

IN THE MATTER OF
JEROME A. DANOFF, P.D.
LICENSE NO.06158,
RESPONDENT

* BEFORE THE
* MARYLAND STATE
* BOARD OF PHARMACY
*

* * * * *

CONSENT ORDER

Based on information received and a subsequent investigation by the Maryland State Board of Pharmacy (the "Board") and subject to the Health Occupations Article, Code Ann., §12-101 et seq., 1994 Repl. Vol. (the "Act") the Board charged **Jerome A. Danoff, P.D., License No. 06158**, (the "Respondent"), with having violated certain provisions of the Act under §12-313 (b).

Specifically, the Board charged the Respondent with having violated the following provisions of §12-313(b) of the Act:

(b) Subject to the hearing provisions of §12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant, reprimand any licensee, place any licensee on probation; or suspend or revoke a license if the applicant or licensee:

(23) Is disciplined by a licensing or disciplinary authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary actions under the Board's disciplinary rules.

The grounds actionable under §12-313 (b) are the following:

(7) (Willfully fails to file or record any report that is required by law);

(14) (without first having received a written or oral prescription for the drug from an authorized prescriber, dispense any drug for which a prescription is required);

(20) (Is professionally, physically, or mentally incompetent).

BACKGROUND

On June 4, 1996 the Virginia Department of Health Professions (the "Virginia Board") summarily suspended the pharmacist's license of the Respondent. On August 14, 1996 the Virginia Board found as fact that the Respondent had violated the Virginia laws as they related to the practice of pharmacy and the Virginia Board revoked the pharmacist's license of the Respondent and imposed a ten thousand dollar (\$10,000.00) penalty. The Respondent filed an appeal in the Arlington County Circuit Court, Chancery No. 97-181.

On August 21, 1997 the Virginia Board issued an Order, vacating the previous Order, and reinstating the Respondent's Virginia pharmacist license, placing him on indefinite suspension, and staying the ten thousand dollar penalty. By way of agreement the appeal was dismissed in the Arlington County Circuit Court with prejudice. (See Exhibit B).

At the request of the Respondent, on May 21, 1998 a case resolution conference was held at the Board's office on Patterson Avenue. The Respondent's attorney, Mr. John Vecchione, submitted the appropriate documentation, and entered his appearance on behalf of the Respondent. Mr. Irving Lottier, Secretary to the Board; Mr. William Johnson, consumer board member; Ms. Norene Pease, Executive Director to the Board; Ms. Cheryl Cresic, Board's office secretary; Mr. Paul Ballard, Assistant Attorney General, Board Counsel; Mr. John Vecchione, Respondent's attorney, the Respondent, and Ms. Lisa B. Hall, administrative

prosecutor were present.

FINDINGS OF FACT

The Board makes the following findings:

1. At all times relevant to the charges herein, Respondent was licensed to practice pharmacy in the State of Maryland.

2. Respondent applied for renewal of his Maryland license to practice pharmacy with the State Board of Pharmacy on August 20, 1996.

3. Respondent disclosed in his renewal application that his pharmacy license in the State of Virginia had been the subject of a disciplinary proceeding for violations of Virginia's Pharmacy Act, as outlined below.

4. On June 4, 1996 the Virginia Board of Pharmacy summarily suspended the pharmacy license of the Respondent. On August 5 and 14, 1996 the Virginia Board held an administrative hearing upon the information that the Respondent may have violated the pharmacy laws in the State of Virginia. On August 14, 1996 the Virginia Board found that Respondent had violated §54.1-3303 (dispensing drugs negligently and not in good faith which were prescribed in excess of recommended dosages and without ensuring that the controlled substances were prescribed for accepted medicinal or therapeutic purposes); §54.3316 (1) (has been negligent in the practice of pharmacy); and (7) (has violated any provision of law relating to practice of pharmacy or any regulation of the Board). See attached Order, marked as

Exhibit A¹.

5. Under Virginia's **original** order, the Respondent's license to practice pharmacy in the State of Virginia was revoked and he was fined a monetary penalty of \$10,000.00. That Order further provided that the Respondent could petition the Virginia Board of Pharmacy for reinstatement of his license not earlier than two years from the date of entry of that Order. Respondent was to become eligible to petition for reinstatement on August 14, 1998.

6. On or about August 21, 1997 the Respondent negotiated a Consent Order with the Virginia Board. The Board and the Respondent entered into a Consent Order accomplishing the dismissal of the appeal with prejudice, a reinstatement of the Respondent's Virginia pharmacy license under probationary conditions which expire on or about August 17, 1998.

7. The disciplinary action taken by the Virginia Board constitutes disciplinary action by a licensing or disciplinary body under H.O. §12-313 (b) (23).

8. The Maryland charging document set out the factual allegations in individual count format and for ease and clarity this Order will address the allegations and findings in such form.

¹ The Virginia Order involved fifteen patients who were treated for chronic pain, with extremely high dosages of narcotics with high abuse potential.

COUNT ONE

(Overages and Shortages in Schedule II controlled substances)

9. The Virginia Board found as fact that an audit, conducted August 9, 1995, by an inspector of the Virginia Department of Health Professions, of Respondent's Virginia Pharmacy, "the Medicine Chest," revealed discrepancies of Schedule II controlled substances during the period May 1, 1993 and May 19, 1995, as outlined below. (See page 17 and 18 of Exhibit A).

- a. Dilaudid 4mg tab (overage of 1,978 tabs representing 1.7%);
- b. Hydromorphone 4mg tab (shortage of 1,798 representing 6.5%);
- c. Percocet 5mg tab (overage of 90 representing 0.4%);
- d. Oxycodone w/APAP (shortage of 3,363 representing 17.3%);
- e. MSIR 30mg tab (shortage of 149 tabs representing 0.2%);
- f. Ritalin 10mg tab (overage of 32 tabs representing 0.2%);
- g. Methylphenidate 10mg tab (shortage of 20 tabs representing 0.3%);
- h. Ritalin 20mg tab (overage of 45 tabs representing 0.6%);
- i. Methadone 10mg tab (shortage of 237 tabs representing 0.3%).

10. The Respondent does not contest and the Board so finds

that there were overages and shortages of Schedule II controlled substances. Subsequent inspections by the Virginia inspectors of the Respondent's pharmacy have not revealed shortages or overages subsequent to the Respondent's return to the practice of pharmacy in that State.

11. The Respondent has installed or had installed a computer system which tracks the inventory and specifically follows the inventory of Scheduled drugs.

COUNT TWO

(Dispensing controlled substances at toxic levels of acetaminophen)

12. The Virginia Board found as fact that the Respondent dispensed controlled substances which in combinations, contained levels of acetaminophen that were at toxic levels. (See Exhibit A: Patient A, Patient E, Patient F, Patient J, Patient L and Patient N).

13. Failure to limit the ingestion of acetaminophen could result in acute liver toxicity. Additionally, the Virginia Board found that acute liver toxicity "further exacerbates the inability of the liver to metabolize opioids." (See Exhibit A, page 20).

14. The Respondent reported that many of the patients whose prescriptions he was filling represented decreases in the level of acetaminophen and that he was aware that the level was outside the norm, however, he states that there was a concerted effort to lower the acetaminophen of the combined prescriptions of the patients and that he spoke to the prescribing physician

concerning acetaminophen dangers.

15. The Respondent has subsequently instituted a policy of alerting patients when their prescriptions are filled, that the level of acetaminophen is elevated above the accepted standard. Respondent has agreed that he will place a mark on the prescription bottles identifying the possibility of acetaminophen toxicity.

COUNT THREE

(Dispensing controlled substances to known arrested drug dealer)

16. The Virginia Board of Pharmacy found as fact that the Respondent dispensed controlled substances to a patient who resided in the State of Washington after learning that the patient had been arrested for the illegal distribution of controlled substances. This same patient had signed for a large quantity of controlled substances which the patient later reported stolen. The Respondent failed to file a suspected drug diversion form, however, he states that he did engage in conversations with the DEA in Washington State and that they were investigating the possible drug diversion. The Respondent states that it is not clear whether under these circumstances he is required under the drug control laws to file the suspected drug diversion form. Respondent states that he ceased all dispensing to this patient upon this patient's plea to the charges against him.

17. The Respondent has addressed this concern by agreeing to file the appropriate form or mail a letter to the proper authorities, retaining a copy for himself, in the event that a

large quantity is mailed, received and later reported as stolen by a patient. Further, the Respondent has limited the number of mailings of large amounts of controlled substances.

COUNT FOUR
(Failure to follow drug control laws)

18. The Virginia Board found and Respondent "testified that he routinely dispensed Schedule II drugs prescribed by Dr. Hurwitz, not for emergency purposes but as a convenience to his patients, pursuant to telephone prescriptions rather than written prescriptions as required by § 54.1-3410." (See Exhibit A, page 19).

19. Under COMAR 10.03.07H(4)² a dispensing pharmacist may dispense Schedule II controlled dangerous substances only upon receipt of a written prescription, but may dispense upon receipt of a telephone call of the physician, if the prescription is called in for an emergency, as opposed to the convenience of the patient, and the prescription call is immediately followed up within 72 hours with a written prescription by the prescribing practitioner. The amount permitted to be dispensed is only an amount to treat the patient only in the emergency period.

20. The Respondent admits that there were occasions when emergency prescriptions were dispensed on the basis of telephone conversations between the medical provider, himself and/or his

² Md. Ann. Code Art. 27, §285 (1996 Repl. Vol.).

staff. Respondent states that the medical provider would provide a hard copy of the written script within forty-eight (48) hours. Respondent admits that the quantity dispensed would exceed the emergency period on some occasions. It is the Respondent's current practice to require emergency dispensing of controlled substances to be followed up with a script in the required time period and that the amount dispensed would be that amount which would cover the emergency period until a written script is received.

COUNT FIVE

(Dispensing controlled substances negligently and contrary to accepted or recognized therapeutic and medicinal purposes)

21. The Virginia Board made a number of findings with respect to the negligent dispensing practices of the Respondent. Specifically the Virginia Board found that, contrary to accepted or recognized therapeutic and medicinal purposes, the Respondent dispensed multiple short acting opioids concomitantly and beyond the recommended dosages; and that notwithstanding his admitted knowledge of the substance of the articles provided by Dr. Hurwitz (the medical provider), he continued to dispense Dr. Hurwitz's prescriptions when the prescribing by Dr. Hurwitz deviated from the suggested guidelines contained in this literature. Respondent denies knowing that Dr. Hurwitz deviated from the suggested guidelines.

22. The Respondent recognizes and admits that a pharmacist has a concomitant duty to the patients who are dispensed medications.

COUNT SIX

(Failure to dispense controlled substances in good faith)

23. The Virginia Board found that Respondent failed to dispense controlled substances in good faith for accepted medicinal or therapeutic purposes, charging that he dispensed Schedule II drugs without regard for the amounts, frequency, potential for abuse and potential for harm, and without regard for the patients' quality of life, without consulting with any regulatory body to determine possible exceptions to the prevailing restrictions regarding dispensing drugs in excess of recommended dosages for the treatment of non-malignant intractable pain; and without conducting any independent professional evaluation regarding the evolving practice relating to pain management of non-malignant intractable pain. Moreover, the Virginia Board found that he continued to dispense with the knowledge that Dr. Hurwitz's prescribing practices also deviated from the suggested guidelines contained in literature provided to him by Dr. Hurwitz. Moreover, the Virginia Board found that the Respondent dispensed prescriptions without providing adequate instructions for their use and with the knowledge that the patients were to be responsible for selecting the particular drug(s) they would use for pain control

24. The Secretary of the Department of Health and Mental Hygiene has adopted certain provisions of the Federal Code of Regulations and has promulgated COMAR 10.19.03.07D(1) which by operation of law is made applicable to a dispensing pharmacist.

It states:

D. Purpose of Issue of Prescription (21 CFR §1306.04).

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 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. An 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 §285 of the Maryland Controlled Dangerous Substances Act, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provision of law relating to controlled dangerous substances.

25. With respect to Counts Five and Six above, the Respondent has instituted a policy in the pharmacy with regard to intractable pain patients whereby he requires that a) patients sign an agreement that they will not share their prescription medications with others; b) that the patients recognize the potential for abuse/addiction in using large quantities of Schedule II drugs; and c) that the patients agree that they will not obtain other scheduled drugs from other prescribers. (Attached as Exhibit A).

26. Additionally, the Respondent now requires that the patients provide proof of an appointment with the prescribing physician before a refill is dispensed for a Schedule II drug which exceeds the recommended dosage amounts. For example, the Respondent may require that the patient appear with a new script or proof of a visit. These precautions will help to ensure that patients who receive large quantities of Schedule II drugs for

intractable pain are being clinically followed and that appropriate assessments of pain management are being met.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that the Respondent violated Health Occupations Article §12-313 (b)(23), to wit (7) and (14). The Board dismisses the charge under §12-313 (b) (20).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 19th day of August, 1998, by a majority of the Board, hereby

ORDERED that Respondent is **REPRIMANDED** and placed on **PROBATION** for a period of one (1) year, subject to the following conditions:

1. During the period of PROBATION, the Respondent shall continue to employ the use of the Schedule II medication form as described above in paragraph 25;

2. During the period of PROBATION, the Respondent shall mark scripts which contain acetaminophen and which when used in combination with other prescription drugs exceeds the recommended limit of acetaminophen;

3. During the period of PROBATION, the Respondent shall maintain a perpetual inventory of intractable pain patients who reside in Maryland and have scripts filled by the Respondent;

4. During the period of PROBATION, the Respondent will

continue to utilize the computer inventory of Schedule II drugs;

5. The Respondent shall cease from dispensing emergency medications, except as provided for in the law;

6. During the period of PROBATION, the Respondent shall continue to require that intractable pain patients present evidence of physician follow-up, which can be evidenced by a newly written script, or a receipt for medical care together with approval for the dispensing of a valid script;

7. The Respondent shall obtain a pharmacist consultant, pre-approved by the Board, for the purpose of reviewing the medication regimens of Maryland intractable pain patients who are dispensed medications at the pharmacy where the Respondent practices;

8. The Respondent shall bear the cost of the review by the pharmacist which review shall be made quarterly and sent to the Board;

9. Respondent shall immediately notify the Board in writing of any change in his address and Respondent shall further furnish the Board with the business address and telephone number of any employment;

10. At the end of the probationary period the Respondent shall petition the Board in writing to be released from the probationary conditions.

ORDERED that in the event the Board finds for any reason in good faith the Respondent has substantially violated any provision of Title 12 of the Health Occupations Article, Maryland

Annotated Code or the regulations thereunder, or if the Respondent violated any of the foregoing conditions of Probation, the Board, *after notification to the Respondent, and an opportunity to be heard*, may take immediate action or impose any lawful disciplinary sanction it deems appropriate, including but not limited to revocation or suspension of Respondent's license to practice pharmacy; and be it further

ORDERED that the conditions of the Consent Order be, and the same hereby are, effective as of the date of this Order; and be it further

ORDERED that for purposes of public disclosure, as permitted by §10-617 (h), State Government Article, Maryland Code Annotated, this document constitutes the Board's Findings of Fact, Conclusions of Law, and Order, resulting from formal disciplinary proceedings.

8/19/98
Date

David Russo
David Russo, P.D.
President

CONSENT of Jerome Danoff, P.D.

I, Jerome Danoff, by affixing my signature hereto, acknowledge that:

1. I am represented by an attorney.
2. I am aware that without my consent, my license to

practice pharmacy in this State cannot be limited, except pursuant to the provisions of §12-315 of the Act and §10-201 et seq. of the Administrative Procedure Act, State Government Article, Annotated Code of Maryland.

3. I am aware that I am entitled to a formal evidentiary hearing before the Board or an Administrative Law Judge.

By this Consent Order, I hereby consent and submit to the foregoing Findings of Fact, Conclusions of Law, and Order provided the Board adopts the foregoing Final Consent Order in its entirety. By doing so, I waive my right to a formal hearing as set forth in §12-315 of the Act and §10-201 et seq. of the Administrative Procedure Act except on connection with any alleged violation of this Order. I acknowledge that by failing to abide by the conditions set forth in this Order, I may, after an opportunity to be heard, suffer disciplinary action, including revocation of my license to practice pharmacy in the State of Maryland.

7/10/98

DATE

Jerome Danoff P.D.

Jerome Danoff, P.D.

STATE OF MD

CITY/COUNTY OF: Rockville/Montgomery

I HEREBY CERTIFY that on this 10th day of July, 1998, a Notary of the State of Maryland and (City/County), Rockville/Montgomery, personally appeared Jerome Danoff, P.D. License No. 06158, 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 WITNESS my hand and notarial seal.

Janice B. Shuff

Notary Public

My commission expires: 11-1-98