HONORABLE RACHELLE L. HARZ, J.S.C.
Superior Court of New Jersey, Law Division
Bergen County Justice Center
10 Main Street, Chambers 359
Hackensack, New Jersey 07601
(201) 221-0700

Prepared by the court

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCT LIABILITY LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

MASTER CASE NO. BER-L-5064-20

CASE NO. 634

ORDER

THIS MATTER having been opened to this Court by Defendants Allergan, Inc. and Allergan USA, Inc. ("Allergan"), by and through their counsel, seeking an Order granting Allergan's Motion to Dismiss Plaintiffs' Master Long Form Complaint on Preemption Grounds (the "Motion") pursuant to R. 4:6-2 predicated on 21 U.S.C. § 360(k) and 21 U.S.C. § 337(a), and therefore this Court limiting its rulings to issues of federal preemption only, and this Court having considered all submissions, and having heard oral arguments of counsel on March 12, 2021, and for good cause shown;

IT IS on this 4th day of May 2021,

ORDERED that Allergan's Motion is **GRANTED IN PART and DENIED IN PART**; and it is further

ORDERED that Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn based on Allergan's alleged failure to update the label of devices approved through the PMA process, other than Allergan's tissue expanders and implants sold before the 2000 PMA, are **DISMISSED** with prejudice; and it is further

ORDERED that, with respect to all devices, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn based on Allergan's alleged failure to conduct post-approval clinical studies are **DISMISSED** with prejudice; and it is further

ORDERED that, with respect to the first segment of BIOCELL implants approved in May 2000, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are **DISMISSED** with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the May 2000 approval date; and it is further

ORDERED that, with respect to the second segment of BIOCELL implants approved in November 2006, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are **DISMISSED** with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the November 2006 approval date; and it is further

ORDERED that, with respect to the third segment of BIOCELL implants approved in February 2013, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are **DISMISSED** with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the February 2013 approval date; and it is further

ORDERED that Plaintiffs' claims for strict liability (Count IV) and negligent (Count V) design defect asserted against the investigational devices used in approved clinical trials and devices approved through the PMA process are **DISMISSED** with prejudice; and it is further

ORDERED that Allergan's Motion, with respect to all devices, is **DENIED** as to Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn claims based

on deliberate nondisclosure to FDA of after-acquired knowledge of harmful effects or other grounds that overcome the rebuttable presumption; and it is further

ORDERED that Allergan's Motion, with respect to all devices, is **DENIED** as to Plaintiffs' claims for strict liability (Count I) and negligent (Count V) manufacturing defect; and it is further

ORDERED that Allergan's Motion is **DENIED** as to Plaintiffs' claims for strict liability (Count IV) and negligent (Count V) design defect asserted against Allergan's tissue expanders and implants sold before the 2000 PMA; and it is further

ORDERED that Allergan's Motion, with respect to all devices, is **DENIED** as to Plaintiffs' claims for breach of express warranty (Count III); and it is further

ORDERED that Allergan's Motion, with respect to all devices, is **DENIED** as to Plaintiffs' claims for consumer fraud (Count VI); and it is further

ORDERED that Plaintiffs' claims for wrongful death (Count VII) and loss of consortium (Count VIII) remain as they have not been challenged in this preemption motion and these claims are derivative in nature.

A copy of this Order is served upon all counsel via eCourts.

Date: May 4, 2021

HON. RACHELLE L. HARZ, J.S.C.