IN RE ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE NO. 295 CIVIL ACTION **REPORT AND RECOMMENDATION TO TERMINATE 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 request that the centralized management of the In Re AlloDerm® litigation be terminated from the Middlesex County Vicinage, as there are no active cases remaining in the centralized management of AlloDerm.

On May 23, 2011, the Honorable Glenn A. Grant, J.A.D. released a Notice to the Bar indicating an application to the Supreme Court of New Jersey, which requested designation of all New Jersey state-court litigation involving the drug AlloDerm as a mass tort. On July 12, 2011, after considering the application and the comments received, the New Jersey Supreme Court determined not to designate the In Re AlloDerm litigation as a mass tort, but rather decided to assign it to the Middlesex Vicinage for centralized case management by Judge Jessica R. Mayer, who was a Superior Court Judge in Middlesex County at the time.

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, J.S.C., including the centralized management of In Re AlloDerm. On June 18, 2017, the New Jersey Supreme Court made the temporary reassignments to the Honorable James F. Hyland, J.S.C. 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, J.S.C.

Via letter dated March 15, 2021, counsel for LifeCell indicated that all counsel agreed that centralized management of the In Re AlloDerm litigation could be closed given that there were no

more pending cases in this litigation. After this information was brought to the Court's attention, the Court thoroughly reviewed the In Re AlloDerm docket and determined that there are in fact no more active cases remaining. As a result thereof this Report is being written to request that the In Re AlloDerm litigation now be decentralized.

A. Background

AlloDerm, a LifeCell product, is a human tissue product derived from processed human cadaver skin. LifeCell initially developed AlloDerm in the 1990s to treat skin burns. Over time, surgeons began using AlloDerm for a number of purposes, including rotator cuff surgery, oral surgery, breast reconstruction, and hernia repair. In the early 2000s, LifeCell began marketing AlloDerm specifically for hernia repair. AlloDerm is regulated by the Food and Drug Administration ("FDA") as a banked human tissue product, regulated separately from medical devices and prescription drugs.

Pursuant to the Supreme Court's Order dated July 12, 2011, although not designated as a mass tort, the AlloDerm litigation was assigned for centralized management purposes to Superior Court, Law Division, Middlesex County. Approximately 360 plaintiffs filed suit, initially alleging that AlloDerm was defective, and asserting a wide variety of product liability claims, including design and manufacturing defects, as well as failure-to-warn. Following a global stipulation of dismissal of all manufacturing defect claims, the plaintiffs pursued failure-to-warn and design defect claims under the New Jersey Products Liability Act ("NJPLA").

Plaintiffs generally alleged that LifeCell failed to properly warn and instruct plaintiffs' physicians of alleged increased risks of hernia recurrence as a result of using AlloDerm in the course of a ventral hernia repair. Regarding their design defect claims, plaintiffs generally alleged that AlloDerm was not safe for use in ventral hernia repairs due to the alleged existence of alternative designs that would have reduced the risk of injury.

B. Current Status of the Litigation

In late 2016 the parties agreed to mediation, from which a confidential global resolution was reached. A third party was used to allocate the net settlement proceeds, which over time were accepted by all remaining plaintiffs. The final event in this MCL was a Friendly Hearing held before Judge Hyland on April 11, 2019 to approve a minor plaintiff's settlement. This litigation has been closed ever since.

C. Summary of Significant Events

- **July 12, 2011:** Supreme Court of New Jersey designates all pending and future New Jersey state court actions seeking damages or other relief arising out of the use of AlloDerm Regenerative Tissue Matrix for centralized management in Superior Court, Law Division, Middlesex County for handling by Superior Court Judge Jessica R. Mayer;
- **July 21, 2011**: Initial Case Management Order entered;
- **October 18, 2011**: Order entered governing fact discovery in all actions that were filed or transferred to the Superior Court of New Jersey, Law Division, Middlesex County;
- **January 16, 2014**: Case Management Order 4 established bellwether criteria and set forth a bellwether procedure as well as established "Trial Pool" criteria and permitted case-specific discovery to commence on "Trial Pool" cases;
- **January 15, 2015**: Case Management Order 6 selected four (4) Bellwether Cases to proceed with additional plaintiff-specific discovery to prepare each of the four (4) cases for trial;
- **August 14, 2015**: Judge Mayer granted summary judgment in favor of LifeCell on all four (4) Bellwether plaintiff's design-defect claims. As to the failure-to-warn, Judge Mayer found that each was a fact-sensitive matter, ultimately dismissing two (2) of the four (4) Bellwether plaintiff's claims in their entirety;
- **April 7, 2017**: Roughly twenty-eight (28) plaintiffs were voluntarily dismissed with prejudice;
- **June 18, 2017:** Supreme Court of New Jersey permanently designated Honorable James F. Hyland, J.S.C. as Middlesex County's MCL/Mass Tort Judge;
- **Late 2016**: Parties agreed to mediate, and a global confidential resolution was reached before the Honorable Mark B. Epstein, J.S.C. (Ret.).
- Thereafter, the allocated settlement amounts were accepted by the remaining plaintiffs and were ultimately paid;
- **April 11, 2019**: The final event in the In Re AlloDerm MCL was a Friendly Hearing before Judge Hyland to approve a minor plaintiff's settlement, bringing the remaining cases in this MCL to zero (0).

D. Conclusion

In light of the fact that there are no active cases remaining in the centralized management of AlloDerm, it is respectfully recommended that the centralized management of the In Re AlloDerm Litigation be terminated.