BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION

MDL Docket No. 2757

Oral Argument Requested

BRIEF OF DEFENDANT THE PROCTER & GAMBLE COMPANY IN OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION PURSUANT TO 28 U.S.C. § 1407

Plaintiffs' motion requests an MDL forcing together different claims regarding different Proton Pump Inhibitors ("PPIs") that allegedly caused a variety of different kidney ailments. As have the other defendants, we submit that the circumstances overwhelmingly weigh against an MDL here. If the Panel disagrees, The Procter & Gamble Company and The Procter & Gamble Manufacturing Company (collectively, "P&G") should not be included in any such MDL, because its involvement is solely with the limited-use, over-the-counter ("OTC") version of Prilosec ("Prilosec OTC"), a product whose labeling, indications, usage instructions, and sale are substantially different from those of the other prescription products that are the subject of plaintiffs' motion. P&G also opposes any transfer and coordination or consolidation pursuant to 28 U.S.C. § 1407, because any purported common facts shared by these actions are greatly outweighed by the highly individualized facts of each plaintiff's claims. Transfer and consolidation into an MDL would not serve the convenience of the parties and witnesses nor promote the just and efficient conduct of the pending actions. For the reasons detailed below, the Panel should deny plaintiffs' motion generally, and specifically as regards to P&G.

INTRODUCTION

These product liability actions involve a number of different pharmaceutical products with different active ingredients, each manufactured, sold or distributed by different companies over different periods of time. The principal products at issue are prescription medications. A few of the lawsuits reference OTC medications; P&G sells one of those OTC medications, Prilosec OTC. P&G has nothing whatsoever to do with the Prilosec prescription product ("Prilosec Rx"). Co-defendant AstraZeneca manufactures and sells Prilosec Rx, which the Food and Drug Administration ("FDA") approved via a New Drug Application ("NDA") in 1989. Prilosec OTC is fundamentally different from Prilosec Rx in important ways, particularly as to

indications and usage, which is at the core of the purported claims here. Prilosec OTC is specifically indicated for frequent heartburn, whereas Prilosec Rx is indicated to treat various ailments, including ulcers and erosive esophagitis. Moreover, the label for Prilosec OTC clearly instructs users not to take the medication for more than 14 days every 4 months unless directed to do so by their physician. This is especially important since the analyses cited by the plaintiffs to support their allegations involves reimbursement claims filed in insurance databases, which by definition would exclude almost all OTC products, focusing instead on chronic use of prescription drugs.

These indisputable facts establish that P&G should not be a party to the proposed MDL requested by plaintiffs. Thus, plaintiffs fail to meet their burden to establish that MDL coordination of these cases in any manner is warranted. They make sweeping, conclusory allegations that "[a]ll of the complaints make very similar factual allegations and, thus, any necessary discovery will arise from common questions of fact" (*see* Memorandum in Support of Plaintiffs' Motion for Transfer ("Memo."), Docs. 1-1, p. 4),[1] but never identify any specific "common" questions. In fact, the products, the plaintiffs, and the defendants here are substantially different, not common.

The cases plaintiffs seek to transfer are not limited to Prilosec Rx or Prilosec OTC, nor are they even limited to the active ingredient in "Prilosec" medications (omeprazole). Instead,

[1] Other plaintiffs who have filed responses likewise identify no common questions of fact but merely make similar conclusory statements. (*See, e.g.,* Crandell Resp., Doc. 10, pp. 2, 3 ("[A]ll of the lawsuits involve identical questions of law and fact that arise from the same course of conduct" and "All of the actions make the common allegation that PPIs are and were not safe and effective medications."); Bekins' Resp., Doc. 46, p. 3 ("Common questions of law and fact exist in the related actions and will play a large role in this litigation."); Goodstein/Spratt Partial Opp., Doc. 40, p. 1 (stating merely that all actions "involve one or more common questions of fact").) As demonstrated in the one response in which plaintiff attempts to identify common questions of fact (*see* Mason Resp., Doc. 43, pp. 2-3), individual issues overwhelm any purported common questions of fact.

plaintiffs seek to transfer into a single MDL cases involving various other pharmaceutical products within the "class" of medications to which Prilosec belongs, known as PPIs. As plaintiffs acknowledge, various PPIs have been manufactured, sold, and distributed by various defendants over time. (*See* Memo., p. 12 ("Plaintiffs name numerous Defendants involved with the manufacture, marketing, and sale of PPIs over the past 20 years.").)

PPIs are not identical medications, nor are they fungible medications, nor do all of them even contain the same active ingredients. In the cases filed to date, plaintiffs allege injury related to various prescription medications, including Prilosec Rx (omeprazole); prescription Nexium (esomeprazole magnesium); Dexilant (dexlansoprazole); Prevacid (lansoprazole); and Zegerid (omeprazole, sodium bicarbonate). A few of the cases also make passing mention of OTC products, Prilosec OTC and Nexium 24 HR. There are numerous other brand name and generic PPIs, each of which (just as those products above) was approved for sale at different times and has a separate regulatory history.

According to their complaints, plaintiffs did not use the same products, nor did they obtain the products in the same way. Some were prescribed products by a physician; some took products "at the direction of" a physician; some took products at the "recommendation" of an unidentified "healthcare professional"; while others provide no pertinent facts at all as to their use. Certain products plaintiffs claim to have used must be obtained via prescription, whereas others can be obtained over the counter. Plaintiffs each will have a different medical profile, and each used different defendants' (and unnamed parties') products at different times for different conditions. Their claims are subject to different proximate cause analyses, including an individual specific causation analysis unique to each plaintiff. Questions regarding the *who, what, where, when, why, and how* related to the warnings each plaintiff received (and/or the

extent of involvement of a healthcare professional as "learned intermediary") are inherently unique to each plaintiff's case. Plaintiffs also allege they experienced an array of personal injuries as a result of their use of one or more of the different medications noted above, which allegedly were manufactured, distributed or sold by one or more different defendants.

Plaintiffs allege that defendants failed to warn them of risks associated with the medications they took and that they sustained various personal injuries as a result. (*See, e.g.,* Memo., p. 4.) Such claims are not common among defendants because, for example, the circumstances surrounding each defendant's manufacture, sale, or distribution of its products, including the regulatory history of those products, necessarily are individualized.

Likewise, given the array of defendants involved (and potentially involved) in these cases, there can be no "same misconduct," as plaintiffs claim. (*See, e.g.,* Crandell Resp., p. 3 (suggesting that defendants' purported "same misconduct" pertains to the "design, testing, manufacturing, advertising, promoting, labeling, selling and/or distribution" of the various PPI medications).) The "conduct" of a defendant who only distributed a product is not the same as the conduct of a defendant who designed the product, nor the same as a defendant who manufactured a different product. Nor is the conduct of a defendant who advertised or promoted a product the same as the conduct of a different defendant who may have advertised or promoted a different product, nor the same as the conduct of a defendant who never advertised or promoted products. Thus, the "conduct" of each defendant will vary from defendant to defendant, from product to product, from time to time, and ultimately from case to case.

Because there is no factual commonality among plaintiffs' claims, there is no benefit to MDL coordination. Individualized factual questions predominate, including facts about each plaintiff, the knowledge and information possessed and conveyed by each plaintiff's healthcare

providers, and the policies and practices of each individual defendant with regard to products having different active ingredients. An MDL would undermine, rather than promote, convenience, economy, and efficiency.

Plaintiffs have not and cannot meet their burden to demonstrate common questions that make MDL coordination more efficient, economical, or convenient, and they certainly have not shown that the Middle District of Louisiana, or any of the other venues they suggest, would be an appropriate or convenient forum for any MDL proceeding. And, even if the Panel orders coordination, cases in which plaintiffs make claims against P&G for Prilosec OTC should be carved out of any transfer order. Finally, if the Panel nevertheless orders coordination that includes P&G, then transfer to Judge Dale Fischer in the Central District of California would best achieve the goals of economy, efficiency, and convenience for all parties.

ARGUMENT

I. Claims against P&G regarding Prilosec OTC® should be excluded from any MDL.

As explained in detail below, MDL coordination is improper and should be denied. If, however, the Panel grants plaintiffs' motion, claims against P&G should be excluded, as the Panel has done in other litigations. *See, e.g, In Re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (non-Vioxx case excluded); *In re Celexa and Lexapro Prods. Liab. Litig.*, 416 F. Supp. 2d 1361, 1363 (J.P.M.L. 2006) (non-Celexa/Lexapro case against Wyeth excluded); *In re Seroquel Prod. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006) (non-Seroquel claims and defendants excluded). In such case, P&G requests that the Panel remand to the transferor court any case that names only P&G. In any case that names P&G and another defendant, the Panel should sever the claims against P&G and remand those claims to the transferor court. In any transfer order, the Panel also should expressly state that any future

potential tag-along case that includes P&G will be tagged and sent to the Panel and then severed by the Panel with the claim against the non-P&G defendant placed on a CTO and the claim against P&G remanded to the transferor court.

P&G is a named defendant in just three of the 15 cases that were the subject of the original motion to transfer and just seven of all cases filed to date. This is likely because P&G's only involvement is with the sale and distribution of Prilosec OTC. As a licensee from AstraZeneca, P&G receives Prilosec OTC from AstraZeneca and packages and sells it in the United States. The circumstances of use of Prilosec OTC are substantially different from Prilosec Rx. For example, Prilosec OTC is indicated for frequent heartburn; Prilosec Rx, in contrast, is indicated for duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), maintenance and healing of erosive esophagitis, and pathologic hypersecretory conditions. Moreover, users of Prilosec OTC are expressly directed not to use it longer than two weeks every four months (i.e. a maximum of 42 days per year), whereas Prilosec Rx is approved for various lengths of time, including long term use, depending upon the condition being treated and the advice of the patient's physician. Consequently, the labeling for Prilosec OTC differs substantially from the prescription product. Indeed, the FDA denied a request to include a statement on non-prescription PPIs that warns of one of the kidney-related conditions at issue in the instant lawsuits, in recognition of the differences in these products:

> Nonprescription PPI labeling…presents somewhat different considerations given that the labeling is directed at consumers. The symptoms of AIN [acute interstitial nephritis]…are indistinguishable from relatively minor viral episodes that would not otherwise require discontinuation of nonprescription PPI products, and thus, inclusion of these symptoms on the labeling of nonprescription products may confuse consumers rather than facilitating their safe use of the product. We expect that consumers would consult a healthcare provider if symptoms of AIN were persistent. The prescription labeling changes for PPIs, which are written for healthcare providers, will appropriately inform healthcare providers of the possibility of interstitial nephritis….In our judgment, the current labeling is

> sufficient. Thus, your request that information regarding AIN be included in nonprescription PPI labeling is denied.

See FDA Response to Citizens' Petition, October 31, 2014 (Exhibit 18 to Plaintiffs' Motion to Transfer) at pp. 17-18.

II. Plaintiffs have failed to show that MDL coordination is warranted.

Plaintiffs have failed to meet their burden to establish that coordination is proper. *See In re: Best Buy Co., Inc., California Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1379 (J.P.M.L. 2011). The Panel will not order transfer unless the moving party establishes three elements. First, the moving party must establish existence of common questions of fact. *See* 15 Charles A. Wright *et al.*, FEDERAL PRACTICE AND PROCEDURE: JURISDICTION AND RELATED MATTERS § 3863, at 380 (2007) (citing 28 U.S.C. § 1407). Commonality of questions of fact is seldom "sufficient, by itself, to justify granting the motion to transfer." *Id*. Second, the moving party must establish that MDL coordination will "serve the convenience of the parties and witnesses." *Id*. at 407. Third, the moving party must establish "that the just and efficient conduct of the actions will be served" by transfer and coordination. *Id*. at 413. Plaintiffs have not established any of those requirements; accordingly, their motion must be denied.

A. Individualized, case-specific questions of fact overwhelm any purported commonality among the few cases filed.

If "a highly individualized inquiry is necessary to determine whether any particular plaintiff" was injured as a result of the defendants' actions, then coordination is not warranted. *In re Lipitor Mktg, Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013); *see also In re Electrolux Dryer Prods. Liab. Litig.*, 978 F. Supp. 2d 1376 (J.P.M.L. 2013) (denying motion to create MDL because individualized facts would predominate over common factual issues); *In re Wells Fargo Bank, N.A., Mtg. Corp. Force-Placed Hazard Ins. Litig.*, 959

F. Supp. 2d 1363, 1364 (J.P.M.L. 2013) (denying motion to create MDL because "individualized discovery and legal issues still will be substantial"); *In re Adderall XR Mktg, Sales Pracs. & Antitrust Litig.*, 968 F Supp. 2d 1343, 1345 (J.P.M.L. 2013) (denying motion to create MDL because the actions did not "significantly overlap"); *In re Cordarone (Amiodarone Hydrochloride) Marketing, Sales Practices and Products Liability Litigation*, 2016 WL 3101841, at *1 (J.P.M.L. June 2, 2016) (denying motion to create MDL because "[g]iven the different defendants sued in these actions, centralization appears unlikely to serve the convenience of a substantial number of parties and their witnesses."). The record here reveals highly individualized factual questions precluding MDL coordination.

1. Plaintiffs' allegations and claims require individualized discovery and investigation.

These are product liability cases in which plaintiffs allege that defendants failed to warn them of risks associated with the medications they took and that they sustained various injuries as a result. (*See, e.g.,* Memo., p. 4 ("In each of these pending PPI cases, Plaintiffs claim that Defendants…and others, failed to adequately warn that the ingestion of these prescription and/or over-the-counter drugs could cause irreparable harm to the kidneys.").) The claims will require individualized discovery and investigation. The cases do not involve one product (or even one active ingredient), or one defendant, or even one avenue of obtaining the product (*e.g.*, prescription vs. OTC). And they do not involve one single medical condition for which the products were taken, or one injury that all plaintiffs allegedly developed. Rather, each plaintiff's case hinges on individualized, fact-specific determinations concerning the particular plaintiff's use of a specific product, as well as on individualized issues of proximate causation and whether the alleged failure-to-warn caused the specific injury complained of by each specific plaintiff. An MDL would be ill-suited to address so many individualized questions. *See, e.g., In re Abbott*

Labs., Inc. Similac Prods. Liab. Litig., 763 F. Supp. 2d 1376 (J.P.M.L. 2011) ("individual facts contained in these actions will predominate over any alleged common fact questions"); *In re Qualitest Birth Control Prods. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014) ("It appears that individualized facts…will predominate over the common factual issues alleged by plaintiffs.").

2. Individualized issues overwhelm any purported common questions.

Plaintiffs acknowledge they used different products under different circumstances. (*See* Memo., p. 2 (explaining plaintiffs obtained products in various ways, including "as prescribed by a physician, recommended by a healthcare professional, and/or otherwise taken for the prevention or treatment of gastric acid related conditions").) They concede "numerous" defendants are involved. (*See id.*, p. 12.) Those differences are significant and are unique to each plaintiff. Resolution of each case will depend on numerous individual factual questions.

For instance, in those cases in which the plaintiff took a product "as prescribed by a physician," it will be critical to determine the particular "gastric acid related condition" or other indication for which each physician prescribed a particular product to the plaintiff. There will be many other important individualized inquiries. What was each patient's condition and medical history at the time of prescription? What dosage did each physician prescribe and did each patient take, and did each patient comply with physician instructions they received? What information did the prescribing physician rely on? What did the physician tell each patient about the risks and potential side effects of the medication? What information did each patient receive from the prescribing physician about the potential side effects of the product prescribed? In other instances in which a certain product was "recommended by a healthcare professional," was that "professional" a physician, a nurse, a pharmacist, a physical therapist, or some other person

that could be considered a "healthcare professional"? Was that individual treating the plaintiff for his or her "gastric acid related condition," or someone (who happened to be in the healthcare field) who gave a "recommendation" in passing? And on what basis did that individual make a "recommendation" to the plaintiff?

Plaintiffs state in their motion that there are other plaintiffs who "otherwise took" a product. (*See* Memo, p. 2.) That statement alone warrants an individualized inquiry. Was the decision based solely on the plaintiff's own judgment? What other medications, if any, had the patient already tried without results? Did the plaintiff take the product according to the directions of use? What information did plaintiff rely upon in deciding to take the product? What other medications was the patient also taking that carried indicated risks for the condition plaintiff claims to have suffered? Did the plaintiff combine use of OTC and Rx medications or of different prescription PPI products?

Not only are the circumstances surrounding the acquisition of the product different, but also the products themselves are different and have different active ingredients, and they were manufactured and sold by different companies. Individual issues will arise depending upon which company's product (or products) each patient took. Plaintiff Mason's implication that "industry wide" MDLs are somehow favored by the Panel (*see* Mason Resp., pp. 3-6) is incorrect.[2] Indeed, in denying a recent request for MDL coordination in a multi-defendant case,

[2] *See, e.g., In Re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (holding that "claims involving a prescription drug other than Vioxx...do not share sufficient questions of fact to warrant inclusion of these non-Vioxx claims in MDL-1657 proceedings."); *In re Celexa and Lexapro Prods. Liab. Litig.*, 416 F. Supp. 2d 1361, 1363 (J.P.M.L. 2006) (separating and simultaneously remanding claims relating to a drug other than Celexa or Lexapro because these claims "do not share sufficient questions of fact...to warrant inclusion" in the MDL proceedings); *In re Seroquel Prod. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006) ("the claims involving prescription drugs other than Seroquel do not share sufficient questions of fact with claims relating to Seroquel to warrant inclusion" in the Seroquel MDL).

this Panel reasoned that "[t]he variance in named defendants virtually ensures that a significant amount of the discovery will be defendant-specific." *See In re Cordarone*, 2016 WL 3101841, at *2. And, notably, in that litigation, only one active ingredient – amiodarone – was involved. Conversely, in these cases, not only are numerous companies involved (and potentially involved), but also, numerous products with different active ingredients, including lansoprazole, dexlansoprazole, esomeprazole, and omeprazole, involved.[3]

Individual causation questions also may arise based upon whether – as plaintiffs note – the plaintiff took a product "for the prevention" of a condition or for the "treatment" of a condition. (*See id.*) Plaintiffs' concession that they took the different products for various conditions points-up another individualized question at the core of these cases. Likewise, whether the product or products the plaintiff took caused that plaintiff's particular injury undeniably is an individualized question. For example, discovery related to the plaintiff's individual medical profile, other medications the plaintiff used, and other potential risk factors must be considered in each plaintiff's case. Thus, the suggestion that "whether PPIs caused kidney disease and related injuries of plaintiffs" somehow is a common question of fact (*see, e.g.,* Mason Resp., p. 3) makes no sense. Even the question of "whether PPIs are capable of causing kidney disease and related conditions" (*see* Mason Resp., p. 3) is not a *common* question of fact at all. In posing that question, plaintiff Mason groups numerous different products and

[3] The Panel has refused to coordinate multi-manufacturer and multi-industry litigation like this one. *See, e.g., In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) (denying motion because "[a]n indeterminate number of different pain pumps made by different manufacturers are still at issue" and "[m]ost, if not all, defendants are named in only a minority of actions; and several defendants are named in but a handful of actions"); *cf. In re Inter-Op Hip Prosthesis Prod. Liab. Litig.*, MDL 1401 (one manufacturer); *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, MDL 1396 (one defendant); *In re Telectronics Pacing Sys., Inc., Accufix Atrial "J" Leads Prod. Liab. Litig.*, MDL 1057 (one manufacturer); *In re Copley Pharm., Inc. "Albuterol" Prods. Liab. Litig.*, MDL 1013 (one manufacturer and one drug).

active ingredients together, assumes "kidney disease" is one condition, and lumps various unidentified "related conditions" together. There is no common question of fact.

Likewise, questions about warnings and labeling are not common among the defendants; even as to a single defendant, warnings and labeling may have varied over time.[4] Additionally, learned intermediary issues may be implicated in any individual plaintiff's case. And various states' laws also give rise to individual analysis. Thus, plaintiffs' suggestion that "whether the defendants failed to warn" or "whether the defendants breached their duty of care to plaintiffs" are common questions of fact (*see, e.g.,* Mason Resp., p. 3) is illogical. Determining whether labeling provided an adequate warning presents distinct fact-specific liability and causation questions in each case. MDL coordination will serve no purpose when those individualized questions will predominate.

All of the questions and issues noted above will dominate the discovery and pretrial process. Core, operative facts must be adduced through the depositions of each individual plaintiff, compilation of each patient's medical and pharmacy records, and the depositions of prescribing and treating physicians, or other "healthcare providers." That discovery is uniquely individualized. MDL coordination will not eliminate the need for this individualized work nor permit it to be completed more economically, efficiently, or conveniently.

[4] Plaintiffs' reference to an August 2011 Public Citizen petition and October 2014 FDA response to that petition further illustrates the lack of commonality among plaintiffs' claims, as plaintiffs acknowledge that FDA "responded by requiring" label changes to "all prescription PPIs" but did not require those same changes to non-prescription PPIs. (*See* Memo., pp. 5-6.) Further, plaintiffs theorize that over-the-counter labels and prescription labels "lack detailed risk information" for different conditions, which, of course, will again result in an analysis of individual issues depending on which product the plaintiff took and which condition the plaintiff allegedly developed. Thus, as plaintiffs themselves point out, different facts will be applicable to the labeling issues of the various PPI products.

3. Plaintiffs' purported "common factual issues" are conclusory, and are neither common nor factual.

In their Motion for Transfer, plaintiffs identify no common questions of fact. Although other plaintiffs attempt to identify common questions of fact (*see, e.g.,* Crandell Resp., p. 3; Mason Resp., pp. 2-3), all of those purported "questions of fact" are not questions of fact at all, let alone *common* questions of fact. Rather, all of these proffered questions-for example "whether the defendants had knowledge of a defect" and "failed to warn about risks"- are mixed questions of law and fact, the resolution of which necessarily will require evaluation and analysis of the laws of various states as applied to multiple, different defendants. These questions cannot be resolved on a "common" basis, nor will the necessary evidence and discovery be common among all cases. Rather, individual issues – specific to each defendant, each product, each transaction, each discussion with a learned intermediary, and each plaintiff's medical condition and profile, just to name a few – will overwhelm any purported common issues. Given those undeniable circumstances, there is no benefit to MDL coordination.

Plaintiffs claim that "[a]bsent coordination or consolidation, the possibility of inconsistent pretrial rulings exists, especially with respect to the proper scope and extent of discovery, causation, and other factual and legal issues." (*See* Memo., p. 4.) As explained above, "causation" is an individualized issue as to each plaintiff *and* as to each defendant. Given the myriad combinations of plaintiffs, defendants, products, time periods, and implicated states' laws, it is not unexpected that legal determinations could vary. Similarly, whether a particular plaintiff's complaint against a particular defendant is subject to a motion to dismiss on the pleadings will be based on individualized issues, including individual determinations of various states' laws. (*See, e.g.,* Crandall Resp. p. 3 (arguing that an MDL is necessary to "prevent duplication of discovery and eliminate the possibility of overlapping or inconsistent pleading

determinations[.]").) Likewise, plaintiffs' contention that similar legal causes of action are asserted by the various plaintiffs (*see, e.g.,* Memo., p. 4) does not satisfy section 1407's requirement that plaintiffs must demonstrate common questions of fact justifying coordination.

Indeed, plaintiffs' effort to create "common factual allegations" reveals just how uncommon their allegations actually are. For example, plaintiffs concede that PPIs are not the same drug at all, but rather are a "group of drugs." They acknowledge that the various separate defendants had different roles, over different periods of time, with regard to those various drugs. (*See* Memo., p. 4 (stating that "PPIs are a group of drugs" and that the various drugs "are and/or were manufactured, developed, marketed and distributed" by several different defendants).) Similarly, plaintiffs admit that the various "group of drugs" have been "used for the prevention and treatment" of an admitted *non-exhaustive list* of various conditions, ranging from ulcers to heartburn to reflux to other syndromes. (*Id.*, p. 5.) And, in a wholly conclusory manner, plaintiffs point to alleged "wide promotion" by the "Defendants" as a group, but fail to identify any particular alleged promotional activities which, even if they occurred at all, were common to all defendants. (*See id.*) Even plaintiffs' attempt to explain various types of kidney-related injuries (*see, e.g.,* Motion, pp. 6-7) reveals just how different those injuries (as well as potential risk factors and associations related to those various injuries) are from one another – again demonstrating that individual issues will overwhelm and dominate each case. There simply is no benefit to be achieved by MDL coordination or consolidation.

B. Plaintiffs have failed to demonstrate that an MDL would enhance convenience, economy, or efficiency.

Other than parroting the section 1407 requirement (*see* Memo., p. 4), plaintiffs do not even attempt to set forth how MDL coordination would enhance convenience, economy or efficiency. Plaintiff Mason claims that MDL coordination would "streamline" the litigation (*see*

Mason Resp., p. 6), but, as explained above, individualized discovery would overwhelmingly dominate each plaintiff's case. There is nothing convenient, efficient, or economical about placing in one arbitrary location a hodge-podge of plaintiffs suing different defendants over their use of different products which allegedly caused different conditions.

The Panel has often stated that centralization under Section 1407 "should be the last solution after considered review of all other options," including "coordination among the parties and the various transferor courts." *In re: Gerber Probiotic Prods. Mktg. and Sales Pracs. Litig.*, 899 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2012) (internal citation omitted). Voluntary cooperation is a preferable "[a]lternative to transfer...that may minimize whatever possibilities could arise of duplicative discovery." *In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384, 1384-85 (J.P.M.L. 2009); s*ee also In re: Rite Aid Corp. Wage and Hour Empl. Pracs. Litig.*, 655 F. Supp. 2d 1376, 1377 (J.P.M.L. 2009) (denying request for an MDL and noting "[c]ooperation among counsel and the parties is particularly appropriate here, where plaintiffs in four of the six actions encompassed by the motion share counsel.") Informal coordination is also preferable when transfer would involve relatively few actions. *See In re Transocean Ltd. Sec. Litig.,* 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010) (citing *In re Royal Am. Indus., Inc. Sec. Litig.*, 407 F. Supp. 242, 243 (J.P.M.L.) ("where only a minimal number of actions are involved, the moving party generally bears a heavier burden of demonstrating the need for centralization."). Even assuming that there would be some "common discovery" (and plaintiffs have identified none), those considerations undermine plaintiffs' motion.

The plaintiffs who filed the Motion to Transfer are represented by one of six plaintiff firms, all of whom "supported" plaintiffs' motion. (*See* Memo., p. 14.) These counsel have filed similar complaints in each of the fifteen cases, so they are already coordinating in this litigation,

and there is no reason they could not continue to do so for any discovery purportedly common to multiple cases. Similarly, defendants can coordinate among the various cases to achieve efficiencies, economy, and convenience that MDL coordination cannot provide. Plaintiffs have offered no reason why cooperation among coordinating counsel for all parties is not a more efficient, cost-effective, and easier method of achieving the intended benefits of coordination, particularly where the number of subject cases remains low. *See, e.g., In re Uber Techs.*, Inc., Wage & Hour Employment Practices, 158 F. Supp. 3d 1372, 1373 (J.P.M.L. 2016) (denying transfer where "Plaintiffs in six of the seven actions on the motion and two related actions are represented by the same counsel, and all of those actions are in their infancy."); *In re Ocala Funding, LLC, Commercial Litig.*, 867 F. Supp. 2d 1332, 1332-33 (J.P.M.L. 2012) (denying motion to create MDL because the movant was represented by common counsel in four actions).

To the extent any common questions exist, they can be handled efficiently through informal discovery coordination and cooperation, without allowing any superficially common questions to hijack the litigation. And to plaintiffs' contention that they will "be seeking the same discovery from common defendants, … and will likely request to depose the same parties" (*see* Crandell Resp., p. 4), the Panel has observed in similar circumstances that "[n]otices of deposition can be filed in all related actions; the parties can stipulate that any discovery relevant to more than one action can be used in all those actions; or the involved courts may direct the parties to coordinate their pretrial activities." *In re Trans Union LLC Fair Credit Reporting Act (FCRA) Litig.*, 923 F. Supp. 2d 1374, 1375 (J.P.M.L. 2013).

Further, where, as here, few actions are involved, the proponent of MDL coordination bears a heavier burden to demonstrate that coordination is appropriate. *See In re Transocean Ltd. Sec. Litig. (No. II)*, 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010) (citing *In re Royal*

American Indus., Inc. Sec. Litig., 407 F. Supp. 242, 243 (J.P.M.L. 1976)). Although plaintiffs asserted in their motion that they expected 100 PPI cases to be filed "in the coming weeks," it appears only about a dozen additional cases have been brought in the month that has since passed. And plaintiffs' suggestion that "over 5,000…possible cases [are] under investigation" does not carry the day. The Panel has made clear that is it "disinclined to take into account the mere possibility of future filings in [its] centralization calculus." *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013); *see also In re Intuitive Surgical, Inc., Da Vinci Robotic Surgical System Prods. Liab. Litig.*, 883 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (denying motion to create MDL and noting "[w]hile proponents maintain that this litigation may encompass 'hundreds' of cases or 'over a thousand' cases, we are presented with, at most, five actions").

III. Although MDL coordination is unnecessary and unwarranted, and should not include P&G, any transfer should be to Judge Fischer in the Central District of California and not to any of the districts proposed by plaintiffs.

Plaintiffs are not in agreement with regard to a proposed transfer venue, which is not surprising given that there is no venue that has a common connection to the litigation. Indeed, plaintiffs' acknowledgment that there "will be no clear geographical nexus to this litigation" is telling. (*See* Memo., p. 12.) They premise their conclusion on the fact that "Defendants are headquartered in several different districts and, upon information and belief, experts, witnesses, and relevant documents will be found in several more states." (*Id.*) In stark contrast to litigation involving one defendant, one transaction, one event, or one defined product, plaintiffs acknowledge there is no common locus of evidence or discovery in these cases. The individual cases will result in individual fact and discovery questions with "no clear geographical nexus." That, yet again, is why these actions are not appropriate for MDL coordination.

A. Transfer to the Middle District of Louisiana would not advance the efficient, economical, and convenient conduct of these actions.

Plaintiffs who filed the Motion to Transfer request transfer to the Middle District of Louisiana. In determining where to transfer consolidated actions, the Panel considers factors such the geographical centrality and convenience of the district; the likelihood of additional actions being filed in the district; the docket of the proposed transferee court; the location of the parties and witnesses; and the preference of the parties. Given those factors, the Middle District of Louisiana is not an appropriate transferee court for these cases.

Plaintiffs who propose the Middle District of Louisiana claim "it is easily accessible to all counsel and witnesses," the court has a "low-volume docket," and the four judges in that district are "experienced." (*See* Memo., pp. 7-8.) The fact that a case or two is currently pending there is not significant; Plaintiff Davis admits that in his case, like the others, no discovery (or "very early stage" discovery) has occurred. (*See id.*, p. 3.) Nor do the judges in that district possess any specialized knowledge that would merit transferring these cases there.

Further, the Middle District of Louisiana is not geographically convenient for any defendant, nor is that the location where most witnesses and documents are located. *See, e.g., In re Navistar 6.0 L Diesel Engine Prods. Liab. Litig.*, 777 F. Supp. 2d 1347, 1348 (J.P.M.L. 2011) (transferring to a district in part because "[d]efendants' headquarters, and therefore relevant documents and witnesses, are located in or relatively near this district"). None of the defendants in these cases are headquartered in Louisiana or have significant operations or employees relevant to the issues in these cases located in or near Louisiana. In fact, the only witnesses who will likely be located in or near the Middle District of Louisiana are the few plaintiffs who reside there and any case-specific witnesses in those few cases. The presence of a few witnesses in a few cases is no reason to establish an MDL in a specific location, particularly when the majority

of other plaintiffs and witnesses are located elsewhere.[5] The Middle District of Louisiana is not a geographically-convenient location, as other plaintiffs to these proceedings have said. (*See* Goodstein/Spratt Partial Opp., p. 4.)

B. Transfer to the other venues proposed by plaintiffs would not advance the efficient, economical, and convenient conduct of these actions.

A similar analysis applies to the other venues proposed by plaintiffs. P&G incorporates the arguments as set forth by co-defendants in their respective oppositions.

C. If there is to be an MDL, transfer to Judge Fischer in the Central District of California would be appropriate.

If the Panel decides to coordinate these cases, in whole or in part, assignment to Judge Dale Fischer in the Central District of California would be a more appropriate venue than any of the others suggested. As explained in greater detail in the oppositions of other co-defendants, Judge Fischer's experience with and efficient handling of the *In re Nexium* MDL 2404 weighs heavily in favor of transferring the cases to her.

CONCLUSION

Given P&G's involvement with Prilosec OTC alone, and the substantial differences between Prilosec OTC and Prilosec Rx (and among the various PPI products), joining P&G to an MDL with one or many prescription PPI products would be inefficient, wasteful, and

[5] Even if more cases are filed, there is no reason to believe that those additional cases would be properly venued in the Middle District of Louisiana. The schedule of actions and interested party responses to date demonstrate that these cases are dispersed in federal courts throughout the U.S., including Tennessee, Ohio, New York, West Virginia, Missouri, New Jersey, Kansas, Illinois, North Carolina, and California. Given the geographic diversity of the cases filed to date and the nationwide sales of the products at issue, there is no reason to believe a disproportionate number of them will come from residents in the Middle District of Louisiana.

inappropriate. P&G should be expressly carved-out of any MDL, if one is established. But there should be no MDL at all. Plaintiffs satisfy none of the requirements for section 1407 coordination. Individualized, case-specific fact questions overwhelm any commonality vaguely identified by plaintiffs. Judicial economy would not be served by an MDL. If the Panel nevertheless determines that MDL coordination including claims against P&G is appropriate, then transfer should be to Judge Fischer in the Central District of California.

Respectfully submitted,

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EXHIBIT A

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

MDL No. 2757 – In re: Proton-Pump Inhibitor Products Liability Litigation

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that on the 22nd day of November, 2016, I electronically filed the foregoing document with the Clerk of the Panel using the CM/ECF system, which will send electronic notification to counsel of record, and that copies of the foregoing also were served on all parties in the following cases via e-mail as noted below:

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