BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION	MDL No. 2642

BRIEF OF 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 IN OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER

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PRELIMINARY STATEMENT

Defendants Johnson & Johnson, Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc., and McKesson Corporation (collectively, "Janssen") hereby oppose the motion ("Mot.") to consolidate pretrial proceedings in federal cases alleging peripheral neuropathy caused by the medicines Cipro®, Levaquin®, and Avelox®. Consolidation—on an "industry-wide" basis, or on a per-medicine basis—neither serves the convenience of the parties and witnesses nor promotes the just and efficient conduct of the actions.

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), and there is no reason to depart from that practice here. There are crucial differences among the medicines that go to the heart of the plaintiffs' failure-to-warn claims, such as the conditions they are used to treat and the extent to which their labels warned of peripheral neuropathy. These differences swamp any efficiencies to be gained from centralization. An industry-wide conspiracy is not alleged; the defendants are direct competitors; and the total number of active plaintiffs identified in the Motion—20—is modest. Moreover, there are no pending state cases requiring coordination, and there is only *one* case alleged to involve both Levaquin® and another fluoroquinolone.

Even in a Levaquin®-only MDL—which was not requested in Plaintiffs' Motion—plaintiff-specific discovery will predominate. As explained below, even beyond the usual plaintiff-specific issues, a Levaquin® MDL would be an atypical pharmaceutical MDL because of predominant generic medication usage and unique statute of limitations issues. Under these circumstances, voluntary coordination is preferable—especially here, as most of the common discovery already took place in a *prior* MDL, *see In re Levaquin Prods. Liab. Litig.*, 560 F.

Supp. 2d 1384, 1385 (J.P.M.L. 2008), and a single attorney—Thomas Sims of Baron & Budd—already is coordinating plaintiffs' general discovery for *all* of these peripheral neuropathy cases.

Moreover, the assertion that the number of Levaquin® peripheral neuropathy cases is large and growing is simply not true. When this litigation began in August 2014, there were thirteen Levaquin® plaintiffs. As of this writing, there are only **eleven** remaining plaintiffs among those cited in Plaintiffs' Motion, and almost half of those were served just before this Motion was filed. Since the beginning of the peripheral neuropathy litigation, **sixteen** other Levaquin® peripheral neuropathy claims have been dismissed. Thus, more plaintiffs have been dismissed than remain, and the litigations have been resolving on their own quickly and efficiently. The number of dismissed Levaquin plaintiffs and flat number of pending claims over the past year is proof that informal coordination and litigation of the claims in the District Courts is working efficiently. And because of the timing of this litigation in Levaquin®'s product lifecycle, additional new filings will be few in number. Levaquin® "went generic" in June 2011, more than four years ago. Sales of name-brand Levaquin® immediately dropped dramatically, as pharmacies began substituting cheaper generic levofloxacin. The upshot is that very few patients have even *received*—let alone allegedly *been injured by*—name-brand Levaquin® in the past four years. Because the claimed association between Levaquin® and neuropathy goes back decades, it is unlikely many patients injured in 2011 or earlier are sitting on unfiled claims, and even if they were, those claims now are time-barred. And because none of these cases were filed before late 2014, every single Levaquin® case that is part of this petition is *prima facie* time-barred and will need to survive a statute-of-limitations motion on the basis of state-specific discovery rules before proceeding to the merits of the claims.

With another Levaquin® tendon-injury MDL formed in 2008 now concluding, this motion is a meritless attempt to get a second bite at the apple. It should be denied. That said, if the Panel decides to consolidate over Janssen's objections, the Southern District of Illinois is an inappropriate transferee district. This litigation has *no* connection to that district, and the Southern District of Illinois is overburdened as it is.

FACTUAL BACKGROUND

A. Overview of Fluoroquinolone Drugs

The quinolones are a family of synthetic prescription antibacterial medicines. Discovered in 1962, they work by preventing bacterial DNA from unwinding and duplicating. Fluoro-quinolones ("FQs"), a subclass of quinolones, play an important role in the treatment of serious infections, especially those resistant to older antibacterial drugs. In fact, FQs are so important that they remain among the few medications approved to combat terrorism, with approvals for the treatment of anthrax and the plague. Though all FQs belong to the same chemical family, they are each unique medicines which were developed and approved for different purposes.

1. Cipro®

Cipro® (ciprofloxacin) is a "second-generation" FQ. It was developed by Bayer A.G. and approved by the United States Food & Drug Administration ("FDA") in 1987. It has thirteen FDA-approved uses (or "indications"): urinary tract infections and acute uncomplicated cystitis; chronic bacterial prostatitis; lower respiratory tract infections; acute sinusitis; skin and skin structure infections; bone and joint infections; complicated intra-abdominal infections; Infectious diarrhea; typhoid fever (enteric fever); uncomplicated cervical and urethral gonorrhea; complicated urinary tract infections and pyelonephritis in pediatric patients; inhalational anthrax postexposure in adult and pediatric patients; and plague in adult and pediatric patients. Generic

ciprofloxacin first entered the U.S. market in June 2004.[1] At least twelve companies have received FDA approval to sell generic ciprofloxacin.

2. Levaquin®

Levaquin® (levofloxacin) is a "third-generation" FQ. It was first patented by Daiichi Pharmaceutical Company, developed in the United States by a Johnson & Johnson subsidiary and approved by the FDA in 1996. The medicine has nine FDA-approved indications: pneumonia (nosocomial and community acquired); acute bacterial sinusitis; acute bacterial exacerbation of chronic bronchitis; skin and skin structure infections; chronic bacterial prostatitis; urinary tract infections (complicated and uncomplicated); acute pyelonephritis; inhalational anthrax, post-exposure; and plague. Generic levofloxacin first entered the market in June 2011.[2] At least 20 companies have received FDA approval to sell generic levofloxacin.[3]

3. Avelox®

Avelox® (moxifloxacin) is a "fourth-generation" FQ. It was developed by Bayer A.G. and approved by the FDA in December 1999. It has five approved indications: acute bacterial sinusitis; skin and skin structure infections (uncomplicated and complicated); acute bacterial exacerbation of chronic bronchitis; complicated intra-abdominal infections; and community acquired pneumonia. Generic moxifloxacin entered the U.S. market in February, 2014.[4] At least four companies have received FDA approval to sell generic moxifloxacin.[5]

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[1] *See* http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredeveloped andapproved/drugandbiologicapprovalreports/andagenericdrugapprovals/ucm063711.htm.
[2] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm259951.htm
[3] *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=LEVOFLOXACIN
[4] *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsAreDeveloped andApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm388134.htm
[5] *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=MOXIFLOXACIN%20HYDROCHLORIDE

B. Fluoroquinolones and Peripheral Neuropathy

"Peripheral neuropathy" refers to damage or disease affecting the nerves, which may impair sensation, movement, gland or organ function, or other aspects of health.[6] It can be associated with exposure to medicines including FQs and a number of others (*e.g.*, metronidazole, phenytoin, nitrofurantoin, isoniazid, and statins).[7] It also is associated with toxic exposures, genetic diseases, metabolic and endocrine diseases, inflammatory diseases, vitamin deficiency, physical trauma, chemotherapy, radiation, electric shock, HIV and shingles.[8]

Levaquin's labeling has warned of a potential risk of peripheral neuropathy as an "Adverse Reaction" since September 2000. In September 2004, after consultation with the FDA, the manufacturers of all FQs updated their warnings regarding peripheral neuropathy. In relevant part, the following language was added to Levaquin®'s label:

> **WARNINGS**
> **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.***[9]

A substantially identical warning was added to Cipro®'s label, while Avelox® added language that warned of peripheral neuropathy but did not expressly use the word "irreversible."[10]

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[6] *See* http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm

[7] *See* Gaist, et al., *Statins and Risk of Polyneuropathy*, NEUROLOGY, Vol. 58 No. 9, at 1333-37 (2002), *available at* http://www.neurology.org/content/58/9/1333

[8] *See* http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm

[9] *See* Mot. at 11 (italicized emphasis added).

[10] S*ee* Mot. at 6-7.

In June 2013, the FDA requested that the fluoroquinolones' labels be revised again. The final revised labeling was approved by FDA and implemented in August 2013. In relevant part, the following language was added to each medicine's label (Levaquin® version):

> ■ **WARNINGS AND PRECAUTIONS**
> *** * ***
> **5.8 *Peripheral Neuropathy***
> ■ 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 LEVAQUIN. ***Symptoms may occur soon after initiation of LEVAQUIN and may be irreversible.*** LEVAQUIN should be discontinued immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.[11]

C. Levaquin® Peripheral Neuropathy Litigation

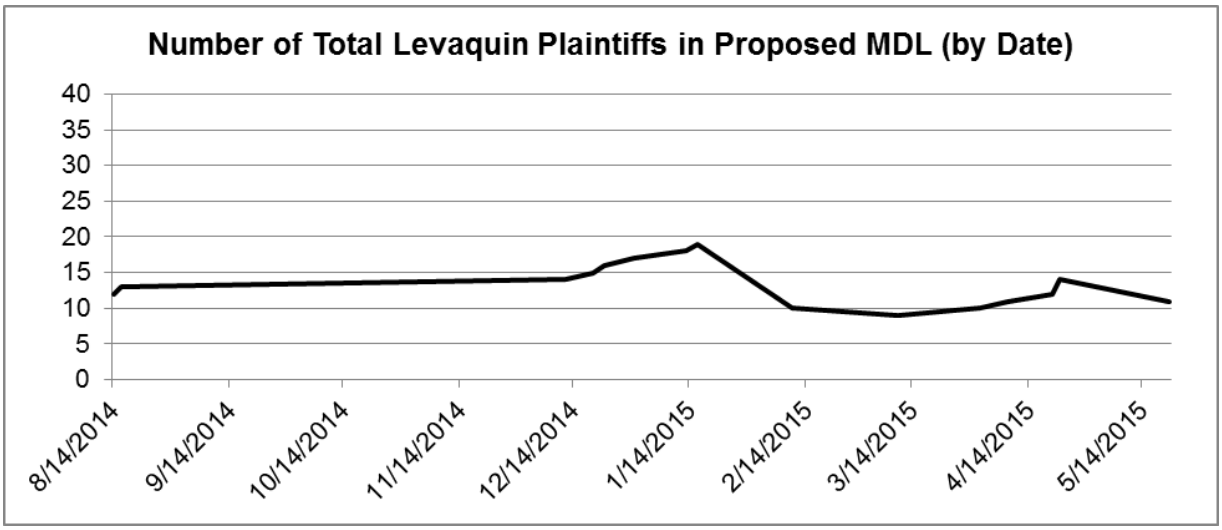
Beginning in August 2014, plaintiffs began filing lawsuits alleging that they had suffered peripheral neuropathy as the result of taking Cipro®, Levaquin®, and/or Avelox®. As reflected in plaintiffs' brief, these lawsuits do not allege that these medicines were defectively *manufactured* or *designed*. Instead, the gravamen of these suits is that, prior to August 2013, defendants *failed to provide sufficient warning* about the risk of irreversible peripheral neuropathy. (*See* Mot. at 8.)

These claims are of questionable merit on their face. As discussed above, the risk of peripheral neuropathy has been expressly disclosed on Levaquin®'s FDA-approved label since 2000. Moreover, since at least November 2004, Levaquin®'s label has stated, under the boldface "WARNING" heading "**Peripheral Neuropathy**," that this may be an "***irreversible condition***." Plaintiffs' claims against Janssen, therefore, turn on the far-fetched argument that

[11] *See* Mot. at 7-8.

the 2004 label—which expressly warned of "irreversible" peripheral neuropathy—failed to "warn[] . . . that the use of [Levaquin®] may result in permanent nerve damage." (Mot. at 6.)

Plaintiffs assert that "this litigation has . . . experienced rapid growth in size and is likely to continue to grow with a large number of filings . . . in the near future." (Mot. at 13.) But this assertion—at least as regards what has happened to date—is demonstrably incorrect. In fact, the number of FQ peripheral-neuropathy plaintiffs in federal court has remained low, and relatively constant. Moreover, considering only those claims that involve Levaquin®, the number of cases has actually *gone down* prior to the filing of this Motion:



As this chart shows, this litigation began on August 14, 2014 with twelve Levaquin® plaintiffs. There are just eleven such plaintiffs listed in the Motion with active cases. Since August 2014, at least sixteen Levaquin® plaintiffs have voluntarily dismissed their claims.[12]

[12] *See Beverly*, 3:14-cv-5246 (N.D. Cal.), Dkt. No. 33; *Campbell*, 4:14-cv-5668 (N.D. Cal.), Dkt. No. 8; *Guest*, 3:15-cv-495-CAB-WVG (S.D. Cal.), Dkt. No. 15; *Ellis*, 3:14-cv-5669 (N.D. Cal.), Dkt. No 33; *Pritchard*, 3:14-cv-5593 (N.D. Cal.), Dkt. No. 30; *Garland*, 3:14-cv-5440 (N.D. Cal.), Dkt. No. 33; *Albring*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Chatelain*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Clark*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Curry*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Femine*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Galati*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Huff*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Kemp*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Nickol*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27; *Powers*, 3:14-cv-4983 (N.D. Cal.), Dkt. No. 27.

D. Prior Levaquin® MDL

This is not the first time that plaintiffs have attempted to create a Levaquin® MDL. In June 2008, over Janssen's objections, this Panel ordered centralization of actions alleging that Janssen failed to warn adequately that Levaquin® caused tendon rupture. *See Levaquin*, 560 F. Supp. 2d at 1385. The plaintiffs' theory in that MDL was similar to their theory here: that Janssen had failed to warn of a potential side effect, even though Levaquin®'s label *expressly described* the condition at issue in the "Warnings" section.

That MDL was not a productive use of the parties' resources and the transferee Court's time. After centralization lowered the barrier to filing, almost 2,000 cases eventually were directly filed or transferred into that MDL.[13] The plaintiffs conducted extensive fact discovery, receiving over nine million pages of written material, and taking a significant number of employee depositions. Three bellwether cases were tried to verdict—the plaintiffs lost two outright, and in the third, the majority of the award was vacated on appeal. *See In re Levaquin Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 163777, at *11-13 & n.7 (J.P.M.L. Nov. 21, 2014). Ultimately, a significant number of the cases in that MDL were dismissed without any payment or with only a token payment (three-figure amounts), and plaintiffs' lawyers withdrew in close to 100 cases that remained. The costs of discovery and case management that Janssen was forced to bear for six years after consolidation far exceeded plaintiffs' recovery in the entire litigation.

[13] *See* U.S. District Court for the District of Minnesota, *Levaquin MDL Current Developments*, http://www.mnd.uscourts.gov/MDL-Levaquin/current-developments.shtml.

ARGUMENT

Section 1407 permits consolidation when (1) the actions "involv[e] one or more common questions of fact," (2) consolidation would serve "the convenience of [the] parties and witnesses," and (3) consolidation would "promote the just and efficient conduct of [the] actions." However, "***centralization under Section 1407 'should be the last solution after considered review of all other options***,'" including voluntary coordination. *In re Nutek Baby Wipes Prods. Liab. Litig.*, 2015 U.S. Dist. LEXIS 44048, at *3 n.3 (J.P.M.L. Apr. 2, 2015) (emphasis added).

The moving party bears the burden of demonstrating that transfer is appropriate. *In re G.D. Searle & Co. "Copper 7" IUD Prods. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980).Even when common questions of fact exist, the movant must still show that "the inherent disadvantages of Section 1407 transfer" do not "outweigh the benefits." *Id.*

I. AN INDUSTRY-WIDE MDL WILL NOT SERVE THE CONVENIENCE OF THE PARTIES OR THE INTERESTS OF JUSTICE

Movants seek to create an unwieldy MDL against unrelated manufacturers and distributors of three different medicines. This goes against the Panel's general practice. *See Fentanyl Patch*, 883 F. Supp. 2d at 1351 ("***[W]e are typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products.***" (emphasis added)). And there is especially good reason for hesitation here.

Movants "have not alleged any conspiracy, collaboration, or other industry-wide conduct by the defendants that would justify centralizing actions naming different [manufacturers and distributors] as defendants." *In re Honey Prod. Mktg. & Sales Practices Litig.*, 883 F. Supp. 2d 1333, 1333 (J.P.M.L. 2012). And industry-wide centralization would "complicate these matters, as defendants may need to erect complicated confidentiality barriers, since they are business competitors." *Fentanyl Patch*, 883 F. Supp. 2d at 1351. But most importantly, the three

medicines are not all alike. Though they are FQs, the three medicines' molecular structures are different, and each is part of a different "generation" and acts in a different way.[14] Because of these differences, they are used to treat different conditions: "All quinolones are not equal and should not be used interchangeably."[15]

This is important, because the failure-to-warn claims asserted here require each plaintiff to "establish that an adequate warning would have convinced [the] treating physician not to prescribe the product for the plaintiff." *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992). Whether the change made to the FQs' labels in 2013 would have changed a physician's prior behavior in any particular instance depends on, among other things, the condition being treated and the availability (and relative risk) of alternative treatments for that condition. Thus, the fact that a stronger warning might have persuaded a doctor not to prescribe Cipro® to treat gonorrhea (for example) does not mean that similar language would have persuaded a physician not to prescribe Levaquin® to treat nosocomial pneumonia, which is fatal in 25-50% of cases.[16] Because the medicines at issue have dissimilar risk/benefit profiles based on their differing indications, "[w]hether the Defendants failed to [adequately] warn about the risks of the fluoroquinolones" *is not*, in fact, a "common question," as plaintiffs claim.

Furthermore, the warnings in the medicines' labels differed. Between 2004 and 2013, the labels for Levaquin® and Cipro® stated that "Peripheral Neuropathy" can be "an irreversible condition," and directed physicians and patients to "discontinue" it "if the patient experiences [various characteristic] symptoms." (Mot. at 6.) The label used for Avelox® during that interval

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[14]Dana E. King, *et al.*, *New Classification and Update on the Quinolone Antibiotics*, Am. Family Physician. 2000 May 1;61(9):2741-48, http://www.aafp.org/afp/2000/0501/p2741.html.
[15]Vincent T. Andriole, *The Quinolones: Past, Present, and Future*, Clin. Infect. Dis. (2005) 41 (Supp. 2): S113-S119, http://cid.oxfordjournals.org/content/41/Supplement_2/S113.full.
[16]*See* Sanjay Sethi, *Hospital-Acquired Pneumonia*, in Merck Manual (Dec. 2014).

did not use the same language. (Mot. at 7.) As a result, the plaintiffs' failure-to-warn theories are different for the respective medicines: they fault Bayer for allegedly "fail[ing] to make any mention [in Avelox® labeling] of the risk of permanent nerve damage," but they fault Janssen for allegedly implying that neuropathy "could be avoided by simply discontinuing [Levaquin®] upon the onset of certain symptoms." (Mot. at 6.)

Given these facts, lumping all three products together is more likely to confuse the issues and prejudice the defendants than to serve the convenience of the parties and the interest of justice. *Cf. 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 different formulations, different risks, and "distinct regulatory responses"); *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010); *Fentanyl Patch*, 883 F. Supp. 2d at 1351.

Plaintiffs point to examples when the Panel placed different pharmaceutical products or manufacturers in the same MDL. (Mot. at 11-12.) But in one of those very cases, the Panel recognized that this was an exception to the rule. *See In re Androgel 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***." (emphasis added)). And the cases plaintiffs cite are easily distinguished:

- ***Number of actions.*** In *Diet Drugs Products Liability Litigation*, 990 F. Supp. 834 (J.P.M.L. 1997), there were more than 209 actions (including tag-alongs) at the time of centralization; in *Bextra & Celebrex Products Liability Litigation*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005), there were more than 131; in *Androgel*, there were 126; and in *Incretin Mimetics Products Liability Litigation*, 968 F. Supp. 2d 1345 (J.P.M.L. 2013), there were 97. Here, there are only 21 pending cases industry-wide; that number has remained flat for months; and, as discussed below, this number is unlikely to do anything but decrease.

- ***Same medicine or same manufacturer.*** In *Androgel*, all of the defendant manufacturers sold the same medicine—testosterone. And in *Bextra & Celebrex Products Liability*

Litigation, 391 F. Supp. 2d 1377 (J.P.M.L. 2005), both of the medicines involved were sold by the same manufacturer—Pfizer. This motion, by contrast, involves different medicines sold by different manufacturers.

- ***Defendants' consent.*** In *Androgel*, *Incretin*, and *Bextra & Celebrex*, there was significant support for centralization on the defendants' side. Here, no defendant supports industry-wide centralization. *Cf. In re Discover Card Payment Protection Plan Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1341, 1342 (J.P.M.L. 2011).

- ***Class actions.*** In *Diet Drugs*, many of the actions were "brought on behalf of alleged nationwide or statewide classes of [drug] users," and the Panel found that centralization was "especially" necessary to avoid "inconsistent . . . rulings . . . with respect to class certification." None of the actions in this litigation is a class action. *See In re Narconon Drug Rehab. Mktg., Sales Practices, & Prod. Liab. Litig.*, 2015 U.S. Dist. LEXIS 14292, at *3 (J.P.M.L. Feb. 5, 2015) (fact that "none of the actions is a class action . . . limits the scope for inconsistent pretrial rulings and practice").

Finally, plaintiffs argue for an industry-wide MDL because "Counsel for movants is anticipating" that "a number of" plaintiffs will have taken more than one FQ. (Mot. at 11.) However, as plaintiffs acknowledge, only *one* complaint contains such allegations. (Mot. at 2 n.4, 11 n.19.)[17] This lone "example" does not justify consolidation.

II. A LEVAQUIN®-ONLY MDL ALSO IS INAPPROPRIATE

A Levaquin®-only MDL would no more serve the ends of Section 1407 than an industry-wide one. Centralization would not create efficiencies: Discovery will be mostly plaintiff-specific; much common discovery has already taken place in a prior MDL; and the circumstances lend themselves especially well to voluntary cooperation. Moreover, the number of pending cases is very low, and these cases are being resolved efficiently in the District Courts.

[17]Despite the fact that this particular case has been pending since January 2015, only Janssen has been served or appeared in it, and plaintiffs have made no attempt to pursue their claims against Bayer. Procedurally, this matter was removed to federal court, set for hearing before a judge in the Southern District of California, adjourned by consent and then transferred to the Eastern District of North Carolina by stipulation—none of which involved notice to or consent from Bayer—and the time to serve the complaint on Bayer has expired pursuant to Fed. R. Civ. P. 4(m). Moreover, Janssen's pending dispositive statute-of-limitations motion may eliminate the matter entirely, as that plaintiff waited almost ten years to file his Levaquin® claim.

A. Centralization Will Not Create Discovery Efficiencies

This Panel has long declined to centralize when it appeared that plaintiff-specific issues would constitute the bulk of discovery. *See, e.g.*, *In re Wireless Lifestyle Inc.*, 842 F. Supp. 2d 1382, 1383 (J.P.M.L. Feb. 3, 2012). Product-liability cases involving prescription medicines (or medical devices) are the archetypal category of case in which plaintiff-specific issues predominate and, for this reason, the Panel has often refused to centralize them. *See, e.g.*, *Pain Pump*, 709 F. Supp. 2d at 1377 ("individual issues of causation and liability appear to predominate," as "[p]laintiffs have different medical histories"); *In re Blair Corp. Chenille Robe Prods. Liab. Litig.*, 703 F. Supp. 2d 1379, 1380 (J.P.M.L. 2010).[18]

The decision to deny consolidation should be the same here. The common issues—such as what warnings Janssen gave, and when—are relatively straightforward. The bulk of discovery across all cases will concern plaintiff-specific issues, such as: whether each plaintiff received Levaquin®, as opposed to generic levofloxacin or another FQ altogether; the particular condition for which each plaintiff received the medicine; the plaintiff's underlying medical history and risk profile; when each plaintiff first experienced and was diagnosed with peripheral neuropathy; when each plaintiff discovered the alleged connection between Levaquin® and peripheral neuropathy; whether each treating physician read the label (and if so, what version they read); whether each treating physician was aware of the risks associated with Levaquin® through other channels; whether each treating physician would have prescribed Levaquin® notwithstanding knowledge of the alleged risks; whether each plaintiff's peripheral neuropathy, in fact, was caused by Levaquin®, or one of the many alternative causes; and whether each plaintiff's

[18]Many of the product-liability litigations for which the Panel denied centralization are far larger than this one. *See, e.g.*, *Pain Pump*, 709 F. Supp. 2d at 1377 (102 actions and "more than 70 additional related actions"); *Asbestos Insulation*, 431 F. Supp. at 909-10 (103 actions).

peripheral neuropathy is indeed "irreversible" (since insufficient warning of "irreversibility" is the crux of plaintiffs' claims).

To the extent the pending cases *may* involve overlapping discovery—*e.g.*, of correspondence with FDA and other regulatory materials—these materials were produced in the previous Levaquin® MDL, which also concerned allegedly inadequate warnings in Levaquin®'s labeling. As noted above, in that MDL, Janssen produced over nine million pages of documents concerning *all* aspects of Levaquin's labeling and regulatory history as well as all adverse events reported to the company—not merely tendon-specific issues. That entire MDL production already has been produced directly to plaintiffs' counsel or their associated counsel in the peripheral neuropathy cases, and Janssen is ready and willing to produce it to any other plaintiff who agrees to the confidentiality order previously entered regarding the production of these documents. Those MDL productions contained responsive Levaquin® documents and databases through 2011; of note, only *one* Levaquin® plaintiff associated with this petition received Levaquin® after the 2011 discovery cut-off of the prior Levaquin® MDL, so all but one plaintiff already has everything that could be relevant to his or her alleged failure-to-warn claim.

In addition, Janssen already provided plaintiffs regulatory and clinical records through 2015 to update those produced in the prior MDL. The custodial files of the Janssen employees that remained assigned to Levaquin® after generic levofloxacin entered the market also already have been collected and will be produced prior to the Panel hearing. In short, many discovery objectives that could benefit from consolidation have been or will be completed before the Panel rules. Under these circumstances, centralization would impose substantial costs for little or no additional benefit and "informal cooperation . . . is both practicable and preferable." *In re Ne. Contaminated Beef Prods. Liab. Litig.*, 856 F. Supp. 2d 1354, 1354-55 (J.P.M.L. 2012). Indeed,

voluntary coordination is especially suitable here because only two law firms (Gomez Trial Attorneys and Baron & Budd) have filed over 80% of the peripheral neuropathy cases that have been commenced prior to filing of this Motion, and Janssen is represented by the same national defense counsel in every action. *See, e.g., In re Boehringer Ingelheim Pharms., Inc.*, 763 F. Supp. 2d 1377, 1378-79 (J.P.M.L. 2011) (when parties share common counsel "alternatives to formal centralization, such as voluntary cooperation . . . , appear viable.").

B. The Number Of Levaquin® Actions Is Small, And Will Remain Small

Plaintiffs assert that "this litigation has . . . experienced rapid growth in size and is likely to continue to grow with a large number of filings . . . in the near future." (Mot. at 13.) However, the number of Levaquin® peripheral neuropathy plaintiffs has actually *decreased* since this litigation began last August, and no state court litigation has commenced *anywhere*. (*Supra* at 6-7.) In addition, the mere "allu[sion] to the prospect of additional actions . . . not now before the Panel" is not a "persuasive reason for transfer." *In re Zimmer, Inc. Centralign Hip Prosthesis Prods. Liab. Litig. (No. II)*, 366 F. Supp. 2d 1384, 1385 (J.P.M.L. 2005). Indeed, for reasons ignored by plaintiffs, the number of Levaquin® claims will remain very low.

First, starting in June 2011, Janssen lost its market exclusivity for Levaquin®, and over 20 manufacturers began selling generic levofloxacin. Thus, in 2011, even though generic levofloxacin was only on the market for six months, sales of name-brand Levaquin® *declined 54.1%* over 2010.[19] The next year sales *declined another 94%*.[20] Thus, after mid-2011, very few patients received (or, *a fortiori*, could have been injured by) name-brand Levaquin®.

[19]Johnson & Johnson, SEC Form 10-K (2012), *available at* http://www.sec.gov/Archives/edgar/data/200406/000119312512075565/d281803d10k.htm.

[20]Johnson & Johnson, SEC Form 10-K (2013), *available at* http://www.sec.gov/Archives/edgar/data/200406/000020040613000038/a2012123010-k.htm.

This has important consequences. Plaintiffs allege that the "onset" of peripheral neuropathy is "rapid" (Mot. at 6-7), and do not suggest that it takes years to manifest. Thus, accepting Plaintiffs' theory of liability, virtually all possible plaintiffs who developed peripheral neuropathy as a result of name-brand Levaquin® must have been injured—and therefore, had their claims accrue—prior to mid-2011, which is more than four years ago. It is unlikely that many plaintiffs have been sitting idly by for that long: as plaintiffs agree, the claims of a link between Levaquin® and peripheral neuropathy are not new, and Levaquin®'s label *expressly warned* of the risk of "irreversible" "[p]eripheral [n]europathy" starting in August 2004. (Mot. at 5-6.) Moreover, in all but three states, the statute of limitations for personal injury claims is four years or less.[21] Thus, virtually all unfiled claims against Janssen are facially time-barred.

Plaintiffs may respond that some states employ a "discovery rule," which starts the limitations clock not when an injury *occurs*, but when a plaintiff would have *discovered* her claim, or (depending on the state) certain elements of it. But whether a "discovery rule" applies is of no moment here because Levaquin®'s label has contained an express warning that peripheral neuropathy is a potential adverse reaction since 2004.Even assuming the 2004 Levaquin® warning was insufficient to foreclose failure-to-warn liability, it was unquestionably enough to place a reasonably diligent plaintiff who had taken Levaquin® and developed peripheral neuropathy on notice that Levaquin® might have been the cause.

Second, plaintiffs do not dispute that Levaquin®'s warning was adequate as of August 2013.Thus, even though a very small number of individuals continued receiving Levaquin® after

[21]*See* Matthiesen, Wickert & Lehrer, S.C., *Statutes of Limitations for All 50 States*, at http://www.mwl-law.com/wp-content/uploads/2013/03/statute-of-limitations-for-all-50-states.pdf.

generic levofloxacin became available in 2011,[22] those individuals could only have a potential claim against Janssen if their injury occurred before the August 2013 label change. In more than half of the states, the statute of limitations for personal injury claims is one or two years.[23] In just weeks—perhaps by the time the Panel rules—the date of that label change will pass outside of the two-year limitations window. (Notably, despite this, there has not been any increase in filings as this deadline has approached.) Therefore, even counting the August 2013 black box warning as the operative limitations date, most claims filed in any peripheral neuropathy MDL would be time-barred as to Levaquin® using the latest possible discovery date.

Third, prior to any merits adjudication, **all** Levaquin® cases proposed for consolidation will need to survive statute-of-limitations motions requiring state-specific findings that a state discovery rule both applies and tolled the statute of limitations on the particular facts of each case.[24] Indeed, there already are such dispositive motions pending in two Levaquin® cases, *Baum* and *Uman*, and Janssen expects to file similar motions in other pending cases soon. This

[22]Of the plaintiffs who have proposed consolidation, initial discovery revealed that only one plaintiff, in *Street*, alleges taking brand-name Levaquin® after 2011.

[23]*See Statutes of Limitations for All 50 States*, *supra* note 21.

[24]Each case cited in the Motion is facially time-barred:

Case Name	Filing Date	Last Use Date	State	SOL	Last Use to Filing
Lampard	8/14/2014	11/16/2010	CA	2 years	3 years, 3 months
Spiegel	8/14/2014	11/28/2010	NY	3 years	3 years, 8 months
Grossman	8/16/2014	8/3/2010	MD	3 years	4 years
Smith	12/19/2014	5/7/2011	MN	2 years	3 years, 7 months
Street	1/13/2015	3/12/2012	AZ	2 years	2 years, 10 months
Uman	1/16/2015	5/13/2005	NC	3 years	9 years, 8 months
Baugh	4/1/2015	1/14/2010	WA	3 years	4 years, 3 months
Reiman	4/8/2015	11/2/2010	CA	2 years	4 years, 5 months
Baum	4/20/2015	9/27/2006	KY	1 year	9 years, 7 months
Bush	4/22/2015	12/13/2010	IL	2 years	4 years, 5 months
Presley	4/22/2015	3/6/2009	GA	2 years	6 years, 1 month

timeliness issue necessarily will hinge on the application of state-specific discovery rules. *See Narconon*, 2015 U.S. Dist. LEXIS 14292, at *3 ("[N]ecessary discovery and pretrial practice in each action also will differ . . . due to the different state and federal laws"). Consolidation would not make these state-specific analyses more efficient. *See id.* To the contrary, district judges sitting in the several states are already familiar with applying their own states' accrual rules.

For these reasons—and contrary to plaintiffs' speculation—the life span of this litigation and the number of claims is inherently bounded, and the costs of centralization are not worthwhile. *See In re Power Balance, LLC, Mktg. & Sales Practices Litig.*, 777 F. Supp. 2d 1345, 1346 (J.P.M.L. 2011) (where the litigation is likely to resolve, centralization would "entail additional expense . . . with little benefit"). Even now, Levaquin® peripheral neuropathy cases are being dismissed as quickly as they are being filed. Indeed, three plaintiffs whose claims are at issue here filed stipulations of dismissal just days after this Motion was filed, and more will likely follow.[25] Any additional cases that may be filed also are likely to be dismissed before substantial discovery is taken for the same reasons so many cases have been dismissed to date.[26]

The only thing that might make the plaintiffs' prophecy of "rapid growth" come true is if the Panel grants their Motion. As one attorney observed, "an MDL proceeding takes on a life of its own," encouraging plaintiffs' counsel to "file their less meritorious claims in federal court, hoping that [they] will stay forever submerged beneath the avalanche of pending cases."[27] And, as the former managing partner of a national plaintiffs' mass-tort firm acknowledged, "the publicity of an MDL . . . attract[s] other lawsuits," and "the more lawsuits the defendant faces,

[25]*See Ellis*, *Garland* and *Pritchard*, *supra* note 12.

[26]To the extent some plaintiffs filed additional lawsuits in the past week to give the appearance of an increasing number of cases, those cases also all appear to be generic and/or time-barred. In addition, one plaintiffs' firm refuses to actually serve their new complaints. *See* Dkt. No. 22.

[27]Mark Herrmann, *To MDL or Not to MDL? A Defense Perspective*, 24 Litigation 43, 45 (Summer 1998).

. . . the more pressure it will feel to settle."[28] In short, creating a new Levaquin® peripheral neuropathy MDL would accomplish little, other than possibly multiplying an otherwise inherently limited number of complaints.

III. IN THE EVENT OF CENTRALIZATION, THE SOUTHERN DISTRICT OF ILLINOIS IS AN INAPPROPRIATE TRANSFEREE FORUM

If the Panel nevertheless orders consolidation, the Southern District of Illinois is not an appropriate transferee forum. This litigation has no connection to that district: No defendant is based in Illinois, the medicines in question were not developed in Illinois, no allegedly wrongful conduct emanated from Illinois, and no relevant company evidence is in Illinois. And while there are two FQ cases in the Southern District of Illinois, that is no more than are currently pending elsewhere. Both are still at the pleadings stage; indeed, the Levaquin® lawsuit in that District was served less than a week before plaintiffs' petition. In addition, the Southern District of Illinois is overtaxed. It has the second-highest caseload per district judge of all districts nationwide: 2,026 per judgeship—more than three times the national average of 629.[29]

Moreover, Judge David R. Herndon, whom plaintiffs request by name, is already overseeing *In re Pradaxa Prods. Liab. Litig.* (MDL 2385) and *In re Yasmin & Yaz Marketing, Sales Practices, and Prods. Liab. Litig.* (MDL 2100). Plaintiffs claim that these proceedings are "substantially resolved" (Mot. at 16), but as of May 15, 2015, Judge Herndon still was presiding over 3,378 cases between those two MDLs—the fifth-highest of any MDL judge in the country.[30] Circumstances also raise the question whether procedural gamesmanship was employed to inflate the number of cases pending before Judge Herndon in order to influence the

[28] Ed Konieczny, *Multidistrict Litigation, Trust the Leaders*, Issue 21 (Spring 2008) at 6.

[29] *See* United States Courts, *National Judicial Caseload Profile*, http://www.uscourts.gov/file/14254/download?token=gJzW0jub.

[30] *See* MDL Statistics Report—Distribution of Pending MDL Dockets by District, http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-October-15-2014.pdf.

Panel's decision. Not a single peripheral neuropathy case was pending before Judge Herndon until *Bush* was served just days before plaintiffs requested an MDL before him, and a second case was abruptly transferred to him after this motion was filed.[31] *See* 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.").

CONCLUSION

For the reasons outlined above, the Panel should deny the motion to centralize.

Dated: June 10, 2015

Respectfully submitted,

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[31] The Levaquin® case before Judge Herndon (*Bush*) initially was filed on April 22, 2015 in the Benton Division of the Southern District of Illinois and assigned to Judge Michael J. Reagan. *See* 3:15-cv-452 (S.D. Ill.), Dkt. Nos. 1-2. *Bush* was reassigned to Judge Herndon for unknown reasons on April 24, but not served until May 12, days before this petition was filed. *See id.*, Dkt. No. 9. The Avelox® case pending before Judge Herndon (*Bullard*) was filed on January 13, 2015, was assigned to Judge J. Phil Gilbert in the Benton Division for more than five months, and was transferred to Judge Herndon on May 26, 2015—after this Motion was filed—despite issue having been joined months before. *See* 3:15-cv-38 (S.D. Ill.), Dkt. No. 23.

PROOF OF SERVICE

I hereby certify that, on June 10, 2015, a copy of the foregoing BRIEF OF DEFENDANTS JOHNSON & JOHNSON, et al., IN OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER was served by ECF and electronic mail on the following:

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