

IN RE LEVAQUIN® LITIGATION

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: MIDDLESEX COUNTY

CASE NO. 286

CIVIL ACTION

**REPORT AND RECOMMENDATION TO  
TERMINATE MASS TORT DESIGNATION  
AND CENTRALIZED MANAGEMENT  
PURSUANT TO DIRECTIVE #02-19 AND R.  
4:38A.**

**TO:** The Honorable Glenn A. Grant, J.A.D., Acting Administrative Director,

The purpose of this Report is to provide both an update and recommendation in regard to the In Re Levaquin Multi-County Litigation (“MCL”). As noted below, with the exception of three (3) remaining cases, all other matters in this MCL have been resolved.<sup>1</sup> It is therefore respectfully recommended that the centralized management of the In Re Levaquin litigation be terminated from the Middlesex County Vicinage and that this Court, independent of the MCL, continue to case manage and preside over the remaining three (3) cases through their conclusions.

On April 29, 2009, the Honorable Glenn A. Grant, J.A.D. released a Notice to the Bar indicating an application to the Supreme Court of New Jersey for designation of all litigation involving the antibiotic drug Levaquin as a mass tort and assignment for centralized management in Atlantic County. Comment on or objection to this application was invited, from which several comments were received. Following same, on June 16, 2009, the New Jersey Supreme Court entered an Order designating all New Jersey State Court actions arising from the use of Levaquin as a mass tort for centralized case management purposes in the Superior Court, Law Division, Atlantic County, assigned to the Honorable Carol E. Higbee.

By Order dated October 31, 2014 the New Jersey Supreme Court transferred all pending Levaquin litigation to Middlesex County, assigning same for management purposes to the

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<sup>1</sup> As will be discussed more fully below, one of the three remaining cases has reached a resolution through mediation, however as of the authoring of this report, same is pending finalization. Thus, the Court is including it in this Report as an active case.

Honorable Jessica R. Mayer. Upon Judge Mayer's appointment to the Appellate Division in June 2017, the New Jersey Supreme Court temporarily reassigned all non-asbestos multicounty litigation matters to the Honorable James F. Hyland, including the centralized management of Levaquin. On June 18, 2017, the New Jersey Supreme Court made the temporary reassignments to Judge Hyland permanent. Upon Judge Hyland's retirement, in January 2021, all mass tort/multi-county litigation ("MCL") matters in Middlesex County were reassigned to the Honorable Bruce J. Kaplan.

During a March 16, 2021 Case Management Conference, the Court informed counsel for the remaining cases of its intent to request termination of centralized management, and for the three (3) remaining cases to proceed as separate litigations. All counsel agreed that same was appropriate at this stage, and therefore raised no objections. With the Court having confirmed that only three (3) cases remain, this Report is being written to request that the In re Levaquin litigation now be decentralized.

#### **A. Background**

Levaquin, a product of Defendant Janssen Pharmaceuticals, Inc.<sup>2</sup> ("JPI"), is a broad-spectrum fluoroquinolone antibiotic first approved for use in the United States by the Food and Drug Administration ("FDA") in 1996. It is a primary choice for treatment of community-acquired pneumonia. The FDA has approved Levaquin to be prescribed for various indications for treatment, including: (1) nosocomial pneumonia and community-acquired pneumonia; (2) acute bacterial sinusitis; (3) acute bacterial exacerbation of chronic bronchitis; (4) complicated urinary tract infections; (5) skin and skin structure infections; (6) chronic bacterial prostatitis; (7) acute pyelonephritis; and (8) to treat inhalational anthrax post-exposure.

It was primarily alleged that use of Levaquin caused injury, namely tendinopathy and/or tendon rupture. In 2008 the FDA informed Defendants that its labeling was inadequate and in need of a Black Box warning. In its July 7, 2008 letter, the FDA stated that the Levaquin labeling "[did] not adequately warn healthcare providers and patients about these possible, rare serious adverse events. We consider this new analysis to be 'new safety information as defined in DFAAA.'" The letter went on to specify, along with other warning improvements, the need for a Black Box

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<sup>2</sup> JPI is wholly owned by Defendant Johnson & Johnson, which had no role in the development, testing, research, or marketing of Levaquin.

warning. Thereafter, in October 2008, the FDA, relying on a new analysis of data, mandated for all fluoroquinolones, including Levaquin, the addition of a boxed warning regarding tendon-related adverse events.

The 2008 black box warning started the consolidated New Jersey litigation before Judge Higbee as well as a federal Multi-District Litigation (“MDL”) in the District of Minnesota. The MDL was disbanded starting in 2015 with the regular remand of cases. As stated above, the New Jersey consolidated Levaquin litigation was transferred from Atlantic County to Middlesex County by order of the Supreme Court of New Jersey dated October 31, 2014.

**B. Current Status of the Litigation**

The Levaquin MCL currently contains three remaining active cases: Warnet (MID-L-9956-14), Utz (MID-L-9959-14), and Fischer (MID-L-9857-14), involve plaintiffs from different states who allege that use of Levaquin caused the above-mentioned injury, namely tendinopathy and/or tendon rupture. All three plaintiffs are represented by different counsel and the cases are at various stages of discovery.

On May 26, 2021 counsel informed the Court that the Warnet case reached a resolution through state mediation. However, as of the authoring of this Report, finalization of that agreement is pending. Thus, although the Court anticipates final resolution of that case in the near future, the Court includes it in the total of active cases remaining as of the authoring of this Report.

**C. Summary of Significant Events**

- **June 25, 2009:** First Case Management Order Entered;
- **September 28, 2010:** Case Management Order No. 11 entered, designating eight (8) cases to constitute a Bellwether trial pool;
- **Between 2008-2011:** There have been four trials involving five plaintiffs claiming an Achilles tendon rupture from their treatment with Levaquin before the 2008 Black Box warning, resulting in defense verdicts in three of four trials for four of five plaintiffs, including a complete defense verdict after a six-week trial before Judge Higbee in 2011. Following these trials, the overwhelming majority of federal and state court cases were settled or dismissed as improvidently filed. In New Jersey alone, approximately 1,000 cases were dismissed by the Court or voluntarily;
- **June 13, 2013:** In Hain, et al. v. Johnson & Johnson, et al., Judge Higbee ruled that the black box warning placed on the Levaquin package insert in 2008 is adequate as a matter

of law. Thereafter, Judge Higbee granted summary judgment in favor of Defendants in Johnson v. Johnson & Johnson, et al., ATL-L-1577-10 and Young v. Johnson & Johnson, et als. ATL-L-286-11, again holding that the black box warning is adequate as a matter of law. Following these decisions, hundreds of post-black box warning cases were voluntarily dismissed;

- **October 31, 2014:** New Jersey Supreme Court transferred all pending Levaquin cases to Middlesex County assigning same for management purposes to the Honorable Jessica R. Mayer;
- **June 18, 2017:** Judge Hyland's temporary mass tort/MCL assignments made permanent;
- **January 25, 2021:** New Jersey Supreme Court enters an Order reassigning the Levaquin MCL to Judge Kaplan, effective February 1, 2021;
- **March 16, 2021:** During a Case Management Conference on the three remaining cases, Judge Kaplan informed counsel of the Court's intent to seek termination of centralized management. All counsel were in agreement with that course of action and no objections were made. The three remaining cases have thereafter been case managed separately;
- **May 26, 2021:** The Warnet case reached an agreeable resolution through state mediation before mediator Kevin Gardner.

**D. Conclusion**

In light of the fact that only three (3) cases remain in in the centralized management of Levaquin, it is respectfully recommended that the centralized management of the In Re Levaquin Litigation be terminated.