and the amount of Viagra taken by a patient. That is, the risk of melanoma was not highest among those men who were most prescribed Viagra or another PDE5 inhibitor, but instead, and counterintuitively, was significantly higher in men who filled a single—just *one*—such prescription. Men who filled *multiple* prescriptions for Viagra or another PDE5 inhibitor were *not* at a significantly increased risk of developing melanoma. Further, if, as Plaintiffs allege, PDE5 inhibition leads to the occurrence or exacerbation of melanoma, then presumably those PDE5 inhibitors with a longer half-life (meaning those PDE5 inhibitors that are retained in the body for a longer period of time after ingestion) should be associated with a higher risk of melanoma. The results in the Loeb study, however, did not bear that out, as the rate of melanoma among men who used any of the studied PDE5 inhibitors, including those with half-lives longer than Viagra's, was virtually identical. Nor was the Loeb study consistent with Plaintiffs' allegation that Viagra exacerbates melanoma—it found no increased risk of more advanced (stages 2-4) melanoma and, indeed, the risk of metastatic melanoma (as compared to stage 0 or 1 melanoma) was *lower* in Viagra users than nonusers. For all of these reasons, the Loeb study authors recognized both that this "pattern of association raises questions about whether this association is causal" and that "the observed association may reflect confounding by lifestyle factors associated with both PDE5 inhibitor use and low-stage melanoma."[3]

[3] In discussing the study findings, lead author Dr. Stacy Loeb stated: "While medications for erectile dysfunction come with serious risk of a drop in blood pressure if taken together with other medicines called nitrates, overall they are safe medications, and our results suggest that physicians

In addition to the Li study, Plaintiffs rely on a few studies in mice or rats (known as in vivo studies) or in human cells tested in a laboratory (known as in vitro studies), none of which involved tests in actual humans. But those studies cannot establish that Viagra causes melanoma, for any number of reasons. *First*, none of the experiments show that Viagra is capable of transforming a normal skin cell into a melanoma cell. Some of the experiments attempt to address whether Viagra can cause already-cancerous melanoma cells to multiply faster (grow) or spread to other organs (metastasize), but none of the experiments even attempt to establish that Viagra use initiates the cancer process in the first place. *Second*, even among the studies that address the growth or spread of melanoma cells, the findings are inconsistent and contradictory. One of the studies purports to show that chronic Viagra exposure at high doses increases melanoma cell growth or increases the likelihood that the melanoma will spread, while others show that Viagra exposure *decreases* melanoma cell growth or that Viagra exposure has no effect on the spread of the melanoma. *Third*, even in the mouse and cell experiments that purport to show an effect on melanoma cell growth, those findings apply only to certain rare melanoma cells that produce high amounts of a protein known as PDE5A, which is true of only a fraction of human melanoma cells. And *fourth*, even for the experiments that involve those rare melanoma cells, the findings from these animal and cell experiments cannot be extrapolated to humans because: (a) the doses of Viagra used were much higher than what patients receive in the real world (for example, in one study, mice received more than 150 times the dose that an average man would receive, even if he took the highest dose of Viagra); (b) Viagra was administered constantly, whereas patients typically take Viagra intermittently, and it clears the body quickly; and (c) the effects of a medication in living humans cannot be predicted reliably based on tests in mice or on human cells in a test tube. *See* Reference Manual on Scientific Evidence (The Admissibility of Expert

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should not be concerned that the drugs cause melanoma[.].… Overall the pattern of the relationship did not support that these medicines cause melanoma." NYU Press Release (June 23, 2015), *Viagra Does Something Very Important – But It Is Unlikely to Cause Melanoma, Researchers Conclude*, http://nyulangone.org/press-releases/viagra-does-something-very-important-but-it-is-unlikely-to-cause-melanoma-researchers-conclude (last visited May 5, 2016).

Testimony) (Third Ed.) at 23 ("Opinions based on animal studies have been rejected because of reservations about extrapolating from animals to humans or because the plaintiff's extrapolated dose was lower than the animals.").

The scientific record contains no reliable evidence—because it does not exist—of a causal relationship between Viagra use and the development or exacerbation of melanoma.

THE REGULATORY RECORD

Before publication of the Li study, there was no suggestion—during the many years that Viagra had been on the market—of an association between the medication and melanoma. In July 2014, after the Li study was published, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (the European equivalent to the FDA) sought to further investigate and evaluate the "signal" first reported in Li. PRAC accordingly requested that Pfizer provide a cumulative review of the available data; the review was to be comprehensive in scope and address, among other things, the published literature, including the Li study, as well as any mechanistic studies, epidemiological studies, and clinical trials.

After receiving Pfizer's extensive analysis of the available data and studying the issue for several months, PRAC issued its Preliminary Assessment Report in October 2014. *See Preliminary PRAC rapporteur assessment report on the signal of melanoma with sildenafil*, EMA PRAC (Oct. 13, 2014). Regarding the Li study, PRAC observed it "has several important limitations . . . and insufficient data for a meaningful study." *Id.* at 7. Regarding the alleged association between Viagra use and melanoma, PRAC concluded "there is no data to indicate, or support a causal role for sildenafil [Viagra] on an increased risk for melanoma. Non-causal reasons should be considered for the observed relationship between sildenafil use and the risk for melanoma skin cancer. . . . No further action is considered necessary." *Id.* at 19. PRAC issued its Final Assessment Report in December 2014, confirming its recommendations. The Final Report, too, was unequivocal in its findings: "[N]on-clinical data did not support a causal mechanism, clinical studies and post-marketing data did not indicate an increased risk for melanoma skin cancer in sildenafil users, and . . . no plausible biological mechanism was confirmed."

Pharmacovigilance Risk Assessment Committee, Minutes of the meeting on 3-6 November 2014, at 29. As such, "[n]o changes to the product information of sildenafil containing medicines [Viagra] are required at this point in time." *Id.*

The FDA has not asked for any submissions regarding the Li study or regarding Viagra and melanoma generally. In February 2016, the agency instead notified Pfizer that a "Tracked Safety Issue," or TSI, had been created for all PDE5 inhibitors (including Viagra) regarding a potential risk of skin melanomas. TSIs are created when FDA, in the course of its routine monitoring, identifies a *potential* signal of a safety issue with an FDA-approved medication. TSIs are placed into one of three categories, in decreasing order of significance—emergency, priority, and standard. *See* Center for Drug Evaluation and Research, Draft Guidance, *Classifying Significant Postmarketing Drug Safety Issues*, at 1 (Mar. 2012); *id.* at 5 ("When the safety issue does not appear to fall clearly into either the priority or standard class, CDER will err on the side of caution and classify it as a priority issue."). FDA has classified the TSI regarding PDE5 inhibitors as "standard."[4]

Often, it is adverse event reporting—in particular a spike in adverse event reporting—that leads to the creation of a TSI. Adverse event reports can be submitted to FDA or to a pharmaceutical company such as Pfizer by physicians, patients, family members, attorneys, and others (indeed, literally anyone can submit a report), regarding any purported undesirable experience with a particular medication. Pfizer submits to FDA any adverse event reports it receives, including personal injury lawsuits filed against the company involving one of its medications. From whatever source (including lawsuits), the reports are compiled in FDA's

[4] As explained by the FDA, "[t]he appearance of a drug on each quarterly list does not mean that FDA has concluded that the drug has the listed risk. It also does not mean that FDA has identified a causal relationship between the drug and the listed risk." Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Policy and Procedures: *FDA Posting of Potential Signals of Serious Risks Identified by the Adverse Event Reporting System*, at 2 (Mar. 29, 2011). *See also* FDA, *Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)*, http://tinyurl.com/z5efjly (last visited May 4, 2016) (FDA's website expressly "emphasize[s]" that TSI inclusion "does not mean that FDA has determined that the drug has the risk.").

Adverse Event Reporting System (FAERS). Adverse event "reports do not provide reliable scientific evidence of causation. Rather, they are merely compilations of occurrences, and have been rejected as reliable scientific evidence supporting an expert opinion that *Daubert* requires." *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1133 (D. Ariz. 2001); *see Rimbert v. Eli Lilly & Co.*, 2009 WL 2208570, at *11 (July 21, 2009) ("The lack of a control group makes it impossible to state whether the adverse events observed were a result of Prozac, part of natural history and fluctuations of depression, or caused by other factors.").

What is notable here is that Plaintiffs themselves are largely (if not entirely) behind the increase in adverse event reporting regarding Viagra and melanoma. A review of the FDA's FAERS database for the last few years confirms that, historically, reports regarding patients who used Viagra and also were diagnosed with melanoma were sporadic, and received at a very low rate, until approximately February 2015, when the rate increased sharply—and that increase was due to the fact that Pfizer dutifully reported to FDA each of the lawsuits that various Plaintiffs here began filing. When the litigation-instigated reports submitted by, or on behalf of, or regarding, Plaintiffs are removed from the analysis, the reporting rates remain at their historical level. At issue here, then, is not a naturally occurring increase in adverse event reporting, but one driven by Plaintiffs and the filing of their complaints.[5]

THE THRESHOLD CRITICAL ISSUE IN THIS LITIGATION

The threshold critical issue in this litigation is general causation—"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 also In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. at 1175 ("general causation inquiry is whether exposure to the challenged substance 'at the

[5] As FDA guidance notes, FAERS data "may be affected by the submission of incomplete or duplicate reports, under-reporting, or reporting stimulated by publicity or litigation." FDA cautions that "these factors should be considered when interpreting a high reporting rate." CDER, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, at 9, 12 (Mar. 2005).

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, then, Plaintiffs must prove—with reliable expert testimony that satisfies *Daubert*—that Viagra is capable of causing melanoma. *See, e.g.*, *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1381 (N.D. Cal. 1995) ("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").

The initial resolution of this threshold issue will streamline the litigation, if not dispose of it entirely. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005) ("Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation."). As such, the Court should adopt a schedule that prioritizes discovery regarding general causation, to be followed by motions practice on that issue. The Manual for Complex Litigation ("Manual") contemplates such "phased, sequenced, or targeted discovery" and advises that "[f]or effective discovery control, initial discovery should focus on matters—witnesses, documents, information—that appear pivotal." Annotated Manual for Complex Litigation (4th ed. 2004) § 11.422 at 69. General causation by its nature is such a pivotal issue, and in fact the Manual expressly identifies issues worthy of being "taken up early in the litigation" as including "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." *Id.* § 22.634 at 519.

Other MDL courts in products liability matters have structured discovery to address general causation as a threshold issue, before the litigation reaches more advanced stages. *See, e.g., In Re Incretin Mimetics Prods. Liab. Litig.*, MDL No. 2452, No.13-md-2452-AJB (C.D. Cal. Feb. 18. 2014) (Initial Case Management Scheduling Order Regarding General Causation) ("initial discovery and document production will be limited to whether the requested information has some tendency in logic to prove or disprove whether Defendants' incretin mimetic drugs cause pancreatic cancer"); *In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, MDL

No. 1699, Case No. M:05-CV-01699-CRB (N.D. Cal. March 16, 2007) (Pretrial Order No. 21). The court presiding over the prior Viagra MDL entered just such an order—directing that "[t]he first phase of discovery for all cases shall be focused on the sole issue of general causation" and, with the exception of the completion of Plaintiff's Fact Sheets, staying "[a]ll fact and/or expert discovery on issues other than general causation issues." *In re Viagra Prods. Liab. Litig.*, MDL No. 1724 (D. Minn. June 30, 2006) (Scheduling Order Relating to Phase I of Discovery, at 1, 2). The court ruled that "targeted discovery and resolution of the issue of general causation serves the interest of all parties and the Court, promotes judicial efficiency, and prevents the potential waste of the parties' and the Court's resources." *Id.* at 1-2.

Given the scientific record here, Pfizer respectfully suggests that it is in the best interests of all parties to conduct an initial phase of fact discovery limited to the issue of general causation, to be followed by expert reports and appropriate *Daubert* motions practice directed to that issue. As of the date of this submission, the parties (Pfizer's counsel and Plaintiffs' proposed lead counsel) have discussed this issue informally, and it is Pfizer's understanding that Plaintiffs are agreeable in concept to such a discovery phasing. The parties plan to formally meet and confer before June 15 to determine whether they can agree on the scope of, and schedule for, an initial phase of general causation discovery to propose to the Court or, alternatively, if they are unable to agree, will so advise the Court at the June 15 conference and request that the Court decide the issue after further briefing.

OTHER FACTUAL AND LEGAL ISSUES

In addition to general causation, there are a host of other factual and legal issues that may warrant consideration at some point in the proceedings, including the following:

- For each Plaintiff, there are fact questions of an inherently individual nature, including those regarding the plaintiff's personal medical history (both before and after alleged Viagra usage); family medical history; use of Viagra (including dose, duration, and frequency of use); use of other medications (prescription and nonprescription); and sun exposure;

- Whether Plaintiffs can reliably demonstrate specific causation, *i.e.*, that their own alleged melanoma was caused by Viagra use and not other factors;
- Whether some or all of Plaintiffs' claims are subject to dismissal, in whole or in part, for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6);
- Whether Plaintiffs' allegations sounding in fraud satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b); and
- Whether Plaintiffs' claims are barred under the relevant statute(s) of limitation.

CONCLUSION

Pfizer will be prepared to address these and all other issues identified in Pretrial Order #1 at the June 15, 2016 conference.

Dated: May 9, 2016

Respectfully submitted,

BY: /s/ John E. Joiner

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CERTIFICATE OF SERVICE

I, John E. Joiner, hereby certify that on this 9th day of May, 2016, I electronically filed the foregoing with the Court using the CM/ECF system.

BY: /s/ John E. Joiner

Exhibit 1

EXHIBIT 1 TO DEFENDANT PFIZER'S POSITION STATEMENT FOR INITIAL CASE MANAGEMENT CONFERENCE

I. CASES FILED IN OR TRANSFERRED TO THIS COURT.

As of May 9, 2016, the following cases have been filed in this Court or transferred here pursuant to an Order of the Judicial Panel on Multidistrict Litigation:

Case Name	Case Number	Pending Court
Ron Rosenwein, Individually and on behalf of the Estate of Lloyd Rosenwein v. Pfizer, Inc.	3:16-cv-1896	N.D. Cal.
Charles Cusimano and Cindy Cusimano v. Pfizer, Inc.	3:16-cv-1898	N.D. Cal.
Larry LeBlanc and Diane LeBlanc v. Pfizer, Inc.	3:16-cv-1897	N.D. Cal.
Joe Holley v. Pfizer, Inc.	3:16-cv-1899	N.D. Cal.
Juliene J. Wood, as Trustee for the next of kin of John W. Wood, Jr., Deceased v. Pfizer, Inc.	3:16-cv-01874	N.D. Cal.
Michael Gardiner v. Pfizer, Inc.	3:16-cv-1900	N.D. Cal.
Robert Eubanks and Teresa R. Eubanks v. Pfizer, Inc.	3:16-cv-02145	N.D. Cal.
Faircloth, Roy Roger v. Pfizer, Inc.	3:16-cv-02223	N.D. Cal.
Harold Troy v. Pfizer, Inc.	3:16-cv-02214	N.D. Cal.
James A. Tune v. Pfizer, Inc.	3:16-cv-02220	N.D. Cal.
Claude Linley v. Pfizer, Inc.	3:16-cv-02121	N.D. Cal.

Case Name	Case Number	Pending Court
Willard Hoffman v. Pfizer, Inc.	3:16-cv-02020	N.D. Cal.
Edwin Kelly v. Pfizer, Inc.	3:16-cv-02005	N.D. Cal.
Sue Matthews, individually and on behalf of the heirs and estate of Robin Matthews, deceased, v. Pfizer, Inc., a Delaware corporation	3:16-cv-02119	N.D. Cal.
Dennis Andrews v. Pfizer, Inc.	3:15-cv-04884	N.D. Cal.
Amador Herrara v. Pfizer, Inc.	3:15-cv-04888	N.D. Cal.
Lyle Toole v. Pfizer, Inc.	3:15-cv-04989	N.D. Cal.
Autumn Allen, Personal Representative of the Estate of Wilfred Phillips v. Pfizer, Inc., a corporation of the State of Delaware doing business in Maine	3:16-cv-02143	N.D. Cal.
Lance Warren v. Pfizer, Inc.	1:15-cv-5206	N.D. Cal.
Edmond Nicholas v. Pfizer, Inc.	3:15-cv-5251	N.D. Cal.
Henri Geier v. Pfizer, Inc.	3:16-cv-02074	N.D Cal.
Edward D. Corboy, Jr. v. Pfizer, Inc.	1:16-00247	N.D. Cal.
Danielle Schoenrock, individually and as Special Administrator on behalf of the heirs and estate of Curtis Stern, deceased v. Pfizer, Inc., a Delaware corporation	3:16-cv-02144	N.D. Cal.

Case Name	Case Number	Pending Court
Martin Mott v. Pfizer, Inc.	3:16-cv-02177	N.D. Cal.
Terrence Hayes v. Pfizer, Inc.	3:16-cv-01093	N.D. Cal.
Michael Smith v. Pfizer, Inc.	3:16-cv-01183	N.D. Cal.
Thomas Brownfield v. Pfizer, Inc.	3:16-cv-01182	N.D. Cal.
Joao Delgado v. Pfizer, Inc.	3:16-cv-01464	N.D. Cal.
Michael W. Giovando v. Pfizer, Inc.	3:16-cv-01607	N.D. Cal.
James L. Gutherie v. Pfizer, Inc.	3:16-cv-01601	N.D. Cal.
Gerald K. Brown v. Pfizer, Inc.	3:16-cv-01594	N.D. Cal.
Robert R. Lunato v. Pfizer, Inc.	3:16-cv-01646	N.D. Cal.
Richard P. Carter v. Pfizer, Inc.	4:16-cv-01645	N.D. Cal.
Michael S. Riggs v. Pfizer, Inc.	4:16-cv-01647	N.D. Cal.
Paul J. Riley v. Pfizer, Inc.	4:16-cv-01654	N.D. Cal.
John A. Wendling v. Pfizer, Inc.	3:16-cv-01652	N.D. Cal.

Case Name	Case Number	Pending Court
Vernon D. Ware, Jr. v. Pfizer, Inc.	3:16-cv-01649	N.D. Cal.
Michael L. Piersol v. Pfizer, Inc.	4:16-cv-01653	N.D. Cal.
Larry Maddux, Sr. v. Pfizer, Inc.	3:16-cv-01675	N.D. Cal.
Joseph Barnes, III v. Pfizer, Inc.	3:16-cv-01674	N.D. Cal.
Stephen Crossland v. Pfizer, Inc.	3:16-cv-01673	N.D. Cal.
Ronald Willoughby v. Pfizer, Inc.	3:16-cv-01681	N.D. Cal.
Paul O'Malley v. Pfizer, Inc.	3:16-cv-01682	N.D. Cal.
Lennart Anderson v. Pfizer, Inc.	4:16-cv-01683	N.D. Cal.
Charles Christensen v. Pfizer, Inc.	3:16-cv-01684	N.D. Cal.
John Reinwald v. Pfizer, Inc.	3:16-cv-01685	N.D. Cal.
James Mulvaney v. Pfizer, Inc.	4:16-cv-01713	N.D. Cal.
Kenneth Jansen, Jr. v. Pfizer, Inc.	3:16-cv-01715	N.D. Cal.
David B. Anderson v. Pfizer, Inc.	4:16-cv-01719	N.D. Cal.

Case Name	Case Number	Pending Court
Lyle Maxey v. Pfizer, Inc.	3:16-cv-01716	N.D. Cal.
John Switalski v. Pfizer, Inc.	3:16-cv-01718	N.D. Cal.
Robert A. Tucker v. Pfizer, Inc	3:16-cv-01734	N.D. Cal.
Gregory Grant v. Pfizer, Inc.	3:16-cv-01731	N.D. Cal.
Russell L. Kight v. Pfizer, Inc.	3:16-cv-01733	N.D. Cal.
James W. Reeder v. Pfizer, Inc.	4:16-cv-01742	N.D. Cal.
Robert Irving v. Pfizer, Inc.	3:16-cv-01753	N.D. Cal.
Wilbert J. Couvillion v. Pfizer, Inc.	3:16-cv-01746	N.D. Cal.
Gregory P. Urbanski v. Pfizer, Inc.	3:16-cv-01750	N.D. Cal.
John W. Smith, Jr. v. Pfizer, Inc.	3:16-cv-01749	N.D. Cal.
Carl B. Hedwall v. Pfizer, Inc.	3:16-cv-01759	N.D. Cal.
Pierce P. Ryan v. Pfizer, Inc.	3:16-cv-01757	N.D. Cal.
Joseph S. Popovec v. Pfizer Inc.	4:16-cv-01758	N.D. Cal.

Case Name	Case Number	Pending Court
DelRay R. Stephens v. Pfizer, Inc.	3:16-cv-01760	N.D. Cal.
Thomas J. Brown v. Pfizer, Inc.	3:16-cv-01751	N.D. Cal.
John J. Schultz v. Pfizer, Inc.	3:16-cv-01761	N.D. Cal.
George Ripps v. Pfizer Inc.	4:16-cv-01748	N.D. Cal.
Randy A. Jumper v. Pfizer Inc.	3:16-cv-01767	N.D. Cal.
Norma S. Chaney, Individually and as Personal Representative of the Estate of Mickey Chaney, Deceased v. Pfizer Inc.	3:16-cv-01766	N.D. Cal.
Peter M. Cox v. Pfizer, Inc.	3:16-cv-01769	N.D. Cal.
Mark D. Callahan v. Pfizer, Inc.	3:16-cv-01770	N.D. Cal.
Harris A. Branaman v. Pfizer, Inc.	3:16-cv-01771	N.D. Cal.
Pamela W. Coots, Individually and as Administrator of the Estate of Kenneth Coots, Deceased v. Pfizer Inc.	3:16-cv-02178	N.D. Cal.
James V. Patrick v. Pfizer Inc.	3:16-cv-01782	N.D. Cal
Tony D. Brown v. Pfizer, Inc.	3:16-cv-01780	N.D. Cal
Sandra K. Coyle, Individually and as Personal Representative of the Estate of Lester H. Coyle, deceased. v. Pfizer Inc.	3:16-cv-01783	N.D. Cal

Case Name	Case Number	Pending Court
John Henry v. Pfizer, Inc.	3:16-cv-01779	N.D. Cal
Raymond L. Rose v. Pfizer Inc.	3:16-cv-01785	N.D. Cal
Timothy J. Meline v. Pfizer Inc.	3:16-cv-01791	N.D. Cal
Bruce Garber v. Pfizer Inc.	3:16-cv-01795	N.D. Cal
James T. Black v. Pfizer Inc.	3:16-cv-01796	N.D. Cal
John C. Wallace v. Pfizer Inc.	3:16-cv-01792	N.D. Cal
Edward Callaci v. Pfizer, Inc.	3:16-cv-01793	N.D. Cal
John Soltesz v. Pfizer, Inc.	3:16-cv-01798	N.D. Cal
Jimmie A. Christensen v. Pfizer Inc.	3:16-cv-01801	N.D. Cal
Richard L. DeSalvo v. Pfizer Inc.	3:16-cv-01797	N.D. Cal
Roy C. Lusch v. Pfizer Inc.	3:16-cv-01802	N.D. Cal
James M. Porter v. Pfizer Inc.	3:16-cv-01800	N.D. Cal
Eugene C. Hendrickson v. Pfizer Inc.	3:16-cv-01799	N.D. Cal

Case Name	Case Number	Pending Court
Barry Diederich v. Pfizer Inc.	3:16-cv-01804	N.D. Cal
Allen L. Lechtman v. Pfizer Inc.	3:16-cv-01805	N.D. Cal
Chester Jones v. Pfizer Inc.	3:16-cv-01809	N.D. Cal
Thomas Riederer v. Pfizer Inc.	3:16-cv-01806	N.D. Cal
Francis Hughes v. Pfizer Inc.	3:16-cv-01808	N.D. Cal
James Davenport v. Pfizer Inc.	4:16-cv-1807	N.D. Cal
Brian M. White v. Pfizer, Inc.	3:16-cv-01972	N.D. Cal
Larry Shultz v. Pfizer, Inc.	3:16-cv-01988	N.D. Cal
Dorn L. Schmidt v. Pfizer, Inc.	3:16-cv-01999	N.D. Cal
Seamus O. Calkins v. Pfizer inc.	3:16-cv-02316	N.D. Cal.
David Cohen v. Pfizer, Inc.	3:16-cv-01778	N.D. Cal
Dan Darr v. Pfizer, Inc.	3:16-cv-01781	N.D. Cal

Case Name	Case Number	Pending Court
Barry Milligan v. Pfizer, Inc.	3:16-cv-02067	N.D. Cal.

II. CASES FILED IN FEDERAL COURT BUT NOT YET TRANSFERRED TO THIS COURT.

As of May 9, 2016, the following cases have been filed in federal courts in other jurisdictions, but have not yet been transferred here pursuant to an Order of the Judicial Panel on Multidistrict Litigation. Pfizer has filed Notices of Potential Tag-Along Actions with the JPML regarding these cases.

Case Name	Case Number	Pending Court
Kenneth L. McDaniel v. Pfizer, Inc.	2:16-cv-00553	N.D. Ala.
Scott Winfrey v. Pfizer Inc.	1:16-cv-01112	N.D. Ga.
Ronnie L. Mounts v. Pfizer, Inc.	2:16-cv-03217	S.D. W.Va.
Thomas Watts v. Pfizer Inc.	1:16-cv-01124	N.D. Ga.
Jody Fyfe v. Pfizer, Inc.	1:16-cv-02985	S.D.N.Y.

III. CASES FILED IN FEDERAL COURT BUT NOT YET TRANSFERRED TO THIS COURT.

As of May 9, 2016, the following cases are pending in state court.

Case Name	Case Number	Pending Court
Thomas P. Baggott v. Pfizer, Inc.	C20153927	Ariz. Super. Ct.; Pima Cnty.
Paul Parker v. Pfizer, Inc.[1]	1522-CC00318-01	Circuit Court, City of St Louis

[1] There are 89 total plaintiffs in this case.