

IN THE MATTER OF * **BEFORE THE**
APPLE DISCOUNT DRUGS * **STATE BOARD**
PERMIT No: P01701 * **OF PHARMACY**
Respondent-Pharmacy * **CASE No.: PT-10-025**

* * * * *

CONSENT ORDER

Based upon information received and a subsequent investigation by the Maryland Division of Drug Control ("DDC"), and subject to the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101 *et seq.* (2009 Repl. Vol.) and the Maryland Administrative Procedure Act, Md. State Gov't Code Ann. §10-226(c) (2009 Repl. Vol.), the State Board of Pharmacy (the "Board") issued an Notice of Intent to Summarily Suspend dated March 25, 2010 to Apple Discount Drugs, Permit Number P01701 (the "Respondent-Pharmacy"). Specifically, the Board found reliable evidence demonstrating that the public health, safety or welfare imperatively required emergency action.

On May 12, 2010, the Board held a show cause hearing before a quorum of the Board to allow the Respondent-Pharmacy the opportunity to show cause why the Respondent-Pharmacy did not pose an imminent threat to the public health, safety or welfare. Prior to the show cause hearing, the State and the Respondent-Pharmacy, by and through its attorney, discussed settlement negotiations, which were presented to the Board. The Respondent-Pharmacy and the Board agree to resolve the matter by way of this Consent Order with the terms contained herein.

FINDINGS OF FACT

1. At all times relevant, the Respondent-Pharmacy was authorized to operate a pharmacy in the State of Maryland. The Respondent-Pharmacy currently holds a permit to operate a pharmacy under permit number P01701. The Respondent-Pharmacy was first issued a permit on March 24, 1992, and its current permit will expire on December 31, 2011.

2. At all times relevant, Jeffrey Sherr, P.D. owned the Respondent-Pharmacy located at 404 N. Fruitland Boulevard, Salisbury, Maryland 21801.¹

3. On or about January 28, 2010, the Maryland Division of Drug Control ("DDC") received a facsimile from Company A² regarding a suspicious order placed by the Respondent-Pharmacy on January 27, 2010. The order was for 12,000 tablets of Carisoprodol 350 mg. The order was suspicious because the Respondent-Pharmacy had ordered only 500 dosage units in the previous 12 months. Carisoprodol is a muscle relaxant known for having a high incidence of abuse. When Company A inquired about the large order, the Mr. Sherr explained that it had recently begun "mail service" and Carisoprodol is a popular drug.

4. On March 8, 2010, DDC visited the Respondent-Pharmacy to conduct a routine inspection and to investigate whether the Respondent-Pharmacy was conducting a Internet/mail order operation in the pharmacy.

¹ The Respondent-Pharmacy has additional locations at 1500 Pemberton Drive, Salisbury, Maryland 21801 (Permit Number: P04379) and 314 Franklin Street, Suite 600, Berlin, Maryland 21811 (Permit Number: 03086). The Respondent-Pharmacy also operates a home infusion pharmacy at it's N. Fruitland Boulevard location, which is its primary location.

² To protect confidentiality, names of individuals and/or companies other than the Respondent are not used in this Consent Order. The Respondent may obtain a listing of the names from the Administrative Prosecutor.

5. On March 8, 2010, DDC inspectors met with Mr. Sherr, who denied that he was currently operating an Internet pharmacy business out of the Respondent-Pharmacy's retail pharmacy. Mr. Sherr stated that in 2008 the Respondent-Pharmacy briefly operated an Internet pharmacy business utilizing a Delaware physician who prescribed Tramadol.

6. Mr. Sherr left the inspectors briefly to obtain a requested report. Upon his return, while the DDC inspectors were reviewing the usage report for Carisoprodol in the retail pharmacy, Mr. Sherr admitted that he had been untruthful with the DDC inspectors. Mr. Sherr altered his statement and admitted to conducting an Internet pharmacy business from his N. Fruitland Boulevard location since December 2009.

7. Mr. Sherr stated that he was dispensing three drugs through his Internet pharmacy, but was, in fact, dispensing four drugs: Carisoprodol 350 mg (Soma), Cyclobenzaprine 10 mg (Flexeril), Tramadol 50 mg, and Butalbital/APAP/Caffeine 5mg/325mg/40 mg (Fioricet).³ Of the four drugs being dispensed via the Respondent-Pharmacy's Internet operation, only Fioricet is a controlled drug (Schedule III) in the Maryland Drug Schedule. Fioricet is not a DEA scheduled drug.

8. Mr. Sherr maintained separate prescriptions records, inventory records, and financial records for the Internet and retail pharmacies.

³ Cyclobenzaprine (Flexeril) is a muscle relaxant used to treat skeletal muscle conditions such as pain or injury. Tramadol is an opioid analgesic used to treat moderate to severe pain. Butalbital/APAP/Caffeine (Fioricet) is a combination drug product used to treat tension headaches. Butalbital is habit-forming and has the potential for abuse.

9. The Respondent-Pharmacy operated its Internet pharmacy business as follows: Individuals are able to obtain prescription drugs by accessing a website, furnishing certain cursory information on a questionnaire, including medical history, and may submit to a telephone consultation. No physical exams are conducted, and a valid doctor-patient relationship is not established. The physicians prescribing the medications are not located in Maryland and the patients are located all over the United States.

10. The DDC investigation revealed that the Respondent-Pharmacy and Mr. Sherr entered into agreements with Internet Intermediary Company A ("Intermediary A") and Internet Intermediary Company B ("Intermediary B"). The Respondent-Pharmacy would receive prescriptions through the Internet, fill the prescriptions and ship the medication directly to the patient.

11. The Respondent-Pharmacy received a payment of \$5.00 for each prescription filled plus the cost of the drugs dispensed. For the week of March 2, 2010, Intermediary A paid the Respondent-Pharmacy \$1422.80 for 124 prescriptions. For the same time period, Intermediary B paid the Respondent-Pharmacy \$3259.56 for 285 prescriptions.

12. According to the documentation gathered during the DDC investigation, during the three month period in which the Internet pharmacy was in business, approximately 1000 prescriptions were filled.

13. Prescriptions were mailed to patients in at least 30 states.

14. The prescriptions received through Intermediary A utilized the same three physicians. Two of the three physicians were located in Pennsylvania and one physician was located in California.

15. The prescriptions received through Intermediary B utilized one physician, who was located in Delaware.

16. During the inspection, the DDC inspectors reviewed invoices and found three orders for Carisoprodol for a total of 12,000 tablets.

17. The DDC inspectors conducted an inventory of drugs found in the Respondent-Pharmacy's Internet pharmacy area. The following is a list of the names and quantities of drugs found in the Internet pharmacy area:⁴

# bottles x # pills	Name & Strength	Total Pills
50 x 180	Tramadol 50 mg vials	9000
1 x 90	Tramadol 50 mg vials	90
1 x 60	Tramadol 50 mg vials	60
32 x 1000	Tramadol 50 mg by Amneal	32,000
1 x 50	Tramadol 50 mg by Amneal	50
19 x 1000	Carisoprodol 350 mg by Qualitest	19,000
1 x 50	Carisoprodol 350 mg by Qualitest	50
16 x 1000	Carisoprodol 350 mg by Watson	16,000
1 x 25	Carisoprodol 350 mg by Watson	25
31 x 500	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg by Watson	15,500
1 x 100	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg by Watson	100
50 x 90	Tramadol 50 mg in vials	4,500
4 x 30	Tramadol 50 mg in vials	120
2 x 60	Tramadol 50 mg in vials	120
4 x 30	Carisoprodol 350 mg in vials	120
3 x 60	Carisoprodol 350 mg in vials	180
29 x 90	Carisoprodol 350 mg in vials	2610
2 x 30	Carisoprodol 350 mg in vials	60
8 x 60	Carisoprodol 350 mg in vials	480

⁴ Also found in the Internet pharmacy area were 110 Federal Express padded envelopes waiting to be shipped.

1 x 250	Cyclobenzaprine 10 mg by Watson	250
21 x 90	Cyclobenzaprine 10 mg by Watson	1890
6 x 30	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	180
5 x 60	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	300
22 x 120	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	2640
32 x 90	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	2880
47 x 90	Carisoprodol 350 mg in vials ⁵	4230
22 x 180	Tramadol 50 mg in vials with prescription labels	3960
1 x 60	Tramadol 50 mg in vials with prescription labels	60
1 x 90	Tramadol 50 mg in vials with prescription labels	90
5 x 120	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials with prescription labels	600
5 x 90	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials with prescription labels	450
6 x 90	Carisoprodol 350 mg in vials with prescription labels	640

Total Carisoprodol 350 mg tabs = 43,295
Total Butalbital/APAP/Caffeine 50mg/ 325mg/40mg tabs = 22,650
Total Cyclobenzaprine 10 mg tabs = 2140
Total Tramadol 50 mg tabs = 50,050

18. While inspecting the Respondent-Pharmacy's Internet pharmacy area, the DDC inspectors found three-part labels for drugs awaiting shipment. The labels included: (1) a shipping label, (2) a prescription bottle label, and (3) the prescription itself, which contained the prescribing physician's electronic signature.

19. Prescriptions for controlled substances require either a written prescription signed by a prescribing practitioner, or a facsimile received by facsimile equipment of a written signed prescription transmitted to the pharmacy. All of the prescriptions being filled by the Respondent-Pharmacy's Internet pharmacy operation were generated using a computer with attached printer

⁵ Filled prescriptions waiting to be mailed.

located in the Internet pharmacy area. The Internet intermediaries generated the labels, which were then printed by the Respondent.

20. In the Internet pharmacy area, DDC inspectors found that Mr. Sherr and/or his designees repackaged the medications in prescription bottles without proper labeling. Each individual, repackaged prescription bottle had a small piece of paper affixed to the lid or to the plastic bin in which the bottles were stored. On the affixed piece of paper was a handwritten, abbreviated name for the medication that was inside the bottle, an abbreviation for the manufacturer's name and the quantity of tablets in the bottle. The bottles were not labeled with a lot number or an expiration date.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated the following:

Md. Health Occ. Code Ann. § 12-403

(b) *In general.* – Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

- (1) Shall be operated in compliance with the law and with the rules and regulations of the Board; [and]
- (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 or a registered pharmacy technician under §12-6B-09 of this title, to wit:

Md. Health Occ. Code Ann., § 12-313

Md. Health Occ. Code Ann. § 12-409

(a) *In general* – Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

- (1) Is conducted so as to endanger the public health or safety;
[and]
- (2) Violates any of the standards specified in § 12-403 of this subtitle[.]

ORDER

Based on agreement of the parties, it is therefore this 15th day of July 2010, by an affirmative vote of the Board, hereby:

ORDERED that the Respondent-Pharmacy's license to operate a pharmacy in the State of Maryland is hereby placed on **PROBATION** for a period of at least three (3) years, subject to the following terms and conditions:

1. During the probationary period, the Respondent-Pharmacy shall be subject to random inspections by the Board; and
2. The Respondent-Pharmacy shall provide training to all pharmacy staff members regarding valid prescriber-patient relationships and non-scheduled drugs of abuse. Such training shall occur within ninety (90) days of the date of this Order and yearly thereafter for the duration of the probationary period;

ORDERED that the Respondent-Pharmacy shall pay a fine in the amount of \$10,000, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and it is further

ORDERED that the Respondent-Pharmacy agrees not to own or operate an Internet pharmacy operation, although nothing in this Order shall prohibit the Respondent-Pharmacy from receiving and processing electronic prescriptions and refills in a manner consistent with applicable laws and regulations; and it is further

ORDERED that the Respondent-Pharmacy shall bear all expenses

associated with this Order; and it is further

ORDERED that the Respondent-Pharmacy shall at all times cooperate with the Board's monitoring, supervision, and investigation of the Respondent-Pharmacy's compliance with the terms and conditions of this Consent Order; and it is further

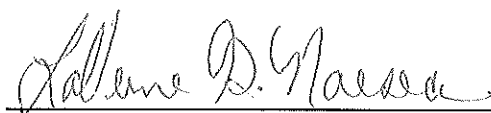
ORDERED that after three (3) years from the date of this Consent Order, the Respondent-Pharmacy may submit a written petition to the Board requesting termination of probation. After consideration of the petition, the probation may be terminated, through an order of the Board. The Board shall grant the termination if the Respondent-Pharmacy has fully and satisfactorily complied with all of the probationary terms and conditions and there are no pending complaints related to the charges; and it is further

ORDERED that if the Respondent-Pharmacy violates any of the terms and conditions of Probation and this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board may impose any appropriate sanction under the Act, including an additional probationary term with conditions of probation, reprimand, suspension, revocation and/or a monetary penalty; and it is further

ORDERED that the Respondent-Pharmacy shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for

purposes of public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 *et seq.* and COMAR 10.34.01.12.

for 
Michael N. Souranis, P.D., President
Maryland Board of Pharmacy

CONSENT

I, Jeffrey Sherr, P.D., owner and operator of Apple Discount Drugs, acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the

language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

7-2-10
Date

Jeffrey Sherr P.D.
Jeffrey Sherr, P.D., owner and operator
Apple Discount Drugs, Respondent

Reviewed and approved by:

Laurence B. Russell
Laurence B. Russell, Esq.
Attorney for the Respondent

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Wicomico :

I HEREBY CERTIFY that on this 2nd day of July, 2010,

before me, a Notary Public of the foregoing State personally appeared Jeffrey Sherr, P.D. License Number 08902, owner and operator of Apple Discount Drugs, Permit Number P01701, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

Elizabeth J. Albert
Notary Public

My Commission Expires: 08/01/2010

