

**BEFORE THE  
UNITED STATES JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION**

IN RE TENOFOVIR DISOPROXIL  
FUMARATE PRODUCTS LIABILITY  
LITIGATION

MDL-\_\_\_\_\_

**BRIEF IN SUPPORT OF THE HOLLEY PLAINTIFFS' MOTION  
FOR TRANSFER OF ACTIONS TO THE NORTHERN DISTRICT  
OF CALIFORNIA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED  
OR CONSOLIDATED PRETRIAL PROCEEDINGS**

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## I. INTRODUCTION

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, plaintiffs in *Holley, et al. v. Gilead Sciences, Inc.*, No. 3:18-cv-6972-JST (N.D. Cal.) (the “*Holley Plaintiffs*”) respectfully move the Panel for an order transferring the actions listed on the accompanying Schedule of Actions, as well as any tag-along actions or other cases that may be filed asserting related or similar claims (the “*Related Actions*”), to the Northern District of California for consolidated or coordinated pretrial proceedings.

There are currently five actions pending in five different federal district courts involving approximately one hundred and fifty plaintiffs who allege they were injured by taking one or more of defendant Gilead Sciences, Inc.’s defective HIV drugs that contain the active ingredient tenofovir disoproxil fumarate (“TDF”). All plaintiffs allege that Gilead intentionally designed its TDF drugs to be unreasonably and unnecessarily toxic to patients’ kidneys and bones, while it purposefully withheld a safer design of the drugs for more than a decade in order to make more money. All plaintiffs also challenge the inadequate warnings Gilead gave to physicians and consumers about the risks and safe use of the TDF drugs. Because the cases involve numerous common questions of fact and law, transfer for centralized proceedings in one federal district court will achieve efficiencies in discovery and motion practice, preserve judicial resources, and alleviate the risk of inconsistent pretrial rulings.

The Northern District of California is, by far, the most appropriate forum for consolidated or coordinated pretrial proceedings. Gilead is headquartered and has its principal place of business in the Northern District of California. The conduct that plaintiffs challenge occurred there, the critical mass of important witnesses and documentary evidence is located there, and the overwhelming majority of plaintiffs’ claims are already pending there. In addition, locating this multidistrict litigation in the Northern District of California will facilitate coordination between

the federal cases and state actions pending in Los Angeles County Superior Court; provide a convenient location in a major metropolitan area with ready access from every region of the country; centralize the actions in the court most likely to advance the litigation the furthest in the shortest amount of time; and permit the assignment of a judge who is experienced in multidistrict and other complex litigation. For these reasons and those further discussed below, the Panel should grant the *Holley* Plaintiffs' motion.

## II. BACKGROUND

### A. The allegations

#### 1. Design defects

TDF is a form of the compound tenofovir, which works by blocking an enzyme HIV needs to replicate. Gilead manufactures, markets, and sells five drugs that contain TDF for the treatment of HIV: Viread (300 mg TDF tablets); Truvada (TDF 300 mg/emtricitabine 200 mg tablets); Atripla (TDF 300 mg/emtricitabine 200 mg/efavirenz 600 mg tablets); Complera (TDF 300 mg/emtricitabine 200 mg/rilpivirine 25 mg tablets); and Stribild (TDF 300 mg/emtricitabine 200 mg/elvitegravir 150 mg/cobicistat 150 mg tablets).<sup>1</sup> The Related Actions challenge Gilead's decision to intentionally withhold a safer design of these drugs in order to make more money.

Before Gilead began selling its first TDF drug, Viread, in 2001, Gilead knew that TDF could be highly toxic to patients' kidneys and bones. And once TDF was on the market, Gilead's knowledge of TDF's toxic effects grew as patients were injured by each successive TDF product. By the time Gilead designed Stribild, it had ten years' worth of cumulative evidence that TDF injured patients' kidneys and bones.

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<sup>1</sup> Viread is also indicated to treat Hepatitis B. And Truvada is also indicated for use in combination with safe sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.



Gilead also knew, before it started selling its TDF drugs, that it had discovered a safer version of tenofovir—tenofovir alafenamide fumarate (“TAF”). TAF is absorbed into the cells HIV targets much more efficiently than TDF. As a result, TAF can be administered at a dramatically reduced dose compared to TDF without sacrificing efficacy. Because TAF can be administered at a much lower dose than TDF, TAF is much less toxic than TDF. A 25 mg dose of TAF achieves the same therapeutic effect as a 300 mg dose of TDF, with a better safety profile. Despite knowing that TAF could be given at a much lower, safer dose, Gilead intentionally designed Viread, Truvada, Atripla, Complera, and Stribild to contain toxic TDF rather than safer TAF.

Falsely claiming that TAF was not different enough from TDF, Gilead abruptly shelved its TAF design in 2004. However, as John Milligan, Gilead’s President and Chief Executive Officer, later admitted to investment analysts, the real reason Gilead abandoned the TAF design was that TAF was *too* different from TDF. Once Viread was on the market, Gilead did not want to hurt TDF sales by admitting that its TDF-based products are unreasonably and unnecessarily unsafe.

In addition, Gilead knew that by withholding the safer TAF design, it could extend the longevity of its HIV drug franchise and make billions two times over: first, with TDF medications until TDF patent expiration, which would begin by no later than 2018, and second, with TAF medications until TAF patent expiration as late as 2032. Only once Gilead realized billions in sales through most of the TDF patent life did it seek to market safer TAF-based versions of its HIV medications.

Finally, in 2015, Gilead began selling the first of its TAF-designed medicines and convinced doctors to switch their patients from TDF-based to TAF-based treatments by

demonstrating TAF's superior safety profile over TDF with respect to kidney and bone toxicity—the very benefits Gilead could have and should have incorporated into its prior product designs but withheld from doctors and patients for over a decade.

The *Holley* Plaintiffs also allege that Gilead made Stribild even more dangerous when it designed the drug to include cobicistat in combination with 300 mg TDF. Cobicistat is a pharmacoenhancer or “booster” that inhibits the breakdown of elvitegravir, another active ingredient in Stribild. Gilead knew years before it developed Stribild that: (a) higher tenofovir concentrations in patients' blood, as opposed to the target cells, endangers the kidneys; (b) tenofovir concentrations in patients' blood increase significantly when patients take tenofovir with a booster like cobicistat; and (c) TDF-associated renal toxicity occurs more frequently in patients taking TDF as part of a boosted regimen.

When Gilead developed its first TAF-based antiviral product, Genvoya—which is Stribild with TAF in place of TDF—Gilead reduced the dose of TAF from 25 mg to 10 mg to account for the fact that cobicistat significantly increases tenofovir concentrations. Gilead knew to reduce the dose of TAF in Genvoya before it submitted Stribild to the FDA for marketing approval. Despite this knowledge, Gilead did not reduce the dose of TDF when it designed Stribild. Stribild is even more toxic to patients' kidneys and bones than Gilead's other TDF drugs.

## **2. Failure to warn**

Gilead also failed to adequately warn physicians and patients about the risks and safe use of TDF. Gilead provided only the weakest, inadequate warnings to doctors and patients about the need for frequent monitoring of all patients for TDF-associated kidney and bone damage—preventing doctors from detecting early signs of TDF toxicity. Gilead provides stronger monitoring warnings to physicians and patients in the European Union than it does in the United

States for the exact same TDF products. Contrary to its U.S. labeling, Gilead has consistently recommended, since the approval of its first TDF drug in the EU, that doctors in the EU monitor all TDF Drug patients for multiple markers of TDF toxicity on a frequent, specified schedule. There is no scientific or medical rationale for these differences. Gilead was more concerned with increasing or maintaining crucial U.S. sales than it was in safeguarding patients from the known risks of TDF.

**B. The Related Actions**

Holley, et al. v. Gilead Sciences, Inc., No. 3:18-cv-6972-JST (N.D. Cal.) asserts claims on behalf of 140 plaintiffs under the laws of Alabama, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Washington, and Wisconsin.<sup>2</sup> Plaintiffs allege they were injured as a result of taking Stribild or Stribild and one or more of Gilead's other TDF drugs, Viread, Truvada, Atripla, and Complera.<sup>3</sup> Although plaintiffs' claims vary somewhat by state, the *Holley* complaint includes claims for strict liability (design defect and failure to warn), statutory product liability, negligence, breach of implied warranty of merchantability, fraud by omission, and violation of state consumer protection statutes.<sup>4</sup> The *Holley* action was the first complaint to assert the additional theory that Stribild is even more toxic to patients' kidneys and bones than the other TDF drugs.

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<sup>2</sup> See Ex. 1 to the Schedule of Actions, *Holley* Docket and Complaint at ¶¶ 389-644.

<sup>3</sup> See *id.* at ¶ 1.

<sup>4</sup> See *id.* at ¶¶ 389-644.

The Honorable Jon S. Tigar set the initial case management conference for March 13, 2019.<sup>5</sup> The parties' joint case management statement is due March 4, 2019.<sup>6</sup> Under the Standing Order for All Judges of the Northern District of California, the parties must confer and attempt to agree upon a multitude of case management issues ahead of the conference, including, *inter alia*: the preservation and production of electronically stored information; the scope of anticipated discovery and proposed limitations or modifications to the discovery rules; a proposed discovery plan pursuant to Fed. R. Civ. P. 26(f); and a proposed trial plan.<sup>7</sup> Pursuant to court order, on January 11, 2019, the parties will begin discussing these case management issues.<sup>8</sup> Gilead's anticipated motion to dismiss will be fully briefed by April 5, 2019.<sup>9</sup>

*Dechow, et al. v. Gilead Sciences, Inc.*, No. 2:18-cv-9362-AB-GSJ (C.D. Cal.) was removed by Gilead from Los Angeles Superior Court on November 1, 2018.<sup>10</sup> The complaint asserts claims under California law (strict products liability, negligence, breach of implied warranty, and breach of express warranty) on behalf of four plaintiffs who took Viread and Truvada.<sup>11</sup> On December 5, 2018, plaintiffs filed a motion to remand, which will be heard by the court on February 1, 2019.<sup>12</sup> Gilead's deadline to respond to the complaint is thirty days after the court's order on plaintiffs' remand motion.<sup>13</sup>

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<sup>5</sup> *See id.*, *Holley* Docket No. 13.

<sup>6</sup> *See id.*

<sup>7</sup> *See id.*, Docket No. 13-2.

<sup>8</sup> *See id.*, Docket No. 23

<sup>9</sup> *See id.*

<sup>10</sup> *See* Ex. 2 to the Schedule of Actions, *Dechow* Docket and Complaint, Docket No. 2.

<sup>11</sup> *See id.*, *Dechow* Docket No. 2-1.

<sup>12</sup> *See id.*, Docket No. 15.

<sup>13</sup> *See id.*, Docket No. 14.

Smith v. Gilead Sciences, Inc., No. 18-cv-01906-JEB (D.D.C.) asserts claims under District of Columbia law (strict products liability and breach of express warranty) on behalf of one plaintiff who took Truvada.<sup>14</sup> Gilead's motion to dismiss the case will be fully briefed on February 22, 2019.<sup>15</sup> There is no case management conference scheduled.

Pierot v. Gilead Sciences, Inc., No. 3:18-cv-975-TAD (W.D. La.) asserts claims under Louisiana law (violation of the Louisiana Products Liability Act and breach of warranty in redhibition) on behalf of one plaintiff who took Truvada.<sup>16</sup> Gilead's motion to dismiss the case will be fully briefed on February 6, 2019.<sup>17</sup> There is no case management conference scheduled.

Hills v. Gilead Sciences, Inc., No. 3:18-cv-718-SDD-EWD (M.D. La.) asserts claims under Louisiana law (violation of the Louisiana Products Liability Act and breach of warranty in redhibition) on behalf of one plaintiff who took Viread.<sup>18</sup> On July 27, 2018, the Clerk of Court for the Middle District of Louisiana notified the Panel that the *Hills* action was a potential multidistrict case.<sup>19</sup> The court cancelled a scheduling conference pending review by the Panel.<sup>20</sup> Gilead's motion to dismiss the case will be filed on December 19, 2018 with plaintiff's opposition due January 9, 2019.<sup>21</sup>

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<sup>14</sup> See Ex. 3 to the Schedule of Actions, *Smith* Docket and Complaint, Docket No. 1.

<sup>15</sup> See *id.*, *Smith* Docket No. 8.

<sup>16</sup> See Ex. 4 to the Schedule of Actions, *Pierot* Docket and Complaint, Docket No. 1.

<sup>17</sup> See *id.*, *Pierot* Docket No. 12.

<sup>18</sup> See Ex. 5 to the Schedule of Actions, *Hills* Docket and Complaint, Docket No. 1.

<sup>19</sup> See *id.*, *Hills* Docket No. 3.

<sup>20</sup> See *id.*, Docket No. 6.

<sup>21</sup> See *id.*, Docket No. 16.

**C. The state cases**

Lujano, et al. v. Gilead Sciences, Inc., No. BC702302 asserts personal injury claims under California law (strict products liability, negligence, breach of implied warranty, and breach of express warranty) on behalf of two plaintiffs who took Truvada and Atripla. The case is pending in Los Angeles County Superior Court.<sup>22</sup>

Martinez, et al. v. Gilead Sciences, Inc., No. BC705063 is a putative California class action brought in Los Angeles County Superior Court to recover under the California Consumer Legal Remedies Act (§1750) and California Business and Professional Code (§17500).<sup>23</sup>

The two California cases have been related before the same judge in Los Angeles County Complex Court. Gilead's motion to dismiss will be heard on January 23, 2019.<sup>24</sup>

**III. TRANSFER AND COORDINATION OF THE RELATED ACTIONS IS APPROPRIATE**

**A. The Related Actions involve common questions of fact and law.**

The Related Actions involve one or more common questions of fact, including:

- What Gilead knew about the risks of TDF-associated damage to patients' kidneys and bones and adverse events associated with TDF, and the timing of such knowledge;
- When Gilead discovered TAF and its benefits over TDF;
- Why Gilead chose to design Viread, Truvada, Atripla, Complera, and/or Stribild to contain toxic TDF rather than safer TAF;
- Whether there existed a safer alternative design to TDF before Gilead began selling Viread, Truvada, Atripla, Complera, and/or Stribild;
- Why Gilead stopped clinical development of TAF in 2004;

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<sup>22</sup> See *Lujano* Complaint for Damages, attached hereto as Ex. A.

<sup>23</sup> See *Martinez* Class Action Complaint for Injunctive Relief and Damages, attached hereto as Ex. B.

<sup>24</sup> See Ex. A.

- Why Gilead obtained seven patents that purportedly cover TAF after it (temporarily) ceased clinical development of TAF;
- Why Gilead renewed clinical development of TAF in 2010;
- Whether Gilead timed the introduction of its safer TAF-designed products as part of a strategy to mitigate the effects of generic competition;
- What Gilead tells physicians and consumers in promotional or other marketing materials about TDF and/or TAF;
- What Gilead has concluded, based on clinical studies and other medical literature, about the safety benefits of TAF over TDF; and
- What Gilead's labeling states about the risks and safe use of TDF and why Gilead's labeling does not include stronger warnings.

The Related Actions involve one or more common questions of law, including:

- Whether plaintiffs' design defect claims are impliedly preempted by federal law governing the approval of prescription drugs;
- Whether plaintiffs' failure to warn claims are impliedly preempted by federal law governing the approval of prescription drugs;
- Whether Gilead's TDF drugs are defective in design;
- Whether Gilead's product labeling for Viread, Truvada, Atripla, Complera, and/or Stribild adequately warned physicians and patients about the risks and safe use of the drugs;
- Whether Gilead was negligent or grossly negligent in designing and/or marketing its TDF drugs;
- Whether Gilead breached its implied warranty that the TDF drugs would be merchantable and safe for their intended use; and
- Whether Gilead's conduct was willful or wanton for the purpose of awarding punitive damages.

The Panel has repeatedly found that centralization of pretrial proceedings was warranted in similar pharmaceutical product liability suits because they involved these type of common

issues.<sup>25</sup> That some plaintiffs ingested different TDF drugs does not defeat the commonality of the issues. The Panel frequently centralizes product liability actions challenging the safety of a drug substance that is a component of different drug products.<sup>26</sup> Here, the toxicity of TDF is a core factual concern of every Related Action. Moreover, common issues predominate even though the *Holley* Plaintiffs assert an additional defect theory with respect to Stribild. Section

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<sup>25</sup> See, e.g., *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, MDL No. 2848, 2018 U.S. Dist. LEXIS 132380, at \*2 (J.P.M.L. Aug. 2, 2018) (centralizing actions that shared common questions with respect to the design, testing, manufacture, regulatory approval, labeling, and marketing of vaccine); *In re Farxiga (Dapagliflozin) Prods. Liab. Litig.*, 273 F. Supp. 3d 1380, 1382 (J.P.M.L. 2017) (centralizing actions that shared common factual questions arising from allegations that taking Farxiga or Xigduo XR may result in kidney-related injuries); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1380 (J.P.M.L. 2011) (ruling that centralization was appropriate because actions shared common factual issues as to whether the products were defectively designed and marketed and whether defendants knew of the risks associated with the medications); *In re Yasmin & Yaz (Drospirenone) Mkg.*, 655 F. Supp. 2d 1343, 1343-44 (J.P.M.L. 2009) (centralizing product liability actions with actions challenging marketing practices because all actions sought to hold defendant responsible for harm arising out of the purchase and use of at least one oral contraceptive containing drospirenone); *In re Chantix Prods. Liab. Litig.*, 655 F. Supp. 2d 1346, 1346 (J.P.M.L. 2009) (centralizing actions because they shared factual issues regarding defendant's design, testing, manufacture, and marketing of a smoking cessation drug alleged to have dangerous side effects); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (centralizing actions because they each focused on alleged increased health risks when taking the drug Vioxx and whether defendant knew about the risks and failed to properly disclose them); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379 (J.P.M.L. 2001) (ruling that centralization was appropriate because all actions "remain rooted in complex core questions concerning the safety" of the drug substance).

<sup>26</sup> See, e.g., *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d 1381, 1382 (J.P.M.L. 2015) (centralizing actions that challenged the safety of three brand-name drugs that contained the same active ingredient); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d at 1380 (centralizing actions that challenged the safety of different medications containing propoxyphene); *In re Avandia Mktg.*, 528 F. Supp. 2d 1339, 1340-41 (J.P.M.L. 2007) (centralizing actions that challenged the safety of multiple brand-name drugs that contained the same active ingredient); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d at 1379 (centralizing actions that challenged the safety of a common drug substance that was an ingredient in multiple different nasal decongestant and weight control products).



1407 does not require a complete or even a majority of common issues.<sup>27</sup> Additional allegations or legal theories will not prevent transfer where, as here, the actions arise from a common factual core.<sup>28</sup> The transferee judge has broad discretion to employ a variety of pretrial techniques, such as separate discovery and/or motion tracks, to address any differences among the cases and efficiently manage the various aspects of the litigation.<sup>29</sup> The Related Actions should be centralized because they share overwhelmingly common issues with respect to Gilead's design, testing, labeling, marketing, and promotion of the TDF drugs and the availability of a safer alternative design.

**B. Consolidation will promote the just and efficient resolution of the Related Actions.**

In light of the many common issues shared by the Related Actions, “[c]entralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary.”<sup>30</sup> For example, if the cases remain on separate

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<sup>27</sup> See *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d at 1381.

<sup>28</sup> See, e.g., *In re Auto Body Shop Antitrust Litig.*, 37 F. Supp. 3d 1388, 1390 (J.P.M.L. 2014) (“Transfer under Section 1407 does not require a complete identity of common factual issues or parties as a prerequisite to transfer, and the presence of additional facts or differing legal theories is not significant where, as here, the actions still arise from a common factual core.”).

<sup>29</sup> See *In re Walgreens Herbal Supplements Mktg. & Sales Practices Litig.*, MDL No. 2619, 2015 U.S. Dist. LEXIS 77377, at \*7 (J.P.M.L. June 11, 2015). Moreover, transferee judges in product liability MDLs routinely employ case management tools such as separate discovery tracks to handle the different issues that arise in such cases. See, e.g., *In re Zolofit (Sertranline Hydrochloride) Prods. Liab. Litig.*, 856 F. Supp. 2d 1347, 1348 (J.M.P.L. 2012) (“[W]e have found that products liability cases often present some individual factual issues, but that coordination of discovery across all actions, with the use of common and individual discovery tracks, can offer efficiencies to all parties.”); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d at 1381 (“Transferee judges can accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits.”).

<sup>30</sup> *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 908 F. Supp. 2d 1362, 1364 (J.P.M.L. 2012); see also *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, 2018 U.S. Dist. LEXIS 132380, at \*2 (same); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d at 1380-81 (same); *In re Farxiga (Dapagliflozin) Prods. Liab. Litig.*, 273 F. Supp. 3d at 1382

tracks, there is a risk that the different courts will reach different results with respect to whether plaintiffs' design defect claims are preempted. Federal district courts are divided on whether state law design defect claims against manufacturers of brand-name prescription drugs are impliedly preempted by federal law that governs the approval of prescription drugs. Some courts have held that such claims are not preempted because the U.S. Supreme Court has not addressed preemption of design defect claims involving brand-name pharmaceuticals, and the Court's precedent with respect to generic drugs does not apply.<sup>31</sup> Others have held that such claims are not preempted if plaintiffs allege that the brand-name manufacturer should have designed a safe product before obtaining regulatory approval.<sup>32</sup> And some have held that such claims are preempted because a design change requires regulatory approval.<sup>33</sup> Centralization will avoid the risk that this inconsistent treatment of design claims in cases involving different drugs will occur here in connection with cases involving the same drug. Moreover, if the cases are centralized, the parties will need to brief this issue only once, conserving the resources of the parties, their

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(same); *In re Yasmin & Yaz Mktg.*, 655 F. Supp. 2d at 1344 ("Transfer under Section 1407 will offer the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs while ensuring that common parties and witnesses are not subjected to discovery demands that duplicate activity that will occur or has already occurred in other actions.").

<sup>31</sup> See, e.g., *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 U.S. Dist. LEXIS 153972, at \*74 (E.D. Pa. Nov. 13, 2015); *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721-22 (E.D. Pa. 2014).

<sup>32</sup> See, e.g., *Young v. Bristol-Myers Squibb Co.*, 2017 U.S. Dist. LEXIS 24730, at \*16-21 (N.D. Miss. Feb. 22, 2017); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1208 (E.D. La. 2016).

<sup>33</sup> See, e.g., *Yates v. Ortho-Mcneil-Janssen Pharms., Inc.*, 808 F.3d 281, 299-300 (6th Cir. 2015); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185-86 (S.D.N.Y. 2016).

counsel, and the judiciary. Centralization at this early stage will achieve precisely the type of efficiencies the multidistrict litigation process was designed to generate.<sup>34</sup>

#### IV. THE PANEL SHOULD TRANSFER AND COORDINATE ALL RELATED ACTIONS IN THE NORTHERN DISTRICT OF CALIFORNIA

##### A. The Northern District of California has the strongest nexus to the litigation.

A potential transferee court's connection to the litigation is among the most important factors the Panel considers in deciding where to locate an MDL.<sup>35</sup>

The Panel has concluded—time and time again—that the most appropriate transferee district is the one where the defendant's principal place of business, and thus critical witnesses and documents, are located.<sup>36</sup> Gilead is headquartered and has its principal place of business in

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<sup>34</sup> “Centralization works best when a group of actions are all in the initial phases of discovery and motion practice.” Hon. John G. Heyburn, II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2238 (2008).

<sup>35</sup> *See id.* at 2239 (“In a given docket, the particular location of the transferee court can be of greater importance because of the nature of the discovery and the concentration of witnesses.”); *see also* Francis E. McGovern & John G. Heyburn, II, *Evaluating and Improving the MDL Process*, 38 Litigation 26-32 (Spring 2012) (“The choice of a transferee judge is subject to few criteria other than the relatedness of the location and our belief in the ability and experience of that judge.”).

<sup>36</sup> *See, e.g., In re RAH Color Techs. LLC Patent Litig.*, MDL No. 2874, 2018 U.S. Dist. LEXIS 206581, at \*2-3 (J.P.M.L. Dec. 6, 2018) (transferring cases to the district where two of three defendants are headquartered); *In re Local TV Adver. Antitrust Litig.*, MDL No. 2867, 2018 U.S. Dist. LEXIS 173833, at \*2-3 (J.P.M.L. Oct. 3, 2018) (transferring cases to the district where the common defendant is headquartered); *In re Chi. Bd. Options Exch. Volatility Index Manipulation Antitrust Litig.*, 325 F. Supp. 3d 1374, 1376-77 (J.P.M.L. 2018) (transferring cases to the district where multiple defendants are headquartered); *In re Facebook, Inc., Consumer Privacy User Profile Litig.*, 325 F. Supp. 3d 1362, 1364 (J.P.M.L. 2018) (transferring cases to the district where a key defendant is headquartered); *In re: Dicamba Herbicides Litig.*, 289 F. Supp. 3d 1345, 1347 (J.P.M.L. 2018) (same); *In re Equifax, Inc., Customer Data Sec. Breach Litig.*, 289 F. Supp. 3d 1322, 1326 (J.P.M.L. 2017) (same); *In re Farxiga (Dapagliflozin) Prods. Liab. Litig.*, 273 F. Supp. 3d at 1382 (same); *In re Invokana (Canagliflozin) Prods. Liab. Litig.*, 223 F. Supp. 3d 1345, 1348-49 (J.P.M.L. 2016) (same); *In re Sprouts Farmers Mkt., Inc.*, 232 F. Supp. 3d 1348, 1348 (J.P.M.L. 2016) (same); *In re 21st Century Oncology Customer Data Sec. Breach Litig.*, 214 F. Supp. 3d 1357, 1358 (J.P.M.L. 2016) (same); *In re Honest Co., Inc., Sodium Lauryl Sulfate (SLS) Mktg. & Sales Practices Litig.*, 222 F. Supp. 3d 1349, 1350 (J.P.M.L. 2016) (same); *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices Litig.*, 178 F.

the Northern District of California. The vast majority of critical documents and witnesses are located within that district. And Gilead's challenged conduct and decision-making with respect to TDF and TAF occurred there too.<sup>37</sup> There is no other district in the country with stronger ties to the subject matter of the Related Actions.

The Panel also frequently transfers cases to the court where the majority of cases are located.<sup>38</sup> Here, although there is one action pending in each of five district courts, the action in the Northern District of California includes the claims of 140 plaintiffs. Thus, there are currently 140 plaintiffs with claims pending in the Northern District of California and only seven plaintiffs

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Supp. 3d 1377, 1379 (J.P.M.L. 2016) (same); *In re Daily Fantasy Sports Mktg. & Sales Practices Litig.*, 158 F. Supp. 3d 1375, 1380 (J.P.M.L. 2016) (same); *In re Kind LLC "All Nat." Litig.*, MDL No. 2645, 2015 U.S. Dist. LEXIS 109441, at \*3-4 (J.P.M.L. Aug. 10, 2015) (same); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d at 1383 (transferring cases to the district where two defendants are headquartered); *In re Home Depot, Inc.*, 65 F. Supp. 3d 1398, 1400 (J.P.M.L. 2014) (transferring cases to the district where defendant is headquartered); *In re Whole Foods Mkt., Inc.*, 65 F. Supp. 3d 1395, 1396 (J.P.M.L. 2014) (transferring cases to the district where defendants are located); *In re Aluminum Warehousing Antitrust Litig.*, 988 F. Supp. 2d 1362, 1363 (J.P.M.L. 2013) (same); *In re Effexor (Venlafaxine Hydrochloride) Prods. Liab. Litig.*, 959 F. Supp. 2d 1359, 1360 (J.P.M.L. 2013) (transferring cases to the district where a defendant is headquartered); *In re New England Compounding Pharm., Inc.*, 924 F. Supp. 2d 1380, 1381 (J.P.M.L. 2013) (transferring cases to the district where defendant's corporate headquarters is located); *In re Lipitor Antitrust Litig.*, 856 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012) (transferring cases to the district where a defendant's corporate headquarters is located); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d at 1382 (same); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 787 F. Supp. 2d 1355, 1357 (J.P.M.L. 2011) (same); *In re Avandia Mktg.*, 528 F. Supp. 2d at 1340-41 (same); *In re Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F. Supp. 2d 1371, 1374 (J.P.M.L. 2007) (same); *In re Am. Honda Motor Co., Oil Filter Prods. Liab. Litig.*, 416 F. Supp. 2d 1368, 1369 (J.P.M.L. 2006) (same).

<sup>37</sup> See, e.g., *In re: Dicamba Herbicides Litig.*, 289 F. Supp. 3d at 1347 (selecting the Eastern District of Missouri as the transferee district because: "Monsanto is headquartered in the Eastern District of Missouri, and it represents that various relevant activities took place there, including research and development of Xtend seeds and XtendiMax, submission of relevant regulatory filings, and oversight of the commercial launch of those products.").

<sup>38</sup> See, e.g., *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 908 F. Supp. 2d at 1364 (transferring cases to the district where the pending actions involved the majority of plaintiffs in the litigation).

with claims pending in four other federal courts. With Gilead and the majority of relevant evidence and plaintiffs' claims located in the Northern District of California, the clear center of gravity of these actions is the Northern District of California.

**B. Multiple other considerations favor the Northern District of California over other districts.**

Other factors the Panel regularly considers also point to the Northern District of California as the best choice for MDL referral.

First, location of the MDL in the Northern District of California will facilitate coordination between the federal actions and state cases pending in Los Angeles Superior Court.<sup>39</sup> This coordination will not be as seamless if the MDL is located in a more far-flung location.

Second, the Northern District of California is the most convenient for the parties and their counsel. In addition to Gilead and its counsel,<sup>40</sup> the attorney for plaintiffs in the Western District of Louisiana and Middle District of Louisiana cases is located in California.<sup>41</sup> The Northern District of California is also convenient for movants' counsel and any additional counsel – no matter where they are located. It is served by three international airports located in San Francisco, San Jose, and Oakland, and the surrounding area possesses an abundance of amenities, including hotels, rental cars, and any needed litigation resources. In sum, it is “an

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<sup>39</sup> See *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d at 1383 (transferring cases to a transferee court within a state where related state court actions were pending in order to facilitate federal-state coordination); *In re Fresenius Granuflo/Naturalyte Dialysate Prods. Liab. Litig.*, 935 F. Supp. 2d 1362, 1363 (J.P.M.L. 2013) (same); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 787 F. Supp. 2d at 1357 (same).

<sup>40</sup> Gilead is represented by Debra E. Pole and Joshua E. Anderson from the Los Angeles, California office of Sidley Austin, LLP.

<sup>41</sup> Plaintiffs' counsel in those cases, Michelle M. Rutherford, has an office in Los Angeles, California. See Ex. A (*Lujano* Complaint).

easily accessible, metropolitan district that is well equipped with the resources that this complex docket is likely to require.”<sup>42</sup>

Third, the Northern District of California case will soon be the most advanced case. *Holley* is the only action that has a scheduled case management conference and a date by which the parties must meet and confer on a number of critical case management issues. In addition, although briefing on Gilead’s anticipated motion to dismiss in *Holley* is currently scheduled to be completed after the briefing in some of the other cases, the court’s decision in *Holley* will determine the sufficiency of the allegations under the laws of 30 states—not just under one state’s laws. *Holley* will advance the litigation the furthest in the shortest amount of time.

Finally, the Northern District of California can manage this MDL effectively. There are many distinguished jurists within the Northern District of California who are highly experienced with MDL and other complex cases. The trial judge assigned to the moving parties’ case, the Honorable Jon S. Tigar, has been a federal judge for nearly six years, and he served as a California state court judge for ten years prior to his appointment to the federal bench. Judge Tigar gained valuable experience presiding over *In re Cathode Ray Tube (CRT) Antitrust Litigation*, MDL 1917,<sup>43</sup> and is thus well-versed in the nuances of multidistrict litigation.<sup>44</sup> He will be able to keep this complex products liability case on a fair and expeditious course.

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<sup>42</sup> *In re Compression Labs, Inc., Patent Litig.*, 360 F. Supp. 2d 1367, 1369 (J.P.M.L. 2005); see also *In re Roundup Prods. Liab. Litig.*, 214 F. Supp. 3d 1346, 1348 (J.P.M.L. 2016) (“The Northern District of California is both convenient and easily accessible for all parties, and we are convinced that the district has the necessary judicial resources and expertise to efficiently manage this litigation.”).

<sup>43</sup> *In re Cathode Ray Tube (CRT) Antitrust Litigation* has been pending since 2007 and is in an advanced stage of the litigation. Plaintiffs have settled with the majority of defendants. See <http://www.crtdirectpurchaserantitrustsettlement.com/>. As a result, that case should not overwhelm Judge Tigar’s ability to effectively manage this MDL.

<sup>44</sup> A judge’s prior experience with multidistrict litigation is a factor considered by the Panel. See, e.g., *In re Qualcomm Antitrust Litig.*, 273 F. Supp. 3d 1373, 1376 (J.P.M.L. 2017) (“By

Considered together, the factors routinely considered by the Panel demonstrate that the clear choice for this MDL is the Northern District of California. The other districts in which Related Actions are pending simply do not compare. They lack any meaningful connection to the subject matter or evidence in the case; they concern a small fraction of plaintiffs' claims; and they are far less convenient for the parties and their counsel.<sup>45</sup>

For these reasons, the *Holley* Plaintiffs respectfully request that the Panel grant this motion and transfer the Related Actions to the Northern District of California for coordinated or consolidated pretrial proceedings.

Dated: December 19, 2018.

Respectfully submitted,

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appointing the Honorable Lucy H. Koh to preside over this matter, we select a jurist with multidistrict litigation experience and the ability to steer this complicated litigation on an efficient and prudent course.”).

<sup>45</sup> For example, movants' counsel was unable to find direct flights from Los Angeles, California to Baton Rouge, Louisiana, where the Middle District of Louisiana is located, or to Monroe, Louisiana, where the assigned judge sits within the Western District of Louisiana. Flight options from Seattle, Washington, where certain movants' counsel is located, are similarly limited.



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