

**IN THE MATTER OF
SMITA PATEL, P.D.
LICENSE NO. 11805**

*** BEFORE THE
* MARYLAND STATE
* BOARD OF PHARMACY
* Case No. 08-047**

Respondent

* * * * *

FINAL DECISION AND ORDER

Background

On or about November 19, 2008, the Maryland Board of Pharmacy (the "Board") issued charges against the pharmacist license (License No. 11805) held by the Respondent, Ms. Smita Patel ("Ms. Patel"), for dispensing large amounts of controlled dangerous substances based on false or invalid prescriptions received via the internet. On May 13, 2009, a contested case hearing was held in accordance with the Administrative Procedure Act, Md. Code Ann., State Gov't, § 10-201 *et seq.* and COMAR 10.34.01, before a quorum for the purpose of adjudicating the charges against Ms. Patel. Upon conclusion of the hearing, the same quorum of the Board convened to deliberate and voted unanimously to sanction Ms. Patel's pharmacist license for the reasons set forth in this Order.

SUMMARY OF THE EVIDENCE

A. Documents.

The following documents were admitted into evidence.

- State's Exhibit No. 1A – Computer printout of pharmacist's info
- B – Computer printout of pharmacy info

State's Exhibit No. 2 – Pharmacy Service Agreement

State's Exhibit No. 3A – Division of Drug Control (DDC) Inspection Report, dated 10/16/06
B – DDC Inspection Report, dated 10/19/06
B-1 – Smeeta's Pharmacy Label for Carisoprodol

State's Exhibit No. 4 – Emails from Anna Jeffers, dated 8/18/06 and 11/30/06

State's Exhibit No. 5A – DEA Order of Immediate Suspension of Registration, dated 2/22/07
5C – Report of Investigation, dated 4/4/07

State's Exhibit No. 6A – Ms. Patel's 3/5/07 closure request
6B – 3/19/07 Closing Inspection

State's Exhibit No. 7 – 7/07 Renewal Application

State's Exhibit No. 8 – 10/12/07 DDC memo to LaVerne Naesea, with attachments

State's Exhibit No. 9 – Board Investigative Report

State's Exhibit No. 10A – 11/24/08 Letter of Procedure
B – Charges
C – Summons
D – Revised Hearing Notice

State's Exhibit No. 11 – Recent Internet ads

Respondent's Exhibit No. 1 – Character reference letters from T. Boarman, P. Sabatiuk, and
P. Klemm

Respondent's Exhibit No. 2 – Facsimile transmittals of various prescriber's DEA
Registration Certificates

Respondent's Exhibit No. 3 – Letter from JR Lopez Palet to Dr. Patel, dated 11/3/06

Respondent's Exhibit No. 4 – Email correspondence between Mr. Patel and Anna Jeffers
(This document was admitted for verification of dates only and
not for its substance).

Respondent's Exhibit No. 5 – Anna Jeffers' call log, dated 8/18/06 – 10/31/06

B. Witnesses.

State: Fred Evans, P.D., Drug Inspector, Division of Drug Control
Chandra Mouli, P.D., Deputy Chief, Division of Drug Control
James Polek, P.D., Drug Inspector, Division of Drug Control

Anna Jeffers, Esq., Legislation and Regulations Manager, Maryland Board
of Pharmacy
LaVerne Stevenson-Maye, Special Agent, Drug Enforcement
Administration
Vanessa Thomas-Gray, Compliance Investigator, MD Board of Pharmacy

Respondent: Smita Patel, P.D., Respondent and co-owner of Smeeta's Pharmacy
Pankaj Patel, Ms. Patel's husband and co-owner of Smeeta's Pharmacy

C. Administrative Notice

Maryland Board of Pharmacy Newsletter, April 2005
Maryland Board of Pharmacy Newsletter, Summer 2005

FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at the evidentiary hearing, the Board finds that the following facts are true:

1. Ms. Patel was first licensed to practice pharmacy in Maryland on April 4, 1988.
(State's Ex. 1A).
2. Ms. Patel first received her permit, No. P01788, to operate Smeeta's Pharmacy in Highland, Maryland on September 20, 1993.
3. At all times relevant herein, Ms. Patel was the 51% owner and sole dispensing pharmacist at Smeeta's Pharmacy, and her husband, Mr. Pankaj Patel, was the 49% owner. (State's Ex. 1B).
4. On August 3, 2006, Ms. Patel and Mr. Patel entered into a contract, the "Pharmacy Service Agreement," with Doral Consulting Group, LLC ("Doral") of Doral, Florida whereby the Patels committed Smeeta's Pharmacy to filling mail-order prescriptions written by licensed U.S. physicians. The contract specified that Doral would work on a "tear [sic] basis. First week 50-100 prescription orders per day, following the

second week 100-250 orders per day, third week 250-300 orders. Orders will increase according to the availability of medications.” (State’s Ex. 2).

5. On October 16, 2006, the Division of Drug Control (“DDC”) conducted a routine inspection of Smeeta’s Pharmacy and discovered that Ms. Patel was dispensing a large number of prescriptions received via the internet. Smeeta’s was a small pharmacy which had filled approximately 30-40 walk-in prescriptions per week prior to contracting with Doral. (State’s Ex. 3A).
6. On October 19, 2006, Chandra Mouli, P.D., Deputy Chief of DDC, conducted a follow-up inspection of Smeeta’s Pharmacy during which Ms. Patel explained the process she used to receive internet prescriptions. (State’s Ex. 3B). This process involved logging on to the website of an internet pharmacy broker¹ where Ms. Patel could select from a list of prescriptions she would like to fill. Once she selected the drugs, Ms. Patel would print a three-part label containing (1) the drug bottle’s label; (2) the prescription with an electronically-created signature; and (3) the shipping label for sending the drug to the patient. (State’s Exhibit 3B-1; Patel Hrg. Tr. at 38-39).
7. During the October 19, 2006 inspection, Mr. Mouli informed Ms. Patel that electronic prescriptions for controlled drug prescriptions were not valid and that she needed to follow DEA regulations related to controlled dangerous substance (“CDS”) prescriptions. Mr. Mouli then obtained the names and DEA registration information of the physicians whose prescriptions Ms. Patel was filling via the internet. (State’s Ex. 3B).

¹ According to the DEA’s Order to Show Cause and Immediate Suspension of Registration, orders placed by individual customers originated from the following websites: www.marioxmedsecomsmile.com; www.mainstreet.com; www.pdgnetwork.com; www.mottonetwork.com; and www.sprintmed.com. (State’s Ex. 5A).

8. During the inspection, Mr. Mouli observed that many of the prescribing physicians whose prescriptions Ms. Patel was accepting were located in Puerto Rico, but their patients were located as far away as Arizona and were having the prescriptions filled in Maryland. Mr. Mouli informed Ms. Patel that a physician-patient relationship was necessary and that a pharmacist must ensure that a prescription is written for a legitimate and medical purpose. (Patel Hrg. Tr. at 40-41).
9. Mr. Mouli documented the amount of prescriptions Ms. Patel had filled over the internet between August 14, 2006 and October 18, 2006 and found a total of 7,449. (State's Ex. 3B).
10. Thereafter, Mr. Mouli contacted the DEA, which initiated an investigation on October 25, 2006.
11. DEA Investigator LaVerne Stevenson-Maye's investigation revealed that there were primarily four physicians located in Miami, Florida and Puerto Rico, who were writing the prescriptions Ms. Patel was dispensing. (State's Ex. 5C).
12. The DEA's investigation revealed that between October 1, 2004 and June 30, 2006, prior to contracting with Doral, Ms. Patel ordered 17,000 doses for Phentermine, whereas between August 1, 2006 and November 16, 2006 Ms. Patel purchased 495,000 doses of Phentermine. (State's Ex. 5A). This is a 2900% increase in the dispensing of a Schedule IV controlled substance.
13. The DEA conducted an authorized search of Smeeta's on February 26, 2007 and seized all of the pharmacy's CDS, three computers, a fax machine, a pill counter, 11 boxes of internet prescriptions, and several boxes of other miscellaneous documents. (State's Ex. 5C).

14. Upon execution of the search, the DEA issued an Order to Show Cause and Immediate Suspension of Registration for Smeeta's Pharmacy based on the large quantities of Phentermine, and other controlled substances which Ms. Patel was dispensing when she knew or should have known they had not been lawfully prescribed. (State's Ex. 5A).
15. Immediately thereafter, Ms. Patel voluntarily surrendered her DEA registration. (State's Ex. 5C).
16. By letter dated March 6, 2007, Ms. Patel informed the Board she wished to close the pharmacy portion of her business and requested the Board conduct an on-site closing inspection. (State's Ex. 6A).
17. On March 19, 2007, DDC inspector James Polek, P.D. performed a closing inspection for Smeeta's Pharmacy. (State's Ex. 6B). Mr. Polek noted that the controlled substances had been impounded by the DEA; the non-controlled drugs and prescription records were sent to Olney Professional Pharmacy; and the DEA registration and unused order forms had been impounded by the DEA. (State's Ex. 6B).
18. Mr. Polek's report also noted that he returned Smeeta's pharmacy permit to the Board. (State's Ex. 6B). Mr. Polek informed Ms. Patel that the signs identifying her business as a pharmacy were required to be removed within 30 days of his inspection. (Patel Hrg. Tr. at 62).
19. On October 11, 2007, Mr. Polek returned to Smeeta's Pharmacy to verify removal of the signs. The store was not open, but Mr. Polek took photographs of the awnings

and signs displaying “Smeeta’s Integrative Pharmacy” and “Smeeta’s Natural Pharmacy.” (State’s Ex. 8).

OPINION

The practice of pharmacy involves more than merely collecting money in exchange for prescriptions. It involves providing quality patient care based on clinical expertise regarding the proper and most effective medications. The practice of pharmacy is regulated by both federal and state laws to ensure that this quality of care is maintained and that each prescription filled is validated prior to being dispensed.

A pharmacist must exercise sound ethical judgment to protect patient safety and welfare and should not place the financial concerns of operating a pharmacy above this duty. Ms. Patel, however, failed to exercise sound ethical judgment and thus jeopardized patient safety and welfare by illegally operating an internet pharmacy as part of a scheme with Doral to earn inflated profits on controlled drugs. In so doing, the Board finds that Ms. Patel violated several provisions of the Pharmacy Act and the Pharmacist Code of Conduct. Md. Code, Health Occ. § 12-101, *et seq.* and COMAR 10.34.10.01, *et seq.*

The Pharmacist Code of Conduct provides that a pharmacist must “[a]bide by all federal and State laws relating to the practice of pharmacy....” COMAR 10.34.10.01.A(1). Ms. Patel disregarded both sets of laws. First, Ms. Patel violated 21 C.F.R. § 1306.21(a) (1997), which clearly states that “[a] pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, *only* pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner....” (Emphasis added).

Ms. Patel violated this provision by dispensing thousands of prescriptions for Schedule III and IV drugs without either a written or faxed prescription.²

Instead, Ms. Patel was accepting illegal electronic prescriptions. A prescription transmitted from a broker's website to Ms. Patel's computer is neither a faxed nor an oral transmission of the prescription but is instead an electronic prescription. As Inspector Mouli testified, an electronic prescription, is not a fax. (Patel Hrg. Tr. at 42). Federal law requires that a prescription be manually signed and presented to the pharmacy, called in by a physician, or manually signed and faxed to the pharmacy. Even after Mr. Mouli, a pharmacist and inspector from the DDC, the Maryland agency charged with the regulation of CDS, personally informed Ms. Patel during his October 19, 2006 inspection that this practice was prohibited for all scheduled drugs, Ms. Patel continued to accept electronic signatures for CDS until at least December 2006. (Patel Hrg. Tr. at 175).

Unsatisfied with Mr. Mouli's instruction and reference to the appropriate DEA regulations (State's Ex. 3B), Ms. Patel's husband sought a different answer from a non-pharmacist Board staff member. On November 30, 2006, Mr. Patel received an inaccurate email from Anna Jeffers, Legislative and Regulations Manager, stating that "[e]lectronic signatures are permissible for internet mail order pharmacies except for CII prescriptions." (State's Ex. 4). Rather than seeking to clarify the difference between Mr. Mouli's advice to her and Ms. Jeffers's reply to her husband, Ms. Patel continued her reliance on electronic signatures for the dispensing of CIIs and CIVs. Had Ms. Patel conducted even minimal research on this matter (or consulted an attorney), she would have discovered that the DEA Pharmacist Manual states under the

² Inspector Mouli's October 19, 2006 report lists the following drugs: Butalbital, Acetaminophen and Caffeine (Schedule III); Carisprodol; Diethylprprion (Schedule III); Phentermine (Schedule IV); Tramadol; and Adipex (Schedule IV). The majority of the drugs stocked in the pharmacy at that time were Phentermine. (State's Ex. 3B.)

section entitled "Schedule III-V Controlled Substance Prescriptions" that "[a]t this time, DEA does not permit a prescription received via the internet to be filled."

Second, regardless of the miscommunication about electronic signatures, Ms. Patel violated 21 C.F.R. § 1306.04 (1997), which provides that in order for a prescription for a controlled substance to be effective, it "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Ms. Patel knew or should have known by virtue of the distance between the prescribing physicians and their "patients" that these physicians did not have a valid physician-patient relationship with these "patients." With prescribing physicians located primarily in Puerto Rico and patients residing as far away as Arizona, one can not reasonably believe that valid face-to-face physician-patient relationships existed. Ms. Patel admitted that she was uncomfortable filling the internet prescriptions and had so many problems with them that she was contacting Doral or the physicians in Puerto Rico on a daily basis. (Patel Hrg. Tr. at 169-172). Further buttressing the dubious nature of the internet prescriptions was the sheer volume of prescriptions for primarily the same drug, Phentermine, being prescribed by the same four physicians. In fact, Inspector Mouli explained the necessity of a physician-patient relationship to Ms. Patel upon his review of her 3-part label and the online system she used to select which prescriptions she would fill. (Patel Hrg. Tr. at 40-41). Ms. Jeffers also emphasized this requirement in her November 30, 2006 email to Mr. Patel. (State's Ex. 4).

Further, the November 30, 2006 e-mail from Ms. Jeffers also referenced applicable articles from the Board's newsletters. (State's Ex. 4). Both the April 2005 and Summer 2005 newsletters, of which the Board takes administrative notice, contain articles discussing this requirement. (Patel Hrg. Tr. at 96). The Summer 2005 article specifically cautions that

“[p]harmacists may expose themselves to potential disciplinary action for filling multiple prescriptions received through Internet services to patients when it is obvious that there is no physician-patient relationship.”³ The April 2005 article even quoted 21 C.F.R. § 1306.04, including the notice that the “responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist** who fills the prescription.”⁴ (Emphasis in original). Ms. Patel knew or should have known, as the article stated, that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. 829].” The Board rejects Ms. Patel’s assertion that the lack of legitimate physician-patient relationships was due to the patients’ desire to keep their diet pill use a secret from their “regular doctors” or “confidential.” (Patel Hrg. Tr. at 166 and 211). Moreover, Ms. Patel admits that she began “winding things down” shortly after receiving Ms. Jeffers’ correspondence, leaving the Board to conclude Ms. Patel did, in fact, realize her operation of an internet pharmacy was indeed unlawful and could result in revocation of her pharmacist’s license. (Patel Hrg. Tr. at 175).

Third, the Board finds Ms. Patel violated Md. Code, Health Occ., § 12-704(b), which prohibits an establishment without a pharmacy permit to “represent to the public by title, by description of services, methods, or procedures, or otherwise, that the establishment is a pharmacy.” Despite having been informed by DDC inspector James Polek at the pharmacy’s closing inspection on March 19, 2007 that Ms. Patel had 30 days to remove the awning and signs identifying her business as a pharmacy, Ms. Patel failed to do so until after Mr. Polek’s October 11, 2007 follow-up inspection.

³ Former Board of Pharmacy President, Melvin Rubin, was the author of this article.

⁴ Melvin Rubin also authored the April 2005 article.

Fourth, the Board finds Ms. Patel in violation of Health Occ., § 12-313(b)(2) for having deceptively used her license in furtherance of a fraudulent scheme designed to dispense thousands of invalid prescriptions. The above findings illustrate this. Moreover, Ms. Patel admits that the hundreds of thousands of doses she dispensed were all being issued by only four physicians located in Puerto Rico. Ms. Patel asserts she was an innocent victim in this scheme, but her testimony proves otherwise. For instance, although Ms. Jeffers' November 30, 2006 email to Mr. Patel stated that "[t]he Board requires that an in-person doctor/patient relationship exists before a pharmacist dispenses a prescription," Ms. Patel testified that she did not realize that "in-person meant face to face." (Patel Hrg. Tr. at 174). Such statements lack credibility, and the Board rejects this explanation. Ms. Patel's lack of integrity is further demonstrated by the statement a Smeeta employee made to an undercover DEA investigator on January 23, 2007 that the investigator could not order Phentermine directly from the pharmacy but instead would need to find a website through which to *order* it since, "We just sell the drugs and ship them out." (State's Ex. 5A). Ms. Patel and her staff did not even convey to the undercover investigator the need for a valid prescription.

Finally, the Board finds Ms. Patel's deceptive practices and blatant disregard for the law amount to professional incompetence, in violation of Md. Code, Health Occ., § 12-313(b)(21). Professional competence includes the ability to adhere to the Pharmacist Code of Conduct by valuing patient safety and the welfare of the public above one's personal gain. Ms. Patel clearly valued her own financial gain above the safety and welfare of the public or she would not have dispensed 495,000 doses of Phentermine, a drug Ms. Patel admits is known to have dangerous side effects, especially when taken in combination with other medications. (Patel Hrg. Tr. at 227-28). Despite the doctors in Puerto Rico "trying to brush [her] off," Ms. Patel continued

dispensing these controlled substances. Her business grew from one which dispensed between 30 – 40 prescriptions a day to one that dispensed as many as 600 internet prescription orders a day. Ms. Patel admitted that her sole motivation for contracting with Doral was financial: (1) she sought to make up for the financial losses she had suffered from new competition in her area, and (2) she sought to stave off the threat from McKesson that it would cease doing business with her if sales did not increase by December 2006. (Patel Hrg. Tr. at 187).

In sum, the Board finds Ms. Patel can not be trusted to operate a pharmacy, even one without CDS, in the near future. Ms. Patel lacks credibility and has shown an attempt to avoid the law in pursuit of financial gain rather than operate a legal establishment. Owning and operating a pharmacy is a serious responsibility, and Ms. Patel's actions show a disregard for the commitment necessary to function professionally, competently and within the requirements of the law as a licensed pharmacist.

CONCLUSIONS OF LAW

Based upon the foregoing summary of evidence, findings of fact, and opinion, the Board concludes that Ms. Patel violated Md. Code, Health Occ., §§ 12-313(b)(2), 12-313(b)(21), 12-313(b)(25), and 12-704(b). The Board dismisses the charge based on Health Occ., § 12-313(b)(29).

SANCTION

The Board's primary duty is protection of the public. Md. Code, Health Occ., § 12-205. To that end, and in light of the fact that most of the above findings remain undisputed, the Board finds it necessary to restrict Ms. Patel's pharmacist license. To the extent Ms. Patel has

mitigated her violations, the Board has granted some leniency in its sanction. Rather than suspend Ms. Patel's license as it has done in the case of other pharmacists who were illegally operating an internet pharmacy,⁵ the Board has instead placed Ms. Patel's license on probation, during which time she is prohibited from owning a pharmacy and must complete education measures, and has imposed a civil monetary penalty of \$10,000.

In determining whether to impose a civil monetary penalty, the Board considered the following factors set forth in COMAR 10.34.11.06:

1. The extent to which the Ms. Patel derived any financial benefit from the unprofessional or improper conduct;
2. The willfulness of the unprofessional or improper conduct;
3. The extent of actual or potential public harm caused by the unprofessional or improper conduct;
4. Ms. Patel's history of previous violations; and
5. The existence of mitigating factors.

Ms. Patel undoubtedly derived substantial financial benefit from having dispensed hundreds of thousands of doses of various controlled substances via the internet. For instance, there was a 2900% increase in the amount of Phentermine Smeeta's Pharmacy purchased prior to contracting with Doral and the amount it ordered subsequently. Ms. Patel also received \$37,000 in advances for start-up costs upon contracting with Doral. It is likely Ms. Patel would not have engaged in the business of internet pharmacy had she not been so motivated by financial considerations; as Ms. Patel testified, her primary motivation in starting an internet pharmacy was to recoup the losses she had suffered as a result of increased competition in her area.

⁵ See *In the Matter of Steven Sodipo* and *In the Matter of Callixtus Nwaehiri*, Case No. 05-162. Both pharmacists were summarily suspended on November 8, 2006 for their illegal operation of an internet pharmacy, and they currently remain on suspension.

The willfulness of Ms. Patel's unprofessional conduct in relying on electronic prescriptions and failing to ensure valid physician-patient relationships was demonstrated by her continued operation of an illegal internet pharmacy despite in-person verbal instruction by Mr. Mouli and email correspondence from Ms. Jeffers. Ms. Patel's reliance on the faxed credentials of the prescribing physicians (Respondent's Ex. 2) does not amount to her verification of a valid physician-patient relationship.

While it is difficult to assess the exact extent of harm Ms. Patel caused those patients who received thousands of doses of CDS from her pharmacy, it is reasonable to conclude that some may have formed addictions to these habit-forming medications or suffered serious side effects such as pulmonary hypertension, palpitation, fainting spells, or liver or kidney damage. (Patel Hrg. Tr. at 158).

The primary mitigating factors considered by the Board were the relatively short period of time Ms. Patel operated her illegal internet pharmacy, her voluntary surrender of her pharmacy permit and DEA registration, and her cooperation with the Board's investigation.

The Board finds Ms. Patel unfit to own a pharmacy, even one that does not dispense CDS, during the period of her probation because it is evident from her disregard of various State and federal pharmacy laws that she is need of additional education before she can be trusted to competently operate a pharmacy on her own or in part.

ORDER

Based on the foregoing Findings of Fact, Opinion, and Conclusion, by a unanimous decision of the Board it is hereby:

ORDERED that the pharmacist's license held by Ms. Patel is placed on PROBATION for a period of at least THREE (3) YEARS from the date of this Order, and be it further,


ORDERED that during the probationary period, Ms. Patel:

1. May not own or operate a pharmacy, in whole or in part, or work for a pharmacy owned, in whole or in part, by a family member;
2. Shall successfully complete six (6) credits in a college-level, Board-approved healthcare ethics course;
3. Shall successfully complete the Multistate Pharmacy Jurisprudence Examination within six (6) months from the date of this Order;
4. Shall submit to the Board payment of a \$10,000 civil monetary penalty pursuant to Md. Code, Health Occ., § 12-314(a); and
5. Shall maintain the required continuing education credits in accordance with Md. Code, Health Occ., § 12-309.

ORDERED that upon full completion of the three years of her probation, Ms. Patel may petition the Board to lift the probation provided she has fully complied with all of the terms and conditions in this Order and provided that she has no outstanding complaints against her, and be it further,

ORDERED that this is a final order of the State Board of Pharmacy and as such is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., State Gov't Art., §§10-611, *et seq.*

November 2, 2009
Date


LaVerne G. Naesea, Executive Director
for
Donald Taylor, P.D.
President, Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Code Ann., Health Occ. Art., §12-316, you have the right to take a direct judicial appeal. A petition for appeal shall be filed within thirty days from the date of mailing of this Final Decision and Order and shall be made as provided for judicial review of a final decision in the Maryland Administrative Act, Md. Code Ann., State Gov't Art., §§10-201, *et seq.*, and Title 7, Chapter 200 of the Maryland Rules.