BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:	)	
Triangle Compounding Pharmacy	)	
(Permit No. 07439)	)	
	)	**FINAL DECISION**
Danny Mack Barnes	)	
(License No. 15485)	)	
	)	
Jose M. Cabaleiro	)	
(License No. 10695)	)	

On October 17, 2006 and November 21, 2006, the North Carolina Board of Pharmacy (Board) conducted a hearing at the office of the Board, located at 6015 Farrington Road, Suite 201, Chapel Hill, North Carolina to determine whether or not Triangle Compounding Pharmacy (Respondent Pharmacy), Danny Mack Barnes (Respondent Barnes) and Jose M. Cabaleiro (Respondent Cabaleiro) violated North Carolina General Statute §§ 90-85.38(a)(6), (7) and (9), which provides that the Board may issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew a license to practice pharmacy or require a licensee to complete remedial education if the licensee has:

> "(6) Failed to comply with the laws governing the practice of pharmacy and the distribution of drugs;
>
> (7) Failed to comply with any provisions of this Article or rules adopted by the Board;
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> * * *
>
> (9) Been negligent in the practice of pharmacy."

Having heard testimony and received evidence, and having judged the credibility of the witnesses, the Board makes the following:

FINDINGS OF FACT

1. At all relevant times, Respondent Pharmacy was the holder of permit number 07439 and was located at 550 New Waverly Place, #110, in Cary, North Carolina.

2. At all relevant times, Respondent Barnes was the holder of license number 15485 and was part owner and Pharmacist-Manager of Respondent Pharmacy.

3. At all relevant times, Respondent Cabaleiro was the holder of license number 10695 and was Vice-President, Treasurer, and part owner of Respondent Pharmacy. Respondent Cabaleiro also worked as a pharmacist at Respondent Pharmacy.

4. Respondent Pharmacy made prescription medications known as Lasergel and Lasergel Plus. Lasergel contained 10% lidocaine and 10% tetracaine. Lasergel Plus contained 10% lidocaine, 10% tetracaine, and 0.5% phenylephrine. Lasergel and Lasergel Plus were often packaged in 30 gram tubes. These products were also made in a lower strength using 4% lidocaine and 4% tetracaine. Lasergel and Lasergel Plus were made, marketed, and sold by Respondent Pharmacy to physicians' practices and clinics. Respondents Barnes and Cabaleiro were personally involved in the preparation of Lasergel and Lasergel Plus.

5. Respondent Pharmacy employed a Pharmacy Services Representative, whose responsibilities included making unsolicited calls at medical practices and clinics, providing promotional brochures, and furnishing lunches at locations visited. Respondents concede that the Pharmacy Services Representative sometimes provided products to practitioners at no cost, but contend that even these free products were not samples because they were dispensed pursuant to an order from a physician.

6. Beginning in late 2003 and continuing through 2004, Respondent Pharmacy prepared and sold Lasergel Plus and Lasergel to Premier Body Laser and Skin Clinics (Premier)

in Raleigh, North Carolina. The sales to Premier were initiated by a request from Premier for 20 tubes of Lasergel Plus 10/10. The Medical Director of Premier at the time was Dr. Samuel H. Wurster. Respondent Cabaleiro contacted Dr. Wurster about the order. Dr. Wurster approved the purchase of Lasergel products by Premier from Respondent Pharmacy on an "as needed" basis.

7. A second and similar "as needed" order for Lasergel Plus 10/10 was made to Respondent Pharmacy. The first order was assigned prescription number 24789 on December 23, 2002 and resulted in two sales totaling 1800 grams, which represented sixty tubes. The second order, received in February 2004, was assigned prescription number 25939 and resulted in 19 sales of Lasergel Plus to Premier totaling 16,200 grams, or 540 tubes.

8. In November 2004, Dr. Ira David Uretzky replaced Dr. Wurster as Medical Director of Premier. The ordering of Lasergel products from Respondent Pharmacy continued in the same fashion through December 2004. An order designated prescription number 32494 and dated November 17, 2004 resulted in two sales of Lasergel Plus totaling 2880 grams, which represented 96 tubes. On December 23, 2004, an order for Lasergel 10/10 was received and assigned prescription number 33377, resulting in the sale of 690 grams, or 23 tubes. An order for Lasergel Plus 4/4 in December 2004 resulted in 690 grams, or 23 tubes, being sold to Premier.

9. The labeling on the tubes of Lasergel products sold to Premier did not contain any patient specific information, directions for use, or pharmacist identification. Some of the tubes contained the words "For Office Use Only."

10. A total of 25,440 grams of Lasergel Plus was sold by Respondent Pharmacy during 2004, which is the equivalent of 848 tubes.

11. Respondents created a "patient package insert" to accompany the Lasergel products. This insert, however, was created by making minor edits to the package insert for a commercially-available product that contained a different active ingredient and, to the extent it contained similar active ingredients, contained them at a different concentration than was present in the Lasergel products.

12. Once received by Premier, Lasergel products were resold to patients. The products were applied to patients at Premier and applied by patients to themselves off-site.

13. Respondents Cabaleiro and Barnes deny that they actually knew that Lasergel products were resold to patients. And based on the record presented at the hearing, the Board cannot conclude that Respondents Cabaleiro and Barnes actually knew that Lasergel products were resold to patients.

14. Shiri Berg was a patient of Premier. Premier sold a quantity of Lasergel compounded at Respondent Pharmacy to Ms. Berg.

15. Ms. Berg applied the Lasergel product to a substantial portion of her body and occluded the Lasergel with plastic wrap.

16. Ms. Berg died, and lidocaine toxicity caused by her use of the Lasergel product contributed to her death.

CONCLUSIONS OF LAW

17. The Board is deeply troubled by this case. All parties to this case agree that North Carolina law prohibits pharmacists for compounding drug products for resale. And no other conclusion is possible. 21 N.C.A.C. 46.1810 provides "Compounded drug products shall not be offered to other entities for resale."

18. 21 N.C.A.C. 46.1810 also provides, however, that "practitioners may obtain

compounded drug products to administer to patients within the scope of their professional practice."

19. There is no dispute in this case that Premier was reselling drug products compounded by Respondents. And there is no dispute in this case that Premier's reselling of drug products contributed to the tragic death of Ms. Berg.

20. The more difficult question is the responsibility that Respondents bear for the reselling of drug products that they compounded.

21. As stated above, the Board cannot, on the basis of the evidence presented at the hearing, state with certainty that Respondents Cabaleiro and Barnes actually knew that the Lasergel products they compounded and sold to Premier was to be resold.

22. Even so, the Board notes a number of troubling facts. Among them: Respondents' use of a sales representative to encourage purchases of their compounded products, the large quantities of Lasergel products compounded and sold to Premier, the means by which Premier ordered Lasergel products, and the inconsistent labeling of Lasergel products compounded and sold to Premier.

23. Respondents Cabaleiro and Barnes testified that had they known Premier was reselling Lasergel products that they compounded, they would have ceased providing the products to Premier. And the Board notes that Respondents no longer compound Lasergel products.

24. The Board concludes, however, that the facts and circumstances of the case were such that, even if Respondents did not "actually" know that Premier was reselling the Lasergel products, Respondents should have taken affirmative steps to ascertain whether Premier was reselling the Lasergel products.

25. Respondents' failure to take affirmative steps to ascertain whether Premier was reselling the Lasergel products constitutes negligence in the practice of pharmacy. N.C.G.S. § 90-85.38(a)(9).

26. Had Respondents taken such steps, then perhaps Ms. Berg's tragic death could have been avoided. The Board notes, however, that it is not making any legal conclusion that any conduct by Respondents was the proximate cause of Ms. Berg's death. The notice of hearing made no such allegation, and the Board received no evidence from the parties on this issue.

27. The Board also rules that the manner in which Respondents provided package inserts with the Lasergel products constitutes negligence in the practice of pharmacy. N.C.G.S. § 90-85.38(a)(9). As discussed above, the package insert Respondents created was, in essence, a cribbed version of a package insert that accompanies a commercially-available product with different active ingredients and active ingredients at different concentrations than found in Lasergel products. Respondents had no reasonable basis to represent that the information in the package inserts that accompanied the Lasergel products was the product of scientific investigation of the Lasergel products or, for that matter, were even factual where Lasergel products were concerned. Such representations were at best misleading to practitioners and patients alike.

28. The Board does not decide in this case whether 21 N.C.A.C. 46.1810 requires that a pharmacist "actually" know that compounded drug products are being offered for resale before a violation of that rule may be found. A "should have known" standard may be sufficient to find a violation of 21 N.C.A.C. 46.1810, and on a different record the Board might have ruled that this regulation was breached. In light of the Board's conclusion that, on the particular facts and

circumstances of this case, Respondents' conduct constituted negligence in the practice of pharmacy, however, the Board leaves the Rule .1810 question for another day.

29. Finally, the Board notes that on December 4, 2006, the United States Food & Drug Administration issued a letter of warning to Respondents stemming from, among other things, Respondents' compounding of Lasergel products. In their responses to both the FDA and the Board, Respondents aver that they have ceased compounding Lasergel products altogether.

30. The Board recognizes that compounding pharmacists can, and do, provide valuable services to patients. But with the ability to compound medications for patients comes a tremendous responsibility to ensure that these products are safe and used appropriately . Where, as here, facts and circumstances should have alerted a pharmacist that compounded drug products were not being used appropriately, that responsibility extends beyond the pharmacy counter.

IT IS, THEREFORE, ORDERED as follows:

1. Respondent Pharmacy permit number 07439 is reprimanded.

2. Respondent Cabaleiro's license to practice pharmacy number 10695 is reprimanded.

3. Respondent Barnes' license to practice pharmacy number 15485 is reprimanded.

This is the 10th day of January, 2007.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell IV
Executive Director