# BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: FLUOROQUINOLONE	§	MDL
PRODUCTS LIABILITY	§	
LITIGATION	§	

# BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS TO THE SOUTHERN DISTRICT OF ILLINOIS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Movants<sup>1</sup> respectfully submit this memorandum of law in support of their Motion for Transfer of Actions for Coordinated Pretrial Proceedings of all currently filed fluoroquinolone actions identified in the included Schedule of Actions, as well as any actions subsequently filed involving similar facts or claims arising from the development of irreversible peripheral neuropathy as a result of using fluoroquinolones, to the United States District Court for the Southern District of Illinois, and to consolidate and coordinate all actions for pretrial proceedings before the Honorable David R. Herndon, United States District Judge, Southern District of Illinois.

<sup>&</sup>lt;sup>1</sup> Movants are the Plaintiffs in the following cases: *Bullard v. Bayer Healthcare Pharmaceuticals, Inc., et al.,* Case No. 3:15-cv-0038; *Bush v. Johnson & Johnson, et al.,* Case No. 3:15-cv-00452; *Grossman v. Johnson & Johnson, et al.,* Case No. 1:15-cv-01082; *Higley v. Bayer HealthCare Pharmaceuticals, Inc. et al.,* Case No. 3:14-cv-05254; *Kellerman v. Bayer HealthCare Pharmaceuticals, Inc., et al.,* Case No. 3:14-cv-03680; *Lampard v. Johnson & Johnson, et al.,* Case No. 1:15-cv-03021; and *Street v. Johnson & Johnson, et al.,* Case No. 3:15-cv-08065.

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Presently, there are at least twenty-four (24) substantially similar federal actions, filed by fifteen (15) different law firms, in sixteen (16) different federal district courts<sup>2</sup> alleging similar wrongful conduct on the part of the named defendants. All actions, including the Movants' actions, by other plaintiffs, and by future plaintiffs, involve common questions of law and fact that arise from plaintiffs' development of irreversible peripheral neuropathy resulting from the ingestion of one or more fluoroquinolone antibiotics, which include the prescription drugs Avelox® (moxifloxacin), Cipro® (ciprofloxacin), and Levaquin® (levofloxacin)<sup>3</sup> (collectively, the "fluoroquinolones")<sup>4</sup>. Cipro and Avelox were manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, promoted and/or sold by Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation, Merck & Co., Inc., Schering Corporation, and McKesson Corporation (collectively, the "Bayer Defendants"). Levaquin was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and/or sold by Defendants Johnson & Johnson, Janssen Research & Development, LLC (f/k/a Johnson & Johnson Pharmaceutical Research & Development, LLC), Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.), and McKesson Corporation (collectively, the "J&J Defendants") (the Bayer Defendants and the J&J Defendants, collectively, are referred to herein as the "Defendants").

<sup>&</sup>lt;sup>2</sup> Currently, cases are pending in the following Federal District Courts: District of Arizona, Central District of California, Northern District of California, District of Columbia, Northern District of Georgia, Southern District of Illinois, Western District of Kentucky, District of Maryland, District of Minnesota, District of Nebraska, Southern District of New York, Eastern District of North Carolina, Western District of North Carolina, Middle District of Pennsylvania, District of South Carolina, and Western District of Washington.

<sup>&</sup>lt;sup>3</sup> Avelox®, Cipro®, and Levaquin®, in any of their forms, shall herein be referred to as "Avelox," "Cipro," and "Levaquin," respectively.

<sup>&</sup>lt;sup>4</sup> There are currently thirteen (13) cases on file involving Levaquin, seven (7) involving Avelox, three (3) involving Cipro, and one (1) involving both Cipro and Levaquin.

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Each action asserts substantially similar claims and seeks substantially similar relief. In each action, plaintiffs allege, inter alia, that the fluoroquinolones manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and/or sold by the Defendants are defective and unreasonably dangerous in that they cause irreversible peripheral neuropathy; that the Defendants marketed distributed, and/or sold the fluoroquinolones without adequate warnings concerning their risks; and that, as a direct and proximate result of use of fluoroquinolones, Plaintiffs suffered serious injuries, physical and mental pain and suffering, as well as economic loss.

Because of the scope of the Defendants' conduct, it is likely that hundreds (or thousands) of other actions will be filed in jurisdictions throughout the country. Transfer for consolidation and coordination is proper because each of the related Actions and any tag-along cases arise out of the same or similar nucleus of operative facts, arise out of the same or similar alleged wrongful conduct, will involve the resolution of the same or similar questions of fact and law, will involve the same or similar scientific and/or medical evidence, and discovery will be substantially similar and will involve many of the same documents and witnesses. As such, Movants respectfully request an Order transferring these related Actions and future-filed actions to the Southern District of Illinois as the most appropriate and convenient forum before the Honorable David R. Herndon.

### I. <u>BACKGROUND</u>

Fluoroquinolones are broad-spectrum antibiotics that attack both the gram-negative and gram-positive bacteria and disease. Because of their effectiveness in penetrating the central nervous system, fluoroquinolones have been among the most commonly prescribed antibiotics in outpatient and inpatient settings. The United States Food and Drug Administration ("FDA")

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reports that approximately 23.1 million patients received a prescription for an oral fluoroquinolone product from a retail pharmacy in 2011.<sup>5</sup> Another 3.8 million hospital patients that year received an injectable fluoroquinolone product. Levaquin, Cipro, and Avelox accounted for 63%, 28%, and 13% of total new patients, respectively, in 2011. Even though established practice guidelines recommend fluoroquinolones as drugs of last resort, physicians have favored these drugs for treatment of simple infections, ranging from urinary tract infections to lower respiratory infections and pneumonias.<sup>6</sup>

Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the U.S. market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992, only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in hypoglycemia.

<sup>&</sup>lt;sup>5</sup> Food and Drug Administration. Drug safety communication. Available at: <u>http://www.fda.gov/downloads/Drugs/DrugSafety/UCM365078.pdf</u>. Accessed May 18, 2015. Patients receiving a dispensed prescription for Cipro, Levaquin or Avelox accounted for 70%, 28% and 9% of the total number of patients, respectively, in 2011. By way of comparison, other fluoroquinolones, such as Factive (gemifloxacin), Floxin (ofloxacin), and Noroxin (norfloxacin) each accounted for less than 1% of total patients during 2011.

<sup>&</sup>lt;sup>6</sup> Francis, et al., Permanent Peripheral Neuropathy: A Case Report on a Rare but Serious Debilitating Side-Effect of Fluoroquinolone Administration. J. Inv. Med. High Impact Case Reports 2014:2 (2014).

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As early as 1992, there was evidence of an association between fluoroquinolones and peripheral neuropathy. <sup>7</sup> Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.<sup>8</sup>

Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.<sup>9</sup> In 2001, Jay S. Cohen published a research study in the United States entitled "Peripheral Neuropathy Associated with Fluoroquinolones." The Cohen study followed forty-five (45) patients and expressed concerns over the link between permanent peripheral neuropathy and fluoroquinolones.<sup>10</sup> In 2002 and 2003, Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified

<sup>&</sup>lt;sup>7</sup> Peripheral neuropathy is a degenerative disorder of the peripheral system. The symptoms, severity, and duration of peripheral neuropathy depend on the nerves affected. Sensory neuropathy is accompanied by burning sensation, numbness, pain, loss of reflexes and sensation to touch. Motor neuropathy is associated with muscular weakness, and problems with mobility, coordination, and respiration. *See* Ali, A.K. Peripheral neuropathy and Guillain-Barre syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. Ann Epidemiol. 2014; 24(4):279-285.

<sup>&</sup>lt;sup>8</sup> Aoun M., Jacquy C, Debusscher L, Bron D, Lehert M, Neol P, et al. Peripheral neuropathy associated with fluoroquinolones (letter). Lancet. 1992;340:127.

<sup>&</sup>lt;sup>9</sup> Hedenmalm, K. and Spigset, O. Peripheral sensory disturbances related to treatment with fluoroquinolones. J Antimicrob Chemother 1996;37(4):831-7.

<sup>&</sup>lt;sup>10</sup> Cohen, JS. Peripheral neuropathy associated with fluoroquinolones. Ann Pharmacother 2001;35:1540. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy, and concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information." *Id*.

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fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

In 2004, the Levaquin and Cipro labels were amended to include the following statement

regarding peripheral neuropathy in the Warnings section:

**Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.<sup>11</sup>

Thus, rather than warning patients and physicians that the use of their products may result in permanent nerve damage, the J&J and Bayer Defendants instead adopted a warning that misleadingly indicated such damage was rare and, in any event, could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

In 2004, the FDA also approved an amended Avelox label concerning peripheral nerve damage. The amended label for Avelox included the following statement in the Warnings section:

<sup>&</sup>lt;sup>11</sup> The 2004 Levaquin label is available at:

http://www.accessdata.fda.gov/drugsatfda\_docs/label/2004/20634s035,20635s035,21721s003lbl. pdf. Accessed May 18, 2015. The 2004 Cipro label is available at: http://www.accessdata.fda.gov/drugsatfda\_docs/label/2004/19537s053,054,20780s017,018lbl.pd f\_Accessed May 18, 2015

<sup>&</sup>lt;u>f</u>. Accessed May 18, 2015.

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**Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.<sup>12</sup>

Thus, rather than warning patients and physicians that that the use of Avelox may result in permanent nerve damage, the Bayer Defendants instead adopted a warning that misleadingly indicated such damage was rare and failed to make any mention of the risk of permanent nerve damage.

Defendants' failure to adequately warn physicians resulted in (1) patients receiving fluoroquinolones instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Avelox and Levaquin. The failure of Defendants to include appropriate warnings in their products' label, as published to the medical community, also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warnings regarding peripheral nerve damage were inadequate.<sup>13</sup> On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the labels for all fluoroquinolones, and which removed the statement that nerve damage occurred only in "rare" cases:

Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including [drug name]. Symptoms may

<sup>&</sup>lt;sup>12</sup> The 2004 Avelox label is available at:

http://www.accessdata.fda.gov/drugsatfda\_docs/label/2004/21277s019,21085s024lbl.pdf. Accessed May 18, 2015.

<sup>&</sup>lt;sup>13</sup>Food and Drug Administration. Drug safety communication. Available at: <u>http://www.fda.gov/downloads/Drugs/DrugSafety/UCM365078.pdf</u>. Accessed May 18, 2015.

occur soon after initiation of [drug name] and may be irreversible. [Drug name] should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.<sup>14</sup>

According to a study conducted by Ayad K. Ali, RPh, PhD, and published in *Annals of Epidemiology* in January 2014, between 1997 and 2012, there were 539 reports of peripheral neuropathy among 46,257 adverse event reports submitted for fluoroquinolone antibiotics to the FDA's Adverse Event Reporting System.<sup>15</sup> A pharmacovigilance analysis of this data further underscored the link between systemic exposure to fluoroquinolones and peripheral neuropathy, and showed a potential association with more severe forms of nerve damage.<sup>16</sup> The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for fluoroquinolones to cause long-term, disabling peripheral neuropathy.

An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.<sup>17</sup> The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users

<sup>16</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> See., e.g.,

http://www.accessdata.fda.gov/drugsatfda\_docs/label/2014/020634s066,020635s072,021721s03 3lbl.pdf. Accessed May 18, 2015.

<sup>&</sup>lt;sup>15</sup> Ali, A.K. Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. Annals Epidemiol. 2014:24(4):279-85.

<sup>&</sup>lt;sup>17</sup> Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. Neurology. 2014; Epub 2014 Aug 22.

having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).<sup>18</sup>

Despite an existing body of literature and numerous complaints of injuries made to the Defendants and the FDA, the Defendants failed to adequately warn prescribers and patients of the increased risk of developing irreversible peripheral neuropathy. As a result, thousands of individuals have likely suffered irreversible peripheral neuropathy as a result of their ingestion of fluoroquinolones.

## II. <u>ARGUMENT</u>

# A. Transfer and Consolidation or Coordination of All Actions Is Appropriate Under 28 U.S.C § 1407.

The purpose of multidistrict litigation is to "eliminate the potential for contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions." *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968). Transfer of related actions to a single district for pretrial proceedings avoids conflicting pretrial discovery and ensures uniform and expeditious treatment in pretrial procedures. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1230 (9<sup>th</sup> Cir. 2006).

Accordingly, pursuant to 28 U.S.C. § 1407, transfer of actions to one district for coordinated or consolidated pretrial proceedings is appropriate where: (1) actions pending in different districts involve one or more common questions of fact, and (2) the transfer of such actions will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions. 28 U.S.C. § 1407(a). Consolidation is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *In re Plumbing Fixture Cases*, 298 F. Supp. at 493.

# 1. Common Fact Issues Require Transfer, Coordination, and/or Consolidation.

Here, transfer, coordination, and/or consolidation are appropriate because many common

questions of fact exist, including, but not limited to:

- Whether the fluoroquinolones were defective;
- Whether the Defendants conducted adequate testing of the fluoroquinolones;
- Whether the Defendants breached their duty of care to Plaintiffs;
- Whether the Defendants had knowledge regarding the existence of a defect;
- Whether the Defendants failed to warn about the risks of the fluoroquinolones;
- Whether the Defendants breached any warranty, express or implied, related to their sale of the fluoroquinolones; and
- Whether the fluoroquinolones are capable of causing and/or did cause the irreversible peripheral neuropathy and related injuries of Plaintiffs.

Determination of these and other common issues in a single district will benefit the parties and witnesses and serve to promote the efficient prosecution and resolution of these Actions. Notably, this Panel has routinely ordered the transfer and consolidation of multidistrict product liability actions involving drug products, often over the objections of one or more parties. *See, e.g., In re Benicar (Olmesartan) Prods. Liab. Litig., ---* F. Supp. 3d ---, 2015 WL 1518503 (J.P.M.L. April 3, 2015); *In re Androgel Prods. Liab. Litig.,* 24 F. Supp. 3d 1378 (J.P.M.L. 2014); *In re Incretin Mimetics Prods. Liab. Litig.,* 968 F. Supp. 2d 1345 (J.P.M.L. 2013); *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.,* 391 F. Supp. 2d 1377 (J.P.M.L. 2005); *In re Vioxx Prods. Liab. Litig.,* 360 F. Supp. 2d 1352 (J.P.M.L. 2005);

# 2. The Fluoroquinolone Actions Should be Coordinated on an Industry-Wide Basis.

Without transfer, coordination, and/or consolidation of these Actions and tag-along cases, there exists a real and significant hazard of inconsistent rulings, in addition to judicial inefficiency, overlapping discovery, and unnecessary expense to all parties. Specifically, the

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majority of scientific studies and research relevant to the Actions consists of results and findings relating to the fluoroquinolone drug class as a whole, and involve a singular, core issue of common fact – the fluoroquinolones' relationship to the onset of irreversible peripheral neuropathy in those patients who ingest them. As noted above, the fluoroquinolones in question (namely, Avelox, Cipro, and Levaquin) are associated with an increased risk of long-term and sometimes permanent peripheral neuropathy, and, as a result, it would be an unnecessary expense and burden to have expert witnesses vetted in multiple federal district courts on the same injuries, studies, evidence, and opinions. Moreover, the prospect of inconsistent rulings and the potential for conflicting, disorderly, and chaotic litigation would be immense absent consolidation of the Actions in a single multidistrict litigation.

Further, Counsel for movants is anticipating that a number of actions will be filed on behalf of plaintiffs who ingested more than one of the fluoroquinolones, which would require each of the Defendants to litigate in multiple federal forums if the Actions are not consolidated on an industry-wide level, subjecting the parties to potentially conflicting rulings on the exact same issues of fact.<sup>19</sup> This Panel has previously held that actions involving more than one drug can be combined into a single consolidated proceeding when, as here, common questions of fact exist. *In re Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378 (J.P.M.L. 2014); *In re Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345 (J.P.M.L. 2013); *In re Bextra and Celebrex Prods. Liab. Litig.*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005); *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L. 1998).

<sup>&</sup>lt;sup>19</sup> Presently, at least one such claim pending in the United States District Court for the Eastern District of North Carolina before the Honorable Louise Wood Flanagan, in which a plaintiff alleges she suffered injuries and damages arising from her use of both the Levaquin and Cipro. *Uman v. Bayer HealthCare Pharmaceuticals, Inc., et al.*, Case No. 5:15-cv-00197.

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For example, in consolidating actions related to Bextra and Celebrex, the Panel noted, in part, the actions were ripe for consolidation and coordination because all actions focused on "alleged increased health risks from taking Celebrex and/or Bextra, anti-inflammatory prescription medications." In re Bextra and Celebrex Prods. Liab. Litig., 391 F. Supp. 2d 1377 (J.P.M.L. 2005). In a similar fashion, when considering consolidation and coordination of actions that named in excess of one dozen unique defendants related to "alleged defects in three prescription drugs [...] used in the treatment of obesity," the Panel held that "the core issues presented in the litigation involve the causal connection between use of the three diet drugs (singly or in combination) and the alleged incidence of serious side effects [...]. Moreover, the sheer size of the litigation, coupled with its rapid growth rate at the present time, serves to underscore the economies of scale that centralized pretrial management of the federal court actions will provide." In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 990 F. Supp. 834 (J.P.M.L. 1998). Keeping in line with these decisions, the Panel most recently centralized litigation involving multiple manufacturers and multiple different testosterone replacement therapy products. See In re Androgel Prods. Liab. Litig., 24 F. Supp. 3d 1378 (J.P.M.L. 2014) (centralizing actions against competing defendants which manufactured several similar testosterone replacement therapy products that allegedly caused cardiovascular injuries, cerebrovascular events and death).

This litigation presents the Panel with a fact pattern that is similar to cases of *In re Bextra*, *In re Diet Drugs*, and *In re Androgel*. First, all Actions are focused on the connection between fluoroquinolones and an increased risk of irreversible peripheral neuropathy. Second, the Actions involve the injured party's use of the fluoroquinolones singly or in combination, and all involve ingestion of a single-class of antibiotics. Finally, this litigation has similarly

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experienced rapid growth in size and is likely to continue to grow with a large number of filings in various state and federal courts in the near future.

Plaintiffs in the Actions have raised common factual questions by asserting claims against the Defendants focused on a singular injury, irreversible peripheral neuropathy, that each Plaintiff alleges was caused by the Defendants' fluoroquinolones. To the extent "non-common" issues of fact exist, the consolidation of all Actions nevertheless ensures the pivotal common issues of fact will be able to proceed in an orderly, consistent, and efficient manner. *See In re Ephedra Prods. Liab. Litig.*, 314 F. Supp. 2d 1373 (J.P.M.L. 2004). As this Panel previously held, "transfer to a single district under Section 1407 has the salutary effect of placing all the related proceedings with respect to any non-common issues to proceed concurrently with pretrial proceedings on common issues [...],; and 2) ensures expeditious resolution of all actions to the overall benefit of the parties." *Id.* 

Moreover, transfer, coordination and/or consolidation are especially appropriate here because this litigation is national in scope already, with at least twenty-four (24) actions pending in sixteen (16) different federal district courts. These cases alone would justify centralization, as the Panel routinely coordinates cases involving substantially fewer actions.<sup>20</sup> Given the widespread use of fluoroquinolones for over a decade and that the first Action was filed on August 6, 2014, Movants expect that the number of similar cases filed in state and federal courts across the country will expand rapidly. *See In re Camp Lejeune, N.C. Water Contamination* 

<sup>&</sup>lt;sup>20</sup> The Panel only requires two actions pending in two federal districts for consolidation under 28 U.S.C. § 1407. *See, e.g., In re Toys "R" Us-Del., Inc., Fair Accurate Credit Transactions Act (FACTA) Litig.,* 581 F. Supp. 2d 1377-78 (J.P.M.L. 2008) (consolidating two actions pending in two districts); *In re Porsche Cars N. Am., Inc., Plastic Coolant Tubes Prods. Liab. Litig.,* 787 F. Supp. 2d 1359, 1360 (J.P.M.L. 2011) (involving four actions in four districts); *In re Milk Antitrust Litig.,* 530 F. Supp. 2d 1359, 1360 (J.P.M.L. 2008) (involving four actions in two districts); *In re Camp Lejeune, N.C. Water Contamination Litig.,* 763 F. Supp. 2d 1381, 1381-82 (J.P.M.L. 2011) (involving four actions in four districts).

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*Litig.*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011) (considering the potential for "a large number of additional related actions to be filed" as a factor weighing in favor of centralization). Consequently, there is a definite need for centralized coordination of these Actions to avoid overlapping discovery and conflicting pretrial rulings. Judicial economy can only truly be achieved through this Panel's formal consolidation of all Actions involving the fluoroquinolones at issue.

Centralizing these Actions will save all parties (and the Court) countless resources by streamlining the litigation in one forum. Because of several common defendants, similar or identical issues of law and fact, the number of current claims, and the expected rapid expansion of claims, transfer and consolidation is appropriate for the just and efficient prosecution of the Actions and for the convenience of all parties and potential witnesses.

# **B.** The Southern District of Illinois is the Most Appropriate Forum for Transfer and Consolidation for Coordination.

The Southern District of Illinois is the most appropriate forum for consolidation and coordination of the instant litigation. The district courthouse is located in East St. Louis, Illinois - in close proximity to mass transit, as well as an international airport and hotels. Furthermore, the Southern District of Illinois is well equipped to manage this multidistrict litigation and provides a convenient and accessible forum for fluoroquinolone actions filed across the country. For these and other reasons further detailed below, the Actions and tag-along cases should be transferred and consolidated before the Honorable David R. Herndon, United States District Judge for the Southern District of Illinois, who is currently presiding over one (1) of the fluoroquinolone cases filed in the Southern District of Illinois.

# **1.** The Southern District of Illinois is a Central and Convenient Venue for Consolidated Proceedings.

This Panel has emphasized the fact that "although air travel renders both [coasts of the United States, California and New York] readily accessible, there is still something to be said for the convenience of a geographically central forum." *In re Library Editions of Children's Books*, 297 F. Supp. 385, 387 (J.P.M.L. 1968). In fact, this Panel recognized the innate benefits of the centrality of the Southern District of Illinois when deciding to consolidate actions in this district for the *Pradaxa* MDL. *See In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355, 1356 (2012) ("[T]he Southern District of Illinois' geographically central location and accessibility also commend it for this nationwide products liability litigation.").

The federal courthouse in the Southern District of Illinois is centrally located for all parties and witnesses, particular in light of the fact that the instant litigation will unquestionably involve parties and witnesses located in a variety of locations throughout the United States. Moreover, the Southern District of Illinois provides a neutral venue since it is not the "hometown" of any of the Defendants.

In addition, traveling to this central location is more convenient and efficient than traveling to other destinations in the country. For instance, the federal courthouse in the Southern District of Illinois, in East St. Louis, is only fifteen minutes from Lambert International Airport. Lambert International Airport not only offers moderately priced flights, but is one of the most central travel hubs in the nation with 250 daily departures to more than 60 nonstop destinations. As such, the Southern District of Illinois is easily accessible for all parties and witnesses and is a convenient option for same day travel for regular status conferences and hearings. For these reasons, the Southern District of Illinois offers a very convenient and central location, and is an appropriate choice to serve as the transferee court for these reasons alone.

# 2. The Southern District of Illinois is Well-Equipped to Efficiently Manage this Multi-District Litigation.

This Panel recently transferred a product liability litigation to the Southern District of Illinois, which is now substantially resolved: *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, 655 F. Supp. 2d 1343 (J.P.M.L. 2009) ("*Yaz MDL*"). In less than 27 months from the time of this Panel's Transfer Order of the *Yaz MDL* to the Southern District of Illinois, discovery was conducted, *bellwether* cases were selected and prepared for trial, *Daubert* motions were ruled upon, and shortly before the first *bellwether* trial, the parties reached a mass settlement initiative resulting in more than 16,000 cases settling in both federal and state courts.

Moreover, the Judges in the Southern District of Illinois understand the importance of coordination efforts between multidistrict litigation and the various state court consolidated litigations in order to promote the just and efficient conduct of the litigation. In the *Yaz MDL*, successful cooperation and coordination efforts with the various state court jurisdictions avoided duplicative discovery and inconsistent court rulings, and ultimately resulted in the inclusion of state court claimants as participants in the global settlement initiative.

Importantly, the Southern District of Illinois provides a well-prepared, well-staffed, and overall top-notch staff and Clerk's office. In light of the previous complex litigations successfully managed and the thousands of cases on file in this district, the staff and Clerk's office in the Southern District of Illinois is experienced, efficient, and well-equipped to provide the necessary support services for managing this litigation. As an added element of efficiency and convenience for all parties, the Southern District of Illinois' Clerk's office has proven its ability to provide a state-of-the art webpage for each multidistrict litigation, which provides an abundance of useful information and easily accessible court documents for attorneys and

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litigants, including a list of court contacts and lead counsel, an organized listing of all Case Management orders, and minutes for each court hearing.<sup>21</sup> In addition, the Clerk's office at the Southern District of Illinois has implemented a streamlined process for direct filing of complaints. The efficiency and experience of the Clerk's office in a district court is absolutely vital to the successful management and administration of large-scale multidistrict litigations, and it is clear that the Clerk's office in the Southern District of Illinois has proven its abilities and exceptional work in this regard.

# 3. Judge David A. Herndon Is Amply Qualified to Manage This Multidistrict Litigation.

Appointed to the Southern District of Illinois 17 years ago, Judge Herndon is an excellent choice for managing this complex litigation. He served as Chief Judge for the Southern District of Illinois from 2007 until 2014, and has gained significant experience in managing complex litigation, as well as consolidated, mass tort litigation in an efficient manner. Moreover, Judge Herndon has an extremely experienced and talented staff that has managed these litigations with great efficiency.

In addition to his extensive qualifications and experience, Judge Herndon has demonstrated his abilities to efficiently handle large-scale multidistrict litigations. In fact, when the decision was made to centralize actions in the *Pradaxa MDL* before Judge Herndon in the Southern District of Illinois, this Panel praised his efforts, experience, and abilities:

[B]y selecting Judge David R. Herndon to preside over this matter, we are selecting a jurist with the willingness and ability to handle this litigation. Judge Herndon, an experienced MDL judge, has deftly presided over *In re Yasmin and Yaz (Drospirenon) Marketing, Sales Practices & Products Liability Litigation*, 655 F. Supp. 2d 1343 (J.P.M.L. 2009), another large pharmaceutical products liability litigation.

<sup>&</sup>lt;sup>21</sup> To see a complete listing of the information and court documents available, the webpage for the *Yaz MDL* is available at: <u>http://www.ilsd.uscourts.gov/mdl/mdl2100.aspx</u>.

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In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig., 883 F. Supp. 2d 1355, 1356 (2012).

While presiding over the *Yaz MDL*, for instance, Judge Herndon managed a docket with over 11,000 filed cases, ruled on over sixty (60) Motions *in Limine* and eighteen (18) Motions to Exclude the Testimony of Expert Witnesses pursuant to *Daubert*, entered sixty-seven (67) Case Management Orders<sup>22</sup>, and held over forty (40) status hearings. The *Yaz MDL* was one of the largest mass tort litigations in history in this respect and by considering the voluminous discovery statistics; however, under Judge Herndon's management, everything was accomplished in under 27 months from the date of this Panel's Transfer Order on October 1, 2009 to the date that the parties reached the mass settlement initiative on December 31, 2011.

Similarly, while presiding over the *Pradaxa MDL*, Judge Herndon managed a docket with over 2,500 filed cases, entered eighty-five (85) Case Management Orders,<sup>23</sup> and held over twenty-eight (28) status hearings. The *Pradaxa MDL* was a very labor intensive multidistrict litigation; yet, under the management of Judge Herndon, all of this was accomplished in under 22 months from the date of this Panel's Transfer Order on August 8, 2012 to the date that the global settlement was announced on May 28, 2014.

In addition, Judge Herndon understands the importance of coordination efforts between the federal multidistrict litigation and the various state court consolidated litigations. In fact, Judge Herndon's coordination efforts have been praised by judges and lawyers alike after he successfully coordinated the *Yaz MDL* and *Pradaxa MDL* with the state court jurisdictions to avoid duplicative discovery and court rulings, and the state court litigants were ultimately included in the MDL settlement programs. The efforts and activities, as described above, clearly

 <sup>&</sup>lt;sup>22</sup> All Case Management Orders are available at <u>http://www.ilsd.uscourts.gov/mdl/mdl2100.aspx</u>.
<sup>23</sup> All Case Management Orders are available at <u>http://www.ilsd.uscourts.gov/mdl/mdl2385.aspx</u>.

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demonstrate that Judge Herndon has the experience, ability, and dedication to efficiently manage this litigation. Accordingly, the Southern District of Illinois is an appropriate and logical choice for consolidated pretrial proceedings in this litigation.

### III. <u>CONCLUSION</u>

For the reasons discussed above, Movants respectfully request that the Panel transfer the above-mentioned actions and all subsequently filed tag-along cases for the coordinated and consolidated pretrial proceedings before the Southern District of Illinois, and assign the matter to Judge David A. Herndon.

Dated this 19<sup>th</sup> of May, 2015

# Respectfully submitted,

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