BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR : N PRODUCTS LIABILITY LITIGATION :

MDL DOCKET NO.: 2757

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FILED ELECTRONICALLY

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ASTRAZENECA'S RESPONSE TO THE PLAINTIFFS' FACTUAL AVERMENTS IN THEIR MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca"), and McKesson Corporation ("McKesson") ("Defendants") hereby file this Response in Opposition to the Motion of Plaintiffs for Transfer of Actions to the United States District Court for the Middle District of Louisiana Pursuant to 28 U.S.C. § 1407 and JMPL 7.2 for Coordinated and Consolidated Pretrial Proceedings (Doc. 1) and respectfully request that the Panel deny transfer of the actions involving proton pump inhibitors to the Middle District of Louisiana. In support of said response, Defendants state as follows:

1. Defendants admit that the actions listed on Plaintiffs' Schedule of Actions, and attached as Exhibits to Plaintiffs' Motion, are civil actions currently pending in federal district courts. Defendants deny the remaining allegations set forth in Paragraph 1 as stated.

¹ Astra USA Inc., Astra USA Holdings Corp., Zeneca Inc., AstraZeneca UK Ltd., AstraZeneca PLC, AstraZeneca AB and KBI Sub Inc., named in various permutations throughout the cases, are not appearing here as AstraZeneca believes they are improper parties and is in the process of finalizing their dismissal with counsel for Movants and other plaintiffs. They otherwise join in opposition without waiving any service or jurisdictional defenses.

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2. Defendants deny the allegations set forth in Paragraph 2 as stated.

3. Defendants admit that the actions listed on Plaintiffs' Schedule of Actions are

civil actions currently pending in federal district courts. Defendants further admit that cases

have been filed in the Eastern District of Arkansas, Eastern District of California. Southern

District of California, Southern District of Illinois, District of Kansas, Eastern District of

Louisiana, Middle District of Louisiana, Western District of Louisiana, Southern District of

Mississippi, Western District of Missouri, District of New Jersey, Eastern District of New York,

Northern District of New York, Western District of North Carolina, Southern District of Ohio,

Eastern District of Tennessee, Western District of Tennessee, and the Southern District of West

Virginia. Defendants deny the remaining allegations set forth in Paragraph 3 as stated.

4. Defendants deny the allegations set forth in Paragraph 4.

5. Defendants deny the allegations set forth in Paragraph 5 as stated.

6. Defendants deny the allegations set forth in Paragraph 6 as stated.

7. Defendants admit that none of the civil actions at issue have progressed beyond

the initial pleadings stage. Defendants deny the remaining allegations set forth in Paragraph 7.

8. Defendants deny the allegations set forth in Paragraph 8 as stated.

Respectfully submitted,

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Dated: November 22, 2016

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR : MDL DOCKET NO.: 2757

PRODUCTS LIABILITY LITIGATION

MDE DOCKET No.: 2757

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BRIEF OF ASTRAZENECA AND MCKESSON IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

ORAL ARGUMENT REQUESTED

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| STATUTES |
| 28 U.S.C. § 1407 |
| EXHIBITS |
| Exhibit A: Listing of Proton Pump Inhibitors (PPIs) and Manufacturers |
| Exhibit B: Pending Actions |
| Exhibit C: <i>Nexium, Prilosec, Prevacid Lawsuit TV Commercial</i> , Bernstein Liebhard LLP (May 24, 2016), www.nexiumlawsuit.com/nexium-prilosec-prevacid-lawsuit-tv-commercial. |
| Exhibit D: Screenshots of advertising by Plaintiffs' counsel (relevant information highlighted by defense counsel) |
| Exhibit E: <i>In re Nexium Esomeprazole</i> , Nos. 14-56845, 15-56484, 2016 WL 6298741 (9th Cir. Oct. 28, 2016) |
| Exhibit F: <i>In re Depakote</i> , No. 3:12-cy-00052 (S.D. Ill. July 6, 2016) (Doc. 485) |

AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca"), and McKesson Corporation ("McKesson") ("Defendants") oppose transfer and centralization. should deny the transfer motion because Movants seek to consolidate cases involving individual plaintiffs who took a wide variety of medications made by a plethora of different manufacturers and allege to have suffered a range of different and distinct injuries. Movants are essentially attempting to draw sprawling Venn diagrams around a commonly occurring category of disease among aging Americans – renal disorders – and one of the most commonly prescribed classes of medications - proton pump inhibitors ("PPIs") - and are asking this Panel to create an incalculable, consolidated proceeding involving the entire, unavoidable overlap. Considering the breadth of renal disorders alleged, the history of pre-existing disease states and concomitant medications of an aging population, and the number of medications and manufacturers in a class that encompasses three decades of brand name, generic, prescription, and over-the-counter products, individualized concerns will inevitably eclipse any aggregate issues that would otherwise weigh in favor of centralization. However, to the extent this Panel is inclined to grant Movants' request, The Honorable Dale S. Fischer, Central District of California, who presided over In re Nexium (Esomeprazole) Prods. Liab. Litig., 908 F. Supp. 2d 1362 (J.P.M.L. 2012) should receive the transferred cases. Her Honor swiftly and adeptly addressed consolidated product liability claims involving many of the same medications (PPIs) and manufacturers. Her in-depth knowledge and experience with Nexium®, Prilosec®, and Prevacid® (as well as AstraZeneca, McKesson, and Takeda) is unrivaled, especially given the infancy of the individual cases sought to be consolidated.

FACTUAL BACKGROUND

A. Class of Medications – PPIs: Movants propose to centralize all kidney-injury related

cases involving an entire class of acid suppressing PPI medications. AstraZeneca pioneered the first prescription-only medication in the class, Prilosec® (omeprazole), approved by the FDA in 1989, followed by Nexium® (esomeprazole magnesium), approved by the FDA in 2001. In addition to AstraZeneca's PPIs, Plaintiffs allege injury from Dexilant® (dexlansoprazole) and Prevacid® (lansoprazole), manufactured by co-defendant Takeda; Zegerid® (omeprazole, sodium bicarbonate), manufactured by Santarus Inc. (not named as a defendant), and over-the-counter ("OTC") PPI formulations Prilosec OTC® and Nexium 24HR®, sold respectively by co-defendants The Procter & Gamble Co. and Pfizer, Inc. There are approximately 30 brand name and generic medications within the PPI class. *See* Ex. A.

- **B.** Alleged Renal Injury Cases: Plaintiffs allege that the various defendants' (and non-parties') products caused them a broad range of kidney-associated injuries, including acute interstitial nephritis (AIN); acute kidney injury (AKI); acute renal failure (ARF); chronic kidney disease (CKD); chronic interstitial nephritis (CIN); interstitial nephritis (IN); end stage renal disease (ESRD); death; and unspecified "kidney failure or injury." Defendants are aware of 27 single-plaintiff cases subject to the pending transfer motion:
- Named Defendants: AstraZeneca (25 cases) (16 as sole manufacturing defendant); Takeda entities (4) (2 as sole manufacturing defendant); Pfizer (1); Procter & Gamble (7); and McKesson (1).
- Named Medications: Nexium (20 cases); Prilosec (7); Prevacid (5); Dexilant (1); Zegerid (1); Prilosec OTC (1); Nexium 24HR (2); and "PPIs" (11).
- Alleged Injuries: AIN (2 cases); AKI (2); ARF (3); CKD (14); CIN (1); IN (2); ESRD (4); death (2); and unspecified "kidney failure or injury" (6).
- **Alleged Dates of Exposure/Injury:** Allegedly, the exposures range from 1993 to 2016 and injuries range from 2006 to 2016. *See generally*, Ex. B.
- C. In re Nexium (Esomeprazole) Prods. Liab. Litig. (C.D. Cal.): In 2012, this Panel transferred 39 actions involving approximately 1200 plaintiffs alleging osteoporotic injury and

use of Nexium/other PPIs to The Honorable Judge Dale S. Fischer, Central District of California ("In re Nexium MDL"). Consistent with arguments made by movant-plaintiffs, and over the defendants' objections, the Panel concluded, inter alia, that the Central District of California is "accessible" and Judge Fischer is "a jurist with multidistrict litigation experience and the ability to handle this litigation." Nexium, 908 F. Supp. 2d at 1364-65.

Judge Fischer adeptly managed the centralized matter through comprehensive case management orders that addressed individual, contemporaneously with aggregate, issues. These included rolling plaintiff fact sheet productions alongside the defense's multi-million page document production concerning the labeling and regulatory histories of Nexium, Prilosec, and Prevacid, including product development, clinical/testing, labeling, safety, adverse event reporting, and medical literature. Her administration resulted in efficient handling of individual cases and ultimately an aggregate general causation determination that was unanimously affirmed by the Ninth Circuit. *See In re Nexium (Esomeprazole) Prods. Liab. Litig.*, No. ML 12-2404 DSF (SSx), 2014 WL 5313871, at *4 (C.D. Cal. Sept. 30, 2014), *aff'd*, Nos. 14-56845, 15-56484, 2016 WL 6298741 (9th Cir. Oct. 28, 2016). Accordingly, Judge Fischer is uniquely familiar with many of the defendants, the PPIs (including their intended uses, risk-benefit profiles, pharmacology and metabolism in the body), and the scientific and regulatory issues. Judge Fischer deftly handled issues ranging from product identification, prima facie ingestion and injury, and the parties' document productions, to *Daubert* and general causation.

ARGUMENT

Movants seek to create an unwieldy MDL with a hodge-podge of divergent defendants, medications (prescription and OTC), and alleged injuries. More than 40 companies manufacturing and/or selling nearly 30 different PPIs (brand and generic) spanning nearly three decades may be implicated. *See* Ex. A. With so many different products, parties, and alleged

injuries, individualized issues will eclipse any purported common ones, and MDL efficiency tools, such as a Master Complaint and bellwether trials, will be, at best, cumbersome and, at worst, unfeasible, and in all likelihood ineffective at efficiently narrowing claims and issues.¹

A moving party must establish three elements to warrant centralization. 28 U.S.C. § 1407. First, the moving party must establish the existence of common questions of fact. *See* 15 CHARLES A. WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE: JURISDICTION & RELATED MATTERS § 3862, 380 (2007). However, 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 consolidation 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 centralization. *Id.* at 413. "[I]t has been argued that the crucial issue in determining whether to grant pretrial consolidation is not whether there are common questions or whether the parties will be inconvenienced, but whether the economies of transfer outweigh the resulting inconvenience to the parties." *Id.* at 414-15 (internal quotations omitted). Here, the pending cases involve such diverse issues as:

- Approximately 30 PPI medications introduced to the U.S. market over a period of almost three decades by numerous named and unnamed defendants;
- No typical plaintiff and a broad spectrum of alleged injuries such as AIN, AKI, CKD, ESRD, death, and unspecified "kidney failure or injury";
- Myriad of common and often naturally occurring risk factors or causes for each alleged injury;
- Individualized plaintiff claims; e.g., wrongful death claims in only two matters;
- Individualized knowledge of each company for the diverse time frames alleged regarding notice, warnings, labeling, disclosures, formulation, and design issues;
- Entirely unique sales and promotional facts relating to each of the more than 30 products;
- Plaintiff-specific issues including medical history, concomitant medications, dosage, period
 of use, frequency and compliance with regimen, differential diagnosis, treatment, nature and

¹ Plaintiffs' counsel have not limited their advertising to the currently named medications. *See, e.g.*, Ex. C, *Nexium, Prilosec, Prevacid Lawsuit TV Commercial*, BERNSTEIN LIEBHARD LLP (May 24, 2016), www.nexiumlawsuit.com/nexium-prilosec-prevacid-lawsuit-tv-commercial.

extent of alleged damages, and knowledge and information from plaintiff's physicians; and
Individualized questions of fact and causation, necessitating different experts for each case.

This Panel is "typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products." *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (internal quotations and citation omitted); *see also In re Androgenal Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014) ("We are typically hesitant to centralize litigation on an industry-wide basis.") PPIs have crucial differences, including active ingredients and the extent to which the labels warned of the numerous renal issues alleged. The defendants are direct competitors and the assertion that the number of PPI renal injury cases "will increase by the hundreds" (if not thousands) (Br. 2) is speculative at best. Consolidation of these matters, on an "industry-wide" basis or even on a per-medicine basis, is unnecessary and neither serves the convenience of the parties and witnesses nor promotes the just and efficient conduct of the actions. Voluntary coordination is preferable. In the alternative, Defendants submit that the only transferee judge and venue that make sense is Judge Fischer in the Central District of California.

I. The Motion for Transfer Should be Denied.

A. The Product and Defendant Differences Support Denial of Transfer.

The existence of multiple medications and defendants, and the ensuing differences in factual issues, should be considered when determining whether transfer is appropriate. *In re Asbestos & Asbestos Insulation Material Prods. Liab. Litig.*, 431 F. Supp. 906, 910 (J.P.M.L. 1977). Here, the complaints allege injury by multiple permutations of different medications and manufacturers. Moreover, there are numerous un-named PPIs and manufacturers, both brand and generic. *See* Ex. A. These medications would be included in Movants' proposed MDL, but are still distinct products. This Panel has denied transfer under similar circumstances. *See*, *e.g.*,

In re OxyElite Pro & Jack3d Prods Liab. Litig., 11 F. Supp. 3d 1340, 1341 (J.P.M.L. 2014) (refusing to centralize actions concerning two dietary supplements, despite plaintiffs' "rel[iance] on the same series of FDA actions to support their claims[,]" because the supplements had key differences and "distinct regulatory responses"). Recently, in In re Cordarone (Amiodarone Hydrochloride) Mktg., Sales Practices & Prods. Liab. Litig., MDL No. 2706, 2016 WL 3101841, at *1 (J.P.M.L. June 2, 2016), this Panel denied a motion to transfer product liability actions pending in different federal districts because "the named defendants vary widely among the cases... Given the different defendants sued in these actions, centralization appears unlikely to serve the convenience of a substantial number of parties and their witnesses." Id. As this Panel recognized, "[t]he variance in named defendants virtually ensures that a significant amount of the discovery will be defendant-specific, as do plaintiffs' allegations themselves." Id. at *2.

Industry- or class-wide MDLs are not appropriate where, as here, "individual issues that result from the differences among each defendant's [product] . . . will predominate over" the individual plaintiffs' factual issues "that are common to all defendants." *In re Power Morcellator Prods. Liab. Litig.*, 140 F. Supp. 3d 1351, 1353 (J.P.M.L. 2015); *see also Fentanyl Patch*, 833 F. Supp. 2d at 1351 (denying centralization where cases against each manufacturer would involve unique product- and defendant-specific issues such as design, manufacturing processes, regulatory history, and company documents and witnesses). In addition, where, as here, the defendants are not uniformly named in the same actions, this Panel has denied transfer. *See In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) ("Most, if not all, defendants are named in only a minority of actions; and several defendants are named in but a handful of actions.").

B. Individualized Plaintiff-Specific Factual Issues Outweigh Common Issues.

The breadth and dominance of individualized plaintiff issues also weighs against transfer.

The panoply of medications – prescription and OTC, brand and generic – as well as the injuries alleged, are wholly disparate. The plaintiffs are not homogeneous due to widely ranging issues including age, gender, condition requiring PPI use, concomitant medications, medical history, and type and extent of alleged damages. This Panel has long recognized significant individual factual questions on liability support denial of transfer. *See In re Rely Tampon Prods. Liab. Litig.*, 533 F. Supp. 1346, 1347 (J.P.M.L. 1982) (denying transfer where Panel was not persuaded "that these common questions of fact will predominate over individual questions of fact present in each action"); *In re Shoulder Pain Pump-Chondrolysis Prods. Liab. Litig.*, 571 F. Supp. 2d 1367, 1368 (J.P.M.L. 2008) (the cases involved "multiple individualized issues (including ones of liability and causation)").

Causation, a threshold element, should be considered when determining whether an MDL is appropriate. These cases do not present any uniform or signature injury which could lead to efficiency through MDL treatment. Even if there were a common issue as to whether one medication could be *capable* of causing the numerous types of injuries alleged (which defendants deny), whether each defendant's product *rather than other well-known risk factors* caused each plaintiff's various alleged injuries will require a plaintiff-by-plaintiff specific inquiry. The individualization of injury would make specific causation an arduous task for the transferee court. Plaintiffs' claims – albeit all involving the "kidneys" – are not medically similar as evidenced by the nine different types of injuries alleged. The discovery and experts needed to prove general and specific causation (as well as failure to warn) will be uncommon, *e.g.*:

• Acute interstitial nephritis (AIN) defines a pattern of renal injury usually associated with an abrupt, but often reversible, deterioration in renal function characterized on biopsy by inflammation and edema in the renal interstitium. AIN is rare, but has multiple potential causes including more than 100 medications, infection, and immune or neoplastic disorders. Because AIN is an allergic reaction, patients who discontinue the medications quickly are likely to recover to baseline kidney function. CHARLES M. KODNER & ARCHANA KUDRIMOTI,

- Diagnosis and Management of Acute Interstitial Nephritis, 67(12) Am. FAM. PHYSICIAN 2527-2534 (2003).
- Acute kidney injury (AKI), in contrast, is the diffuse medical term for sudden damage to the kidneys causing them not to work properly. The term does not refer to any particular cause of the kidney damage or even damage to one part of the kidney. AKI is common in hospitalized patients, especially in the elderly and those in intensive care units (ICU). Most cases of AKI are caused by pre-renal damage, *i.e.*, reduced blood flow to the kidneys, usually in someone who is already unwell. AKI can also be caused by intrinsic damage to the kidneys or post-renal, by blockage of the urinary tract. AKI is only linked to AIN in a small minority of cases. *Acute Kidney Injury (AKI)*, NATIONAL KIDNEY FOUNDATION, https://www.kidney.org/atoz/content/AcuteKidneyInjury (last visited June 7, 2016).
- Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD) are also diffuse medical terms. Diabetes and high blood pressure cause up to two-thirds of CKD cases, although many other conditions can similarly impair kidney function, including glomerulonephritis, polycystic kidney disease, lupus, and repeated urinary infections. CKD is comparatively common, affecting approximately 13.6% of adults in the United States, and characterized by a gradual loss of kidney function over time. About Chronic Kidney Disease, NATIONAL KIDNEY FOUNDATION, https://www.kidney.org/kidneydisease /aboutckd (last visited June 7, 2016). ESRD is the progression of CKD. Like AKI, only a small minority of CKD or ESRD cases are linked to AIN. ALAN S. GO ET AL., Chronic Kidney Disease and the Risks of Death, Cardiovascular Events, and Hospitalization, 351 NEW ENG. J. MED. 1296-1305 (2004).

For nearly every plaintiff, individualized issues will be present, making the determination of whether the medication caused the alleged injury a uniquely case-by-case determination unsuitable for centralized supervision. Each of the claimed conditions has a multitude of accepted common causes (e.g., diabetes, high blood pressure, infection) and risk factors (e.g., obesity, smoking, age, race, family history) unrelated to PPIs. Thus, plaintiff-specific causation determinations will overwhelm common issues. See In re Abbott Labs., Inc., Similac Prods. Liab. Litig., 763 F. Supp. 2d 1376, 1376-77 (J.P.M.L. 2011); Ambulatory Pain Pump-Chondrolysis, 709 F. Supp. 2d at 1377 ("[I]ndividual issues of causation and liability continue to appear to predominate, and remain likely to overwhelm any efficiencies that might be gained by centralization."); In re Repetitive Stress Injury Prods. Liab. Litig., MDL No. 955, 1992 WL 403023, at *1 (J.P.M.L. Nov. 27, 1992) (denying consolidation even though 159 actions were pending because the "degree of common questions of fact among these actions [did not] rise[] to

the level that transfer under Section 1407 would best serve the overall convenience of the parties and witnesses and promote the just and efficient conduct of this entire litigation.").

C. Alternatives to Centralization Exist.

Benefits of centralization can be achieved through informal coordination. See Shoulder Pain Pump-Chondrolysis, 571 F. Supp. 2d at 1368 (noting that "parties can avail themselves of alternatives to Section 1407 transfer to minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings"). Such coordination is already occurring amongst the spokespersons for plaintiffs' counsel, amongst the defendants' national counsel, and between opposing counsel on a variety of issues. The cases involve common plaintiffs' firms and plaintiffs' counsel who are already mobilizing to work together beyond the five coordinating firms ("Consulting counsel") listed by Movants. (Br. 14.) See In re Goodman Mfg. Co., HVAC Prods. Liab. Litig., 987 F. Supp. 2d 1380, 1380 (J.P.M.L. 2013) (denying transfer where there was overlapping plaintiff's counsel in some of the actions; finding that "alternatives to transfer exist[ed]"); In re Boehringer Ingelheim Pharms., Inc., 763 F. Supp. 2d 1377, 1378 (J.P.M.L. 2011) (when parties share common counsel, "alternatives to formal centralization, such as voluntary cooperation . . ., appear viable"). Indeed, informal coordination should be particularly efficient in these cases in light of the pre-existing productions from the *In* re Nexium MDL. AstraZeneca is updating that production to documents relevant to the pending litigation, and is willing – indeed has already offered to various counsel – to produce again subject to entry of a protective order and electronically stored information ("ESI") discovery agreement consistent with that entered by Judge Fischer in *In re Nexium*. Thus, "[g]iven the few involved counsel and limited number of actions, informal cooperation among the involved attorneys is both practicable and preferable to centralization." In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig., 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014).

D. Plaintiffs' Warning of Additional Cases is Irrelevant.

Movants boldly claim that their counsel "have over 5,000 [PPI] cases under investigation" and that "nearly 100 PPI cases will be filed in the coming weeks." (Br. 1-2.)² However, the Panel has repeatedly held that the possibility of additional actions is irrelevant in deciding whether to establish an MDL proceeding. *In re Qualitest Birth Control Prods. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014) ("we are disinclined to take into account the mere possibility of future filings in our centralization calculus") (internal quotations and citation omitted). In any event, Movants filed their Petition on October 17, 2016 and, five weeks later, their counsel have filed zero additional cases.

II. If this Panel Finds that Transfer is Appropriate, AstraZeneca Requests Transfer to The Honorable Dale S. Fischer in the Central District of California.

A. Centralization Before Judge Fischer Is Most Appropriate.

If this Panel concludes that coordination is proper, Judge Fischer in the Central District of California (C.D. Cal.) would be the most sensible choice for multiple reasons. The cases are not filed in one common jurisdiction or geographic area and there is no one judge presiding over a majority of cases. The 27 cases are presently pending before district courts in eighteen different districts. The few served cases are in preliminary pleadings stages. The parties have not appeared before any of the proffered judges. None of the jurisdictions in which the actions are pending are an obvious (or appropriate) venue, particularly those plaintiffs have handpicked.

Judge Fischer is an experienced MDL jurist, appointed in 2003, who presided over *In re Nexium*. In contrast to any other federal district judge, she is well situated to efficiently manage this litigation. When choosing an appropriate transferee judge, it is critical to identify a judge

² Zonies Law, counsel for Interested Party Plaintiff *Moore*, claims to be representing "thousands of other individuals whose cases are not yet filed but are expected to be filed in the near future." (Doc. 51 at 2.) Zonies Law is counsel of record in only one matter to date.

with the knowledge, skill, and experience in the efficient management of complex cases and the willingness "to consider approaches that weed out non-meritorious cases early, efficiently, and justly." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, Case No. 4:08-MD-2004, 2016 WL 4705827, at *2 (M.D. Ga. Sept. 7, 2016) (noting "the evolution of the MDL process . . . has produced incentives for the filing of cases that otherwise would not be filed"). This is of particular concern here considering the respective prevalence of, and inevitable (but not causally related) overlap between, PPI use and kidney injuries in the United States. Judge Fischer meets those criteria. Specifically:

- **Products:** *In re Nexium* also involved PPI medications, including prescription Prilosec, Nexium, and Prevacid, the predominant products named in the instant complaints.
- Parties and their Counsel: AstraZeneca, Takeda, and McKesson and their counsel (Ice Miller LLP and McCarter & English LLP for AstraZeneca and McKesson and Venable LLP for Takeda) are involved in both litigations.
- **Science**: From *In re Nexium*, Judge Fischer is familiar with certain PPIs and their intended uses, risk-benefit profiles, pharmacology, and metabolism.
- **Adverse Events:** Eight (30%) of the instant complaints state averments about the risks of PPIs and osteoporotic fracture, the core claims in *In re Nexium*. Many of the instant plaintiffs' attorneys are advertising regarding PPIs and osteoporotic fracture alongside kidney injury claims. *See* Ex. D, relevant information highlighted.
- **Mechanism of Action:** According to literature relied upon by Movants, the fracture and kidney allegations share a similar alleged mechanism of action direct action on acid pumps in cells advanced by the plaintiffs' general causation expert in *In re Nexium*.
- **Discovery:** Judge Fischer and Magistrate Suzanne Segal presided over agreements regarding a discovery protocol, a Plaintiff Fact Sheet, the parameters of defendant discovery, a protective order, and production by defendants of documents and electronically stored information. The defendants produced millions of pages of documents and hundreds of GB of data in accordance with Judge Fischer's discovery orders.
- Case Management: Judge Fischer oversaw a smooth, relatively dispute-free discovery and case management process. She is aware of the product identification issues posed by multisource pharmaceutical cases and implemented procedures to efficiently winnow meritless cases while ensuring that individualized issues were being addressed contemporaneously with aggregate handling.
- Complex Pharma Issues: Judge Fischer has experience with Daubert issues, including in

³ See, e.g., White v. AstraZeneca, Case No. 1:16-cv-00443 (E.D. Tenn.), Compl. ¶ 30.

the context of omeprazole/esomeprazole, and application of the well-known Bradford Hill criteria for attempting to infer causation from epidemiologic evidence such as that cited by Movants. The MDL Panel has recognized that coordinating pretrial motions such as *Daubert* motions is a key role of an MDL court. *See, e.g., In re GNC Corp. TriFlex Prods. Mktg. & Sales Practices Litig.*, 988 F. Supp. 2d 1369, 1369 (J.P.M.L. 2013) (centralizing overlapping cases, nothing that "[i]n our view, extensive common expert discovery likely will be required, as will one or more *Daubert* hearings").

• **Dependability:** Judge Fischer's *Daubert* rulings were recently unanimously upheld by the Ninth Circuit Court of Appeals. *See In re Nexium Esomeprazole*, Nos. 14-56845, 15-56484, 2016 WL 6298741 (9th Cir. Oct. 28, 2016), attached as Ex. E.

It is well-settled that "the availability of an experienced and capable judge familiar with the litigation is one of the more important factors in selecting a transferee forum" In re Ampicillin Antitrust Litig., 315 F. Supp. 317, 319 (J.P.M.L. 1970). This Panel has previously seen the wisdom of centralizing cases before a judge with prior MDL experience over the same or similar class of products. See, e.g., In re Pella Corp. Architect & Designed Series Windows Mktg., Sales Practices & Prods. Liab. Litig., 996 F. Supp. 2d 1380, 1382-83 (J.P.M.L. 2014) (transferee judge's experience involving allegedly defective windows "is likely to benefit the parties here"; the absence of an action in the proposed transferee district "is no impediment to its selection as transferee district"); In re Lumber Liquidators Chinese-Manufactured Flooring Durability Mktg. & Sales Practices Litig., MDL No. 2743, 2016 WL 5845991, at *1 (J.P.M.L. Oct. 4, 2016) ("[w]e are confident that Judge Anthony J. Trenga, who presides over MDL No. 2627, which involves allegedly inappropriate emissions of formaldehyde from the same laminate flooring and some of the same plaintiffs as here, will steer this litigation on a prudent course").

In *In re Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378, 1381 (J.P.M.L. 2015), this Panel elected to transfer actions involving allegations of peripheral neuropathy relating to the flouroquinolones ("FLQ") class to The Honorable John R. Tunheim, District of Minnesota, who had presided over the Levaquin® (a FLQ) tendon rupture MDL. This Panel stated: "Judge Tunheim is an experienced transferee judge familiar with the scientific and

regulatory background of Levaquin in his capacity as transferee judge for a separate Levaquin MDL concerning tendon rupture injuries. In our view, Judge Tunheim's experience in overseeing [the Levaquin MDL] will benefit the parties and facilitate the just and efficient conduct of this litigation." *Id.* (citation omitted). The Aylstock firm (Interested Party and Consulting counsel to Movants), who now seek transfer to W.D. La. or M.D. La. (Doc. 10), which have no nexus to this litigation, shared the Panel's view at the time of the FLQ briefing:

A multi-product MDL is by necessity more difficult, so it stands to reason that a multi-product fluoroquinolone MDL would benefit from a District and a judge with prior MDL experience Judge Tunheim currently presides over the *In re Levaquin Products Liability Litigation* (MDL 1943). Judge Tunheim . . . has become thoroughly familiar with the product (Levaquin®), the manufacturer (Bayer), and the relevant issues involved in that product liability litigation. As such, assigning this litigation to Judge Tunheim will conserve judicial resources and facilitate the just and efficient resolution of this action.

Response of Interested Party Plaintiff Kathleen M. Smith at 6-7, *In re Fluoroquinolone Prods*. *Liab. Litig.*, MDL No. 2642 (J.P.M.L. June 5, 2015), Doc. 22.⁴

Defendants agree that creating a multi-product MDL before a different judge, who does not have the same unique experience as Judge Fischer, would not be efficient or serve the purposes of 28 U.S.C. § 1407. Moreover, the C.D. Cal. – located in Los Angeles, one of the largest transit and hospitality hubs in the nation – clearly has the infrastructure necessary to allow Judge Fischer to handle these actions. *See In re Classicstar Mare Lease Litig.*, 528 F. Supp. 2d 1345, 1347 (J.P.M.L. 2007) ("[T]he district's general docket conditions permit us to make the Section 1407 assignment knowing that the court has the resources available to manage this litigation."). C.D. Cal. is the largest district court in the country. There are currently eleven pending MDLs in C.D. Cal., low for a district of such size. ⁵ Moreover, although C.D. Cal.

⁴ Interested Party Plaintiff *Mason* cites similarities here to *In re Fluoroquinolone*. (Doc. 43 at 5.) ⁵ Judge Fischer presides over *In re CitiMortgage Inc.*, a small MDL consisting of only 12 active cases. *Pending MDLs*, U.S. J.P.M.L. (http://www.jpml.uscourts.gov/pending-mdls-0) (last

processes a high number of civil matters, it ranks fifty-sixth among district courts nationwide in the number of cases pending per district judge. At the end of June 2016, judges in the C.D. Cal. had 227 fewer pending cases than the national average, and also fewer pending cases than in D.N.J., S.D. Ill., D. Kan., and W.D. La. *Table N/A – U.S. District Courts – Combined Civil and Criminal Federal Court Management Statistics*, UNITED STATES COURTS (June 30, 2016), http://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2016/06/30-1 (hereinafter "U.S. District Court Stats."). C.D. Cal. efficiently handles litigation, ranking eleventh among district courts nationwide in the average time in months from filing to a civil trial. On average, it takes only 19.8 months for a civil matter to reach trial after it is filed – 7.3 months faster than the national average. *Id*.

Finally, C.D. Cal. is easily accessible. Los Angeles has three major airports (LAX, LA/Ontario International, and John Wayne) and three smaller airports (Bob Hope, Palm Springs International, and Long Beach). LAX is a hub for two of the four largest U.S. airlines, United and American, and offers 742 daily nonstop flights to 101 cities throughout the U.S. LAX provides 1,273 weekly nonstop flights to 76 cities in 41 different countries, which will help accommodate any international witnesses. *Airport Information*, Los Angeles World Airports (July 2016), http://www.lawa.org/welcome_lax.aspx?id=40.

B. The District of Delaware Would Also Be an Appropriate Venue.

To the extent that Judge Fischer is unavailable, the District of Delaware would be a logical second choice. AstraZeneca's principal place of business is in Wilmington, DE and many of the relevant documents and witnesses, and individuals with substantive knowledge regarding the development, labeling, regulatory compliance, marketing, and sale of prescription

visited Nov. 15, 2016) (hereinafter "Pending MDLs"). *In re Nexium* is administratively closed and would not constitute a drain of resources.

Prilosec and Nexium in the United States who may be potential witnesses, are located there. In addition, defendants McKesson, Takeda, and Pfizer, and numerous potential defendants, are incorporated in Delaware. Coordinating the actions in D. Del. will facilitate swift and convenient discovery and allow plaintiffs access to the court and many witnesses in one trip. This is often a decisive factor when choosing a transferee forum. *See*, *e.g.*, *In re Johnson* & *Johnson Talcum Powder Prods. Mktg.*, *Sales Practices* & *Prods. Liab. Litig.*, MDL No. 2738, 2016 WL 5845997, at *2 (J.P.M.L Oct. 4, 2016) ("As Johnson & Johnson is headquartered in New Jersey, relevant evidence and witnesses likely are located in the District of New Jersey.").

In creating an MDL in the district where defendant is headquartered, the Panel has expressly stated that "[t]hough a related action is not currently pending in the [selected MDL district], we have found that is not a bar to centralization in a particular district." *In re Bard IVC Filters Prods. Liab. Litig.*, 122 F. Supp. 3d 1375, 1377 (J.P.M.L. 2015); *Darvocet, Darvon & Propoxyphene*, 780 F. Supp. 2d at 1381-82 ("[T]he location of the currently filed cases is not a particularly significant factor in our decision Since all the actions in this docket are at an early stage, transfer to another district should not be disruptive.").

D. Del. is centrally located in the middle of the Northeast Corridor. *See In re Ameriquest Mortg. Co. Lending Practices Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L. 2005) (transferring cases to a "geographically central district [that] will be a convenient location for a litigation

⁶ See also In re Benicar (Olmesartan) Prods. Liab. Litig., 96 F. Supp. 3d 1381, 1383 (J.P.M.L. 2015) (selecting D.N.J. for MDL because "defendants, are headquartered in that district, and thus many witnesses and relevant documents are likely to be found there"); In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig., 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014) (establishing MDL in S.D. Ind. in part because "[defendant] Cook is headquartered in Indiana, where relevant documents and witnesses are likely to be found"); In re Mirena IUD Prods. Liab. Litig., 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013); In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., 780 F. Supp. 2d 1379, 1382 (J.P.M.L. 2011) ("Relevant documents and witnesses likely are located within the Eastern District of Kentucky at defendant Xanodyne's Newport headquarters.") (citing In re Polyurethane Foam Antitrust Litig., 753 F. Supp. 2d 1376, 1377 (J.P.M.L. 2010) (choosing a district that has a "nexus to the litigation

already nationwide in scope"). Adjacent Philadelphia International Airport (typically thirty minutes or less by car) is also an American Airlines hub and offers service on every major domestic airline. AMTRAK has regular, less than 90 minutes, train service between Wilmington and major international airports Baltimore-Washington and Newark. While Movants resort to citing the benign amenities offered by Baton Rouge hotels ("Automated Teller Machines, a fitness room and pool, laundry and shoe shining services") (Br. 12) to offset travel complexities, Wilmington (adjacent to Philadelphia, the fifth largest city in the U.S.) is a convenient and accessible forum.

D. Del.'s low caseload would enable it to efficiently handle an MDL proceeding. As of June 2016, D. Del. judges had 211 fewer pending matters than the national average, and time from filing to civil trial is lower than the national average among district courts. (U.S. District Court Stats.) Delaware is an underutilized district with only two pending MDLs⁷ (Pending MDLs), a fact weighing in favor of transfer here. *See, e.g., In re Lumber Liquidators Chinese-Manufactured Flooring Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 109 F. Supp. 3d 1382, 1383 (J.P.M.L. 2015) ("Centralization . . . allows us to assign this litigation to a district to which we have transferred relatively few MDLs.").

C. Plaintiffs' Proposed Venues are Inappropriate.

There is no consensus amongst the plaintiffs regarding venue. More importantly, no factual nexus supports centralization in any of plaintiffs' proffered districts, where none of the defendants are headquartered, no named medications were developed, and no relevant company

through the location of the headquarters of one [of the defendants]")).

However, D. Del. judges have vast experience with pharma litigation, as D. Del. has long been one of the leading jurisdictions for pharma patent litigation involving similar regulatory and science issues. See, e.g., Katherine Rhoades, Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive Yet Efficient Procedures in Hatch Waxman Litigation, NW J. TECH. & INTELL. PROP. 81, 83 (2016).

evidence, documents, or witnesses are located. None have a remarkable number of cases, and none of the proffered judges are "familiar" with the litigation given that the cases have not progressed beyond the pleadings stage. Transfer to any of these venues would amount to a reset button, which could be avoided if the Panel centralizes before Judge Fischer. Considering the tenuous connection to this litigation coupled with the timing of Movants' filings, these venue proposals should be seen for what they are: forum-shopping.

Movants propose M.D. La. (2 cases), D.N.J. (3 cases), S.D. Ill. (1 case), D. Kan. (2 cases) and W.D. La. (3 cases). The location/timing of the filings suggest that counsel pre-selected Louisiana as a favorable venue in which to create an MDL and then filed a handful of cases there to engineer an otherwise nonexistent connection. *See In re CVS Caremark Corp. Wage & Hour Emp't Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010) ("where a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute, we would certainly find less favor with it"). Not a single PPI case was pending in Louisiana until the business day prior to Movants' motion, when counsel filed the *first* case in the M.D. La. (*Davis*) and the *first* in the W.D. La. (*Modicue*). In the two days following, plaintiffs' counsel, including Consulting counsel Aylstock, filed two cases in the W.D. La. (*Miller, Crandell*) and one case in the M.D. La. (*Smith*). 9

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⁸ Interested Party Plaintiffs ("IPP") represented by Aylstock request W.D. La. and M.D. La. IPP represented by Seeger Weiss request D.N.J. IPP represented by Baron & Budd, P.C. requests S.D. Ill. or D.N.J. IPP represented by Andrus Anderson requests S.D. Ill. IPP represented by Zonies Law requests W.D. La.
⁹ Indeed, the *only* connection to M.D. La. or W.D. La. are the single plaintiff claims strategically

Indeed, the *only* connection to M.D. La. or W.D. La. are the single plaintiff claims strategically filed there in conjunction with the motion to transfer. *See In re CVS Caremark*, 684 F. Supp. 2d at 1379 (the moving plaintiffs "are all represented by the same law firm, which filed the first action in early 2009 but then commenced the two others immediately prior to filing this Section 1407 motion Such an unusual alignment of parties and counsel suggests the possibility of other considerations at play"). *Cf. In re Cal. Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 n.3 (J.P.M.L. 2015) (noting that certain parties argued "movant's counsel caused the filing of the related actions before the Panel for the sole purpose of bolstering his motion"; Panel "denied the motion on other grounds" and thus did not need to "delve into

M.D. La.: Plaintiffs contend it is easily accessible and conveniently located. However, the travel parties would undertake for court proceedings would be arduous and time-consuming, as only four U.S. airports have non-stop flights to Baton Rouge. Movants emphasize the daily flights to Baton Rouge from Atlanta, but Atlanta has absolutely no relevant connection to the litigation. Los Angeles and Philadelphia, with convenient nonstop flights nationwide, are *certainly* more accessible. Plaintiffs' cite lack of "winter weather problems," but Los Angeles likewise has none, and Baton Rouge is known for hurricanes and epic flooding.

Movants contend that the skill and experience of the M.D. La. judges supports transfer there. While Defendants do not dispute the qualifications of any of these Judges, Defendants respectfully assert that Judge Fischer is particularly, and indeed uniquely, well-qualified to preside over *these* actions given her existing familiarity with the products, science, and discovery. Moreover, until a couple of years ago, M.D. La. had two long-term vacancies on a three judge court. Upon information and belief, the district was so overwhelmed with work that judges from the W.D. and E.D. were routinely travelling to the M.D. La. to assist. Currently, M.D. La. ranks fiftieth among district courts in the average time in months from filing to civil trial: it takes an average of 34 months for a civil matter to reach trial after it is filed, which is 6.9 months longer than the national average. (U.S. District Court Stats.) It would not be optimal to assign an MDL (particularly in which "over 5,000" cases may be filed (Br. 1)) to this district.

W.D. La.: Various plaintiffs proffer The Honorable Rebecca Doherty whose resources are already employed in *In re Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299. Putting aside that this potentially prejudicial venue (*see* Takeda Brief in Opposition at III. c.) has

movant's motives"). See also Hon. John G. Heyburn II, The Problem of Multidistrict Litigation: A View from the Panel: Part of the Solution, 82 Tul. L. Rev. 2225, 2241 (2008) ("The Panel . . . will act to avert or deflect attempts by a party or parties to 'game' the system.").

no meaningful connection to the dispute, ¹⁰ judges in W.D. La. have some of the highest caseloads of district judges in the nation. The district has the sixth-highest caseload per district judge of all districts nationwide, with 921 cases per judge, and the average time from filing to civil trial is higher in W.D. La. than among district courts nationwide. (U.S. District Court Stats.) Furthermore, travel to Lafayette, Louisiana is not convenient for the parties or their counsel, and is certainly less convenient than travel to Los Angeles or Philadelphia.

D.N.J.: Plaintiffs also suggest D.N.J., but this district currently has seventeen pending MDLs, six of which are pharma/device product liability MDLs. (Pending MDLs.) Many were only recently formed. *See In re Johnson & Johnson Talcum Powder Prods.*, MDL No. 2738, 2016 WL 5845997, at *2; *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 96 F. Supp. 3d at 1383. The parties in *In re Invokana (Canagliflozin) Prods. Liab. Litig.*, MDL No. 2750, set for oral argument before this Panel in December 2016, also seek consolidation in D.N.J. The district ranks sixty-fourth among district courts in the average time in months from filing to civil trial: it takes an average of 47.8 months for a civil matter to reach trial after it is filed, which is 20.7 months longer than the national average. (U.S. District Court Stats.)¹¹

S.D. Ill.: IPP *Mason* requests transfer to The Honorable David Herndon or The Honorable Staci Yandle because his case was "first-filed" there in May. This argument falls flat given that *Mason* has not progressed beyond the pleadings stage; a fully dispositive motion to dismiss on statute of limitations and repose grounds is pending and could soon dispose of the only case in this district. Thus, S.D. Ill. has no particular experience with these cases. S.D. Ill. is

¹⁰ IPP *Moore* argues that Judge Doherty is "already familiar with the issues that are unique to Takeda," (Doc. 51 at 5), but Takeda's development and promotion of an entirely unrelated product is of no moment. Moreover, this argument at least equally supports transfer to Judge Fischer, who is familiar with AstraZeneca and Takeda *and their PPI medications*.

¹¹ Plaintiffs request The Honorable Claire Cecchi, currently handling one MDL, namely, *In re Insurance Brokerage Antitrust Litigation*, MDL No. 1663.

already heavily taxed with the eighth highest caseload per district judge nationally. The average time from filing to civil trial is much higher in S.D. Ill. than other district courts nationwide. (U.S. District Court Stats.) There are currently already two pharma/med device product liability MDLs in the S.D. Ill., both assigned to Judge Herndon, and one of which still has more than 1300 plaintiffs. (Pending MDLs.) Moreover, Judge Rosenstengel recently noted in *In re Depakote* consolidated proceeding that she intends to "ensure that the majority, if not all, of the cases pending in this district are tried by the end of 2017," "a massive undertaking involving *all* of this district's resources." *See* Order at 1-2 (Doc. 485), *In re Depakote*, No. 3:12-cv-00052 (S.D. Ill. July 6, 2016) (attached as Ex. F.) (emphasis added).

D. Kan.: Movants also offer The Honorable Daniel D. Crabtree, who has already recused himself,¹² and The Honorable Kathryn Vratil of D. Kan. While Judge Vratil is an accomplished jurist, she lacks Judge Fischer's familiarity with these matters. Only two cases are pending in D. Kan. and Defendants have not served a pleading in either action. Finally, the accessibility to the Los Angeles and Philadelphia makes C.D. Cal. or D. Del. significantly more convenient.

CONCLUSION

Defendants respectfully request that the JPML deny the pending Motion for Transfer or, in the alternative, if the JPML determines that these actions should be consolidated, transfer the cases to the Central District of California with Judge Dale S. Fischer presiding.

¹² Koon v. AstraZeneca, Case No. 2:16-cv-02605-DDC-TJJ (D. Kan.), Doc. No. 3. While Judge Crabtree did not specify, Defendants suspect he recused himself due to his representation of AstraZeneca while still in private practice.

Respectfully submitted,

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Dated: November 22, 2016

Exhibit A

| LISTING OF PROTON PUMP INHIBITORS (PPIs) AND MANUFACTURERS ¹ | | |
|---|-----------------------------|--|
| <u>Drug Name²</u> | <u>Drug Manufacturer</u> | |
| Aciphex® | Eisai Inc. | |
| Dexilant® | Takeda Pharmaceuticals | |
| Dexilant Solutab | Takeda Pharmaceuticals | |
| Esomeprazole magnesium | Teva Pharmaceuticals | |
| Esomeprazole magnesium | Mylan Pharms Inc. | |
| Esomeprazole magnesium | Hetero Labs Ltd III | |
| Esomeprazole magnesium | Dr. Reddy's Laboratories | |
| Esomeprazole magnesium | Torrent Pharmaceuticals | |
| Esomeprazole magnesium | Aurobindo Pharma | |
| Esomeprazole Strontium | Hanmi Pharmaceutical Co Ltd | |
| Esomeprazole Magnesium/Naproxen | Dr. Reddy's Laboratories | |
| Kapidex® | Takeda Pharmaceuticals | |
| Lansoprazole | Anchen Pharms | |
| Lansoprazole | Dr. Reddy's Laboratories | |
| Lansoprazole | Krka Tovarna Zdravil | |
| Lansoprazole | Mylan Pharms Inc. | |
| Lansoprazole | Natco Pharma Ltd | |
| Lansoprazole | Sandoz Inc. | |
| Lansoprazole | Sun Pharma Global | |
| Lansoprazole | Teva Pharmaceuticals | |
| Lansoprazole | Wockhardt USA | |

^{*} The information provided collectively herein was obtained from the Orange Book, from 2009 to September 2016. This information covers the time period from January 1, 2008 to September 2016.

¹ This table does not represent an exhaustive list of all PPIs that have been manufactured, marketed, and distributed throughout the United States. Rather, the table identifies various PPIs and manufacturers to illustrate that numerous drug manufacturers, in addition to AstraZeneca, have manufactured PPIs.

 $^{^{2}}$ All of the PPIs identified in the table are manufactured in various dosage forms. For the purpose of brevity, the varying doses are not identified in the chart.

| Lansoprazole | Zydus Healthcare |
|---------------------------------------|------------------------------------|
| Lansoprazole OTC | Dexcel Pharma |
| Lansoprazole OTC | Dr. Reddy's Laboratories |
| Lansoprazole OTC | Mylan Pharms Inc. |
| Lansoprazole OTC | Natco Pharma Ltd |
| Lansoprazole OTC | Perrigo |
| Lansoprazole OTC | Wockhardt |
| Nexium® | AstraZeneca |
| Nexium® 24HR | Pfizer |
| Omeprazole | Actavis Laboratories |
| Omeprazole | Apotex Inc. |
| Omeprazole | Aurobindo Pharma USA |
| Omeprazole | Dr. Reddy's Laboratories |
| Omeprazole | Glenmark Generics |
| Omeprazole | Impax Laboratories |
| Omeprazole | Kremers Urban Pharmaceuticals Inc. |
| Omeprazole | Lupin Ltd |
| Omeprazole | Mylan Laboratories Inc. |
| Omeprazole | Sandoz Inc. |
| Omeprazole | Zydus Pharms USA Inc. |
| Omeprazole OTC | Dexcel Pharma |
| Omeprazole Magnesium OTC | Dr. Reddy's Laboratories |
| Omeprazole Magnesium OTC | Perrigo |
| Omeprazole and Sodium Bicarbonate | Ajanta Pharma Ltd |
| Omeprazole and Sodium Bicarbonate | Aurolife Pharma LLC |
| Omeprazole and Sodium Bicarbonate | Dr. Reddy's Laboratories |
| Omeprazole and Sodium Bicarbonate | Par Pharmaceutical |
| Omeprazole and Sodium Bicarbonate OTC | Actavis Elizabeth |

| Omeprazole and Sodium Bicarbonate OTC | Par Pharmaceutical |
|---------------------------------------|-------------------------------------|
| Omeprazole and Sodium Bicarbonate OTC | Perrigo |
| Pantoprazole Sodium | Actavis Totowa |
| Pantoprazole Sodium | Amneal Pharmaceuticals |
| Pantoprazole Sodium | Apotex Inc. |
| Pantoprazole Sodium | Aurobindo Pharma Ltd |
| Pantoprazole Sodium | Dr. Reddy's Laboratories |
| Pantoprazole Sodium | Hetero Labs Ltd V |
| Pantoprazole Sodium | Jubilant Generics |
| Pantoprazole Sodium | Kremers Urban Pharmaceuticals Inc. |
| Pantoprazole Sodium | Macleods Pharms Ltd |
| Pantoprazole Sodium | Mylan Pharms Inc. |
| Pantoprazole Sodium | Orchid Healthcare |
| Pantoprazole Sodium | Perrigo |
| Pantoprazole Sodium | Ranbaxy Labs Ltd |
| Pantoprazole Sodium | Sun Pharma Global Inc. |
| Pantoprazole Sodium | Teva Pharmaceuticals |
| Pantoprazole Sodium | Torrent Pharmaceuticals |
| Pantoprazole Sodium | Wockhardt |
| Prevacid® | Takeda Pharmaceuticals |
| Prevacid 24 HR OTC® | GlaxoSmithKline Consumer Healthcare |
| Prevacid Naprapac® | Takeda Pharmaceuticals |
| Prilosec® | AstraZeneca |
| Prilosec OTC® | Proctor & Gamble |
| Protonix® | Wyeth Pharmaceuticals Inc. |
| Rabeprazole Sodium | Amneal Pharmaceuticals |
| Rabeprazole Sodium | Breckenridge Pharmaceutical, Inc. |
| Rabeprazole Sodium | Dr. Reddy's Laboratories |

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| Rabeprazole Sodium | Kremers Urban Dev |
|--------------------|-------------------------|
| Rabeprazole Sodium | Lupin Ltd |
| Rabeprazole Sodium | Mylan Pharms Inc. |
| Rabeprazole Sodium | Teva Pharmaceuticals |
| Rabeprazole Sodium | Torrent Pharmaceuticals |
| Vimovo® | AstraZeneca |
| Vimovo | Horizon Pharma |
| Zegerid | Santarus Inc. |
| Zegerid OTC® | Bayer Healthcare LLC |

Exhibit B

PENDING ACTIONS

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|------------------------------|---|--|--|--|---|
| Bekins, Cindi (S.D. Cal.) | "Nexium and/or other Nexium branded products and PPIs" | AstraZeneca Pharmaceuticals LP ("AZPLP") AstraZeneca LP ("AZLP") | Acute Kidney Failure | "approximately 2003-2016" | "approximately 2011" |
| Bowers, Charles (W.D. Tenn.) | Nexium | AZPLP AZLP | Acute interstitial nephritis; chronic interstitial nephritis | July 7, 2003 through approximately May 14, 2008 | Acute interstitial nephritis – May 09, 2008; Chronic active interstitial nephritis – May 11, 2009 |
| Boyd, Barbara (D.N.J.) | Nexium | AZPLP AZLP | Acute interstitial nephritis; acute renal failure | June 5, 2007 through September 22, 2011 | "as early as September 22, 2011" |
| Burnett, Joey (S.D. Ohio) | Nexium | AZPLP AZLP Astra USA Inc KBI Sub Inc Zeneca Inc Astra USA Holdings Corp. AstraZeneca AB AstraZeneca PLC AstraZeneca UK Limited | End stage renal disease | 2014 | September 18, 2014 |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|--------------------------|--------------------------|--|---------------------|------------------------------------|--|
| Buzbee, Terry (E.D.N.Y.) | Prevacid | AZPLP AZLP Astra USA Inc. KBI Sub Inc. Zeneca Inc. Astra USA Holdings Corp AstraZeneca, AB AstraZeneca, PLC AstraZeneca, UK Limited Takeda Pharmaceuticals USA, Inc. (fka Takeda Pharmaceuticals North American, Inc.) Takeda Pharmaceutical Company Limited Takeda Pharmaceuticals LLC Takeda Pharmaceuticals International Inc. Takeda Global Research & Development Center Inc Takeda California Inc. (fka Takeda San Diego Inc.) | Acute kidney injury | October 2006 through April 2016 | [Complaint is silent to alleged date of injury.] |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|--------------------------------|--------------------------|--|---|---------------------------------|--|
| | | McKesson Corporation Takeda Pharmaceutical USA, Inc. | | | |
| Church, Linda (S.D. W.Va.) | Nexium | AZPLP AZLP Astra USA Inc KBI Sub Inc Zeneca Inc Astra USA Holdings Corp AstraZeneca, AB AstraZeneca, PLC AstraZeneca, UK Limited | Interstitial nephritis; end stage renal disease | 2003 through 2016 | [Complaint is silent to alleged date of injury.] |
| Crandell, Denise (W.D. La.) | Prevacid Prilosec Nexium | AZPLP AZLP Astra USA Inc. AstraZeneca, AB AstraZeneca, UK LTD AstraZeneca, PLC Takeda Pharmaceuticals USA, Inc. Takeda Pharmaceuticals America, Inc. | "serious injuries to her kidneys" | "approximately 2013 to 2016" | [Complaint is silent to alleged date of injury.] |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|----------------------------|--------------------------|--|------------------------|---------------------------------|---------------------------------|
| | | International, Inc. Takeda Development Center Americas, Inc. Takeda Pharmaceutical Company Limited Procter & Gamble Manufacturing Company The Procter & Gamble Company | | | |
| Davis, Dinez (M.D. La.) | "PPIs and Nexium" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC | Chronic kidney disease | "approximately 2010 to 2012" | "approximately 2012" |
| Foster, Richard (W.D. Mo.) | "PPIs and Nexium" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC | Chronic kidney disease | "approximately 2010 to 2016" | "approximately 2010" |
| Goodstein, Steven | Nexium | AZPLP | Chronic kidney | "2004 through the | 2014 |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|--|--------------------------|--|-------------------------------|--|---|
| (D.N.J.) | | AZLP | disease | present" | |
| Hornfeck, Anthony (N.D.N.Y.) | "PPIs and Prilosec" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC Procter & Gamble Manufacturing Company The Procter & Gamble Company | Chronic kidney disease | "approximately 2009 to 2016" | "approximately 2014" |
| Johnson, Bianca, et al. (E.D. La.) | Nexium | AZPLP AZLP | Chronic kidney disease; death | January 2004 through August 2016 | "suffered Chronic Kidney Disease (CKD) and ultimately passed away from CKD in August 2016" |
| Koon, Jackie (D. Kan.) | Prilosec | AZPLP AZLP Astra USA Inc. KBI Sub Inc. Zeneca Inc. Astra USA Holdings Corp. AstraZeneca AB AstraZeneca, PLC | End stage renal disease | 2010 through 2013 | [Complaint is silent to alleged date of injury.] |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|---|--|--|---|--|--|
| | | AstraZeneca UK Limited | | | |
| Labiche, Sharon and Labiche, William, Sr. (E.D. La.) | Nexium | AZPLP AZLP | Chronic kidney disease | January 2002 through December 2012 | January 2016 |
| Mason, Harry (S.D. Ill.) | Nexium | AZPLP AZLP | Kidney failure requiring a kidney transplant | "including but not limited to, in or about 2006" | 2006 |
| Miller, Daniel (W.D. La.) | "PPIs, Dexilant, Nexium, Prevacid and Zegerid" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC Procter & Gamble Manufacturing Company The Procter & Gamble Company | Chronic kidney disease | "approximately 1993 to the present" | "approximately 2013" |
| Modicue, Tagi (W.D. La.) | "PPIs, Prilosec and Nexium" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC | Chronic kidney disease; acute kidney injuries | "approximately 2010 to 2012" | Chronic kidney disease in "approximately 2012" Acute kidney |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|------------------------------------|--------------------------------|---|--|---|--|
| | | Procter & Gamble Manufacturing Company The Procter & Gamble Company | | | injuries – "approximately 2013 and 2015" |
| Moore, Frank (W.D.N.C.) | Prevacid | Takeda Pharmaceuticals USA, Inc. Takeda Pharmaceuticals America, Inc. Takeda Development Center Americas, Inc. Takeda Pharmaceuticals International, Inc. Takeda Pharmaceutical Company Limited | Renal insufficiency; renal failure | [Complaint is silent to alleged dates of exposure.] | "late 2015" |
| Mullen, George (E.D.N.Y.) | Nexium | AZPLP AZLP | Chronic kidney disease | "including but not limited to, in or about September 2006 through September of 2013" | 2008 |
| Ratshidaho, Isaac (W.D. Mo.) | "PPIs, Prilosec and Nexium" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC | Chronic kidney disease, acute renal failure, and end- stage renal disease | "approximately 2011 to 2016" | Chronic kidney disease – "approximately 2015" Acute renal failure – |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|---|---|---|---|---------------------------------|---|
| | | Procter & Gamble Manufacturing Company The Procter & Gamble Company | | | "approximately 2016 End-stage renal disease – "approximately 2016" |
| Rodriguez, Alejandro (Individually and as Surviving Heir of Frank Rodriguez, Deceased) (D. Kan.) | "PPIs, including Prilosec" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC | "serious injuries to his kidneys" and death | 2006 to October 30, 2014 | October 30, 2014 |
| Smith, Richard Witty (M.D. La.) | "PPIs, including Prilosec and Prilosec OTC" | AZPLP AZLP Astra USA Inc. AstraZeneca AB AstraZeneca UK LTD AstraZeneca, PLC Procter & Gamble Manufacturing Company The Procter & Gamble Company | "serious injuries to his kidneys" | "approximately 2006 to 2016" | [Complaint is silent to alleged date of injury.] |

| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|-----------------------------------|---|---|--|---|--|
| Smith, William (E.D. Ark.) | Nexium | AZPLP AZLP | Chronic kidney disease stage 3 | October 11, 2007 through approximately September 16, 2013 | March 27, 2012 |
| Spratt, Lakeisha (D.N.J.) | Nexium Nexium 24HR | AZPLP AZLP Pfizer Inc. | Kidney failure | 2014 | 2014 |
| Thomas, Sharron (E.D. Cal.) | "PPIs and Prevacid" | Takeda Pharmaceuticals USA, Inc. Takeda Pharmaceuticals America, Inc. Takeda Pharmaceuticals International, Inc. Takeda Development Center Americas, Inc. Takeda GmbH Takeda Pharmaceutical Company Limited | Chronic kidney disease, interstitial nephritis | 1996 through 2016 | Chronic kidney disease – "approximately 2008" Interstitial nephritis – "approximately 2010" |
| White, Linda (E.D. Tenn.) | Nexium | AZPLP AZLP | Chronic kidney disease Stage 3 | March 20, 2008 through approximately September 29, 2012 | May 14, 2012 |
| Winters, Carolyn (S.D. | "PPIs, including Nexium, Nexium 24HR" | AZPLP AZLP Astra USA Inc. | Chronic kidney | 2009 to 2012 | [Complaint is silent to alleged |

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| PLAINTIFF | ALLEGED MEDICATION(S) | NAMED DEFENDANTS | ALLEGED INJURY | ALLEGED DATES OF EXPOSURE | ALLEGED DATE(S) OF INJURY |
|-----------|--------------------------|---|-------------------|---------------------------------|---------------------------------|
| Miss.) | | AstraZeneca AB AstraZeneca UK Ltd. AstraZeneca PLC | disease | | date of injury.] |
| | | Procter & Gamble Manufacturing Company The Procter & Gamble Company | | | |

Exhibit C



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Nexium Lawsuit

Prevacid Lawsuit

Prilosec Lawsuit

Proton Pump Inhibitor Lawsuit

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Nexium, Prilosec, Prevacid Lawsuit TV Commercial

Published on May 24, 2016 by Sandy Liebhard



Did you recently view a Nexium, Prilosec or Prevacid lawsuit TV commercial? These advertisements have begun airing across the country, following the publication of several studies that suggest the use of heart burn drugs called proton pump inhibitors, or PPIs, may increase a patient's risk for chronic kidney disease, renal failure, and other kidney complications.

Bernstein Liebhard LLP is investigating the kidney side effects that may be associated with proton pump inhibitors. If you recently saw a TV commercial advertising legal assistance for a Nexium, Prilosec or Prevacid lawsuit, and believe you might have a case, please call our office at (888) 994-8177. A member of our legal staff will evaluate your claim at no cost or obligation to you, and take the time to answer any questions you might have.

What are Proton Pump Inhibitors?

In 2014, some 14 million Americans used proton pump inhibitors like Nexium, Prilosec or Prevacid to treat indigestion, peptic ulcers, acid reflux and other gastric ailments. As a class, the drugs rank among the top-10 most prescribed medications in the U.S. They are also sold over-the-counter.

Prescription proton pump inhibitors include:

Nexium (esomeprazole)

Prilosec (omeprazole)

Prevacid (lansoprazole)

Dexilent, Kapidex (dexlansoprazole)

Aciphex (rabeprazole)

Protonix (pantoprazole)

A number of over-the-counter versions are also available, including Nexium 24HR, Prilosec OTC, and Prevacid 24HR.

Proton pump inhibitors work by turning off pumps in the stomach that produce gastric acid. They are intended for short-term use, and should be taken at the lowest dose for the shortest duration possible to appropriately treat a specific condition.

Proton Pump Inhibitor Kidney Complications

Free Case Evalution

Have you or a loved one suffered a heart attack while taking Nexium, Prilosec, or Prevacid?

Full Name

Email

Telephone

Tell me about your case...

Submit Information

I agree to the Privacy Policy and Terms of Services

Nexium Lawsuit News

Nexium Lawsuit Claims AstraZeneca Marketed Defective, Unreasonably Dan...

August 24, 2016 5:11 PM

Nexium Overuse Results in Unnecessary Patient Harm: Editorial

August 15, 2016 6:58 PM

Nexium Lawsuit Filed by AstraZeneca Claims
Patent Infringement

August 9, 2016 5:17 PM

<u>Case Study Links Nexium to Serious Muscle</u> <u>Disorder</u>

August 2, 2016 4:57 PM

Osteoporosis Risk Increases With Proton Pump Inhibitor Use

July 26, 2016 6:36 PM

Case MDL No. 2757 Document 58-3 Filed 11/22/16 Page 3 of 3

Because they are so-widely used, most people believe that proton pump inhibitors are completely safe. However, these heart burn drugs have been tied to a number of serious side effects, especially when used over a long period of time. These complications include:

Rebound hypersecretion (increased gastric acid hypersecretion can occur in patients who stop taking the drugs following 2 to 3 months of use)

Osteoporosis and bone fractures

diff infections

Magnesium deficiency

B12 deficiency

Drugs like Nexium, Prilosec and Prevacid have also been linked to serious kidney complications. In 2014, the U.S. Food & Drug Administration (FDA) ordered the manufacturers of all prescription proton pump inhibitors to add information to their product labels regarding acute interstitial nephritis, a serious inflammation of the kidneys that can lead to chronic kidney disease, and ultimately kidney failure. The labeling for OTC proton pump inhibitors does not include this information.

In 2016, two studies raised serious concerns about the potential for proton pump inhibitors to damage the kidneys. The first, which appeared in <u>JAMA Internal Medicine</u> in January, drew data from the medical records of more than 10,000 patients treated in community-based settings, as well as 248,000 people treated in a Pennsylvania hospital system. The findings suggested that proton pump inhibitors might increase the risk of chronic kidney disease by as much as 50%.

In April 2016, research that appeared in the <u>Journal of the American Society of Nephrology</u> reported that long-term users of proton pump inhibitors may be 96% more likely to develop kidney failure and 28% more likely to develop chronic kidney disease compared to patients using H2-blockers, a class of acid reducing medications that includes Zantac and Tagamet. The study, which compared 73,321 proton pump inhibitor uses to a group of 20,270 H2-blocker patients, also indicated that risk increased the longer the medications were taken.

Contact an Attorney Today

As noted by Nexium, Prilosec and Prevacid lawsuit TV commercials, users of proton pump inhibitors may be entitled to financial compensation if they were diagnosed with serious kidney injuries, including renal failure and chronic kidney disease. To learn if you might be eligible to take legal action against a proton pump inhibitor manufacturer, please call (888) 994-8177 to contact an attorney at Bernstein Liebhard LLP today.

| CLICKY | ANALYTICS | |
|--------|-----------|--|
| | | |

Nexium Lawsuit Prevacid Lawsuit Prilosec Lawsuit

Free Case Evalution

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Exhibit D



Nexium: Is the Purple Pill Shutting Your Kidneys Down? – Should You Be Taking It?

April 5, 2016

An estimated 15 million Americans are currently taking drugs like Nexium which work to control heartburn, indigestion, and acid reflux. Unfortunately, those who turn to Nexium and other Proton-pump inhibitors will need to proceed much more cautiously as studies have confirmed that taking these drugs increase the chance of kidney problems – and even kidney failure – by as much as fifty percent.

Proton-pump inhibitors are a class of drugs which include Nexium, Prilosec, and Prevacid which work by blocking the secretion of acid into the stomach. These extremely common medications are sold both by prescription and over-the-counter. The recent discovery of this increased risk of chronic kidney disease and even failure means that much more care must be taken in determining if a person should be popping the purple pill.

The issue with Nexium and other drugs in its class is that since their creation in the 1980s, they were considered to be very safe, with no real side effects. This led to the popularity of the drug and a much more lax attitude about taking large doses and prescribing it to any and all patients with reflux issues.

It is very possible that these drugs, prescribed and taken in such massive numbers, are being over-prescribed. Studies have suggested that as many as 75 percent of those who take proton-pump inhibitors need not do so.

In addition to being connected to chronic kidney disease, Nexium and other drugs like it have been linked to increased rates of heart attack, bone fracture, and infections of the gut.

The research was conducted by Johns Hopkins University and it studied over 250,000 patients to reach its conclusion that Nexium and proton-pump inhibitors increase the rate of kidney disease. Researchers concluded that doctors and patients should take a greater degree of caution when prescribing and purchasing proton-pump inhibitors, but say that further research is needed to draw stronger connections between the drugs and the disease. Doctors recommend that patients first try to control their acid issues by changing their diet and creating a healthier lifestyle.

Over 13 percent of the population suffer from kidney disease. A case of chronic kidney disease, if prolonged, can lead to kidney failure and the necessity of a kidney transplant, a dangerous and invasive surgery.

With 15 million Americans currently taking these drugs, it is clearly a massive market for big pharma. As of now, the companies that produce proton-pump inhibitors have either declined to comment on the study or have maintained that their drugs are safe to take according to the label.

Find out more about Nexium & Prilosec litigation, by going to the Levin Papantonio Nexium & Prilosec Lawsuit website.

Sydney Robinson

Sydney Robinson is a contributor at Ring of Fire. She would love to hear from you on Twitter @SydneyMkay or via email at srobinson@ringoffireradio.com





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Nexium & Prilosec Lawsuit - Kidney Failure

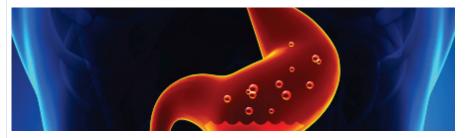
The lawsuits involving Nexium and Prilosec state the manufacturers failed to warn patients and physicians of the increased risks of kidney damage and renal failure.

Plaintiffs lawyers argue that if the manufacturers had properly warned of the risks, patients would have been prescribed a different medication for their acid-related stomach issues, and certainly would have had their health monitored on a more frequent basis for potential signs of kidney disease.

Nexium & Prilosec linked to increased risk of kidney and renal issues

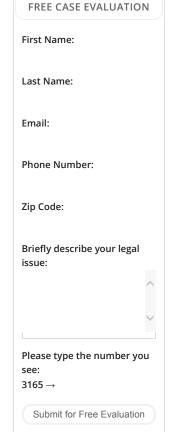
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Why is Nexium and Prilosec Utilized



Nexium & Prilosec are drugs called proton pump inhibitors. They are used to treat gastroesophageal reflux disease, by reducing the amount of acid in a person's stomach. They also may be prescribed to heal acid-related damage to the lining of the esophagus; to reduce stomach ulcers; and to treat stomach infections.

Approximately 15 million Americans use proton pump inhibitors. However, as many as 25% of long-term users could stop taking the medication without suffering increased heartburn or acid reflux, according to researchers at Johns Hopkins University.





the primary use of Nexium and Prilosec is to treat acid reflux

Nexium and Prilosec Injuries & Side Effects

The most serious potential side effects and risks caused through the use of Nexium & Prilosec are bone fractures, kidney disease, renal failure and heart damage.

People who take multiple daily doses for a long period of time (a year or longer), especially those 50 years of age or older, have an increased risk of fractures of the hip, wrist, and spine. Additionally, people who use the drugs appear to have a 20 percent to 50 percent higher risk of chronic kidney disease compared with

Less Serious Side Effects

Abdominal pain

Chronic inflammation of the stomach lining

Constipation

Diarrhea

Drowsiness

Dry mouth

Gas

Headaches

Low magnesium levels

"PPI users [such as Nexium and Prilosec] are at increased risk for heart attack, stroke and renal failure," says Dr. John P. Cooke, Houston Methodist Research Institute.

It's very important to tell your doctor if you have any of the following issues: (i) kidney disease; (ii) osteoporosis; (iii) low bone mineral density (osteopenia); or (iv) low levels of magnesium in your blood.

Read More

nonusers.

Nexium & Prilosec Lawsuit Videos

Nausea

Nexium: Is the Purple Pill Shutting Your Kidneys Down? - Should You Be Taking...

"I am so appreciative of the hard work and dedication that you put forth on my case. I cannot thank you enough for making my mom and I feel so comfortable throughout this whole process. You are one amazing lawyer. I wish you the best and I wanted to let you know that I will never forget you!"

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\$42 Million in Defective

Drug Case

\$42 Million in Fraud Ca



\$25 Million in Defective Drug Case

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9:3

Nexium: Is the Purple Pill Shutting Your Kidneys Down? - Should You Be Taking It?



Nexium: Is the Purple Pill Shutting Your Kidneys Down? - Should You Be Taking It?



Nexium And Prilosec Causing Massive Health Problems, Including Kidney Failure 3:52

To read the transcripts, click Nexium and Prilosec Video Transcripts

Click for Free Case Evaluation

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Our law firm has been in existence for more than 60 years, and is considered a national leader in these types of lawsuits. We have received well over 150 jury verdicts throughout the country in the amount of \$1 million or more, and achieved verdicts and settlements in excess of \$3 billion.

We are the founder of Mass Torts Made Perfect, which is a national seminar attended by approximately 800 lawyers twice per year where we help teach the successful handling of cases against pharmaceutical companies. For more information, please visit our **About Us** section.

in business 60 years - \$3 billion in verdicts and settlements - listed in Best Lawyers in America, SuperLawyers and Trial Lawyers Hall of Fame

What Does It Cost

Our lawyers provide absolutely free confidential consultations, and if we are fortunate enough for you to hire us, we never will charge you any fees or costs unless you first recover. To review a summary of our fees and costs, click **Fees** & Costs.

Contact Information



To contact us for a free confidential consult, you can call us at (800) 277-1193 (toll free). You also can request a confidential consultation by clicking Free & Confidential Consult, which form will be immediately reviewed by one of our attorneys handling the Nexium and Prilosec litigation.

Read More



Nexium & Prilosec Lawsuit News

Nexium and Prilosec Linked to Kidney Damage, Heart Damage and Bone Fractures:

News of the connection between proton pump inhibitors (PPIs) such as Prilosec and Nexium has been out for several months, having been reported on Ring of Fire and elsewhere. That's grim enough, but the latest news is even more alarming. It turns out that when it comes to PPIs, kidney disease is just the tip of the iceberg. These drugs do far more damage in more ways than previously thought. To read more, click Drug Safety News

Commonly used heartburn drugs may lead to kidney damage: study:

Long-term use of a common type of medication used to treat heartburn, acid reflux, and ulcers may lead to an increased risk of kidney disease and kidney failure, new research shows. The study, published in the Journal of the American Society of Nephrology, adds to prior research that suggests proton-pump inhibitors (PPIs), a group of drugs which reduces gastric acid production, can lead to serious kidney damage. To read more, click CBS News

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FDA and Scientific Studies Regarding Nexium & Prilosec





Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease

Proton pump inhibitors (PPIs) are among the most commonly used drugs worldwide and have been linked to acute interstitial nephritis. Less is known about the association between PPI use and chronic kidney disease (CKD). . . . Proton pump inhibitor use is associated with a higher risk of incident CKD. To read more, click Journal of American Medical Association

PPIs and kidney disease: from AIN to CKD

Proton pump inhibitors (PPIs) are commonly prescribed and available over-the-counter, and are taken by millions of patients around the world, often for many months to years. While PPIs have an excellent overall safety profile, concerns have been raised about adverse renal events, specifically their association with acute interstitial nephritis (AIN). While only a small proportion of patients develop AIN from PPIs, these drugs are now a common cause of drug-induced AIN in the developed world due to their widespread and prolonged use. To read more, click Journal of the American Society of Nephrology

Nexium and Prilosec Recall Information

As of this time, there has not been a recall of Nexium or Prilosec related to kidney damage. However, the investigation into these drugs, from a legal standpoint, are still at the early stages. It often takes many years; tens of thousands of hours of attorney time; and the expense of many millions of dollars before all the facts come out that will lead to a recall.

Nexium and Prilosec Settlement Information

As of this time, there have been no large group settlements involving Nexium or Prilosec and the potential link to kidney injuries. Litigation likes this takes many years to resolve, with teams of lawyers spending millions of dollars trying to determine exactly what occurred, and how it could have been prevented. Generally, large groups of settlements do not occur until such time as a few cases are tried before a jury, and the manufacturer is able to more thoroughly understand its financial risk.

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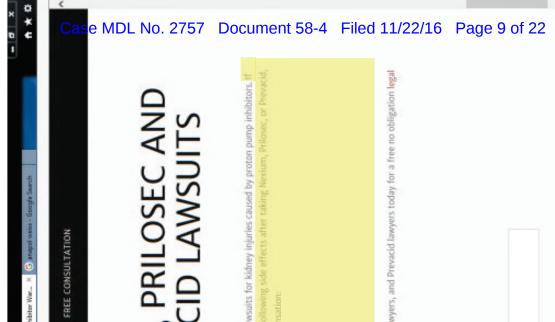
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Proton Pump Inhibitors & Kidney Failure



Proton pump inhibitors (PPIs) are oral medications used to treat acid reflux and the conditions associated with it. Many heartburn and acid reflux medications are PPIs, including prescription versions sold under the brand names Nexium, Prilosec, and Prevacid.

PPIs are one of the most prescribed medications in the world with more than 15 million Americans using the drugs in 2013, but recent studies show use of these drugs – especially overuse - is associated with an increased risk for chronic kidney disease (CKD), also known as renal failure.

The newest developments come following two population-based analyses published in the January 2016 issue of JAMA Internal Medicine in which authors suggested PPIs could play a role in why CKD prevalence is rising faster than expected. The study was observational so there is no evidence of causality, but it still links PPI use with CKD and the information warrants further investigation.

Also of concern is the over and unnecessary use of the drugs. Studies showed that 70% of the prescriptions for PPIs were without indication and that about a quarter of long-term users could discontinue therapy without suffering any negative consequences. Some doctors believe dietary and lifestyle education could increase that number even further.

About the Analyses

The analyses included an examination of the medical records of patients from the JAMA study and showed those taking PPIs had an increased risk for CKD of 20 to 50 percent. Another study, presented at the American Society of Nephrology meeting in the fall of 2015, showed similar results. Both indicated the longer or more frequent the use of medication the greater the risk is for complications.

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There were more than 10,000 patients evaluated in the studies and many were observed for up to 14 years.

Specific study results were as follows:

Among 10 482 participants in the Atherosclerosis Risk in Communities study, the mean (SD) age was 63.0 (5.6) years, and 43.9% were male. Compared with nonusers, PPI users were more often of white race, obese, and taking antihypertensive medication. Proton pump inhibitor use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score—matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

About CKD

Chronic kidney disease, or renal failure, is the gradual loss of kidney function. This means kidneys are no longer able to perform their natural function of filtering waste and excess fluids from the blood. Advanced stage CKD can result in dangerous levels of fluid, electrolytes and wastes can build up in your body.

Because the symptoms of kidney disease can be few at the earliest stages, many patients are not diagnosed until the disease has progressed to later stages.

Symptoms include:

- · Nausea, vomiting, and loss of appetite
- · Fatigue and weakness
- · Chronic itching
- · Muscle twitches and cramps
- · Insomnia and other sleeping problems
- · Changes in urine output
- · Decrease in mental clarity
- Hiccup:
- · Swelling in the feet and ankles
- · Fluid buildup that can result in chest pain or shortness of breath
- · Difficult-to-control hypertension

Treatment is focused on slowing the progression of kidney damage, often by controlling the underlying cause. End-stage kidney failure is considered fatal, unless a patient undergoes ongoing dialysis treatment or receives a kidney transplant.

Other Risks Associated with PPIs

In addition to CKD, there is also evidence PPI use could be related to:

- Acute interstitial nephritis
- Hypomagnesemia
- Clostridium difficile infection
- Community-acquired pneumonia
- Osteoporotic fractures
- Birth defects
- · Myocardial infarction

What You Can Do

If you or someone you love has been using PPIs and experienced adverse effects, including CKD or other kidney problems, you might be entitled to compensation. Speak with your doctor before starting or stopping usage of any medications.

Sources:

- http://archinte.jamanetwork.com/article.aspx?articleid=2481157
- http://www.medscape.com/viewarticle/857060

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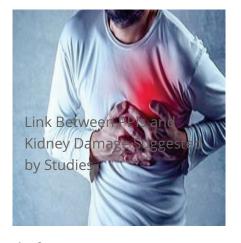
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Proton Pump Inhibitors

Proton Pump Inhibitors



Proton pump
inhibitors (PPIs)
are a type of
medication used
to treat certain
kinds of
gastrointestinal

dysfunction.

These problems may include:

- Gastroesophageal reflux disease
 (GERD)
- Inflammation of the esophagus

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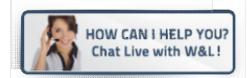
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Small ulcers in the stomach or intestines

Proton pump inhibitors are intended to reduce the amount of stomach acid. In 2009 alone, almost 120 million patients had prescriptions filled for PPIs at U.S. pharmacies. Over-the-counter (OTC) formulations of some proton pump inhibitors have been available for over a decade, as well.

Some proton pump inhibitors you may be familiar with are:

- AcipHex (rabeprazole)
- Dexilant (dexlansoprazole)
- Nexium (esomeprazole)
- Prevacid (lansoprazole)
- Prilosec (omeprazole)
- Protonix (pantoprazole)
- Zegerid (omeprazole and sodium bicarbonate)

In recent years, the U.S. Food and Drug

Administration (FDA) has issued a number of safety

communications related to proton pump inhibitors.

Some of the concerns they have noted include

severe diarrhea caused by specific bacteria, low

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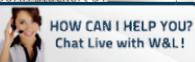
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magnesium levels with prolonged use of PPIs and fractures of the wrist, hip and spine in those taking PPIs at high doses for a prolonged period of time.

Increasing Concerns About PPIs: Life-Threatening Risks Possible

Recent research suggests that using proton pump inhibitors may lead to serious, even life-threatening kidney problems. Specifically, proton pump inhibitor medications have been linked to people developing:

- Chronic kidney disease (CKD)
- Acute kidney injury (AKI), sometimes
 called acute renal failure
- Interstitial nephritis
- End-stage renal failure, sometimes
 called end-stage renal disease (ESRD)

Proton Pump Inhibitors and Chronic Kidney Disease, End-Stage Renal Disease

Chronic kidney disease is a loss of kidney function that happens gradually, over months or even years. In the beginning, an individual may not have any noticeable symptoms because the loss of kidney function in CKD can occur slowly.

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The kidneys can no longer filter waste products and excessive fluid from the body. When this occurs, a person must either undergo kidney dialysis or receive a kidney transplant to stay alive. Chronic kidney disease and end-stage renal disease can cause many complications and may result in death.

PPIs and Acute Kidney Injury

Acute kidney injury (AKI) is also called acute kidney (renal) failure. This form of loss of kidney function happens suddenly, over hours or days.

CLIENT TESTIMONIALS

Ilea e thank everyone that worked on my husband's case for everything. It does not bring Bob back, but it is somewhat of a comfort to know he was watching over us to make sure Nick and I will be financially OK.

Cyndy P. -



Acute kidney injury can be life-threatening because the kidneys are suddenly no longer able to filter waste products and remove excess fluid from the body. When waste products accumulate in your blood, your entire body can be affected.

The implications of having acute kidney injury can be far-reaching for a person's body. Healthy kidneys not only remove wastes and toxins from the blood, but they help maintain blood pressure and blood acid-base balance, as well as reabsorb vital nutrients the body needs.

In addition, some patients suffering from acute kidney injury may develop respiratory failure. This increases the possibility that a patient may die from complications related to acute kidney injury.

If someone suffering from acute kidney injury does not receive immediate treatment, abnormal levels of salts, wastes and toxins can build up in the body. If the kidneys stop working completely, kidney dialysis or a kidney transplant are necessary to sustain life.

Severe loss of kidney function and complications caused by kidney failure can lead to death.

Possible symptoms of acute kidney injury include:

- Nausea
- Shortness of breath



- · Urinating much less than normal
- Seizures or coma
- Confusion
- Drowsiness
- Fluid retention (edema), especially in the legs, ankles or feet

PPIs and Interstitial Nephritis

Interstitial nephritis is a condition involving inflammation of a specific part of the kidneys.

Interstitial nephritis refers to inflammation of the spaces between the kidney tubules.

Interstitial nephritis may be temporary (acute) or last for a longer period of time (chronic). Symptoms can vary from mild to severe, the most serious being acute kidney failure.

Symptoms of interstitial nephritis may include:

- · Blood in urine
- Change in urine output
- Fever
- Drowsiness, confusion or coma
- Nausea or vomiting
- Rash
- Swelling of any part of the body
- Weight gain due to fluid retention



Depending on a patient's specific circumstances, someone suffering from interstitial nephritis may only require short-term treatment. In other instances, however, dialysis may be required and interstitial nephritis may cause permanent damage, such as chronic kidney disease, also called chronic kidney failure.

Victims of Kidney Damage Associated with Proton Pump Inhibitor Use May Be Entitled to Compensation

If you took a proton pump inhibitor medication and developed chronic kidney disease, interstitial nephritis, an acute kidney injury or end-stage renal disease that required hospitalization, surgical intervention, or dialysis, you may be entitled to compensation.

If you are the loved one of someone who took a proton pump inhibitor medication and died from complications related to severe kidney damage, please contact us. You may be able to receive compensation for your loved one's death.

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Exhibit E

In re Nexium Esomeprazole, --- Fed.Appx. --- (2016)

2016 WL 6298741

2016 WL 6298741

Only the Westlaw citation is currently available.

This case was not selected for publication in West's
Federal Reporter.

See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also U.S.Ct. of App. 9th Cir. Rule 36-3.

United States Court of Appeals, Ninth Circuit.

In re: Nexium Esomeprazole Susan Orrell, et al., Plaintiffs–Appellants,

AstraZeneca Pharmaceuticals LP, et al., Defendants—Appellees. Janice Allen, et al., Plaintiffs—Appellants,

AstraZeneca Pharmaceuticals LP, et al., Defendants—Appellees.

No. 14–56845, No. 15–56484 | Submitted October 20, 2016 Pasadena, California | Filed October 28, 2016

Appeal from the United States District Court for the Central District of California, Dale S. Fischer, District Judge, Presiding, D.C. No. 2:12–ml–02404–DSF–SS

Attorneys and Law Firms

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James J. Freebery, Esquire, Attorney, McCarter & English, LLP, Wilmington, DE, for Defendants–Appellees (Case No. 15–56484).

Before: TALLMAN, PARKER,** and CHRISTEN, Circuit Judges.

MEMORANDUM***

*1 Plaintiffs in this MDL proceeding filed product liability claims against AstraZeneca alleging that the drug Nexium caused plaintiffs' reduced bone mineral density and related fractures. Nexium is an FDA-approved medication marketed and sold by AstraZeneca, Nexium belongs to a class of drugs called proton-pump inhibitors (PPIs), which "work by reducing the amount of acid in the stomach." The plaintiffs designated orthopedic surgeon Dr. Sonny Bal as their general-causation expert, produced his expert report, and made him available for a deposition. The plaintiffs offered no other general-causation evidence. The defendants moved to exclude Dr. Bal's testimony and for summary judgment.

The district court ruled Dr. Bal's testimony did not satisfy the standard required by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and granted summary judgment for the defendants. The district court denied plaintiffs' motion to be relieved entirely from costs under Federal Rule of Civil Procedure 54(d)(1). We have jurisdiction under 28 U.S.C. § 1291. We affirm.

1. "We review the district court's decision to exclude expert scientific testimony for abuse of discretion, even in the context of a summary judgment motion." Kennedy v. Collagen Corp., 161 F.3d 1226, 1227 (9th Cir. 1998) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)). "Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the [reliability] prong of Rule 702." Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1318 (9th Cir. 1995). "[I]f these guarantees of reliability are not satisfied, the expert 'must explain precisely how he went about reaching his conclusions and point to some objective source to show that he has followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in his field." Lust ex rel. Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 598 (9th Cir. 1996) (internal alterations omitted) (quoting Daubert, 43 F.3d at 1319).

In re Nexium Esomeprazole, --- Fed.Appx. --- (2016)

2016 WL 6298741

Dr. Bal formed his general-causation opinion for the purposes of this litigation and his causal theory was not subjected to peer review. In order to serve as an expert in this case, Dr. Bal reviewed thirteen references. In his three-page expert report, Dr. Bal discussed the materials he reviewed and explained his opinion that there are three ways in which PPI use could contribute to an increased fracture risk. But Dr. Bal did not adequately explain how he inferred a causal relationship from epidemiological studies that did not come to such a conclusion themselves. "When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied." *Lust*, 89 F.3d at 598.

*2 At best, Dr. Bal analyzed three of the nine Bradford Hill factors that guide scientists in drawing causal conclusions from epidemiological studies. See Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 17 (1st Cir. 2011) (citing Arthur Bradford Hill, The Environment and Disease: Association or Causation?, 58 PROC. ROYAL SOC'Y MED. 295 (1965)). We agree with the district court that Dr. Bal's analysis of the factors he did discuss was "extremely thin." For example, at his deposition, Dr. Bal explained "a causal relationship can be inferred because of a number of studies that seem to point the same way." But Dr. Bal admitted that the meta-analyses he relied on found "significant heterogeneity among the studies that they pooled," indicating that the underlying studies "are all over the map." Dr. Bal also acknowledged that one of the meta-analyses he relied on warned that its results must be interpreted with "caution" in part because of this heterogeneity. Dr. Bal did not explain how he came to a different conclusion than the studies' authors, or how this heterogeneity affected his causal conclusion.

The district court did not abuse its discretion in excluding Dr. Bal's testimony as unreliable. Because the district court properly excluded this testimony, and the plaintiffs offered no other evidence on general causation, the district court correctly granted summary judgment to the defendants.

2. We also review the district court's award of costs for abuse of discretion. *Miles v. California*, 320 F.3d 986, 988 (9th Cir. 2003). Federal Rule of Civil Procedure 54(d)(1) "creates a presumption for awarding costs to prevailing parties; the losing party must show why costs should not be awarded." *Save Our Valley v. Sound Transit*, 335 F.3d 932, 944–45 (9th Cir. 2003). Only "in the rare occasion where severe injustice will result from an award of costs" does a district court abuse its discretion "by failing to conclude that the presumption has been rebutted." *Id.* at 945. This is not such a case. The district court did not abuse its discretion in awarding costs to the defendants as prevailing parties under Rule 54(d)(1).

Costs of this appeal shall be awarded to the appellees.

AFFIRMED.

All Citations

--- Fed.Appx. ----, 2016 WL 6298741

Footnotes

- * The panel unanimously concludes this case is suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).
- The Honorable Barrington D. Parker, Jr., United States Circuit Judge for the U.S. Court of Appeals for the Second Circuit, sitting by designation.
- This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36–3.

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In re Nexium Esomeprazole, --- Fed.Appx. --- (2016)

2016 WL 6298741

Exhibit F

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ILLINOIS

| IN RE DEPAKOTE: |) |
|----------------------------|-----------------------------|
| RHEALYN ALEXANDER, et al., |) |
| Plaintiffs, |)) |
| vs. |) Case No. 12-CV-52-NJR-SCW |
| ABBOTT LABORATORIES, INC., |) LEAD CONSOLIDATED CASE |
| Defendant. | ý , |
| | |

ROSENSTENGEL, District Judge:

This Court currently has 129 cases, involving approximately 691 plaintiffs, pending on its docket. The first cases were filed in 2012, and cases continue to be filed each month. One bellwether case was tried in this Court in March 2015, and three other cases have been tried since then in other venues. At this point, three additional cases are set for trial in this district later this year. A case scheduled for trial in June 2016 has been continued generally in light of the unavailability of Plaintiffs' liability expert.

ORDER

As the Court noted in its Order dated April 25, 2016 (Doc. 467), global settlement efforts have failed. Thus, it appears that a massive undertaking involving all of this district's resources will be required to try the majority of cases on the Court's docket. At the current pace of case resolution, the undersigned has calculated it will take over 34 years to close each case on the docket. The undersigned is currently consulting with Chief Judge Michael J. Reagan and the Circuit Executive for the Seventh Circuit to obtain the resources necessary to ensure that the majority, if not all, of the cases pending in this

district are tried by the end of 2017. This will obviously mean that many claims will necessarily be tried together at the same time, with multiple judges in several courthouses. While the issues are complicated and joint trials may in some circumstances be impracticable, at this point the Court can only focus on finding common issues to try, and extensive efforts will be spent to identify where the issues overlap.

While the Court recognizes trying all the cases by the end of 2017 is an ambitious timeframe, counsel is reminded that the majority of these cases have been pending in this district for almost four years. Unfortunately, it appears that the "bellwether" process has failed for these cases, given that there have been four Depakote trials in this country since 2013, and yet only *one* of hundreds of cases (in another district court-following a jury trial) has settled. The Court is also mindful that there are many attorneys representing both sides of this litigation, and both sides have significant resources to accomplish the work that needs to be done.

The parties are advised that the Court is now considering a variety of methods to allow for the joint and expedient resolution of all claims, including bifurcation of the issues, limitation of testimony, shortened trials, and, of course, to the extent possible, multiple trials of claims involving the same label and/or other overlapping issues. These methods will assist the Court in its obligation to "secure the just, speedy, and inexpensive determination" of these cases (*see* FED. R. CIV. P. 1) and are consistent with Rule 42.

In order to allow the Court to select groups of similar claims for trial, the parties are **ORDERED** to conduct the deposition of the prescribing physician(s) in the 132 cases attached as Exhibit A within **90 days** of the date of this Order. The parties shall report the following information to the Court within **14 days** of each deposition: (1) a summary of the physician's testimony, including the details of the prescribing decision, the indication, and the warning given; (2) the relevant Depakote label; (3) details concerning the warnings given as reflected in the medical records, and (4) any other relevant information related to the individual claim. The parties shall file a *joint* report (not to exceed five pages) for each deposed prescriber and, to the extent counsel is unable to agree on a summary of the testimony, counsel shall state their respective positions separately within the *same document* and attach a copy of the complete deposition transcript.

Counsel for Plaintiffs shall alert the Court concerning any prescribing physicians who cannot be located and/or produced for deposition within this timeframe as soon as possible but in any event before the expiration of the 90 day deadline and/or move for voluntary dismissal of those individual claims. Subpoena requests for depositions of any recalcitrant prescribing physicians will be liberally granted. The Court will review the summaries of the prescribing physician testimony as they are submitted and determine whether the case should proceed to a deposition of the mother and/or full discovery on that claim. The Court also will continue to review the pending cases and select the next group of cases to proceed with prescriber depositions.

Finally, because trial counsel will be consumed in the coming months with conducting these depositions and preparing mass cases for trial, both sides are *strongly encouraged* to retain independent, separate settlement counsel to pursue the possibility that at least some of these claims could be resolved without a trial and the inevitable costly appeal that will follow. While the Court's suggestion of this tactic has fallen on deaf ears in the past, it continues to be quite apparent that trial counsel is focused on trying individual claims, something the Court cannot do for the next 34 years. The parties shall continue to consult with the mediators in this case, attorneys Randi Ellis and John Perry, in an effort to resolve at least some of the cases on the Court's docket.

IT IS SO ORDERED.

DATED: July 6, 2016

NANCY J. ROSENSTENGEL United States District Judge

Many J. Roensteng

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR : PRODUCTS LIABILITY LITIGATION :

MDL DOCKET NO.: 2757

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FILED ELECTRONICALLY

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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Pursuant to 28 U.S.C. § 1407 and Rule 11.1(b) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation ("JPML"), AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and McKesson Corporation (collectively "Defendants"), respectfully submit this request that oral argument be heard on the pending Motion for Transfer for the following reasons:

The factual issues of the litigation are such that oral argument will benefit the JPML in its deliberations and ultimate decision-making role. Further, as the defendants are opposing the Motion for Transfer, and there is disagreement between the parties as to the proper transferee forum, if any, the Motion for Transfer raises issues that are particularly appropriate for argument.

WHEREFORE, Defendants request relief, pursuant to Rule 11.1(b), in the form of a hearing for oral argument set prior to the JPML consideration of, and decision upon, the requested transfer of the litigation to a single forum for coordinated pre-trial proceedings.

Respectfully submitted,

ICE MILLER LLP

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Attorneys for Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP and McKesson Corporation

Dated: November 22, 2016

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR : MDL DOCKET NO.: 2757

PRODUCTS LIABILITY LITIGATION

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PROOF OF SERVICE

I hereby certify that on this 22nd day of November 2016, a copy of the foregoing DEFENDANTS ASTRAZENECA AND MCKESSON RESPONSE IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 4.1 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS was served to all parties of record as indicated below.

Served via Email on 11/22/2016

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Attorneys for Plaintiff Carolyn Winters

/s/ Amy K. Fisher

Amy K. Fisher

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2016, I electronically filed the foregoing document with the clerk of the court for the Judicial Panel on Multidistrict Litigation, using the CM/ECF system which will send notification of such filing to the CM/ECF participants to receive service in this matter.

| /s/ Amy | K. Fisher | |
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