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SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: ALICE SCHLESINGER Justice

PART 16

Index Number : 800047/2011
PITKOW, LISA
vs.
LAUTIN, EVERETT M.
SEQUENCE NUMBER : 005
SUMMARY JUDGMENT

INDEX NO. _____
MOTION DATE _____
MOTION SEQ. NO. _____

The following papers, numbered 1 to _____, were read on this motion to/for _____

Notice of Motion/Order to Show Cause — Affidavits — Exhibits _____ No(s). _____

Answering Affidavits — Exhibits _____ No(s). _____

Replying Affidavits _____ No(s). _____

Upon the foregoing papers, it is ordered that this motion is granted in accordance with the accompanying memorandum decision.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

RECEIVED
DEC -8 2014
GENERAL CLERK'S OFFICE
NYS SUPREME COURT - CIVIL

FILED
DEC 09 2014
COUNTY CLERK'S OFFICE
NEW YORK

DEC 08 2014

Dated: December 2, 2014

ALICE SCHLESINGER, J.S.C.

1. CHECK ONE: ..... ☐ CASE DISPOSED ☒ NON-FINAL DISPOSITION

2. CHECK AS APPROPRIATE: .....MOTION IS: ☒ GRANTED ☐ DENIED ☒ GRANTED IN PART ☐ OTHER

3. CHECK IF APPROPRIATE: ..... ☐ SETTLE ORDER ☐ SUBMIT ORDER

☐ DO NOT POST ☐ FIDUCIARY APPOINTMENT ☐ REFERENCE

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----------X

LISA PITKOW,

Plaintiff,

-against-

EVERETT M. LAUTIN, M.D., individually, SUZANNE M. LEVINE, D.P.M., individually, EVERETT M. LAUTIN, M.D. and SUZANNE M. LEVINE, D.P.M. d/b/a INSTITUTE BEAUTE, AVENTIS PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC,

Defendants.

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Index No. 800047/11
Motion Seq. No. 005

FILED
DEC 09 2014
COUNTY CLERK'S OFFICE
NEW YORK

SCHLESINGER, J.:

Plaintiff Lisa Pitkow commenced this action in February 2011 in connection with cosmetic injections commonly known as "Sculptra" that she allegedly received from the defendants Everett M. Lautin, M.D., and Suzanne M. Levine, D.P.M., at their office Institute Beaute. The product Sculptra was manufactured by defendants Aventis Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC ("the Sculptra Defendants"). Plaintiff asserts claims in this action against the individual doctors Lautin and Levine and their Institute for medical malpractice and for lack of informed consent, and against the Sculptra Defendants for negligence, strict products liability, breach of express warranty, and breach of implied warranty. (Second Amended Verified Complaint, Exh A to Motion by the Sculptra Defendants[1]).

Before the Court at this time is a motion for summary judgment by the Sculptra Defendants pursuant to CPLR § 3212 on the ground that the premarket approval of Sculptra by the federal Food and Drug Administration (FDA) preempts the state claims

[1] All Exhibits cited hereafter are appended to the Motion, unless otherwise noted.

asserted here against the Sculptra Defendants. Because it appeared at oral argument that prevailing case law by the United States Supreme Court compelled the granting of the motion, the Court gave all counsel an opportunity to submit additional papers further discussing the cases. Those papers have been submitted, and the motion is ripe for a determination. The defendant doctors did not submit any papers in connection with this motion, as the issues raised have no bearing on the claims against them.

Background Facts

Plaintiff Lisa Pitkow was a patient at Institute Beaute, a podiatry clinic and medical spa allegedly owned by the defendant doctors Lautin and Levine. (Complaint, Exh A, ¶ 4, citing http://institutebeaute.com). Ms. Pitkow sought treatment for aesthetic purposes, and she visited the doctors various times between 2007 and 2009. (Verified Bill of Particulars, Exh D, ¶3). It appears that on at least two occasions in 2008, Ms. Pitkow received facial injections of a product known as "Sculptra" from Dr. Lautin at Institute Beaute. (See Plaintiff's Bill of Particulars, Exh D, ¶10, and March 22, 2012 decision of this Court determining the motion by Dr. Lautin to dismiss).

"Sculptra" is an injectable poly-L-lactic acid manufactured, distributed, and sold by defendants Aventis Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC. Sculptra was approved by the Food and Drug Administration (FDA) as a "medical device" via the Premarket Approval (PMA) process on August 3, 2004. (FDA approval letter, Exh G).

In its approval letter, the FDA indicated that Sculptra was "intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) ***in people with human immunodeficiency virus [HIV].***" (Exh G)(emphasis added). Plaintiff's counsel in his opposition papers (Exh A) has submitted an Affirmation from Amy Newburger,

M.D., a member of the General and Plastic Surgery Devices Panel of the FDA that held proceedings on March 25, 2004 as part of the premarket approval process for Sculptra. Dr. Newburger emphatically asserts there that the Sculptra Defendants expressly represented to the FDA at that time that Sculptra was intended to be used only to correct facial fat loss in HIV patients, and the transcript of the proceedings suggests that the intended limited use was a significant factor in the Panel's decision to recommend approval in 2004. (Exh B to Aff in Opp at 293).[2]

As stated above, the plaintiff here did not suffer from HIV. Rather, she suffered from pre-existing Multiple Sclerosis, and she contends that she advised defendant Dr. Lautin of that fact before she received the Sculptra injection. (Complaint, ¶ 16-17). Plaintiff further alleges that, after receiving the Sculptra injections, she developed facial bumps or granuloma, began experiencing aggravation of her pre-existing MS, and developed autoimmune consequences and the reawakening of her latent thyroid condition. (Bill of Particulars, ¶ 18).

Plaintiff then commenced this suit, asserting claims against the Sculptra Defendants sounding in negligence, strict products liability, and breach of express and implied warranties in connection with the design, testing, manufacturing, labeling and distribution of Sculptra. Specifically, plaintiff argues, among other things, that defendants negligently and recklessly encouraged the "off-label" use of Sculptra in non-HIV patients and failed to warn that its use was contraindicated in patients like Ms.

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[2] A separate product known as "Sculptra Aesthetic" was approved by the FDA on July 28, 2009, about five years after Sculptra was approved (FDA Letter, Exh H). The FDA granted premarket approval to "Sculptra Aesthetic" noting that it was "indicated for use in ***immune-competent people*** as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles..." (emphasis added).

Pitkow who suffer from MS. (Bill of Particulars, ¶ 31). The Sculptra Defendants seek dismissal of those claims in the instant motion, arguing that the state law claims are barred by federal preemption.

Statutory Background

The Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 USC § 360c *et seq.*, provide for heavy regulation of medical devices. As explained by the Supreme Court in *Riegel v Medtronic, Inc.*, 552 U.S. 312, 316-17 (2008), the FDCA had long before that time regulated new drugs entering the market and had left the regulation of medical devices to the States. However, as more and more complex medical devices entered the field in the 1960's and 1970's, with some such as the Dalkon Shield intrauterine device causing serious injury, Congress stepped in and passed the MDA, which "swept back some state obligations and imposed a regime of detailed federal oversight." 522 U.S. at 317.

As part of that new sweeping federal oversight for medical devices, Congress included in the MDA an express preemption provision §360k(a), which states that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The purpose behind the preemption provision was the legislature's desire to create uniformity in order to encourage research and development and prevent

innovations in device technology from being "stifled by unnecessary restrictions." H.R. Rep. No. 94-853 at 12, 45 (1976). Also, as the Supreme Court explained in *Riegel* (at 325), the idea of the preemption legislation was to create a balance between safety versus effectiveness and individual protections versus the public good. Thus, the pre-emption legislation avoids situations where, for example, one State's tort law might require a device to be safer, but thereby less effective, than the model approved by the FDA so as to protect its own citizens from injury without necessarily recognizing the loss to the public as a whole of the decreased effectiveness, whereas another State may do the opposite, creating a quandary for the manufacturer seeking to design a device with broad appeal and application. Thus, the federal law is the final word on the safety and effectiveness of FDA-approved medical devices, and is for the most part all-inclusive with respect to those issues.

To carry out its system of regulation, the MDA classifies medical devices into three groups, with different levels of oversight applicable to each classification. Class I devices are by definition low-risk devices such as elastic bandages and examination gloves that are not life-supporting or life-sustaining. Because these devices do not present a potential unreasonable risk of illness of injury, they are subject only to general controls such as labeling requirements. *Riegel,* 552 U.S. at 316-17, citing 21 USC 360c(a)(1)(A). Class II devices, such as powered wheelchairs and surgical drapes, pose a greater risk of harm than Class I and are thus subject to "special controls" such as performance standards and post-market surveillance measures. *Id.,* citing 21 USC 360c(a)(1)(B).

The devices receiving the most federal oversight are Class III devices, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. A device is assigned to Class III if it cannot be established that a less stringent classification would provide a reasonable assurance of safety and effectiveness, and the device either is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury." *Id.*, citing 21 USC 360c(a)(1)(C)(iii). Although no specific citation could be found, the Sculptra Defendants state throughout their memoranda of law that the FDA has classified Sculptra as a Class III medical device (see, e.g., Reply Memorandum at p 2).

Class III medical devices enter the market through premarket approval by the FDA. *Riegel*, 552 US at 317. However, there are two significant exceptions to the PMA requirement: "grandfathering," where the FDA approved certain devices that were already on the market before the MDA was passed in 1976; and the "§ 510(k) process," where a device is found to be "substantially equivalent" to another device already on the market. *Id.*; *see also, Medtronic, Inc. v Lohr*, 518 US 470, 477-78 (1996). Sculptra did not fall under either exception and was required to undergo the PMA process.

The PMA process is "rigorous," including reports and investigations of a device's safety and effectiveness, a "full statement" of the device's components, a description of the methods, facilities, and controls used in the manufacturing, processing, packing and installation of the device, samples of the device, and proposed labeling. *Riegel*, 552 US at 317-18, citing *Lohr*, 518 US at 477. Each application for PMA requires an average of

1,200 hours of review by the FDA, whereby the agency weighs any probable benefit to consumers against the probable risks of the device. *Id.* at 318. The FDA may then grant or deny premarket approval, or condition approval on adherence to certain performance standards or other restrictions. *Id.* at 319. The manufacturer of a device that has entered the market through the PMA process is then forbidden from making any modifications that would affect the safety or effectiveness of the device without first receiving approval from the FDA as to those modifications. *Id.*

Discussion

The Sculptra Defendants argue here that the approval of "Sculptra" by the FDA through the premarket approval process preempts plaintiff's claims. Relying in large part on *Riegel v Medtronic*, 552 US 312 (2008), defendants assert that all of plaintiff's claims challenging the safety or effectiveness of Sculptra, or which require a finding that Sculptra should have been designed, manufactured, tested or labeled differently from the manner approved by the FDA, are barred by the Medical Device Amendments discussed above.

Riegel is directly applicable to the case at bar. The plaintiff in *Riegel* alleged that he suffered severe and permanent injuries from a medical device known as an Evergreen Balloon Catheter, used during his coronary angioplasty. The manufacturer there had warned that the device was contraindicated for use in patients with diffuse or calcified stenosis and that it should not be inflated beyond eight atmospheres. *Id.* at 320. Although Charles Riegel reportedly suffered from a "diffusely diseased and heavily calcified" coronary artery, his doctor used the device on him and inflated it to ten atmospheres, which purportedly caused the catheter to rupture. *Id.* Riegel then sued,

alleging that Medtronic's device "was designed, labeled, and manufactured in a manner that violated New York common law." *Id.*

The *Riegel* court noted that the Evergreen Balloon Catheter was a Class III medical device that had received FDA premarket approval in 1994, two years before Mr. Riegel's surgery. *Id.* at 320. To determine if the claims were preempted by federal law pursuant to 21 USC §360k(a), the court considered whether the plaintiff's common law claims were "based upon ***New York requirements*** with respect to the device that are 'different from, or in addition to,' the federal ones and that relate to safety and effectiveness." *Id.* at 321-22 (emphasis added). Finding that the state-imposed duties underlying negligence, strict liability and implied warranty claims related to safety and effectiveness and were indeed included in the "requirements" referenced in the federal law, the court held that the claims were preempted by the MDA. *Id.* at 324-25.

The court also noted the limits on preemption, stating that: "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law," as opposed to being "parallel" to the requirements imposed by federal law. *Id.* at 328. However, that argument was not discussed further, as the issue of parallel claims had not been preserved for appellate review.

The Sculptra Defendants are correct that *Riegel* is controlling here. Sculptra is a Class III medical device that was undeniably approved through the PMA process. What is more, all of the plaintiff's claims against the Sculptra Defendants regard the safety and effectiveness of the device or require a finding that Sculptra's design, labeling, and/or manufacturing process should have differed from that approved by the FDA via

the PMA process (see Second Amended Complaint at ¶ 42-59, 70-75). Thus, the claims are preempted by the federal law.

To the extent plaintiff argues that her claims are "parallel" to federal law and thereby exempt from preemption, the claim must fail. To qualify as a "parallel" claim that avoids preemption, plaintiff must show that the Sculptra Defendants violated a specific federal requirement related to the PMA process which caused her injury, and she must also identify a state law tort theory that imposes obligations that are "identical" to or "genuinely equivalent" to the federal requirement. *Medtronic, Inc. v Lohr*, 518 US 470, 495 (1996).

Plaintiff appears to claim that the defendants promoted an off-label use of Sculptra that was contrary to the representations the Sculptra Defendants made to the FDA during the PMA process (see, e.g., Aff in Opp, ¶31). However, plaintiff has failed to cite a specific federal regulation that was violated, or an obligation existing under state law that was "identical" or "generally equivalent" to a specific obligation imposed by federal law. Thus, the exception from preemption for parallel claims has not been established.

What is more, any claims based on alleged off-label promotion and/or misrepresentations to the FDA during the PMA process are barred by *Buckman Co. v Plaintiffs' Legal Comm.*, 531 US 341 (2001). The Supreme Court there indicated that only the FDA, and not private litigants, may sue based on alleged noncompliance with the Medical Device Amendments, stating (at 347) that the FDA is "amply empower[ed]" to police fraud against the Administration, and policing this fraud is not a field the States have traditionally occupied." The Court explained that while the doctrine may be read to

allow for some state-law claims that are parallel to the requirements under the MDA, "it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 353.

The Court rejects plaintiff's claim here (at ¶ 42) that *Buckman* should not be applied because the fraud on the FDA allegedly committed by the Sculptra Defendants was of a greater magnitude than usual. *Buckman* makes no such distinction. What is more, the plaintiff in *Riegel* had alleged that the medical device was used in an off-label and contra-indicated manner, similar to the plaintiff's claims here, but those claims did not escape preemption.

Wholly misplaced is plaintiff's reliance on *Wyeth v Levine,* 555 US 555 (2009), to avoid preemption. *Wyeth* discusses claims against the manufacturer of a *drug*, not a *medical device* like the one in the instant case. Thus, the *Wyeth* court did not apply the preemption clause in the Medical Device Amendments that is applicable in this case. Nor does a comparable preemption provision even exist with respect to drugs. And while plaintiff may argue that "Sculptra is in reality a drug that has been mislabeled by the FDA as a 'device'" (see Opp at ¶3), the fact remains that the FDA classified Sculptra as a Class III medical device, and plaintiff cannot here challenge that classification.

Similarly misplaced is plaintiff's reliance on *Medtronic, Inc. v Lohr*, 518 US 470 (1996), to support her contention that her claims here are not preempted. *Lohr* is readily distinguishable from the case at bar as it dealt with medical devices approved through the "§ 510(k) process," where a device is found to be "substantially equivalent" to another device already on the market that has gained FDA approval. 518 US at 477-78.

As discussed above, the 510(k) process is an exception to the premarket approval rules, as the FDA allows "substantially equivalent" devices to be marketed without the rigorous scrutiny inherent in the PMA process. The *Lohr* Court expressly rejected defendant's claim of preemption because of the distinction between the §510(k) "substantially equivalent" process and the premarket approval process. 518 US at 493-94. That same distinction directly applies here such that the preemption provision of the Medical Device Amendments, which applies only to devices like Sculptra approved through the PMA process, did not come into play at all in *Lohr*.

In sum, the Sculptra Defendants have established that the preemption provision in the Medical Device Amendments bars the plaintiff's claims here, and the plaintiff has failed to establish in response that any exception to the preemption doctrine applies here. Accordingly, it is hereby

ORDERED that the motion by defendants Aventis Pharmaceuticals, Inc., and Sanofi-Aventis U.S., LLC, for summary judgment dismissing the complaint herein is granted, and the complaint is dismissed in its entirety as against said defendants, and the Clerk is directed to enter judgment accordingly in favor of said defendants; and it is further

ORDERED that the action is severed and continued against the remaining defendants, who are directed to appear in Room 222 on Wednesday, February 18, 2015 at 3:00 p.m. for oral argument on the recently scheduled motion for summary judgment by defendant Dr. Levine.

Dated: December 2, 2014

DEC 02 2014

FILED

DEC 09 2014

COUNTY CLERK'S OFFICE
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J.S.C.

ALICE SCHLESINGER