

**Before the
New Hampshire Board of Medicine
Concord, New Hampshire 03301**

In The Matter Of:

Docket No.: 11-02

Peter T. Pacik, M.D.
License No.: 4674
(Adjudicatory/Disciplinary Proceeding)

FINAL DECISION AND ORDER

Before the New Hampshire Board of Medicine ("Board") is an adjudicatory/disciplinary proceeding in the matter of Peter T. Pacik, M.D. ("Respondent" or "Dr. Pacik").

Background Information:

In September 2009, the Board received a complaint alleging that the Respondent, through a website, was selling prescription-strength skin-care products without first establishing a valid physician-patient relationship with the customer. On February 17, 2011, the Board issued a Notice of Hearing, scheduling a hearing for June 1, 2011.

On May 25, 2011, Hearing Counsel filed a Motion to Amend the Notice of Hearing. In the Notice of Hearing, the single charge against the Respondent (paragraph 6A) ended with "as described at RSA 329:17, VI (c) and/or (d);". The motion would amend it to "as described at RSA 329:17, VI (c), (d) and/or (i);". No objection to the motion was filed. Accordingly, the motion to amend is granted.

On Wednesday, June 1, 2011, at 1:00 p.m., the Board commenced with the adjudicatory/disciplinary hearing in the above captioned matter. Board members present¹ were:

Robert Andelman, Physician Member, Chair and Presiding Officer
Edmund Waters, Jr., Public Member
Gail Barba, Public Member
John Wheeler, Physician Member
Robert Cervenka, Physician Member
Nick Perencevich, Physician Member
Daniel Morrissey, Public Member

¹ These same Board members also deliberated and voted on this Final Decision and Order, except for Daniel Morrissey, Public Member, who was absent for the final vote.

The prosecution was represented by Hearing Counsel Attorney Jason Reimers of the Administrative Prosecutions Unit ("APU") of the Office of the Attorney General. The Respondent was represented by Attorney Peter Mosseau of Nelson, Kinder, Mosseau & Saturley, PC.

Findings of Fact:

At the outset of the hearing, the attorneys presented a Stipulation of Facts. The Board accepted the Stipulation of Facts and that stipulation is incorporated herein ("Stipulation"). See Appendix (Stipulation of Facts). The Respondent made a lengthy statement to the Board. After, he responded to the Board's questions. At times, Janet Pacik, the Respondent's practice manager/administrator and wife, assisted the Respondent with details.

The following exhibits were introduced into evidence and accepted into the record:

- Hearing Counsel's exhibits: 1 through 5.
- The Respondent's exhibits: A through F(2).

In light of the testimony and exhibits, the Board finds the following facts:

The Respondent has had a long career of medical care in New Hampshire since 1972. Exhibit A. The Respondent is board certified as a surgeon and as a plastic surgeon and has practiced as such. Exhibit A. In the Respondent's own words, he is "very dedicated and conscientious and care[s] about [his] patients." Transcript, page 10; see also page 16 and 31.

In 2003, the Respondent began to sell the Obagi Nu-Derm System ("Obagi system") through his website Skincare-MD.com. The Obagi system is a skin care regimen developed by Dr. Zein Obagi, a dermatologist in Beverly Hills, California. Included in the multiple products sold for the skin care regimen are two topical products at issue. One of the products is Tretinoin. The other product contains 4% Hydroquinone.² Neither product is available OTC. At all times relevant to this matter, both products require a prescription. Stipulation, paragraph B.

² In 1982, the FDA characterized 1.5 and 2% Hydroquinone as GRASE (Generally Regarded As Safe and Effective). Exhibit 3, 4. This allowed 1.5 and 2% Hydroquinone to be sold 'over-the counter' ("OTC" or without a prescription). In 2006, due to concerns surrounding the safety and efficacy of these products, the FDA removed the GRASE characterization and banned OTC sales for 1.5 and 2% Hydroquinone. Exhibit 3, 4. The FDA has appeared to waffle on this subject, and has asked for evidence based testing. The matter is still under review. Exhibit 3, 4. Notwithstanding, the 4% Hydroquinone, at issue here, has consistently been characterized as prescription-strength only.

In 2004, the Board issued a document entitled "Guidelines for Physician Internet and Telephone Prescribing." Exhibit 5. In this document, the Board reviewed the in-person examination requirement in the context of Internet prescribing. The Board opined that prescribing prescription drugs – over the Internet and without a physical examination – "shall be considered unprofessional conduct in violation of RSA 329:17, VI, and may be cause for discipline." Exhibit 5. In 2008, the New Hampshire Legislature amended the Board's statutory practice. See RSA 329:1. RSA 329:1-c, entitled Physician-Patient Relationship, states in relevant part (emphasis added):

"Physician-patient relationship" means a medical connection between a licensed physician and a patient that **includes an in-patient exam**, a history, a diagnosis, a treatment plan appropriate for the licensee's medical specialty, and documentation of all prescription drugs including name and dosage. ... Prescribing drugs to individuals without a physician-patient relationship shall be unprofessional conduct subject to discipline under RSA 329:17, VI. ..."

RSA 329:1-c became effective on January 1, 2009.

At some point, the Board received two letters of complaint. Transcript at 21. The complaints were not from complainants alleging that harm was caused. The complaints did allege that the Respondent was selling prescription strength medications to customers via the Internet without first establishing a physician-patient relationship. The Board's customary practice, upon the receipt of a complaint, is to request a written response from the licensee and to send the licensee a subpoena for relevant medical records.

On September 3, 2009, the Respondent received the Board's informal investigation letter and became aware that he was "out of compliance". Stipulation, paragraph G. In response, the Respondent discontinued the sale of generic Tretinoin from his website. Transcript, page 26. The Respondent discontinued the sale³ of this product from his website "because this product can be obtained from a prescription at a pharmacy." Transcript, page 31; also Transcript, pages 45-46. The Respondent, however, did not stop selling the product containing 4% Hydroquinone from his website (without conducting prior in-person examinations). The Respondent rationalized that this product "cannot be obtained through a pharmacy." Transcript 31-32. The reason this product

³ It is unclear whether the Respondent was prescribing the Tretinoin but not selling it himself to website customers. The Board is not making a finding as to Tretinoin prescribing/selling subsequent to that time.

cannot be found in pharmacies is because it is specially made for the Obagi system. Transcript 31-32. (“[Customers] can get 4% Hydroquinone, but they can’t get it in the vehicle that the Obagi Nu-Derm system is sold with.”). Obagi is a for-profit private company which markets skin-care products and sells them for a profit margin. Transcript 18, 20, 32, 38-40, and 41-42. The Respondent also sells these trade-protected products at a profit margin. Transcript 42, 52-53. As of the date of the hearing, the Respondent is continuing the sale of the formulated-product containing 4% Hydroquinone from his website without conducting prior in-person examinations. To summarize, “Dr. Pacik did not conduct in-person examinations of customers prior to customers purchasing [T]retinoin and products containing 4% [H]ydroquinone from Skincare-MD.com.” Stipulation, paragraph F. As for the latter product, the Respondent has been continuing to violate the law in this manner, despite being put on notice that it violates the law. Transcript, page 21.

Rulings of Law:

The Respondent claims that he should not be singled out and sanctioned by this Board because there are many websites on the Internet where 4% Hydroquinone is available for purchase without a prescription. Transcript, page 32. The Respondent points to two other physicians, who also sell prescription drugs, namely the 4% Hydroquinone in the Obagi system’s topical solution, from their websites. These are Dr. Joel Schlessinger in Nebraska, whom the Respondent holds in the highest regard (Exhibit F(1) and F(2)), and Dr. Mitchell Schwartz in Vermont. Transcript, pages 26-28. Notwithstanding the Respondent’s claims, it is unclear what the laws are in those jurisdictions. Transcript, pages 43-44. In this jurisdiction, however, RSA chapter 329 controls. Regardless of whether or not such sales are lawful in other jurisdictions, pursuant to RSA 329:1-c, in New Hampshire, an in-person exam is a necessary part of a valid physician-patient relationship. Stipulation, paragraph E. Regardless of what those physicians, acclaimed or otherwise, are doing in other jurisdictions, the Respondent was (and is) selling prescription strength medications to customers via the Internet without first establishing a physician-patient relationship. Stipulation, paragraph E.

The Respondent claims that his sale of the two products in question should not be considered a violation of the law. The Respondent attributes his knowledge of the safety and efficacy of these products to his own lengthy career and the literature from like-minded physicians. Transcript, pages 22, 25, 28, 29, 32, 47, 50. He requests that the Board allow him to continue to sell these products over the Internet without a valid physician-patient relationship. Transcript, pages 28 and 32. The Respondent bases this request on his careful selection of customers, on his providing of information, advice and warnings on his website, and on his follow-up care including his ability to be on call at all times for patients and customers alike. Transcript, pages 18, 19, 22, 32, 40 and 50; Exhibits B-E; Stipulation, paragraphs C and D. First, the FDA has determined that the two products in question are topical drugs for which a prescription is required. Stipulation, paragraph B. Since 2004, the Board has interpreted its statutes as requiring an in-patient examination for physician-patient relationships. More importantly, this state's legislature has expressly determined that a physician-patient relationship requires, among others, an in-patient examination. RSA 329:1-c. The Legislature further proscribed prescribing drugs without a physician patient relationship. RSA 329:1-c. This Board cannot override these regulations; rather, the Board's function is to enforce the law to protect the public. RSA 329:1-aa. Second, by the Respondent's own admissions not only he, but Obagi Nu-Derm Systems as well, believe that these products (as part of the Obagi system) should be used under the direction of a physician. Transcript, pages 37 and 47.

The Respondent and his attorney have requested that to the extent the Board does make an affirmative finding under RSA 329:17, VI, that any discipline imposed by the Board be non-public. Transcript, page 31 ("I feel that it is important not to be publicly sanctioned by the medical board.") and page 36. The Board does not have the authority to issue non-public discipline. See RSA chapter 329, especially RSA 329:17, VII; see also RSA 329:17, VII-a (characterizing confidential letters of concern as non-disciplinary). Additionally, the Board finds the Respondent's own testimony contrary to his actions. On the one hand the Respondent states: "I do not need to be penalized to be compliant with the Board's wishes" (Transcript, page 31), and, as to Tretinoin: "[S]o I decided that I didn't want to play games. The Board said that I can't sell it and I took it off the

internet.” (Transcript, page 46; see also 32). However, the Respondent purposely evaded answering the Board’s questions about ceasing to prescribe/sell the 4% Hydroquinone after he learned that doing so violated New Hampshire law. Transcript, pages 45-47. Moreover, the Respondent continues to sell the 4% Hydroquinone to this date.

Applicable Laws:

- RSA 329:17, VI states in pertinent part:

The board, after hearing, may take disciplinary action against any person licensed by it upon finding that the person: ...

(c) Has displayed medical practice which is incompatible with the basic knowledge and competence expected of persons licensed to practice medicine or any particular aspect or specialty thereof.

(d) Has engaged in dishonest or unprofessional conduct or has been grossly or repeatedly negligent in practicing medicine or in performing activities ancillary to the practice of medicine or any particular aspect or specialty thereof, or has intentionally injured a patient while practicing medicine or performing such ancillary activities.

...
(i) Has willfully or repeatedly violated any provision of this chapter or any substantive rule of the board.
...

Rulings:

The Board makes the following findings by a preponderance of the evidence:

1. In accordance with paragraph 6A of the Notice of Hearing (“NOH”), the Board finds that the Respondent displayed medical practice which is incompatible with the basic knowledge and competence expected of persons licensed to practice medicine and “board certified in both surgery and in plastic and reconstructive surgery,” when he “did not conduct in-person examinations of customers prior to customers purchasing Tretinoin and products containing 4% Hydroquinone from Skincare-MD.com” in violation of RSA 329:17, VI (c). See Transcript, page 10; Stipulation, paragraph F.

2. In accordance with paragraph 6A of the NOH, the Board finds that the Respondent has engaged in unprofessional conduct by selling “prescription strength medications to customers via the Internet without first establishing a physician-patient relationship” (as an in-person exam is a

necessary part of a valid physician patient relationship pursuant to RSA 329:1-c) in violation of RSA 329:17, VI (d). See Stipulation, paragraph E.

3. In accordance with paragraph 6A of the NOH, the Board finds that the Respondent has both willfully and repeatedly violated RSA 329:17, VI (d) as he became aware "he was out of compliance [when] he received the Board's informal investigation letter dated September 3, 2009," and is continuing to sell 4% Hydroquinone to customers via the Internet without first establishing a physician-patient relationship in violation of RSA 329:17, VI (i).

Disciplinary Action:

After making its findings of fact and rulings of law, the Board deliberated on the appropriate disciplinary action. RSA 329:17, VII ("The board, upon making an affirmative finding under paragraph VI, may take disciplinary action in any one or more of the following ways:..."). In this deliberation, the Board considered the mitigating factors that the Respondent has been forthcoming and cooperative throughout the Board's investigation and that he has had a long career in this State without previous matters before this Board.

Based upon the above the Board has voted the following:

IT IS ORDERED that the Respondent is Reprimanded.

IT IS FURTHER ORDERED the Respondent pay the amount of one dollar (\$1) for each day he has willfully and repeatedly violated this chapter. From September 3, 2009 to the date of the hearing on June 1, 2011, 635 days⁴ have elapsed. Therefore, the Respondent is assessed an administrative fine in the amount of six hundred thirty-five dollars (\$635). The Respondent shall pay this fine in full within sixty (60) days of the effective date of this Order, by delivering a money order or certified check, made payable to "Treasurer, State of New Hampshire," to the Board's office at 2 Industrial Park Drive, Suite 8, Concord, New Hampshire 03301.

⁴ 118 days in 2009; 365 days in 2010; 152 days in 2011.

IT IS FURTHER ORDERED that the Respondent is to Cease and Desist from selling prescription strength medications to customers via the Internet without first establishing a physician-patient relationship, effective ten (10) days from the effective date of this Order.

IT IS FURTHER ORDERED that if the Respondent does not Cease and Desist from selling prescription strength medications to customers via the Internet without first establishing a physician-patient relationship, the Board will hold a subsequent hearing and, pursuant to RSA 329:17, VII (g), assess an administrative fine in the amount of \$300 for each day that the violation continues.

IT IS FURTHER ORDERED that this Final Decision and Order shall become a permanent part of the Respondent's file, which is maintained by the Board as a public document.

IT IS FURTHER ORDERED that this Final Decision and Order shall take effect as an Order of the Board on the date an authorized representative of the Board signs it.

*BY ORDER OF THE NEW HAMPSHIRE
BOARD OF MEDICINE

Date: July 11, 2011

Penny Taylor
(Signature)

PENNY TAYLOR
(Print or Type Name)

Authorized Representative of the
New Hampshire Board of Medicine

*\ Amy Feitelson, M.D., Louis Rosenthal, M.D. and Mark Sullivan, P.A., Board members, recused.
Board members Robert M. Vidaver, M.D. and Daniel Morrissey, Public Member, not participating.