BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: FLUROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 2642

BAYER'S OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS TO THE SOUTHERN DISTRICT OF ILLINOIS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATION OR CONSOLIDATED PRETRIAL PROCEEDINGS

Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Merck. & Co., Inc., Schering Corporation, and McKesson Corporation (together "Bayer") respectfully submit this opposition to Plaintiffs' Motion for Transfer of Actions to the Southern District of Illinois Pursuant to 28 U.S.C. § 1407 for Coordination or Consolidated Pretrial Proceedings.

Plaintiffs seek centralization of twenty-four lawsuits (several of which are inactive or likely to be dismissed) alleging injuries caused by three of the most popular and effective antibiotics available to physicians today. Two of those medications, Cipro® and Avelox®, are manufactured by Bayer; the third, Levaquin®, is manufactured by Janssen Pharmaceuticals, Inc. The underlying plaintiffs assert that these medications caused them to suffer from a multifaceted condition known as peripheral neuropathy, or "PN." Despite differences in the drugs' regulatory histories, indicated uses, clinical testing, and other characteristics, and notwithstanding the dearth of evidence of a causal link between these drugs and irreversible PN, Plaintiffs ask this Panel to consolidate the litigation on an industry-wide basis.

Centralization is entirely inappropriate here for a number of reasons. Most critically, individual issues will predominate in these actions, which assert claims such as failure to warn and product defect that inherently turn on defendant- and drug-specific facts. Plaintiffs point to no circumstances that warrant departure from this Panel's typical reluctance to consolidate

litigation involving different products made by different defendants. None of the complaints that have been served upon Bayer allege exposure to more than one of the three drugs. Properly characterized, Plaintiffs' petition actually involves three different litigations, distinct from one another and each with only a very small number of cases. Further, Plaintiffs offer no evidence that the number of claims is likely to increase substantially, and the litigation's track record to date suggests otherwise. Nor can Plaintiffs show that voluntary coordination of discovery across the pending suits would be infeasible.

Nonetheless, if the Panel disagrees and orders consolidation of some or all of the pending claims, it should not send the litigation to the Southern District of Illinois. That district has only a tenuous connection to this dispute, and Judge Herndon is already managing another active MDL. Plaintiffs' efforts to promote the Southern District of Illinois as an appropriate venue are a thinly-veiled attempt at forum shopping that should not be rewarded.

I. PROCEDURAL AND FACTUAL BACKGROUND

A. Cipro® and Avelox® are Among the Most Popular and Effective Antibiotics Available to Medical Professionals.[1]

The two Bayer drugs at issue in this case – Cipro® and Avelox® – are well-respected and powerful broad-spectrum antibiotics. Both are members of a class of drugs known as "fluoroquinolones," which combat infection by preventing bacterial DNA from unwinding and duplicating. Cipro® and Avelox® play a critical role in physicians' treatment of serious bacterial infections: as Plaintiffs admit, "fluoroquinolones have been among the most commonly prescribed antibiotics in outpatient and inpatient settings." (Br. at 3.) As discussed below,

[1] The unique attributes and indications of Levaquin®, the third drug for which Plaintiffs seek centralization, are addressed in Defendant Johnson & Johnson's Brief in Opposition to Plaintiffs' Motion for Transfer (Dkt. # 25).

however, Cipro® and Avelox® differ in key respects, from their indications and usage to their clinical and regulatory histories.

Ciprofloxacin hydrochloride, a second-generation fluoroquinolone, was developed by Bayer in the late 1980s in response to the growing need for broad-spectrum antibiotic drugs to combat bacterial resistance. Approved by the FDA in 1987, ciprofloxacin was manufactured and sold exclusively by Bayer as Cipro® until 2004, when generic versions reached the market following the expiration of Bayer's patent. Over the years, Cipro® has been one of the most widely-used fluoroquinolone antibiotics: in 2010 alone, more than 20 million outpatient prescriptions were written for ciprofloxacin.

Avelox®, by contrast, is a fourth-generation fluoroquinolone developed by Bayer and approved by the FDA in 1999, over 10 years after Cipro®'s approval. Because the two drugs belong to different "generations" of fluoroquinolones, they have different properties and effects within the body:

> First-generation drugs . . . achieve minimal serum levels. Second-generation quinolones . . . have increased gram-negative and systemic activity. Third-generation drugs . . . have expanded activity against gram-positive bacteria and atypical pathogens. Fourth-generation quinolone drugs . . . add significant activity against anaerobes. The quinolones can be differentiated within classes based on their pharmacokinetic properties.[2]

The FDA-approved labels for Cipro® and Avelox® reflect their differences, including Avelox's unique chemical composition (moxifloxacin hydrochloride) and its somewhat narrower indicated uses, as shown in the following table:

[2] King, D.E. et al. (2000). New Classification and Update on the Quinolone Antibiotics. *American Family Physician*, *61*(9), 2741-2148, http://www.aafp.org/afp/2000/0501/p2741.html.

INDICATED USES OF CIPRO® AND AVELOX®	
Cipro® (Ex. A (August 2013 label) at 8-9)	Avelox® (Ex. B (August 2013 label) at 1)
• Urinary tract infections • Acute uncomplicated cystitis • Chronic bacterial prostatitis • Lower respiratory tract infection • Acute sinusitis • Skin and skin structure infections • Bone and joint infections • Complicated intra-abdominal infections • Infectious diarrhea • Typhoid fever • Uncomplicated cervical and urethral gonorrhea • Complicated urinary tract infections and pyelonephritis in pediatric patients • Inhalational anthrax	• Acute bacterial sinusitis • Acute bacterial exacerbation of chronic bronchitis • Community acquired pneumonia • Uncomplicated skin and skin structure infections • Complicated skin and skin structure infections • Complicated intra-abdominal infections

Unlike Cipro®, Avelox® remained patent-protected through at least 2014, when the first generic versions came onto the market. Other differences exist in the drugs' marketing and distribution: although McKesson Corporation is the wholesaler for both Avelox® and Cipro®, Avelox® is promoted and distributed in the United States by Merck & Co., Inc. One trait Avelox® does share with Cipro®, however, is popularity among physicians: since its release, physicians have written over 155 million prescriptions for 186 million patients worldwide.

B. Peripheral Neuropathy is a Non-Specific Disorder with Multifactorial Causes and Symptoms.

The cases Plaintiffs seek to centralize all involve a condition known as peripheral neuropathy, or PN. As evidenced by Plaintiffs' own cited articles, PN is not a single disease – rather, it is a term used to describe damage to nerves that can have numerous symptoms and potential causes. *See, e.g.*, Ali, A.K. (2014). Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. *Annals of Epidemiology*, *24*(4), 279-285, at 284 ("PN is multifactorial in etiology and

variable in presentation and severity."). PN affects an estimated 20 million people in the United States.

The potential causes of PN are wide-ranging and can include diabetes, autoimmune diseases, alcoholism, exposure to poisons, inherited disorders, nerve trauma or pressure, tumors, vitamin deficiencies, bone marrow disorders, and – perhaps most pertinent here – infections. PN's symptoms vary greatly as well, and may consist of anything from numbness or tingling to sharp, jabbing pain, sensitivity to touch, loss of coordination, muscle weakness or paralysis, heat intolerance or altered sweating, bowel, bladder, or digestive problems, or lightheadedness. Diagnosis can require various medical interventions, including physical exam, review of medical history, neurological examination, imaging tests such as CT or MRI scans, nerve function tests, or nerve and skin biopsies.

Although some medical literature suggests that the use of fluoroquinolones may be associated with PN, Plaintiffs misstate the evidence considerably. Contrary to their suggestion, any association between PN and fluoroquinolones is rare, as reflected in the title of a recent case report cited by Plaintiffs. Francis, J.K., Higgins, E. (2014). Permanent Peripheral Neuropathy: A Case Report on a **Rare** but Serious Debilitating Side-Effect of Fluoroquinolone Administration. *Journal of Investigative Medicine High Impact Case Reports*, 2014(2), 1-4 (emphasis added) (cited in Br. at 4 n.6). Moreover, the thrust of the underlying complaints is that Cipro®, Avelox®, and Levaquin® are defective because they allegedly cause "irreversible" PN, and that their manufacturers failed to warn doctors about the risk of irreversible PN. (Br. at 3 (emphasis

added).) But nearly all of the articles Plaintiffs cite deal with a potential link between fluoroquinolones and PN generally – not irreversible PN.[3]

Plaintiffs cite just one article in support of their assertion that Bayer was put on notice of a risk of irreversible PN, and they overstate the import of that study. (Br. at 5 (citing Cohen J.S. (2001). Peripheral Neuropathy Associated with Fluoroquinolones. *Infectious Diseases, 35*(12), 1540-1547 (cited in Br. at 5) ("Cohen 2001")).) Plaintiffs incorrectly state that the Cohen study "followed forty-five (45) patients and expressed concerns over the link between permanent [PN] and fluoroquinolones." *Id.* In reality, Dr. Cohen conducted an Internet survey by posting a message in which he requested that fluoroquinolone users provide certain information if they believed they had symptoms of PN. *Id.* at 1541. Dr. Cohen recognized the serious limitations of this "survey" and warned that his article was "not intended or capable of establishing a cause-effect association between the described events and fluoroquinolone therapy, and no statistical tests were performed." *Id.* at 1545 (emphasis added).

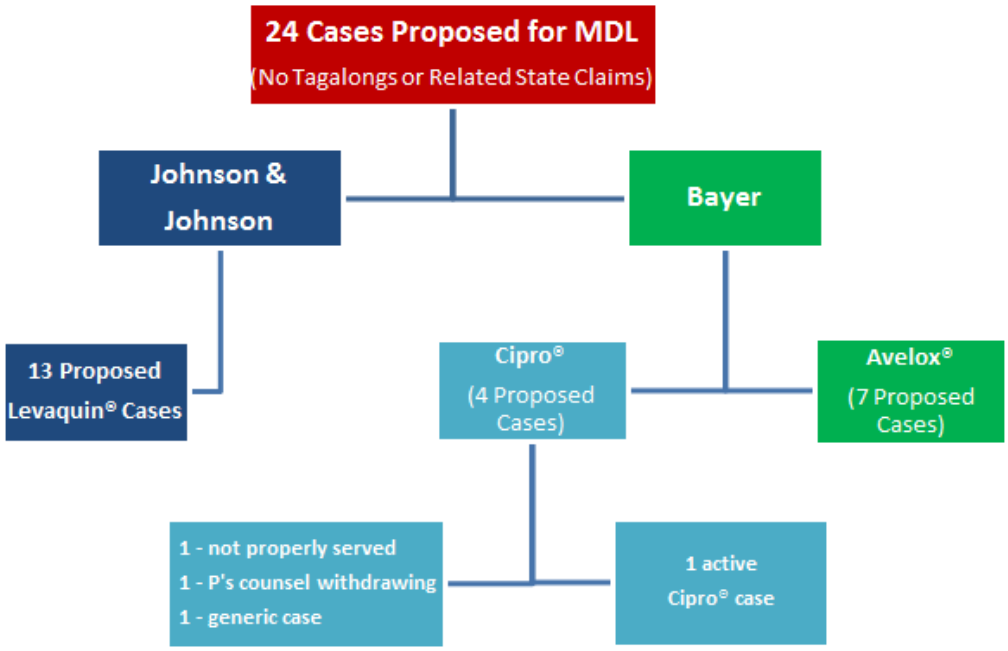
In short, PN is a non-specific group of nerve disorders with multifactorial symptoms and causes. Although some medical literature suggests PN may be associated with fluoroquinolone use, there is no evidence establishing a causal association between the use of drugs like Cipro® or Avelox® and the development of irreversible PN. As such, any case alleging PN will involve a highly individualized inquiry into the plaintiff's medical history, as evidenced by medical

[3] *See, e.g.*, Aoun et al. (1992) (cited in Br. at 5) (Letter to the Editor of Lancet regarding one FQ user who developed peripheral neuropathy while taking fluoroquinolones and resolved after discontinuation); Hedenmalm et al. (1996) (cited in Br. at 5) (review of 37 cases of peripheral sensory disturbances in fluoroquinolones users reported in Sweden's Drug Information System); Etminan et al. (2014) (cited in Br. at 8) (pharmacoepidemiologic study assessing the risk of fluoroquinolones and peripheral neuropathy in older men); Ali 2014, at 281 (analysis of 539 cases of peripheral neuropathy reported in FDA's Adverse Event Reporting System).

records and treating physician testimony. Discovery of this sort is particularly ill-suited for management in a consolidated proceeding.[4]

C. Procedural History

Plaintiffs seek centralization of 24 lawsuits against two manufacturers who manufacture three different drugs. They suggest these cases are homogeneous, but even a cursory glance reveals key distinctions. As shown in the chart below, Bayer is a defendant in just 11 of the 24 suits. Of those cases, four involve Cipro®, but two of those are inactive for varying reasons – namely, improper service (*Uman*) and counsel's efforts to withdraw due to the plaintiff's non-responsiveness (*DeSalvo*). Further, one Cipro® claim (*Lombard*) involves generic drug use.



[4] Despite the absence of compelling scientific data on the issue, Bayer has included warnings concerning PN on its Cipro® and Avelox® labels since 2004. *See* Ex. C at 13-15 (July 2004 Cipro® label); Ex. D at 13 (July 2004 Avelox® label). This labeling is important when considering the dearth of cases alleging PN over the past 10 years (see *infra*). But the labeling also is important to note because, under the learned intermediary doctrine, any PN case will involve a case-specific inquiry into what information the prescribing physician was aware of at the time of the prescription. This individualized warnings causation inquiry is in addition to the individualized examination of injury causation that also will be a part of every case.

Thus, properly understood, the pending claims against Bayer concerning Cipro® consist of just one viable lawsuit, which would not justify centralization under any set of conditions. The remaining cases are a small handful of claims that relate to a different drug, Avelox®, and differ internally in myriad other ways. Critically, none of the complaints served to date allege that the plaintiff used more than one fluoroquinolone, and only two active federal tag-along actions have been identified to date.[5]

II. ARGUMENT

This Panel is empowered to transfer actions for coordinated or consolidated pre-trial proceedings if transfer "will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). Although the preliminary inquiry in any Section 1407 transfer analysis looks to common questions of fact, this Panel has identified a variety of factors that counsel against transfer even when common questions of fact exist. Here, denial of transfer will promote the just and efficient conduct of the actions addressed in Plaintiffs' motion for several reasons.

First, given the differences between the drugs and the nature of the underlying plaintiffs' claims, individual factual and legal issues will predominate over any common issues if some or all of the claims are centralized. ***Second***, nothing in the record warrants departing from the Panel's typical reluctance to centralize litigation on an industry-wide basis. ***Third***, contrary to Plaintiffs' suggestion, the number of Avelox® and Cipro® claims is likely to remain low,

[5] In an effort to create the appearance of an increasing number of cases, last week counsel for underlying plaintiff Kathleen M. Smith filed an Interested Party Response identifying fourteen additional and purportedly related federal claims, only six of which name Bayer as a defendant. (*See* Dkt. ## 22.) Many of these claims appear to be time-barred. Further, only two of the six Bayer complaints have actually been served to date. *Mandel v. Bayer Healthcare Pharmaceuticals, Inc.*, No. 8:15-cv-01269-SDM-TGW (M.D. Fla.) (served on June 1, 2015); *Taylor v. Bayer Corporation et al.*, No. 1:15-cv-00468 (D.N.M.) (served on June 9, 2015). Smith also alleges "on information and belief" that an unspecified number of related cases "are pending in state courts in California and Pennsylvania against one or more of the Defendants," without providing any factual detail whatsoever. (Dkt. # 22 at 5.)

particularly given the near-absence of active tag-along or related state claims. ***Fourth***, voluntary coordination among counsel is ongoing and provides an efficient alternative to industry-wide centralization of claims involving different products and manufacturers. ***Fifth*** and finally, the Southern District of Illinois would be an inappropriate venue for any centralized litigation involving these defendants and drugs.

A. Centralization is Inappropriate Given the Predominance of Individualized Factual Issues.

This Panel has long been reluctant to centralize litigation where individual issues would predominate, thus requiring piecemeal discovery and analysis by an MDL court. *E.g., In re Wireless Lifestyle Inc.*, 842 F. Supp. 2d 1382, 1383 (J.P.M.L. 2012) (denying centralization despite "some overlap among the actions" where "the differences among them appear to predominate, and thus centralization would likely hinder the just and efficient conduct of the litigation, considered as a whole"). Claims alleging defects in prescription drugs are a classic context in which individual issues predominate, since the litigation naturally focuses on context-specific issues such as the regulatory and clinical history of a given drug, the warnings provided, the manufacturing process, and the circumstances of each plaintiff's alleged injuries – not to mention state-by-state variations in the law applied to all of these facts.

The predominance of individual issues is particularly pronounced here because Plaintiffs seek centralization of litigation involving not just one, but three drugs – each of which has its own unique regulatory history. As discussed above, Cipro® and Avelox® were developed and FDA-approved more than ten years apart. Levaquin® also is a different chemical entity that was developed and tested by a different company through different clinical trials run by different scientists. Particularly because the underlying plaintiffs assert claims based upon theories of failure-to-warn, individualized discovery regarding each drug's regulatory approvals and

labeling at times pertinent to each case will be necessary. This Panel has declined centralization under similar circumstances. *E.g., In re: Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (denying centralization of product liability actions across manufacturers because "[e]ach group of cases against each manufacturer will involve unique product—and defendant-specific issues (such as the different product designs, manufacturing processes, regulatory histories, and company documents and witnesses) that will overwhelm the few common issues").

Differences between the drugs themselves will also require particularized fact discovery. As discussed above, Cipro®, Avelox®, and Levaquin® have distinct chemical formulations and indicated uses. Resolution of design defect claims will therefore require drug-specific discovery into what scientific evidence (if any) might link a given drug to irreversible PN. Here again, Plaintiffs' own cited studies reveal substantial differences in the purported association between PN and Avelox®, Cipro®, and Levaquin®, respectively. Ali, A.K. (2014). Signal Detection and Clarification of Peripheral Neuropathy and Guillain-Barré Syndrome Associated with Exposure to Systemic Fluoroquinolones. *British Journal of Pharmaceutical Research*, 4(4), 407-417, at 413-14 (disproportionality analysis results for Avelox® were 1.34 (signal threshold not reached) versus 3.24 for Cipro® and 3.36 for Levaquin®). And of course, individualized discovery concerning each plaintiff's medical history will be needed to rule out other potential causes of a plaintiff's alleged PN. Thus, centralization would needlessly force a single judge to shepherd omnibus discovery over issues that would otherwise be addressed on an orderly, case-by-case basis. *See In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) (denying centralization where claims involved "pain pumps . . . in different

sizes and designs, with differing volume, duration, and flow capacities," as well as plaintiffs with different medical histories).

Individualized legal issues make centralization inconvenient as well. For example, the statute-of-limitations analysis in each case will depend on when each plaintiff took the drug in question.[6] The result in each case will depend on the applicable state law and must account for differences in the application of the discovery rule, equitable tolling, and any other arguments plaintiffs may invoke. Moreover, because generic ciprofloxacin (Cipro®) has been available much longer than generic moxifloxacin (Avelox®), the accrual dates for claims premised on branded drug use will likely be much earlier for Cipro® than for Avelox® – another key factual distinction that will confound the statute-of-limitations analysis if that responsibility is thrust upon a single MDL judge.

A similar issue arises with respect to one of the four Cipro® cases, in which the plaintiff seeks to impose liability on Bayer despite having taken generic ciprofloxacin under the innovator liability doctrine set forth in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008). *See Lombard v. Bayer Healthcare Pharmaceuticals, Inc. et al.*, No. 2:15-cv-03120-FMO-GJS (C.D. Cal. filed Apr. 27, 2015), Dkt. # 1, ¶¶ 52-53. The vast majority of courts nationwide have declined to follow *Conte*. *See, e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284 (10th Cir. 2013) (noting that every federal circuit court to address the issue, "applying the law of numerous states," has rejected *Conte*); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a

[6] Anticipating this issue, some – but not all – of the complaints filed against Bayer assert exceptions to the statute of limitations.

product"). An MDL court would therefore be faced with the need to analyze, for each case claiming innovator liability, whether such liability could lie under applicable state law. As with statutes of limitations, there is nothing efficient about an MDL court ruling on state-specific legal issues such as innovator liability.

Plaintiffs' own list of purported common issues of fact (Br. at 10) only serves to highlight the differences between Cipro®, Avelox®, and Levaquin®. The list also demonstrates that, even if Plaintiffs had sought separate MDLs for each drug, individual issues of fact and law would still predominate. Taking Plaintiffs' bullet points one by one:

- "***Whether the fluoroquinolones were defective***" → this depends on the clinical evidence and medical literature pertinent to each drug. As discussed above, even Plaintiffs' own cited studies reflect differences in the evidence concerning each drug's possible association with occurrences of PN.
- "***Whether the Defendants conducted adequate testing of the fluoroquinolones***" → this inquiry will naturally require fact-finding for each defendant and each drug, since the drugs were developed at different times by different manufacturers and were tested in different pre-clinical, clinical, and post-marketing studies.
- "***Whether the Defendants breached their duty of care to Plaintiffs***" → here again, the inquiry varies from defendant to defendant. Critically, the existence of a legal duty also depends on the applicable law, which differs as discussed above (e.g., the *Conte* issue). Demonstrating breach will also require discovery into each defendant's conduct as to each specific drug.
- "***Whether the Defendants had knowledge regarding the existence of a defect***" → this issue once again turns on the state of the science regarding each particular drug, as well

as each defendant's knowledge concerning any potential risk of irreversible PN. Further, the inquiry will vary depending on Defendants' knowledge at the time of each plaintiff's alleged exposure. Although not every complaint against Bayer alleges an exposure date, those that do vary from as early as 2003 (*Uman*) to as late as August 2013 (*Morris*).

- "***Whether the Defendants failed to warn about the risks of the fluoroquinolones***" → this inquiry, like those listed above, is necessarily defendant-, drug-, and case-specific, given the evolution of each drug's labeling over time. As with Defendants' knowledge of an alleged defect, the court must consider the state of the warnings at the time of each plaintiff's alleged exposure. *Compare, e.g.*, Exs. A and B (August 2013 Cipro® and Avelox® labels) with Exs. C and D (2004 labels); *see also* Ex. E at 4 & Ex. F at 6 (Bayer's 2008 and 2011 "Dear Health Care Professional" letters warning that "[f]luoroquinolones have been associated with rare cases of sensory or sensorimotor axonal peripheral neuropathy, which may be irreversible."). Similarly, in assessing the adequacy of Defendants' warnings in each case, the court must consider whether the plaintiff has PN or <u>irreversible</u> PN, as well as when the plaintiff's symptoms developed (*i.e.*, in the course of taking the drug, or after). Finally, for any cases alleging failure to warn prior to September 2007, the court must take into account the different regulatory scheme that existed prior to the effective date of the FDA Amendments Act of 2007, as well as the redesigned label format that took effect at that time.
- "***Whether the Defendants breached any warranty, express or implied, related to their sale of the fluoroquinolones***" → in addition to turning on fact-intensive questions involving the language of any warranties actually made by each defendant or its sales representatives with respect to each drug, this inquiry will depend upon the applicable

law in each jurisdiction concerning both express and implied warranties. *See, e.g.*, *Makripodis by Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 377 (Pa. Super. Ct. 1987) (holding under Pennsylvania law that claims for breach of the implied warranty of merchantability do not lie in the prescription drug context).

- "***Whether the fluoroquinolones are capable of causing and/or did cause the irreversible peripheral neuropathy and related injuries of Plaintiffs***" → as noted above, general causation will depend on scientific evidence that differs from drug to drug. Specific causation will similarly turn on case-specific issues related to the plaintiff's medical history, including his or her PN diagnosis (a highly case-specific inquiry that depends on treating physician and expert testimony) and concurrent medications.[7] Additionally, the failure-to-warn claims will require each plaintiff to prove that an adequate warning would have persuaded the prescribing physician not to prescribe the product for the plaintiff. *Thomas v. Hoffman-LaRoche, Inc*., 949 F.2d 806, 812 (5th Cir. 1992). That inquiry necessarily depends on the plaintiff's unique medical history, the treating physician's knowledge of risk of PN, the physician's individual risk/benefit assessment, and the specific indication for which the medicine was prescribed.

In short, Plaintiffs' own analysis serves only to highlight the numerous individualized issues that, following centralization, would predominate and inefficiently consume an MDL court's time and resources.

[7] With regard to the relevance of concurrent medications, one of Plaintiffs' cited articles notes that four out of five patients on Cipro® who developed PN were also receiving treatment with metronidazole or chloramphenicol, both of which are associated with neuropathy. Thus, the authors concluded, "[w]hether [ciprofloxacin] alone was responsible for the neuropathy is unknown." Hedenmalm, K., Spigset, O. (1996). Peripheral sensory disturbances related to treatment with fluoroquinolones. *Journal of Antimicrobial Chemotherapy*, 37(4), 831-837, at 836.

B. Plaintiffs' Authorities Do Not Warrant Deviating from This Panel's Typical Hesitance to Centralizing Litigation on an Industry-Wide Basis.

As Plaintiffs' cited cases make clear, this Panel is "typically hesitant to centralize litigation on an industry-wide basis." *In re: AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014); *In re: Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345, 1346 (J.P.M.L. 2013) (same). The above issues exemplify the reasons for this presumption. For several additional reasons, the cases cited by Plaintiffs are distinguishable and do not warrant departing from the general rule disfavoring industry-wide centralization.

First, in the cases Plaintiffs cite where the Panel granted an industry-wide MDL despite its "typical hesitance," many of the underlying claims involved plaintiffs exposed to multiple drugs. *See id.* at 1346-47 ("Several plaintiffs took more than one of the drugs at issue, which suggests that discovery specific to the plaintiffs in those cases will involve many of the same or substantially similar documents and witnesses"); *Androgel*, 24 F. Supp. 3d at 1379 ("Significantly, in the actions and potential tag-along actions already filed, a number of plaintiffs used more than one testosterone replacement therapy"). This key factor is not present here: as discussed above, no complaint properly served upon Bayer alleges multiple drug exposure.[8] The potential for overlapping discovery is therefore much lower.

Second, several of Plaintiffs' cases involved claims targeting a single drug, or drugs sharing the same active ingredient. *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, MDL No. 2606, 2015 WL 1518503 (J.P.M.L. Apr. 3, 2015) (centralizing litigation over drugs containing olmesartan medoxomil); *In re Yasmin, Yaz (Drospirenone) Mktg., Sales Practices and Prods.*

[8] The complaint in the *Uman* case was never served upon Bayer, despite having been pending since January 2015. The matter was removed to federal court, set for hearing, adjourned by consent of plaintiffs, and transferred to a North Carolina federal court by stipulation. None of these steps involved notice to or consent from Bayer. Further, only two of the purportedly related claims against Bayer identified by Kathleen Smith allege multiple drug exposure, and to date neither complaint has been served. (*See* Dkt. # 22-1.)

Liab. Litig., 655 F. Supp. 2d 1343 (J.P.M.L. 2009) (centralizing litigation involving drospirenone-containing oral contraceptives); *In re Ephedra Prods. Liab. Litig.*, 314 F. Supp. 2 d 1373 (J.P.M.L. 2004) (centralizing claims regarding ephedra-containing products); *Androgel*, 24 F. Supp. 3d at 1378 (centralizing claims involving testosterone). Here, by contrast, Plaintiffs seek centralization of claims involving three antibiotics, each of which has its own chemical composition and clinical testing history.

Third, some of the cases Plaintiffs rely upon involved the conduct of just a single drug manufacturer. *In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 391 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005) (common question was "whether Pfizer, as the manufacturer of both medications, knew of these increased risks and failed to disclose them to the medical community and consumers and/or improperly marketed these medications to both of these groups"); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) ("All actions focus on alleged increased health risks (including heart attack and/or stroke) when taking Vioxx, an anti-inflammatory drug, and whether Merck knew of these increased risks and failed to disclose them to the medical community and consumers."). Notably, in *Vioxx*, the Panel denied centralization of claims involving a second drug because, in its view, such claims would "not share sufficient questions of fact with claims relating to Vioxx." *Id.*

Fourth and finally, several of Plaintiffs' cases involved centralization of claims brought on behalf of putative nationwide or statewide classes – a feature missing here. *In re Porsche Cars N. Am., Inc.*, 787 F. Supp. 2d 1349 (J.P.M.L. 2011); *In re Yasmin/Yaz*, 655 F. Supp. 2d at 1344; *In re Toys "R" Us-Delaware, Inc., Fair & Accurate Credit Transactions Act (FACTA) Litig.*, 581 F. Supp. 2d 1377 (J.P.M.L. 2008); *In re Se. Milk Antitrust Litig.*, 530 F. Supp. 2d 1359, 1360 (J.P.M.L. 2008); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine)*

Prods. Liab. Litig., 990 F. Supp. 834, 836 (J.P.M.L. 1998). Because none of the underlying claims are brought as putative class actions, there is no risk of inconsistent rulings on class certification – which the Panel found critical in the above cases.

In summary, the cases upon which Plaintiffs rely are distinguishable in key respects. Because the special circumstances that warranted consolidation in those cases are not present, the Panel need not and should not depart from its typical reluctance to industry-wide centralization in this action.

C. Contrary to Plaintiffs' Speculation, The Number of Avelox® and Cipro® Claims is Likely to Remain Low.

Citing no evidence except "the widespread use of fluoroquinolones for over a decade" and the fact that the first underlying claim was filed ten months ago, Plaintiffs assert that "the number of similar cases filed in state and federal courts across the country will expand rapidly." (Br. at 13; *see also id.* at 3 (speculating that "hundreds (or thousands)" of new claims will soon be filed).) This Panel has given little weight to such bare assertions in the past. *In re Qualitest Birth Control Prods. Liab. Litig.*, 38 F. Supp. 3d 1388 (J.P.M.L. 2014) ("As we have stated previously, we are disinclined to take into account the mere possibility of future filings in our centralization calculus.") (quotation marks omitted).

Further, the available evidence suggests that Plaintiffs' guesstimate is far off the mark. Cipro®'s labeling has warned of the risk of PN since 2004 – yet the first PN-related Cipro® claim against Bayer was not filed until December 2014, more than a decade later. Ex. C at 13-14 (July 2004 Cipro® label, warning that "[c]iprofloxacin should be discontinued if the patient experiences symptoms of neuropathy. . . in order to prevent the development of an irreversible condition"); *Higley v. Bayer Healthcare Pharmaceuticals, Inc. et al.*, No. 3:14-cv-5254 (N.D. Cal. filed Dec. 1, 2014). That claim, moreover, was filed more than a year after the FDA's

August 2013 safety alert and revisions to the PN warnings on the labeling for Cipro®, Avelox®, and Levaquin®. (*See* Br. at 7-8.) Today – nearly two years after the safety alert, and eleven years after Bayer's first warning regarding PN – fewer than ten cases alleging PN as a result of taking Cipro® or Avelox® are pending and active against Bayer. The dearth of claims is particularly notable given the tremendous volume of prescriptions – a fact Plaintiffs concede. (*See* Br. at 3-4.)

It is also worth noting that, unlike most cases for which centralization is sought, this action involves only a small handful of purported federal tag-along actions or related state claims, only two of which have been served upon Bayer. This stands in stark contrast to the situation in most of the cases cited by Plaintiffs, which involved dozens or even hundreds of tag-along cases. *E.g.*, *In re Benicar*, 2015 WL 1518503, at *1 n.1 (23 tag-alongs); *In re Androgel*, 24 F. Supp. 3d 1378 n.1 (81 tag-alongs); *In re Yasmin/Yaz*, 655 F. Supp. 2d at 1343 n.1 (60 tag-alongs); *In re Bextra*, 391 F. Supp. 2d at 1378 n.1 (100+ tag-alongs); *In re Vioxx*, 360 F. Supp. 2d at 1353 n.1 (300 tag-alongs); *In re Ephedra*, 314 F. Supp. 2d at 1374 n.1 (200 tag-alongs); *In re Diet Drugs*, 990 F. Supp. at 835 n.1 (200+ tag-alongs).

Simply put, Plaintiffs' bald prediction that this litigation will expand rapidly has already failed the test of time and is not borne out by the current facts. Under these circumstances, the Panel should not give it any weight.

D. Voluntary Coordination among Plaintiffs' Counsel is Ongoing and Preferable.

"The Panel has often stated that centralization under Section 1407 should be the last solution after considered review of all other options." *In re: Gerber Probiotic Prods. Mktg. & Sales Practices Litig.*, 899 F. Supp. 2d 1378, 1379 (J.P.M.L. 2012) (quotation marks omitted). As an alternative to centralization, Defendants are willing to cooperate with Plaintiffs in a

coordinated discovery process. In an effort to suggest that such coordination might be unwieldy, Plaintiffs state that the underlying plaintiffs are represented by fifteen different law firms. (Br. at 2.) This account is incomplete, given that a small number of firms represent the majority of the underlying plaintiffs. Specifically, the plaintiffs in 16 of the 24 pending cases listed in Plaintiffs' Schedule of Actions are represented by one or more of the following four law firms: Baron & Budd, P.C., Gomez Iagman Trial Attorneys, Heard Robins Cloud LLP, and Aylstock Witkin Kreis & Overholtz PLLC.

These facts suggest that, contrary to Plaintiffs' suggestion, voluntary coordination is feasible and provides a convenient alternative to wholesale centralization. *In re Boehringer Ingelheim Pharms., Inc.*, 763 F. Supp. 2d 1377, 1378-79 (J.P.M.L. 2011) ("Because plaintiffs in three actions share counsel and [defendant] is represented by common counsel, alternatives to formal centralization, such as voluntary cooperation . . . , appear viable."); *In re Rite Aid Corp. Wage & Hour Emp't Practices Litig.*, 655 F. Supp. 2d 1376, 1377 (J.P.M.L. 2009) (denying centralization "where plaintiffs in four of the six actions encompassed by the motion share counsel.") Given the substantial downsides to centralization, voluntary coordination is a viable and attractive alternative.

E. Should an MDL be Granted, the Southern District of Illinois Is Not an Appropriate Venue.

Finally, in the event the Panel decides to centralize some or all of the lawsuits brought by Plaintiffs, it should do so in a forum other than the Southern District of Illinois. That district has no connection whatsoever to Defendants, and Plaintiffs do not suggest (nor could they) that any documents or common witnesses are located there. Nor is the Southern District of Illinois remarkable in terms of the number of cases currently pending there (only two). By way of comparison, eight cases are pending in the Northern District of California alone. Further, Judge

David Herndon, Plaintiffs' first choice for centralization, already has an active MDL on his docket. *See In re Yasmin/Yaz*, 655 F. Supp. 2d at 1344 (selecting Judge Herndon partly because, at the time, he was "not currently presiding over another multidistrict litigation docket"). Because the Southern District of Illinois has only a tenuous connection to this litigation, Plaintiffs' proposal should be seen for what it is: forum-shopping.

III. CONCLUSION

For the foregoing reasons, Bayer respectfully requests that the Panel deny Plaintiffs' Motion for Transfer of Actions to the Southern District of Illinois Pursuant to 28 U.S.C. § 1407 for Coordination or Consolidated Pretrial Proceedings.

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Respectfully submitted,

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