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

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, INSTITUTE BEAUTE, AVENTIS PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC,

Defendants.

Index No.: 800047/2011
AFFIRMATION IN OPPOSITION

(Hon. Alice Schlesinger)
Motion Seq. No. 005

FRANK C. PANETTA, ESQ., an attorney duly admitted to the practice of law before the Courts of the State of New York, and a Partner in the Law Firm of Massimo & Panetta. P. C., Attorneys for Plaintiffs herein, hereby affirms the following to be true under the laws of perjury:

1. I am a member of the law firm, MASSIMO & PANETTA, P.C., attorneys for the Plaintiff, LISA PITKOW, and as such, I am fully familiar with the facts and circumstances herein. I submit this Affirmation in Opposition to AVENTIS PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S., INC. (hereinafter the "Sculptra Defendants"), Order to Show Cause, pursuant to CPLR § 3108.

2. The Corporate Defendants submit through their Motion Papers and Memorandum of Law that this Court should dismiss this matter because of federal preemption for medical devices, under what I refer to here as the "Medtronic Law." The Corporate Defendants are wrong that this law applies to them. Their motion should be denied in its entirety because *under the circumstances of this case*, the Corporate Defendants, through their product or "device" known as "Sculptra." are not, and cannot be accorded the exemption in question, federal pre-

emption for medical devices or, as I characterize it, the "Medtronic Law," due to the corporate defendant with this name and the case law associated with it.

3. Sculptra, the product manufactured and distributed by the Corporate Defendants, is an injectable substance approved by the Federal Drug Administration (hereafter, the FDA) solely for use by AIDS patients with lipoatrophy or fat loss conditions. Sculptra is in reality a drug that has been mislabeled[1] by the FDA as a "device."

4. Placing aside for the moment the issue of the FDA's mislabeling of Sculptra as a "device," here, even if Sculptra were to be such a "device," the Corporate Defendants still have failed to establish their entitlement to the relief they presently request -- Summary Judgment. They claim that their product Sculptra entitles them to receive the pre-emption protections of the Medical Device Amendments of 1976 (hereafter the MDA), 21 U.S.C. § 360c et seq., and cite a host of legal authority purporting to convince this Court to rule in their favor here. Yet, this "weight" of legal authority does not help the Corporate Defendants here, because it is inapposite to the factual background and its legal predicates.

5. For example, at page 8 of their Memorandum of Law, the Corporate Defendants state their understanding of the "Legal Standard" to be utilized in deciding a motion for summary judgment. In conclusory terms, they state their entitlement to summary judgment, by reciting the well-known litany, "where the moving party establishes a *prima facie* case, and the opposing party fails to set forth evidentiary facts to demonstrate that a triable issue of fact exists with respect to a bona fide defense," suggesting that they have met this legal standard. In fact, the

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1. [1] Even the doctors that approved the so-called "device" had no idea they were approving a "device". We do not mean to give false hope to the Defendants that we are taking the position that the incorrect labeling of this drug affects our arguments or the efficacy of our opposition here whatsoever. We only mention it in passing that even the doctors that approved it for the limited purpose of facial wasting in HIV victims didn't realize it was a "device".

Corporate Defendants have *not* met this standard, and as will be demonstrated below, said Defendants should have known that they cannot meet this legal standard. There are indeed "evidentiary facts" leading to "triable issues of material fact" in this controversy -- well known to the Corporate Defendants, that they have concealed from this Court -- mandating denial of the their instant summary judgment motion.

6. Moreover, by their loading up of their Memorandum of Law with a massive quantity of case law appearing to collectively hold that the pre-emption protections of the MDA of 1976 constitute a legally impenetrable barrier of massive strength and breadth, the Corporate Defendants have created a virtual legal *Maginot Line*, that, apparently, no mere mortal torts plaintiff may dream of successfully attacking. According to them, the key case in this supposedly impenetrable legal barrier is Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Examining the Table of Authorities to the moving Defendants' Memorandum of Law (pp. iii - v, thereof) to see where in the Memorandum the Riegel case appears, rather than there being page numbers next to the case, there appears the word "passim;" in other words, the case appears ubiquitously throughout the Memorandum.

7. Further, at page 17 of the Sculptra Defendants' Memorandum of Law, in the bottom paragraph in the page, the Corporate Defendants claim to "understand" our -- that is Plaintiff's Counsel's -- very thought process in the presentation of Plaintiff's case. Said Defendants write:

> Despite a complete absence of any factual support, [Defendant] Sanofi anticipates Plaintiff may attempt to argue her allegations regarding off-label promotion establish a viable, non-preempted claim against Sanofi.

First of all, Plaintiff has no shortage of factual support for her contentions in this action. The Defendants are totally in fear of what Plaintiff knows and has in his possession—lest their fear be misinterpreted as cockiness. Plaintiff's counsel singularly has access to the FDA panelists that were duped by the deceitful Sculptra Defendants. See Exhibit "A", the Affidavit of Dr. Amy Newburger, which the Defendants are aware of. The FDA hearing was rife with misrepresentations by the Corporate Defendants (See Exhibit "B", the repeated misrepresentations made by Sanofi and Dermik at the FDA approval hearing. The Corporate Defendants here seek to pre-empt Plaintiff's arguments in opposition by falsely articulating her arguments. Then again, if you knew that Plaintiff had evidence of fraud in the approval process on the part of the Sculptra Defendants, you of course, would want to cushion the blow as well. Here, the Defendants have nowhere to run and nowhere to hide.

8. While it may be true that Plaintiff intends to utilize the "off-label" promotion issue to establish that she has viable, non-preempted claims against *all* Defendants in this case, the Corporate Defendants were wrong to anticipate Plaintiff's arguments in opposition to their summary judgment application and distort them. Said Defendants have twisted Plaintiff's viable argument (not as yet even made) into some sort of "straw argument" to be readily defeated—because they know they cannot overcome it. Defendants try to avoid their responsibility to Plaintiff by falsely claiming her cause of action to be governed by another case that appears ubiquitously in their Memorandum of Law, Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). The Corporate Defendants should permit Plaintiff to articulate her own argument in support of the "off-label" promotion issue and to distinguish Buckman, as will be done below. Their attempt to explain Plaintiff's thought process before she asserts an argument is quite ambitious. Too bad it falls flat.

9. While supposedly being able to "foresee" the operation of the thought process of Plaintiff's Counsel, surprisingly, the Corporate Defendants did not cite in their Memorandum of Law the one case that they should have anticipated Plaintiff would cite in support of her contentions in this motion, Wyeth v. Levine, 555 U.S. 555 (2009). This case is entirely on point with the issues presented in this controversy, and may readily be cited in limitation or modification to the principles stated in Riegel. It is beyond credibility that the Corporate Defendants could be unaware of Wyeth. One may conclude that adversary counsel were motivated by a wish to conceal the case from the attention of this Court. That's because it torpedoes their motion and renders it an exercise in futility. It is no small coincidence that they conveniently skip it.

10. The can be no doubt about the proposition that Plaintiff (and many other men and women) has been grievously harmed by the actions of all Defendants in this Controversy. Review of the Second Amended Verified Complaint (attached as Exhibit A to the Affirmation of Aurora Cassirer, Esq., in the Corporate Defendants' Moving Papers) and Plaintiff's Responses to Defendant Santofi's Demand for a Bill of Particulars (attached as Exhibit D to the Affirmation of Aurora Cassirer, Esq., in the Corporate Defendants' Moving Papers) more than adequately established the nature and extent of Plaintiff's injuries, all due to the actions of all Defendants, corporate and individual.

11. It must be understood that for the purposes of their instant Motion for Summary Judgment, the Corporate Defendants who we have named at the outset of this writing to be the Sculptra Defendants, do not deny that Plaintiff suffered the harm and injuries that she complains of in this case. Rather, the Sculptra Defendants submit that they should be relieved of all responsibility toward the present Plaintiff by operation of federal law, to wit, the MDA of 1976,

codified at 21 U.S.C. § 360c et seq., as well as subsequent case law and federal regulation further defining said statute.

12. Although Plaintiff has strong misgivings about this, the FDA has recognized Sculptra as being a "medical device" under the definitions thereto under the MDA of 1976. Medical devices -- a large variety of instrumentalities that are implanted inside the human body, such as replacement heart valves, pacemakers, hip prostheses -- are complicated products, that may become dangerous when they malfunction, if not deadly. Congress passed the MDA of 1976 to provide the federal government -- through the FDA -- with a system of oversight over the medical device industry. It was because a pacemaker is more helpful to the public than harmful. Sculptra cosmetic "wrinkle buster" is no pacemaker. It's a killer of beauty and aesthetics, not a life-saver.

13. Along with oversight, Congress also included a preemption clause in the MDA of 1976, something Congress had not included in the comparable FDCA statutory provisions governing drugs. 21 U.S.C. Section 360-k(a) prohibits the states from enforcing any requirement regarding a medical device that (1) "is different from, or in addition to, any requirement applicable under this Act" [MDA of 1976], and that (2) "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device."

14. Since the MDA of 1976 became law, manufacturers of medical devices covered by said statute (as are the Corporate Defendants), have argued that the statute's preemption provision in Section 360k(a) protects them from all state Common Law claims when their medical devices malfunction, causing substantial injury or death. This type of argument has been adopted by the Corporate Defendants extensively throughout their 25 pages of legal

argument in their Memorandum of Law. Yet, pertinent case law from the United States Supreme Court does not always support this type of reckless argument that would permit a corporation to hide behind a federal agency to avoid its responsibility to a plaintiff who relied upon the corporation's promises of safe usage of its products and who thereby suffered substantial loss.

15. There is a presumption against the preemption doctrine's general applicability, which is mentioned even in Corporate Defendants' favorite case, Riegel, at 126 S.Ct. 999. "The presumption against preemption is heightened "where federal law is said to bar state action in fields of traditional state regulation." New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 at 655 (1995). Given the traditional "primacy of state regulation of matters of health and safety" (Lohr, 518 U.S., at 485, *see, infra*), courts assume "that state and local regulation related to [those] matters . . . can normally coexist with federal regulations," Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 718 (1985)."

16. There is, of course, the just mentioned Lohr case (*see* Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), which involved medical devices that were "substantially equivalent" to devices that had already been on the market when the MDA went into effect. The Supreme Court of the United States held that a new medical device was not required to undergo the rigorous premarket approval process known as the PMA, if it was "substantially equivalent to pre-1976 devices, which also meant that the plaintiff's case was not subject to the preemption provision of Section 360k(a).

17. The former Chief Counsel to the FDA described the operation of this presumption as follows:

> "FDA's view is that *FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.* FDA regulation of a device *cannot anticipate and protect against all safety risks to individual consumers.* Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot [*338] protect against all possible injuries that might result from use of a device over time. *Preemption of all such claims would result in the loss of a significant layer of consumer protection . . . .*" [Emphases supplied] Porter, The *Lohr* Decision: FDA Perspective and Position, 52 Food & Drug L. J. 7, 11 (1997).

The thought process in this description of how the operation of the presumption against preemption is on that this Court might wish to consider in deciding the present motion for summary judgment. The thinking within the upper echelons of the FDA seems to have been very wise in 1997. To utilize the preemption provision of the MDA of 1976 as a sword to strike down litigation from affected plaintiffs, certainly causes the "loss of a significant layer of consumer protection" in an area of products liability that is (1) inherently dangerous, and (2) has a consumer who more often than not, requires the product as a matter of necessity, not option.

18. Twelve years after Lohr was decided, the Supreme Court rendered its decision in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), *supra*, which held that the MDA's preemption clause adversely affects Common Law causes of action challenging the safety or effectiveness of medical devices that have received FDA premarket approval.

19. As per Riegel, a Court is to make two findings as part of the process to consider whether the cause of action is to be preempted under the MDA. First, the Court must determine whether the FDA has imposed device-specific requirements on the particular device. Second, the Court must determine whether the state requirements that relate to the device's safety and effectiveness are requirements that are "different from, or in addition to the federal

requirements." In short, for a plaintiff to succeed under Riegel, his cause of action must constitute a "claim premised upon a violation of FDA regulations," or where his state cause of action "parallels" federal requirements, rather than "adds" any non-federal requirements.

20. It is apparent that Riegel leaves only a narrow gap for bringing state actions in cases governed by the MDA. Defining what types of state causes of action may be considered to be "parallel" claims is pivotal to determining viable state actions in this area. Clearly, state common law claims are not "parallel" state law claims and are preempted by operation of the MDA. Presumably, state claims that plead violations of federal law may be deemed to be "parallel." Presumably, state claims premised upon a medical device's failure to comply with FDA standards will survive preemption. Presumably, in cases where the litigant identifies one or more specific representations by the manufacturer that exceeded the scope of FDA approval of the device, the case will not be dismissed by MDA preemption. It is submitted that for reasons that will be explained below, the present case may be safely navigated through this "gap" and will survive the Corporate Defendants' motion for summary judgment.

21. About a year after the Supreme Court handed down the Riegel decision, that Court decided Wyeth v. Levine, 555 U.S. 555 (2009). In Wyeth, the Supreme Court held that federal law does not preempt failure-to-warn state claims involving brand-name drugs, even though there is a similar premarket approval process for drugs as there is for medical devices. Apparently in an attempt to avoid a seemingly strong conflict in law between the holdings of Riegel and Wyeth, the decision in Wyeth seems to be downplaying the broad preemption strokes set forth in the Riegel decision. In Wyeth, we read the following:

> Wyeth's argument that requiring it to comply with a state-law duty to provide a stronger warning would interfere with Congress'

> purpose of entrusting an expert agency with drug labeling decisions is meritless because it relies on an *untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law*. The history of the FDCA shows that *Congress did not intend to pre-empt state-law failure-to-warn actions*. In advancing the argument that the FDA must be presumed to have established a specific labeling standard that leaves no room for different state-law judgments, Wyeth relies not on any statement by Congress but on the preamble to a 2006 FDA regulation declaring that state-law failure-to-warn claims threaten the FDA's statutorily prescribed role. Although an agency regulation with the force of law *can pre-empt conflicting state requirements, this case involves no such regulation but merely an agency's assertion that state law is an obstacle to achieving its statutory objectives*. Where, as here, Congress has not authorized a federal agency to pre-empt state law directly, the weight this Court accords the agency's explanation of state law's impact on the federal scheme depends on its *thoroughness, consistency, and persuasiveness*. Cf., *e.g., Skidmore v. Swift & Co., 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124*. Under this standard, *the FDA's 2006 preamble does not merit deference*: It is inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity for comment on the pre-emption question; it is at odds with the available evidence of Congress' purposes; and *it reverses the FDA's own longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation. Geier v. American Honda Motor Co., 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914*, is distinguished. Pp. 573-581.
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> *183 Vt. 76, 2006 VT 107, 944 A.2d 179*, affirmed. [Emphases supplied]

22. As was the case with the Lohr decision, the Supreme Court in Wyeth looked with disapproval upon the effort of the FDA to utilize the preemption provision of the MDA of 1976 as a sword to strike down litigation from affected plaintiffs, at least in the area of failure-to-warn consumers of medications. Riegel (and the other case that is so favored by the Corporate Defendants in this motion, Buckman Company) should be looked upon as a "shield" for the FDA to utilize in its effort to properly promulgate an appropriate scheme of regulations in the area of

medical devices and thus support the Congressional intent in its passage of the MDA of 1976 to the FDCA.

23. Thus, Lohr, Riegel, Wyeth and Buckman Company are all in harmony with one other, as they each play a role as part of the law providing protection to consumers of medicine and medical products. All of the four cases function as shields for various legitimate concerns of society at large, as well as individual members of society. None of the four cases was ever intended to function as a sword to cause any party or part of society to suffer undue harm. What the Corporate Defendants seek to do in their present motion for summary judgment is wrong. Their effort to turn the Riegel and Buckman Company cases into swords to improperly deprive the Plaintiff in the present case of her day in Court should not be countenanced. As stated in Lohr, the unwarranted striking down of properly instituted litigation from affected plaintiffs (which undeniably is the Corporate Defendants' aim in this litigation), causes the "loss of a significant layer of consumer protection," and it should be condemned.

* * *

24. Sculptra, the product at issue in this case, was approved by the FDA as an "injectable poly-L-lactic acid device" which was intended to "correct, shape and contour deficiencies resulting from facial fat loss, lipotrophy," occurring to patients suffering from Human Immuno Deficiency Virus (hereafter referred to as AIDS), upon the application of DERMIK LABORATORIES, a subdivision of one of the Corporate Defendants, on behalf of said Defendants.

25. Annexed hereto as Exhibit A is a Doctor Affirmation by AMY NEWBURGER, M.D., a Board Certified Dermatologist, who served as a panel and voting member for the

Department of Health and Human Services, The Food and Drug Administration (FDA), General and Plastic Surgery Devices Panel at the time that the application for Sculptra was made by said subdivision of the Corporate Defendants to the FDA in 2004.

26. In her Doctor Affirmation, Dr. Newburger related what occurred during the Sculptra application process. At the FDA hearing on the application that was held on March 25, 2004, Corporate Defendants' representative, Dr. Kim Forbes-McKean stated,

> The subject of today's advisory panel is Sculptra, and the propsed indication that DERMIK is seeking for this injectable poly-L-lactic acid device is to correct, shape and contour deficiencies resulting from facial fat loss, lipotrophy, in people suffering from Human Immuno Deficiency Virus.

27. Dr. Newburger stated that at all times during the hearing, Corporate Defendants, through their agent or employee, represented that Sculptra was intended solely for treating patients suffering from AIDS. Its use was said to be an effective way to treat lipoatrophy, or face wasting, which is common for AIDS sufferers. Studies that involved the use of Sculptra by HIV patients suffering from severe lipoatrophy were submitted at the hearing.

28. From Defendants' presentation at the hearing, Dr. Newburger concluded that Sculptra was only to be marketed, advertised and sold for the sole purpose of treating HIV patients, and not to be publicized to a wider audience.

29. Accordingly, on August 3, 2004, the FDA approved Sculptra for usage to correct facial wasting on patients with HIV. The use of this product for other indications, such as to treat wrinkles, was not approved by the FDA.

30. At some time after the FDA approved Sculptra for use by AIDS and HIV sufferers, one of Defendants' salesmen specifically identifying themselves and/or a party known

to Dr. Newburger as a salesperson for the Sculptra Defendants, contacted Dr. Newburger and described the product as a "wrinkle buster," and, presumably, tried to sell it to the Doctor to be administrated to her non-HIV patients for cosmetic purposes.

31. Dr. Newburger has concluded that the Corporate Defendants intentionally mislead the FDA as to their true intentions concerning the use of Sculptra. Rather than use the "device" to treat AIDS and HIV patients suffering from severe lipoatrophy conditions, the Corporate Defendants intended to advertise, market and sell Sculptra for "off-label" purposes that would be far more profitable. Specifically, according to Dr. Newburger, the "off-label" purposes were to market Sculptra as a cosmetic drug similar to Botox or some other "wrinkle buster,"

* * *

32. Defendant EVERETT M. LAUTIN, M.D., a physician, is duly licensed to practice medicine in the State of New York. Defendant SUZANNE M. LEVINE, D.P.M., is a duly licensed podiatrist in the State of New York. Said Defendants jointly operate Defendant INSTITUTE BEAUTE (hereafter referred to as the Institute), a podiatry clinic and medical spa, located at 885 Park Avenue IN New York City.

33. Plaintiff does not suffer from AIDS and is not infected with HIV. During 2007, 2008 and 2009, Plaintiff was a patient of Defendants Lautin, Levine and the Institute, and was treated by them for facial cosmetic issues for aesthetic purposes. Prior to being treated by said Defendants, Plaintiff advised them that she had an existing multiple sclerosis condition, and that she was not an AIDS sufferer or infected with HIV. As part of the treatment for the cosmetics, Defendant Lautin injected Plaintiff's face with Sculptra many times on certain dates in 2007, 2008 and 2009.

34. Defendant Lautin represented to Plaintiff that Sculptra was the correct drug to be injected into her face to resolve her cosmetic aesthetic issues. He stated that Sculptra was to be used in a manner that was "off-label." He explained that this meant the drug would be used in a manner not authorized by the FDA, but that it was entirely safe for Plaintiff. Plaintiff told Defendant Lautin that she was concerned about Sculptra not being approved for this usage, but Defendant Lautin assuaged her fears. In 2009, sometime after the last time Defendant Lautin injected Plaintiff, she learned how wrong Defendant Lautin had been from the nature and extent of her facial and other injuries.

35. The two Doctor Defendants and their Institute had limited to no prior experience with Sculptra. They had swallowed whole the Corporate Defendants' marketing concerning the "wrinkle-busting" capabilities of Sculptra. The Corporate Defendants provided the Defendant Institute and its two Defendant Doctors absolutely no training or guidance in the application and use of Sculptra. Further, the were not given any warnings about any dangerous hazards of side-effects attendant to the use of the device-drug.

36. Under such circumstances, where the Corporate Defendants deviated from the intended use of their "device" -- replete with marketing Sculptra to a pair of doctors who were treating female patient with an anti-aging remedy -- it is submitted that the MDA cannot provide any protection to the Corporate Defendants.

37. Off-label usage, as was done in this case, voids the protections for medical devices. Therefore, since Sculptra, as a lipoatrophy -- a so-called "device' intended for injection in the cheeks, is then used "off-label" for the filling of wrinkles, as occurred here in Plaintiff's

case, the preemption claimed by Defendants is not available to them, effectively being voided by **the Corporate Defendants' own conduct**.

38. After all, here the Corporate Defendants, themselves, represented to the FDA that their product was intended as an AIDS/HIV treatment for serious cases, and said Corporate Defendants turned around and actually marketed Sculptra as a "wrinkle-buster," entirely safe for injection into eyes, around the mouth, among other areas (and precisely, these are the areas that Plaintiff complains of in as having been harmed by the product in her Complaint). The Corporate Defendants not only fooled the FDA and Plaintiff, but, apparently their co-defendants the Institute and Doctors Lautin and Levine, as well.

39. There is a difference between a "real" medical device such as a hip implant and something injectible as is Sculptra. The "real" implant is manufactured in the condition that it is going to be implanted. With Sculptra, there is a variable. The so-called "device" ***must be mixed, altered and created*** and must sit for a period in its mixed form to be ready for injection. The device can then be injected or implanted by a doctor with very varying techniques. In this case, Doctor Lautin was not properly trained in administering Sculptra. He was not aware of all the risks and complications of this "device". Therefore, he thought it would be okay to deviate from the manufacturer's technique of injecting close to the surface and inject deeper, subcutaneously. This doctor, ill-informed by Defendant manufacturer, acted recklessly and, in effect, carelessly in the injection process of Lisa Pitkow. It is submitted that the Corporate Defendants, in creating an environment of carelessness in the injection process, must bear a greater share of responsibility than any ordinary co-tortfeasor.

40. The circumstance that the harm that occurred to Plaintiff was "off-label" in the manner that it was caused is what differentiates this case from all of the cases where preemption was applied. In the usual case where preemption lies, The FDA gives approval for the use of a device, something goes wrong with the device, and a plaintiff suffers injury. In a case of an "ordinary" "off-label" situation, the doctor uses the device in an unforeseen methodology, something goes wrong, and a plaintiff suffers injury. In both fact patterns, preemption is a likely possibility to occur. Here, the circumstances were entirely different.

41. The Corporate Defendants have acted in an extraordinarily active manner. They did not mere apply for a medical device to be accepted by the FDA, then market and sell the device. They applied for the medical device to the FDA. The marketed and sold the device for a totally different purpose then initially reported to the FDA. Their selling of the device was fraudulent upon the middle men and the consumers, and it was done with full knowledge that the federal government would shield them from lawsuit when the Preemption provision in the MDA of 1076. They apparently thought they could injure people with impunity once their product was approved by the FDA—after all, they must be protected, right? Wrong.

42. In terms of the Buckman Company case, where "fraud-on-the FDA" cases are to be preempted because allowing a state law cause of action to stand would interfere with the federal scheme, it is submitted that while the Corporate Defendants may have committed a fraud upon the FDA, here, they committed far greater frauds upon Plaintiff and, even, upon their co-defendants the Institute and Drs. Lautin and Levine. Their culpability being far greater that in the usual "fraud-on-the FDA" case, the preemption provisions of Buckman Company are simply inapposite here.

43. Because of the conduct of the Corporate Defendants, this case involves more than a Plaintiff seeking to hold a manufacturer accountable for a defective PMA-approved medical device that she utilized to her detriment. The manufacturer here, in the personages of the Corporate Defendants, did more than merely have its factory make device which turned out to be flawed in some way. Here, as set forth above, the manufacturer acted with deceit at each step of the way: applying for approval from the FDA for a medical device for a false purpose; marketing the device for a totally different purpose without FDA approval, and selling the device not only without FDA approval, but also without instructions as to the device's proper and safe use.

44. None of the other cases cited by the Corporate Defendants in support of their motion for summary judgment are on point with any of the true issues in this portion of the litigation.

45. This Court should find that in harmony with the Supreme Court decisions in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) and Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court's decision in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) should be applied to this case to find it not subject to preemption for the following reasons:

a) the state law claims here are deemed to parallel federal regulations,

b) the state law claims are premised upon the medical device's failure to be in compliance with FDA standards.

c) Plaintiff has clearly identified one or more specific representations by the manufacturer that have exceeded the scope of FDA approval of the device.

In addition, the intentional conduct of the Corporate Defendants was so egregious that application of Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) to this case would be inapposite.

WHEREFORE the Plaintiff requests this Honorable Court render a decision consistent with the Plaintiff's cited law, including, but not limited to Wyeth v. Levine, 555 U.S. 555 (2009) and deny the Defendants motion in its entirety and grant costs and sanctions for the time expended on this most frivolous and offensive motion and for further and other relief as this Court deems just and proper.

Dated: Mineola, New York
April 7, 2014

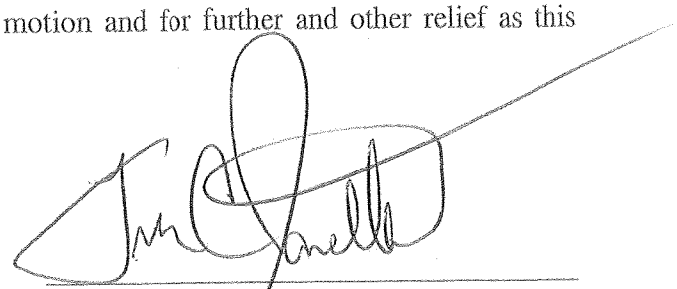

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EXHIBIT A

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

----------X

[redacted] and DR. [redacted]

Plaintiff,

DOCTOR AFFIRMATION

-against-

[redacted], M.D., DERMIK LABORATORIES, INC., SANOFI-AVENTIS PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.

INDEX NO.: 1065[redacted]/10

Defendants.

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AFFIRMATION OF LICENSED N.Y.S. DOCTOR

I, AMY NEWBURGER, M.D. do hereby certify under oath the following:

1. I am not being compensated for my statement and have no financial interest or investment in this law suit.

2. On or about March 25, 2004, I served as a panel and voting member for the Department of Health and Human Services, The Food and Drug Administration (hereinafter "The FDA"), General and Plastic Surgery Devices Panel.

3. I am a board certified dermatologist with an office at 2 Overhill Road #330 Scarsdale, New York. I also teach at St. Luke's Roosevelt Hospital Medical Center, specifically in regards to a dermatology residency program.

4. At the FDA hearings on or about March 25, 2004, representatives were given an opportunity to present data and information to the panel.

5. The DERMIK LABORATORIES, INC. **(hereinafter, "DERMIK")** a division of AVENTIS PHARMACEUTICALS, INC. **(hereinafter AVENTIS)** representative, Dr. Kim Forbes-McKean, stated at the hearing "[t]he subject of today's advisory panel is Sculptra ™, and the proposed indication that DERMIK is seeking for this injectable poly-L-lactic acid devices is to correct shape and contour deficiencies

resulting from facial fat loss, lipoatrophy, in people with *Human Immuno Deficiency Virus (hereinafter HIV).*

6. That at all times during the FDA hearing, DERMIK represented that Sculptra ™ was intended solely for patients with HIV.

7. Specifically, Dermik Laboratories asserted that Sculptra™ was an effective way to treat lipoatrophy, or facial wasting, only in those individuals with HIV.

8. That at all times during the FDA hearing, DERMIK only reported on studies conducted involving the use of Sculptra™ by HIV patients with severe wasting or facial lipoatrophy.

9. Based on my education, professional training and experience, as well as the presentations given by Sculptra™ representatives, I was reasonably certain that Sculptra™ was only to be marketed, advertised, and sold for the sole purpose of treating HIV patients, and not a wider audience.

10. That on August 3, 2004, the FDA approved Scupltra to correct facial wasting on patients with HIV. The use of the product for other indications, such as to treat wrinkles, or for any use in the immuno competent population, had not been approved by FDA.

11. As a physician and a member of the FDA panel, I felt duped when, post approval of Sculptra for HIV patients, a DERMIK sales representative contacted me and described the product to me as a "wrinkle filler".

12. Based upon the data that was presented to me, I believe the panel was intentionally misled by the manufacturer and the distributor of Sculptra™ , DERMIK and SANOFI-AVENTIS PHARMACEUTICALS, INC. respectively, as to the purpose and intended audience of Sculptra ™.

13. Further, it is my belief this product was marketed, and sold for off-label uses.

14. It is my opinion that DERMIK LABORATORIES, INC. and AVENTIS PHARMACEUTICALS, INC. intentionally misled the panel into thinking it would only be used on very sick HIV patients and would not be marketed as a cosmetic device

similar to another "wrinkle filler". It was also clear that special training is required for reconstitution and for injection and that it is very technique dependent. The sponsor agreed to require training for the users of this device.

15. It is further my opinion that the reason the drug was cleared solely for HIV patients, was because the adverse side-effects were not known in the immuno-competent population. The belief of the other panelists was that it was cleared for the HIV positive individuals on a compassionate basis.

Affirmed to be true under penalties of perjury pursuant to § 2106[1] of the Civil Practice Law and Rules on August 17, 2011

AMY NEWBURGER, M.D.

JANET P. BROWN
Notary Public, State of New York
No. 01BR6178765
Qualified in Westchester County
Term Expires December 10, 2011

Janet Brown

[1] **Rule 2106. Affirmation of truth of statement by an attorney, physician, osteopath or dentist**
The statement of an attorney admitted to practice in the courts of the state, or of a physician, osteopath or dentist authorized by law to practice in the state, who is not a party to the action, when prescribed and affirmed by him to be true under penalties of perjuries, may be served or filed in an action in lieu of and with the same force and effect as an affidavit.

EXHIBIT B

UNITED STATES OF AMERICA
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
MEDICAL DEVICES ADVISORY COMMITTEE

+ + + + +

GENERAL AND PLASTIC SURGERY DEVICES PANEL

+ + + + +

65TH MEETING

+ + + + +

THURSDAY,
MARCH 25, 2004

+ + + + +

The panel met at 8:00 a.m. in Salons A-D of the Gaithersburg Hilton Hotel, 620 Perry Parkway, Gaithersburg, Maryland, Dr. Michael Choti, Chairman, presiding.

PRESENT:

MICHAEL A. CHOTI, M.D., Chairman
GRACE T. BARTOO, Ph.D., RAC, Industry Representative
BRENT A. BLUMENSTEIN, Ph.D., Voting Member
PHYLLIS CHANG, M.D., Voting Member
LEELEE DOYLE, Ph.D., Consumer Representative
DOUGLAS G. FISH, M.D., Temporary Voting Member
MICHAEL J. MILLER, M.D., Voting Member
ROBERT J. MUNK, Ph.D., Patient Advocate
AMY E. NEWBURGER, M.D., Voting Member
MICHAEL J. OLDING, M.D., Temporary Voting Member
NEAL S. PENNEYS, M.D.,
Ph.D., M.B.A., Temporary Voting Member
DAVID KRAUSE, Ph.D., Executive Secretary

which needs to be defined a little bit more clearly, but the theme is that it's incorporated a combination of improved or quality and technique as well as clarifying indications.

Can we have a vote? A show of hands for those in favor of this second condition as described. Those in favor? And those opposed?

Let the record show an unanimous decision in favor of the second condition.

Do we have a motion for a third condition? Dr. Newburger?

DR. NEWBURGER: Thank you, Dr. Choti.

We're being asked to approve this device on a compassionate basis. Not on a scientific basis really, but on its empirical performance. And as such, I would like to take whatever steps are necessary to limit its use to those who require it on a compassionate basis. I don't know if the best way to do that would be to have a physician registration program such as is being anticipated now for Accutane, which is above and beyond the SMART program which was initiated by the manufacturer, the original

manufacturer or whether it would be to provide documentation in the records that those for whom it is being used have presence of virus, CD4 counts that have been compromised in some way. I don't know what that mechanism is. But I would like to take stringent measures at this time until we have more information about its activity; all the other things that we normally require to approve such an injectable device where this would be used offlabel.

CHAIRMAN CHOTI: Can you summarize that in a sentence?

DR. NEWBURGER: I'd like to limit in the employment of this device for those who have HIV associated lipoatrophy. I would like to do that either by documentation that the subject has HIV induced lipoatrophy or by registration of the physician who gets the device shipped.

CHAIRMAN CHOTI: Okay. So the motion is as stated to limit this device to HIV by some form of documentation or registration. Do I have a second for this motion? Dr. Olding seconds it.

This condition is open for discussion.

Dr. Penneys?

DR. PENNEYS: Dr. Newburger, I'm just curious, what does registration of the physician do? In other words, suppose they order it and they use it anywhere they want? Is there any penalty for that in this type -- in other words, I can understand limiting it to HIV positivity. That absolutely limits it pretty much to this group. But what does physician registration really do?

DR. NEWBURGER: Physician registration could -- physicians who would be registered would be those, really who you could be sure have read the package insert. Because most physicians don't read package inserts of devices they use or medications even that they prescribe. And sometimes you have to get someone's attention by with a 2x4 when they won't listen to your words.

So it would just be a way to triple underline the use of this device and put the physician really on notice.

DR. PENNEYS: But they still, because they have a license to practice medicine, can take this

material and use it cosmetically, for example, or for something else?

DR. NEWBURGER: Indeed. My preference would be the documentation of HIV associated lipoatrophy.

DR. OLDING: Is it possible for us to make that recommendation as two separate or just as a documentation of HIV? It would be my preference that we do the former rather than the latter.

DR. FISH: Yes, I would agree. I think I would potentially keep them a separate issue and just have the indication or the recommendation for the indication to be restricted to those who are HIV positive, period. And the documentation of that being in the hands of the physician.

DR. NEWBURGER: I would agree with that.

CHAIRMAN CHOTI: So we're going to reformulate this motion, this description as to limit this device to HIV by documentation.

DR. FISH: Of HIV positive sero status.

CHAIRMAN CHOTI: And we have a second for the motion. So now this condition is open for

discussion now as rephrased.

Yes, Dr. Li?

DR. LI: Perhaps this is a question for Dr. Witten. I'm completely in agree with Dr. Newburger's wishes.

How is this different from perhaps putting an exclusion in the labeling, like we can exclude patients that are not HIV positive? Which would be the most effective way to do that?

DR. WITTEN: Well, I think what I'm hearing the recommendation is that -- at least what it sounds like is that it not actually provided unless there is documentation that the patient is HIV positive. I mean, I'm responding to what I'm hearing the panel recommend.

DR. LI: Okay. But that's kind of a practical suggestion or that -- that is the question?

DR. WITTEN: That's a very good question. And as I said earlier, it's not something that we've ever done that I'm aware of or at least since I've been there in my division I'm not aware of that. And so we will do with this panel's recommendation for

this product, as we do anytime we have a panel recommendation, is take the recommendation back and evaluate it as we complete or review and see whether there is something that we need to explore that would accomplish the goal incorporated into this recommendation from the panel. If this is actually a condition that you all vote and agree on.

CHAIRMAN CHOTI: But, Dr. Witten, this may limit the ability to vote for this approval with condition if we don't know whether this condition can actually be met. Is there a way we can find out a little bit more detail about a restricted condition that would actually restrict its use?

DR. WITTEN: Well, when you vote if you vote, you're voting with recommendations. You know, with recommendations for conditions. So that's your vote. I mean, that's the same with any recommendation for conditions that a panel makes.

You know, the panel makes recommendations and we don't follow all of them.

CHAIRMAN CHOTI: Right.

DR. WITTEN: But the panel's made its

recommendation based on their best advice to us about what they thin would lead to safe and effective use of the product. So we're just asking you to make your recommendation about what you think would lead to safe and effective use of the product. And if that incorporates this recommendation, you make this recommendation and you make your vote accordingly.

CHAIRMAN CHOTI: But it sounds like the panel needs to know that this condition may not be possible to be met, it sounds like. We don't know enough about it.

Yes, Dr. Monk?

DR. MUNK: Yes. I'm wondering if perhaps an effective way to do this would be in the labeling as a contraindication that the product should not be used in any patient without evidence of HIV infection?

CHAIRMAN CHOTI: Dr. Newburger?

DR. NEWBURGER: That still has an issue as is the physician going to comply with the insert. As I mentioned before, Thalidomide is a medication which is available for certain specified conditions that the treating physician has to document to the manufacturer

before the manufacturer will allow the pharmacy to sell it. Now, once a patient fulfills those conditions, they can certainly gain access to it very easily. Myeloid dysplasia is one condition. And these people get a month's supply at a time, and they go through this documentation every single month they get the medication.

And I don't see that this would be onerous. After at least the first few treatments, it wouldn't be on a monthly basis, you know, for a couple of years. So I'm wondering if that would give us closer control.

DR. MUNK: My thinking, too, is that if is a contraindication, that it's clearly a liability exposure for a physician who uses in a patient without HIV infection. And perhaps FDA can work on the best way to implement this. I don't know.

CHAIRMAN CHOTI: Although that may be more in a labeling condition.

And then the other issue is the definition of contraindication without hard data supporting its contraindication as opposed to -- yes. So anyway we

can discuss that if that's proposed as a separate condition.

Yes, Dr. Leitch?

DR. LEITCH: Well, the idea of reporting to someone that the patient is HIV positive in order to get the product, that may be unacceptable to the patients and maybe somebody should speak to that who is a patient. But I would think there would be some reluctance on the part of physicians to reveal that information, you know, all these HIPAA issues that have come up these days. So I think particularly that type of information to be released to a company might be distasteful both to physicians and to patients.

CHAIRMAN CHOTI: Well, it sounds like we've modified this condition not to a registry, per se, a registration but not --

DR. LEITCH: No, not registering the physician, but you said one way would be like with the Thalidomide, confirming to the company that the patient is HIV positive.

CHAIRMAN CHOTI: But this is really restricted to HIV patients. It's just like antiviral.

It's a therapy that we're recommending restricted to HIV patients with lipodystrophy.

Dr. Fish?

DR. FISH: Yes. I think a parallel could be using zidovudine, using AZT in someone who doesn't have HIV. I mean, it would be malpractice, it wouldn't be done or if it was done, you know, it just wouldn't happen. So I think that the labeling if we just restrict it, I agree with you that we don't need a patient registration sent into the company. I'm not advocating for that. But just documentation the physician needs to know that they are treating HIV associated lipoatrophy.

CHAIRMAN CHOTI: Two separate things, though. It is not a labeling issue, this is a recommendation that it has -- if possible, a restricted use.

Yes. Dr. Blumenstein?

DR. BLUMENSTEIN: Well, I think there's lots of levels of restriction on this. One is that you identify the specific patient to the company before their product is released. The other is that the

physician who wants to use the product or the health care provider, I suppose I should say it that way, would just, in the order that there would be a pledge that it is being ordered for a patient to take that's HIV positive, in which case you're not revealing the-- I think the FDA has to be the one to work this out. And I believe that they have some analogies. The Accutane. What was it you said? Thalidomide and so forth. So I think that this is a problem we have to let the FDA figure out the details. But I don't believe -- I think if the spirit of your recommendation is to have something more than just words in the label, and I think that's -- I definitely go along with that.

CHAIRMAN CHOTI: Any other comments?

So the condition as specified is condition 3, which is to limit the use of this device in a restricted fashion to patients with HIV and lipodystrophy.

This is now up for a vote. Those in favor of such a condition raise your hand? It looks like it's unanimous. So let the record show that it's a

unanimous vote in favor of this condition.

A motion for an additional condition? Dr. Li?

DR. LI: This must be the first application for something for a device where the material specifications are still being worked out before they get to the panel. So I think the product specifications have to be specific and in place. Specially going over the information they provided, I believe that the primary specification should be based on the final objected project, although the starting material and process are important, I think the most important thing is the characteristics of the final injected product. This includes molecular weight, crystallinity.

We're injecting small particles. It's a little peculiar to me, i spend the rest of my life trying to keep small particles out of the human body and now I'm here sitting on a panel, presumably to approve injecting particles into the body. But we don't really have a good idea of the particle size distribution of these. And we do know that that is a

very important factor in cell response.

We've conflicting data on resorption rate. And near as I could tell, no in vivo resorption rate for this rate.

And the thing I'm perhaps most bothered about, we don't seen to have any positive or negative controls on this. You know, we don't really know how much is too much. We don't know how fast is too fast. And the other variables superimposed upon that.

So I think the product specifications have to be worked out and they have to be worked out in the absence of, I think I've said this before, in the absence of a mechanism I think the product specifications have to be in a very narrow band limited to their actual experience. Because we have very little scientific data. This whole application, it's all based on experience. So I think the product specifications must be -- and they may be doing this already, be limited very specifically to things they have already direct experience with.

CHAIRMAN CHOTI: So you're not a post-approval trial to look at some of these questions,

but--

DR. LI: Well, I think when we talked about -- I meant, anyway, when we talked about the post-approval studies are things like the actual concentration of the lactic acid remaining at different time periods be assesses and the histology I think which was raised. So I think those would be my material characteristic that I would like in the post-market study.

But I guess what I'm raising here is I'd like to put in this -- the approvable has to be, in my mind, a specification sheet of what this material actually is at the time it's injected, which we don't have in front of us right now.

CHAIRMAN CHOTI: Okay. So the motion is for product specification. Is there a second to that motion? Dr. Pennys second.

This condition is open for discussion. Any other comments?

So this information would be identified if not currently available, then through additional animal studies or other studies, is that your

suggestion?

DR. LI: Well, the only thing I could see where you'd want to do an animal study would be if you wanted to do some in vivo resorption rate. But if you're going to histology on patients, I would propose that would be a better source rather then get into an animal study. So I could get it however you could get it. If it's already done, that's great. But if they don't have the information to do these specifications, they should get it.

CHAIRMAN CHOTI: Any further discussion on that condition? Dr. Chang?

DR. CHANG: I'm presuming that there is a standard of good manufacturing practices so that any product that has been on the market has to have some range and consistency. That's what I'm presuming that it is even for this PMA, that there has been some consistency in the product that's being used for the clinical studies.

And so the question to Dr. Li is do you want that tightened up so that they know specifically what is in this vial that's being injected? Is that

what you're --

DR. LI: Well, what I saw -- and again you could me if I missed it in the volumes of data that was supplied, was what I saw was a lot of characteristics of what was used, but no list of what the product should be. In other words, if they said for instance the molecular weight was 40 to 60,000 after milling and in gamma irradiation. Well, if they get a 30,000 is that acceptable, or if they get a 70,000 is that acceptable? That information is nowhere in there.

In other words, they told us reasonably well what they're using, they just didn't provide us any limits of what that window is.

DR. CHANG: So you want a tighter limit?

DR. LI: Well, I want limits, period. I didn't see any. Okay.

CHAIRMAN CHOTI: Any further discussion?

So this motion number 4 is up for a vote, that is of providing more specifics regarding product specification.

Those in favor raise your hand. I think

it's unanimous, is that right? Yes. So for the record it's unanimous to approve that specification or that condition.

Is there a motion for an additional condition? Yes, Dr. Mock?

DR. MUNK: I'd like to propose that the Committee consider some wording changes in the labeling.

CHAIRMAN CHOTI: So a condition regarding specifications within labeling. Is there a second? Dr. Fish seconds.

This is open for discussion. Yes, Dr. Olding?

DR. OLDING: Are we going to go through them individually as part of this now?

DR. FISH: I have some specific ones to propose.

DR. OLDING: Okay.

CHAIRMAN CHOTI: Yes. So the motion is really to define some aspects, specific aspects regarding labeling.

DR. FISH: And these are all in the first

two pages of the labeling. The first under intended use and indications, it currently reads "Intended to correct shape and contour deficiencies resulting from facial fat loss, lipoatrophy in people with human immunodeficiency virus." I would propose changing that to facial fat loss, lipoatrophy caused by human immunodeficiency virus infection or its treatment, the reason being the possibility that some reimbursement programs may bulk at the fact that we've got HIV and we've got lipoatrophy but we have no statement connecting them causally.

CHAIRMAN CHOTI: Yes, Dr. Olding?

DR. OLDING: If I could just make a friendly maybe amendment to that. Because I feel so strongly about the use in this population, I would say Sculptra is only intended.

CHAIRMAN CHOTI: And particularly if that third condition, that is the restricted use, becomes difficult then I think it makes sense if we're concerned about it to emphasize it again as strongly as possible in the labeling, if that's what the feeling is.

DR. MUNK: I don't know if you want to go to the other comments?

CHAIRMAN CHOTI: Yes, why don't you.

DR. MUNK: Under the warnings, I would like to see a stronger statement about overcorrection. It currently simply says that it should be avoided, but the information we heard is that overcorrections may persist for two or more years.

CHAIRMAN CHOTI: Okay.

DR. MUNK: On the second page there is a statement that the safety of Sculptra for use during pregnancy or in infants and children has not been studied. And I think there ought to be a parallel statement about populations other than caucasian adult males. I mean, I don't know how you would word it exactly. There has been some study, but insufficient study to reach conclusions about safety.

CHAIRMAN CHOTI: We can also specify that that be highlighted in a black box or emphasized within the label as well.

DR. MUNK: I'm not making that suggestion.

CHAIRMAN CHOTI: Okay.

DR. MUNK: And then the last one I have is under adverse events, the "nodules" appears several times. And I would defer to my esteemed colleagues who know more about dermatology than I do and suggest a change in wording to something that is consistent with dermatologic practice.

CHAIRMAN CHOTI: Any other discussion on labeling recommendations?

DR. OLDING: I have some other recommendations also in the warnings?

CHAIRMAN CHOTI: Dr. Olding?

DR. OLDING: Should I do that now or--

CHAIRMAN CHOTI: Yes.

DR. OLDING: I would say in the warnings, you know 52 percent of these patient have nodule formation whether it's palpable or visible, they have nodule formation. So I would like to include that in the warnings. It brings it more to the forefront rather than just putting in with a whole bunch of other things. And I would suggest that in the warnings we write "Nodular formation occurs in 52 percent of the patients and extreme caution must be

exercised in the per-orbital and peri-oral areas." Perhaps taking out from the overcorrection should be avoided change, just removing that peri-orbital and peri-oral area and moving it up to the separate out.

And I would also suggest that in the precautions to be consistent with what we're recommended for the training program that we add to the -- it should be only used by health care providers with expertise in the correction of valan defects and after completing the required training program, or something to that effect, and familiarizing themselves with the product and its complete package insert.

CHAIRMAN CHOTI: Since we're going to vote on these as a group, the recommendations that were brought up, are there any discussion regarding any specific points that were mentioned, agree or disagree?

DR. MILLER: Can I make one more recommendation? Can I make more?

CHAIRMAN CHOTI: Yes, please, Dr. Miller.

DR. MILLER: In the warnings, just again to emphasize the fact that this is not to be use din

non-HIV patients, maybe we could say something like the performance of this device in immunocompetent individuals is uncertain and unproven and may be hazardous to your health, or something like that. Something to emphasize that this is not to be used in that population because it really has not been demonstrated satisfactorily that the -- the risk profile has not been demonstrated satisfactorily.

CHAIRMAN CHOTI: Not to be used in non-HIV patients.

DR. MILLER: And we keep saying it over and over, I know. I mean, if a person reads this and sees in over and over again, then I mean every little reenforcement of that may be one fewer episode where a person gets this who doesn't fit this criteria.

DR. OLDING: Yes, Dr. Bartoo?

DR. BARTOO: I have another recommendation under the precautions. There's a section on no studies of interactions with other drugs. Perhaps a statement that there have been no studies of long term safety or efficacy.

CHAIRMAN CHOTI: Any other discussion

regarding labeling changes or specifications, recommendations?

So the fifth condition is that of the recommendations of changes in the labeling as specified in the transcripts. I'm not going to go over all of them. This is as a group of labeling changes, this is now up for a vote.

Those in favor of these labeling changes, raise your hand. Let the record read that it is unanimous in favor of that condition.

Any other motions for additional conditions? It looks like we have a total of five conditions.

Just to summarize them briefly, the first condition is that of a post-approval study with various issues that we're concerned about. The second is that of a training program. The third condition is to define restricted use to HIV patients only with lipodystrophy. The fourth condition is product specification regarding providing more information about the specifics of the product. And the fifth condition about labeling recommendations.

So now this PMA is -- we are to vote on whether approvable. So this has been moved and seconded for the pre-market approval application for Sculptra from Dermik Laboratories to recommend approvable with conditions. Those in favor, raise your hand.

Let the record show that it's unanimous for approval with conditions.

At this point, I'd like to just briefly go through and -- why don't we briefly go through the group and just a summary statement regarding why you voted as you did. Why don't we start with Dr. Li?

DR. LI: Well, I have to say I voted for approval, interestingly enough, more with my heart than my head. I'm moved by the general need by this specific patient population. I was moved by the personal presentations of those who have benefitted from the device. And I was also convinced of the efficacy by the physicians that made the presentations.

But what we seem to have here from my view on a scientific side is a really large anecdote. And

as I tell my students, data is not the plural of anecdote.

The science really just isn't there. It seems to work, but we don't really know why. And the scary part there is we just really don't know what the boundaries of this are; you know if you put in a little too much, if you change your particle size, if this really works there'll be competitors that will use PGA, PGA-PLA blends and there's basically no basic understanding for this device although it seems to work in this patient population that they've studied.

I'm really bothered by we can't even answer the question is this material dependent or not. You know, we don't even know that much about it. So the fundamentals are really virtually absent in why this works the way it does.

So this is a vote from my heart and not from my head.

CHAIRMAN CHOTI: Dr. Olding?

DR. OLDING: I won't spent a lot talking. I'll just tell you that I am not comfortable with the science involved. I believe that a great deal more

work needs to be done by the company on that science, and I think that, hopefully, the conditions we've placed on the approval of this product and the limitation to the people who it is intended for have at least done those things.

And I would echo the fact that one must vote from one's heart to approve this today. And I will be happy to see it on the market for the patients for its intended use.

CHAIRMAN CHOTI: Dr. Penneys?

DR. PENNEYS: Well, I certainly with that. I keep having images of a Trojan Horse in my mind, but I hope I'm wrong. In the end, there's real pain and there's real improvement in the real time, and I think in this case I'll take the real gain and the real time and hope that we can work out these unknowables going forward.

CHAIRMAN CHOTI: Dr. Fish?

DR. FISH: My approval vote is based largely on the urgency of the need. Clearly that has been demonstrated by those of you who have taken the time to come today, and that is much appreciated.

I think that I, too, am bothered by the really hard scientific data that we really like when we're going for approval and it puts you in somewhat of an uncomfortable situation when we're making a recommendation based on somewhat empiric information. Our basic tenant is do no harm, and we don't want to be back in five or ten years seeing pictures and people very, very unhappy with treatment outcomes. And so I think that's the intent of the conditions.

CHAIRMAN CHOTI: Dr. Miller?

DR. MILLER: Yes, I agree with the sentiments that have been expressed. And it's really the desire to see something done for these people suffering with this problem that motivates me to vote for it. But I would so much prefer to have a lot of these questions resolved before we ever had to vote to release this. And I will be extremely disappointed if in the future we see that this has been sort of a back door way of getting a product available whose real intention is for basically to handle the hundreds of thousands of people who want tissue fillers rather than the thousands of people who have HIV and