#0304
08.07.15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w, Plaintiffs, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-5972-11 CM
PATRICIA JULIEN, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-507-12 CM
THOMAS DUTCHER, Plaintiff, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-1469-12 CM

DEBBIE FOSTER and DAVID FOSTER, w/h, Plaintiffs, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-6841-12 CM Civil Actions **ORDER**

FILED
AUG 14 2015
JUDGE JESSICA R. MAYER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring all bellwether plaintiffs from introducing any argument or evidence at trial regarding LifeCell Corporation's compliance or lack thereof with the regulations of the Food and Drug Administration, and the Court having considered all papers submitted by the parties, and for good cause and the reasons ~~stated on the record by the Court~~ in the attached memorandum of decision,

It is on this the 14th day of August, 2015,

ORDERED that defendant's motion is hereby granted*; and it is further

ORDERED that all bellwether plaintiffs are hereby barred from introducing any argument or evidence at trial of LifeCell Corporation's compliance or lack thereof with the regulations of the Food and Drug Administration; and it is further

ORDERED that a copy of this Order be ~~served on~~ posted counsel of record within 7 days hereof.

Hon. Jessica R. Mayer, J.S.C.

* For the reasons set forth in court's memorandum of decision dated August 14, 2015.

OPPOSED

0305
08-07-15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-5972-11 CM

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-507-12 CM

THOMAS DUTCHER,

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v.

LIFECELL CORPORATION,

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SUPERIOR COURT OF NEW JERSEY
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Hon. Jessica R. Mayer, J.S.C.

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

OPPOSED

#0306
#C8-7-15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-5972-11 CM

PATRICIA JULIEN,

Plaintiff,

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LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-507-12 CM

THOMAS DUTCHER,

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Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
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ORDERED that a copy of this Order be ~~served~~ posted online & on all counsel of record within 7 days hereof.

Hon. Jessica R. Mayer, J.S.C.

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

OPPOSED

#0307
08-07-15

DEBBIE FOSTER and DAVID FOSTER, w/h, Plaintiffs, v. LIFECELL CORPORATION, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY Docket No. MID-L-6841-12 CM Civil Actions **ORDER**

FILED
AUG 14 2015
JUDGE JESSICA R MAYER

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ORDERED that all bellwether plaintiffs are hereby barred from introducing any argument or evidence at trial of LifeCell Corporation's compliance or lack thereof with the regulations of the Food and Drug Administration; and it is further

ORDERED that a copy of this Order be ~~served~~ posted date for on all counsel of record within 1 days hereof.

Hon. Jessica R. Mayer, J.S.C.

* For the reasons set forth in the court's memorandum of decision dated August 14, 2015.

OPPOSED

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-5972-11 CM

PATRICIA JULIEN,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-507-12 CM

THOMAS DUTCHER,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-1469-12 CM

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-64

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion *In Limine* to Exclude Evidence and Testimony

In Re: AlloDerm® Litigation, Case Code 295

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

Debbie Foster and David Foster v. LifeCell Corporation

Docket No. MID-L-6841-12 CM

Patricia Julien v. LifeCell Corporation

Docket No. MID-L-507-12 CM

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Dated August 14, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to exclude all evidence and testimony relating to LifeCell's compliance (or lack thereof) with the regulations of the United States Food and Drug Administration ("FDA"). Defendant also moves to bar Plaintiffs'

experts, Dr. Roger Huckfeldt, Dr. Gregory Dumanian, and Dr. Kristen Billiar from testifying regarding FDA regulations.[1]

I. BACKGROUND

AlloDerm® is a human tissue product derived from processed human cadaver skin.[2] LifeCell initially developed AlloDerm® in the 1990s to treat skin burns.[3] Over time, surgeons began using AlloDerm® for a number of purposes, including rotator cuff surgery, oral surgery, breast reconstruction, and hernia repair.[4] In 2002, LifeCell began marketing AlloDerm® specifically for hernia repair.[5] AlloDerm® is generally regulated by the FDA as a banked human tissue product (known as a "human cells, tissues, and cellular and tissue-based product" or "HCT/P").[6] HCT/Ps are regulated separately from medical devices and prescription drugs. See 21 C.F.R. § 1271 et seq. The FDA defines HCT/Ps as products "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d). HCT/Ps that are "minimally manipulated" and "intended for homologous use only" are not subject to any other FDA regulations. 21 C.F.R. § 1271.10(a)(1)-(2). "Homologous use" is defined as "the repair, reconstruction, replacement, or supplementation

[1] Defendant filed two separate motions relating to FDA testimony: (1) a motion to bar all testimony as to FDA regulations and compliance, and (2) a motion to bar specific Plaintiffs' experts from testifying as to FDA regulations and to bar Dr. Roger Huckfeldt from testifying regarding elastin. This memorandum of decision deals with the FDA-related aspects of both motions. All citations in this memorandum referring to the first motion will be referred to as "Def.'s Br." All citations to the second motion will be referred to as "Def.'s Elastin Br." The court's disposition on the matter of Dr. Huckfeldt's testimony on elastin is set forth in a separate Order and Memorandum of Decision, dated August 14, 2015. The court notes that neither of these motions is a dispositive motion. The court deems a motion to bar portions of an expert's testimony, or testimony as to one topic, to be an *in limine* motion. In accordance with Paragraph 13 of Case Management Order No. 6, only dispositive motions and motions related to the admissibility of expert testimony were to be filed and served at this time. Motions *in limine* limited to the trial selected case are due on October 16, 2015 in accordance with Paragraph 17 of Case Management Order No. 6. In the future, the court will not address motions that are filed contrary to the timeframes specified in the court's case management orders.

[2] Def.'s Br. 2.

[3] Ibid.

[4] Ibid.

[5] Def.'s Br. 5.

[6] Def.'s Br. 2.

of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c). HCT/Ps which are more than minimally manipulated, or are intended for non-homologous use, may be subject to additional regulation as medical devices under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. See 21 C.F.R. § 1271.20.

A manufacturer/distributor of HCT/Ps must register with the FDA as a "tissue establishment" and follow certain guidelines for designation of a product as an HCT/P. 21 C.F.R. §§ 1271.10; 1271.21-22. The FDA imposes labeling requirements for HCT/Ps. See 21 C.F.R. § 1271.370. HCT/P labeling must include, inter alia, "[i]nstructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases," and "[o]ther warnings, where appropriate." 21 C.F.R. § 1271.370(c)(3)-(4). Unlike prescription drugs, HCT/P labels do not have to be individually pre-approved by the FDA before distribution.

II. LEGAL STANDARDS

A. SUMMARY JUDGMENT

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof . . . ." R. 4:46-1. Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to judgment as a matter of law." R. 4:46-2(c). In determining whether there are disputed issues of material fact, the court must "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co., 142 N.J. 520, 540 (1995). It is not the court's function "to weigh

the evidence and determine the truth of the matter but [rather] to determine whether there is a genuine issue for trial." Id.

B. ADMISSIBILITY OF EVIDENCE

Unless subject to specific exclusions, "all relevant evidence is admissible." N.J.R.E. 402. Under the New Jersey Rules of Evidence, "'[r]elevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. Evidence is considered relevant if there is a logical connection between the proffered evidence and what the party seeks to prove. See Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (citing State v. Hutchins, 241 N.J. Super. 353, 358, (App. Div. 1990). Evidence which is relevant to the action may nonetheless be excluded "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury . . . ." N.J.R.E. 403.

III. THE PARTIES' ARGUMENTS

Defendant moves to preclude Plaintiffs from introducing evidence at trial that: 1) AlloDerm® should be regulated by the FDA as a medical device, not a human tissue product, when used for hernia repair; 2) LifeCell misled the FDA regarding the use of AlloDerm® in hernia repair; and 3) LifeCell improperly manipulated the regulatory process to avoid additional regulatory requirements for medical devices under the FDCA.[7] Defendant also moves to preclude Plaintiffs' experts, Drs. Huckfeldt, Dumanian and Billiar, from testifying about FDA regulations arguing these experts lack the required expertise pursuant to N.J.R.E. 702.[8] Defendant sets forth three arguments in support of its motions. First, there is no factual basis for the assertion that LifeCell misled or circumvented the FDA. Second, a jury should not be permitted to second-guess

[7] Def.'s Br. 1.
[8] Def.'s Elastin Br. 2-10.

the regulatory classification decisions of the FDA. And, third, allowing testimony as to LifeCell's alleged fraud on the FDA and the alternate regulatory status of medical devices would only serve to confuse, mislead, and unduly prejudice the jury.

For support, Defendant cites the history of the written communications between LifeCell and the FDA regarding the classification of AlloDerm® as an HCT/P when used for burn wounds, as well as subsequent alternative uses that underwent FDA scrutiny and classification.[9] Defendant argues that, in the course of these written communications, LifeCell notified the FDA that AlloDerm®'s was being used for hernia repair. The court notes, and the parties do not dispute, that the FDA has not issued any warning letters or requests for information to LifeCell regarding AlloDerm®'s use for hernia repair. Defendant claims its inclusion in its letters to the FDA of AlloDerm®'s use for hernia repair precludes Plaintiffs' argument that LifeCell misled or defrauded the FDA. LifeCell also argues the lack of any agency inquiry means the FDA classifies AlloDerm® as an HCT/P when used for hernia repair.

Plaintiffs counter Defendant's motions by raising three arguments. First, AlloDerm®'s status as a human tissue product when used for hernia repair has never been specifically evaluated by the FDA and, as such, a jury would not infringe on agency decision-making by determining the proper classification of AlloDerm®. Second, LifeCell's compliance or noncompliance with "industry standards" is relevant to a failure-to-warn claim.[10] Third, LifeCell's compliance or noncompliance with FDA regulations is relevant in Plaintiffs' cross-examination of the testimony proffered by Defendant's proposed FDA expert, Dr. David Feigal.

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[9] Def.'s Br. 4-6.

[10] For reasons discussed below, the court need not address Plaintiffs' opposition to the expertise of their expert witnesses with regard to FDA regulations.

Plaintiffs argue that Defendant's communications with the FDA, which admittedly include one-off comments about AlloDerm®'s use for hernia repair, do not constitute a formal approval process specifically asking the FDA to evaluate hernia repair as a "homologous use." Accordingly, Plaintiffs claim there has never been an official FDA determination on the classification of AlloDerm® for hernia repair.[11] Thus, Plaintiffs conclude that the issue of AlloDerm®'s regulatory classification should be determined by a jury due to the alleged classification ambiguity. As to the relevance of regulatory compliance, Plaintiffs provide a lengthy explanation of the different requirements between HCT/Ps and medical devices, and argue that such differences are "directly relevant to Plaintiffs' claims under the New Jersey Product Liability Act," because "[m]ere compliance with an FDA . . . regulation or order, does not mean that state tort law becomes irrelevant." [12] Finally, Plaintiffs argue that Defendant's proffering of Dr. Feigal's testimony on AlloDerm®'s compliance with HCT/P regulations "opens the door" for cross-examination of the witness on FDA compliance.[13]

Defendant, in its reply brief, raises one argument in addition to the arguments set forth in its moving briefs. Defendant asserts it is only proffering Dr. Feigal's FDA classification testimony as a rebuttal to the anticipated claims by Plaintiffs on that topic. Defendant concedes that if the court grants the motions barring testimony on FDA classification and compliance, Dr. Feigal's testimony on these subjects is moot. Similarly, Plaintiffs' claimed need to cross-examine Dr. Feigal on these topics would be equally moot.

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[11] Plaintiffs' Brief in Opposition to Defendant's FDA motion *in limine* ("Pls.' Opp.") 3-4.
[12] Pls.' Opp. 7.
[13] Pls.' Opp. 4-6.

IV. ANALYSIS

A. THE REGULATORY CLASSIFICATION OF ALLODERM

The primary factual dispute between the parties in this motion is whether AlloDerm® has been "officially" determined by the FDA to be an HCT/P when used for hernia repair. If so, Defendant argues that judicial deference for agency decision-making precludes the jury from considering the matter. See, e.g., Canavera v. Twp. of Edison, 271 N.J. Super. 125, 129 (App. Div. 1994) ("Historically, our courts have accorded substantial deference to regulatory determinations made by administrative agencies charged with the responsibility of implementing legislative policy.") If not, Plaintiff argues that a jury is free to decide whether AlloDerm® should be classified as a medical device, thereby subjecting it to FDCA requirements for testing, approval, and labeling.

Defendant introduced AlloDerm® for treatment of burn victims in 1994.[14] In 1995, the FDA issued a letter to the president of LifeCell stating the FDA believed AlloDerm® was a medical device, and therefore must comply with the appropriate FDA regulations.[15] This began an information exchange between LifeCell and the FDA, over the course of a year, in which the FDA was provided with information on AlloDerm® for the purpose of confirming its classification as a HCT/P. After this exchange of information between LifeCell and the FDA, on September 17, 1996, the FDA issued a letter determining that:

> [a]fter considering the information you have submitted, and consulting with appropriate officials in [the Center for Drug Evaluation and Research] and [the Center for Biologics Evaluation and Research] . . . Alloderm intended for use for repair or replacement of damaged or inadequate integumental tissue, including the gingival dermis, is banked human tissue . . . .
>
> [FDA Letter Dated Sept. 17, 1996, Def.'s Br. Ex. D.]

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[14] Def.'s Br. 4.

[15] FDA Letter Dated Nov. 9, 1995, Def.'s Br. Ex. A.

The letter further noted that "the regulatory status of the product when it is promoted for other uses – e.g., as a void filler for soft tissue, for cosmetic augmentation, or as a wound-healing agent – would need to be determined by the Agency on a case by case basis."[16]

Thereafter, there were several occasions when the FDA communicated with LifeCell regarding new uses for AlloDerm® and the appropriate classification for such new uses. The continued dialogue between LifeCell and the FDA included communications in 1997 regarding AlloDerm®'s use as a dura matter replacement,[17] in 2001 regarding AlloDerm®'s use as a bladder sling,[18] and in 2003 regarding AlloDerm®'s use as a rotator cuff reinforcement.[19] The FDA determined dura matter replacement to be a non-homologous use and required LifeCell to comply with the FDCA for such a use, but approved both the pelvic sling and rotator cuff uses as homologous, falling within HCT/P regulations. Defendant's 2001 and 2003 letters to the FDA in these matters stated the following: "AlloDerm for implantation is also used to provide functional connective tissue support such as in hernia repair, incisional reinforcement, and facial suspension."[20] To date, the FDA has not issued any warning letters to Defendant regarding AlloDerm®'s use in hernia repair as a non-homologous use.

The court notes the FDA's inaction in this regard may be rationally viewed as either tacit approval, or a lack of explicit approval. Plaintiffs argue that any ambiguity in AlloDerm®'s regulatory classification is a factual dispute to be determined by the jury.[21] Plaintiffs overlook one critical fact: while it may be unclear whether AlloDerm® is "officially" sanctioned for use in

[16] FDA Letter Dated Sept. 17, 1996, Def.'s Br. Ex. D.
[17] Pls.' Opp. Ex. A.
[18] Def.'s Br. Ex. F.
[19] Def.'s Br. Ex. G.
[20] Def.'s Br. Exs. G, H.
[21] Pls.' Opp. 2-3.

hernia repair under the HCT/P regulations, it is undisputed that the FDA has not classified AlloDerm®'s use in hernia repair as a medical device, and has never required LifeCell to comply with the FDCA medical device regulations for such use. It is equally clear that the FDA has not resisted taking action to compel a manufacturer's compliance with FDA medical device regulations, as it did when LifeCell presented AlloDerm® for use as a dura matter substitute.[22]

It is not for a jury to second-guess the actions or inactions of the FDA in rendering complex decisions about product classification. See, e.g., In re Fleming, 290 N.J. Super. 195, 201 (App. Div. 1996) ("We are bound also to defer to [an] agency's expertise and discretion in administering a subject matter area committed to its supervision . . . ."); Canavera v. Twp. of Edison, 271 N.J. Super. 125, 129 (App. Div. 1994). Moreover, asking a layperson to make a decision that ordinarily is made by the FDA with the assistance of dedicated and experienced FDA medical experts, would only serve to confuse the jury and obfuscate the real issues in these cases – the adequacy of AlloDerm®'s warnings, medical and legal causation, and the extent of Plaintiffs' alleged harm. As such, any testimony for the purpose of establishing that AlloDerm® should be classified as a medical device, or what regulations would apply if AlloDerm® were classified as a medical device, is precluded under N.J.R.E. 403.

B. NON-COMPLIANCE WITH FDA REGULATIONS

Plaintiffs assert that testimony on FDA regulations is relevant because "compliance or noncompliance with industry standards . . . is relevant to a failure-to-warn claim."[23] Plaintiffs cite to Feldman v. Lederle Laboratories, 125 N.J. 117 (1991), for the proposition that "[m]ere compliance with an FDA . . . regulation or order, does not mean that state tort law becomes

[22] Pls.' Opp. Ex. A.
[23] Pls.' Opp. 6.

irrelevant."[24] Feldman dealt with the issue of conflict preemption as between the FDCA and traditional state tort law claims. The portion of Feldman cited by the Plaintiffs simply notes that compliance with FDA regulations will not automatically insulate a manufacturer from all liability. This concept is well established, as the New Jersey Products Liability Act ("NJPLA") itself only provides a rebuttable presumption of adequacy (rather than an absolute defense) when the manufacturer's warnings have been pre-approved by the FDA. N.J.S.A. § 2A:58C-4 ("If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the [FDCA] or the [Public Health Service Act], a rebuttable presumption shall arise that the warning or instruction is adequate.").

In general, claims of manufacturer fraud on the FDA are preempted. See Cornett v. Johnson & Johnson, 211 N.J. 362, 389 (2012) (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)). An exception to this rule applies where the manufacturer relies on the NJPLA's presumption of adequacy, allowing the plaintiff to present evidence of fraud to rebut the presumption. See, e.g. Bailey v. Wyeth, Inc., 424 N.J. Super. 278, 312 (Law Div. 2008), aff'd sub nom. DeBoard v. Wyeth, Inc., 422 N.J. Super. 360, 361 (App. Div. 2011), certif. denied, 211 N.J. 274 (2012) ("[T]he presumption of an adequate warning based on compliance with FDA regulations will be deemed rebutted only if the following proof is presented: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ('Perez/Rowe exception') or (ii) manipulation of the post-market regulatory process ('McDarby exception')."). Defendant has explicitly declined to rely on the statutory presumption.[25] Without the need to rebut

[24] Pls.' Opp. 7.

[25] Def.'s Reply Br. 13, n.3 ("LifeCell is not seeking to invoke any presumption as to the adequacy of the Alloderm labeling, as it was neither subject to FDA approval or [sic] submitted to the FDA for approval . . . .).

a presumption of adequacy, any testimony alleging fraud on the FDA is not only irrelevant, it is also impermissibly prejudicial and must be precluded. See State v. Thompson, 59 N.J. 396, 421 (1971) (evidence is unduly prejudicial when its probative value is "so significantly outweighed by [its] inherently inflammatory potential as to have a probable capacity to divert the minds of the jurors from a reasonable and fair evaluation.").[26]

C. PLAINTIFFS' EXPERTS

Because the court is precluding all testimony on FDA classification and LifeCell's alleged non-compliance with FDA regulations, Defendant's motion to bar Plaintiffs' experts, Drs. Huckfeldt, Dumanian and Billiar, from opining on such issues is moot.

V. CONCLUSION

For the reasons stated above, Defendants' motion to bar all testimony that AlloDerm® should be classified as a medical device, what regulations would apply if AlloDerm® were a medical device, and that LifeCell violated FDA regulations is **GRANTED**.

Defendant's motion to bar the FDA-related testimony of Drs. Huckfeldt, Dumanian and Billiar is **DENIED AS MOOT**.

9/14/15

JESSICA R. MAYER, J.S.C.

[26] This court precluded other forms of "bad actor" evidence sought to be admitted by Plaintiffs in its Order and Memorandum of Decision on Defendant's In Limine Motion to Bar Corporate State of Mind Testimony, dated August 14, 2015.