

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

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JANET ~~BARAN~~ and DR. WILLIAM ~~WINKLER~~

Plaintiff,

**DOCTOR  
AFFIRMATION**

-against-

~~RICHARD W. SWIFT~~, M.D., DERMIK  
LABORATORIES, INC., SANOFI-AVENTIS  
PHARMACEUTICALS, INC., and AVENTIS  
PHARMACEUTICALS, INC.

INDEX NO.: 106530/10

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

1. DERMIK LABORATORIES, INC., SANOFI-AVENTIS  
PHARMACEUTICALS, INC.<sup>1</sup>, and AVENTIS PHARMACEUTICALS, INC. will  
hereinafter be referred to as "THE SCULPTRA DEFENDANTS".

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. That I am a board certified dermatologist with an office at 2 Overhill Road  
#330 Scarsdale, New York.

4. That in addition to being a practicing treating physician, I teach at St.  
Luke's Roosevelt Hospital Medical Center, specifically in regards to a dermatology  
residency program.

5. That I am also a Consultant for the Office of Professional Medical  
Conduct (OPMC) of the New York Department of Health.

<sup>1</sup> Should Plaintiff amend the caption to include Sanofi-Aventis, US, LLC, this Affirmation shall still be applicable.

6. That I have published numerous articles and papers regarding dermatology.

7. That on or about said March 25, 2004 date, a hearing took place in which one or all of the above-referenced Defendants urged that Sculptra™, a form of Poly-L-Lactic Acid was an effective way to treat HIV patients with lipoatrophy, or facial wasting<sup>2</sup>.

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

9. That said Panel was assured 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 Sculptra™ to correct facial wasting on patients with HIV.

11. That at said time, it was known that Poly-L-Lactic Acid injection, including Sculptra™ brand, caused papules and granulomas<sup>3</sup>, however, this appearance of "gravel" (bumps and lumps) in the cheeks was weighed against the facial appearance or "wasting" or gaunt facial appearance of persons with HIV or AIDS.

12. During the course of the Panel deliberations, the panel members and the FDA staff present believed that we could put restrictions on the use of said substance. We found later that the conditions that we wished imposed to restrict its use to those with HIV+ lipoatrophy could not be enforced. The enforcement of such restrictions, at that time, was limited to drugs, and Sculptra is a device. Medical devices do not have the same set of rules, and restrictions that drugs must comply with.

13. That due to the lack of restrictions and in spite of said known adverse side-effects, said device has been marketed as and used as a plastic surgery alternative, specifically to treat wrinkles.

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<sup>2</sup> Said condition makes HIV positive persons easily identifiable due to their gaunt appearance in the lower face.

<sup>3</sup> Papules and granulomas can create an effect or appear to look like gravel, or a gravel-like appearance.

13. The use conditions were only presented as pertaining to those with HIV+ associated lipoatrophy at that hearing. In my opinion, using said device for purposes other than this specific wasting in HIV patients is unacceptable.

## PART II: THE SWIFT RECORDS

14. That I have reviewed the records of Defendant, RICHARD W. SWIFT in this matter, including his notes regarding treatment of Plaintiff, JANET BARAN.

15. Based on my education, professional training and experience as both a doctor and as a member of the OPMC, I have formed the opinion that RICHARD W. SWIFT records bear resemblance to other records I have come to find modified or "back-filled" post-care and post-treatment by the doctor.

16. That in my capacity as a disciplinary panelist, I have reviewed several records in which the records were modified to mask or cover-up deficiencies and therefore am familiar with records of this type.

17. That more likely than not<sup>4</sup>, RICHARD W. SWIFT modified or back-filled JANET BARAN's records for his own purposes.

Affirmed to be true pursuant to § 2106<sup>5</sup> of the Civil Practice Law and Rules.

Scarsdale, New York

June 13, 2012

  
AMY NEWBURGER, M.D.

<sup>4</sup> A greater than 50% standard is the applicable benchmark in a civil trial.

<sup>5</sup> CPLR §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.