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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF THE

DISCIPLINARY PROCEEDINGS AGAINST

RALPH G. KOCH, R.Ph.,

RESPONDENT.

FINAL DECISION AND ORDER

98 PHM 50

LS-9901061-PHM

The parties to this action for the purposes of Wis. Stats. sec. 227.53 are:

*Ralph G. Koch, R.Ph.
3614 Highcliff Ct.
Sheboygan, WI 53083*

*Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935*

*Department of Regulation and Licensing Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935*

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Respondent Ralph G. Koch (dob 11/28/1952) was at all times relevant to this proceeding duly licensed under the provisions of Chapter 450, Wis. Stats., to practice as a registered pharmacist in the State of Wisconsin, under license number 9023. At all times relevant to the matters set forth below, respondent was the managing pharmacist of Aurora Pharmacy located at 509 Superior Ave., Sheboygan, WI where the conduct set forth below took place.
2. The Pharmacy Examining Board previously disciplined respondent on 2/9/93 for dispensing non-controlled prescription drugs doxepin and Elocon cream for himself without a valid physician prescription order, in case 92 PHM 106. Respondent was reprimanded, forfeited \$250, and was suspended with quarterly stays for two years. Respondent's license was restored to unlimited status on 4/12/94.
3. On or about 1/31/96, respondent was convicted of OWI in Sheboygan County. The offense occurred on 1/12/96, and at the time respondent had a breath alcohol concentration of 0.15% by weight. At the time, respondent was in treatment for depression and was taking medication for this condition. He had been repeatedly instructed by his treating therapists not to drink alcohol, as such consumption is contraindicated by his condition and therapy, and because they believed that respondent was abusing or dependent upon alcohol. Notwithstanding this advice, respondent continued to drink beverage alcohol.

4. When respondent was stopped by the police on 1/12/96, at 11:01 PM, he told the officer that he had just come from his then-employing pharmacy. Respondent was, in fact, coming from a holiday staff party at the pharmacy, and the pharmacy had been closed since 8:00 PM.
5. On 12/30/97, respondent entered into the pharmacy computer Relafen 500mg for patient J.N. and entered into the pharmacy computer the usage directions as "once a day". The prescription order was for Relafen 750mg and the usage directions were "twice a day."
6. The error set forth in ¶5, above, did result in the patient receiving the incorrect strength and dosage instructions. After the consultation, and when the patient was making payment to the auxiliary staff person, the patient looked at the bottle and asked the auxiliary staff why the strength and dosage were not as the doctor had prescribed. The staff person then looked up the original hard copy, and discovered the error.
7. On an exact date unknown in the spring of 1998, respondent received by telephone and transcribed a prescription for an allergy medication, Zyrtec®, but wrote it in a manner which was not clearly legible. Auxiliary staff incorrectly read and entered the order into the computer system as being for an antidepressant, Zyprexa®, and filled the prescription for the patient as such. Respondent failed to detect the error upon checking the prescription, and the prescription was transferred to the patient. The patient discovered the error after the consultation, but before leaving the pharmacy, during a conversation with auxiliary staff.
8. During the period between November, 1997, and ending 4/14/98, respondent made a number of documented computer entry errors which he did not detect during the normal error-correcting process in place at that time. If they had not been detected by auxiliary staff, some could have posed a risk to a patient.
9. On 4/14/98, respondent took a medical leave of absence. He has since returned to work with a different employer, who is aware of the Interim Order entered in this matter.
10. From 5/11/98 - August, 1998, respondent underwent an AODA assessment and was in an outpatient alcohol abuse treatment program at The Center at Sheboygan Memorial Medical Center. Respondent was diagnosed with alcohol dependence with physiological dependence, and major depression with anxious features, recurrent. Before 3/26/98, respondent had been practicing pharmacy while untreated for alcohol dependence, and while actively drinking several alcoholic beverages daily, after work.
11. Respondent continues in treatment for depression at Lakeshore Mental Health.

CONCLUSIONS OF LAW

- A. The Wisconsin Pharmacy Examining Board has jurisdiction over this matter and authority to take disciplinary action against the Respondent pursuant to §450. 1 O(I), Wis. Stats. and § Phar 10, Wis. Adm. Code.
- B. The Wisconsin Pharmacy Examining Board is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.
- C. The facts set forth in paragraphs 3, and 4, above, constitute unprofessional conduct pursuant to §450. 10 (1)(a)2., Wis. Stats.
- D. The facts set forth in paragraphs 5, 7 and 8, above, constitute unprofessional conduct pursuant to §450. 10 (1)(a)6., Wis. Stats. and § Phar 10.03 (2), Wis. Adm. Code.
- E. The facts set forth in paragraphs 2 and 10, above, constitute unprofessional conduct pursuant to §450. 10 (1)(a)3., Wis. Stats.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED:

That the STIPULATION of the parties, attached hereto, is ACCEPTED.

PART I

IT IS FURTHER ORDERED, that the license to practice pharmacy of Ralph G. Koch, R.Ph., is LIMITED in the following manner:

- (a) Respondent shall not be a managing pharmacist, nor shall he practice pharmacy in any business

entity in which he has an ownership interest.

(b) Respondent shall practice in a setting and under a protocol which requires that all prescriptions dispensed or labeled by respondent, or pursuant to telephoned prescriptions transcribed by respondent, are checked for accuracy by another pharmacy employee before being transferred to the patient or institution. Respondent shall meet with his supervisor monthly to review any practice errors and determine methods to prevent such errors.

(c) Respondent shall cause his immediate supervisor to file quarterly reports with the Board, commencing on the first day of June, 1999. These reports shall state the number of dispensing or other practice errors committed by respondent, the circumstances surrounding each, the response to the error, the general progress of respondent in reducing such errors, and any other information regarding respondent's ability to practice pharmacy with skill and safety to patient and public. Copies of all incident reports shall accompany these quarterly reports. Any error causing patient harm shall be reported to the Board on the following business day.

(d) Respondent shall furnish each of his employers with a copy of this order, and shall report the names and addresses of all current employers to the Board within 10 days of this order. He shall report any changes in his employer(s), address, and telephone number to the Board within 5 days of such change. Respondent shall furnish the Board with releases for his entire personnel file at each of his employers.

(e) Respondent may petition the Board for an order terminating this limitation on his license after January, 2001. It shall be totally within the discretion of the Board to grant or deny such a petition, and a denial of such a petition in whole or in part shall not be deemed a denial of license and shall not entitle respondent to a hearing on such a denial.

(f) Failure to comply with the conditions and limitations set forth herein may subject respondent to summary suspension and to other an independent discipline.

PART II

IT IS FURTHER ORDERED that effective on the date of this Order, the pharmacist license of respondent is SUSPENDED indefinitely.

1. STAY OF SUSPENSION. The suspension is STAYED for a period of three months, conditioned upon compliance with the conditions and limitations outlined in paragraph 2., below.

a. Respondent may apply for consecutive three (3) month extensions of the stay of suspension, which shall be granted upon acceptable demonstration of compliance with the conditions and limitations imposed on the respondent for rehabilitation and practice during the prior three (3) month period. "Three months" means until the third regular Board meeting after the meeting at which any stay of suspension is granted.

b. The Board may without hearing deny an application for extension of the stay, or commence other appropriate action, upon receipt of information that respondent has violated any of the terms or conditions of this Order. If the Board denies the petition by the respondent for an extension, the Board shall afford an opportunity for hearing in accordance with the procedures set forth in ch. RL 1, Wis. Adm. Code upon timely receipt of a request for hearing.

c. The applications for extension under La. and all required reports under 2.a-c. shall be due on each and every March 1 st, and each three months thereafter, for the period that this Order remains in effect.

d. Respondent shall forthwith surrender all indicia of licensure to the Department by

mail or in person, and the Department shall then issue limited licensure credentials to respondent. Respondent shall also surrender all indicia of licensure to any agent of the Department who requests them.

2. CONDITIONS OF STAY AND LIMITATIONS. The initial stay of suspension and any subsequent stay shall be conditioned upon the following terms and limitations:

a. Non-Prescription Use of Drugs and Alcohol Prohibited. Respondent shall remain free of alcohol, prescription drugs and controlled substances not prescribed by a practitioner for legitimate medical purposes. Respondent shall have his physician report in writing to the supervising physician or therapist under paragraph 2.b.(1) all medications prescribed to the respondent within 3 days of such prescribing. Respondent shall in addition refrain from the consumption of over-the-counter medications or other substances which may mask consumption of controlled substances or of alcohol, or which may create false positive screening results, or which may interfere with respondent's treatment and rehabilitation.

b. Rehabilitation, Monitoring and Treatment Program. Respondent shall continue to participate in a rehabilitation, monitoring and treatment program acceptable to the Board for the treatment of chemical abuse and dependency. Such program shall consist of the following elements and requirements:

(1) AODA Rehabilitation. Respondent shall continue to participate in an AODA rehabilitation program under the care and supervision of a qualified physician or therapist (hereinafter, "supervising physician or therapist"), at an accredited drug and alcohol abuse/dependency treatment facility. Respondent shall obtain from the Pharmacy Examining Board prior approval of the drug and alcohol abuse/dependency treatment facility and the supervising physician or therapist. The supervising physician or therapist shall be responsible for the Respondent's total rehabilitation program. Respondent shall immediately provide a copy of this order to his supervising physician or therapist. Respondent shall participate in and

comply with all recommendations for treatment, subject to the requirements of this order.

(2) Individual/Group Therapy. The rehabilitation program shall include and respondent shall participate in individual and/or group therapy sessions for the first year of the stayed suspension upon a schedule as recommended by the supervising physician or therapist, but not less than twice per month, in view of the fact that respondent has been in therapy since March, 1998. Such therapy shall be conducted by the supervising physician or therapist, or another qualified physician or therapist as designated by the supervising physician or therapist and acceptable to the Board. After the first year under this Order, this requirement for therapy sessions may be modified only upon written petition, and a written recommendation by the supervising physician or therapist expressly supporting the modifications sought. A denial of such petition for modification shall not be

deemed a denial of the license under §§ 227.01(3) or 227.42, Wis. Stats., or ch. RL 1, Wis. Adm. Code, and shall not be subject to any right to further hearing or appeal.

(3) AA/NA Meetings. Respondent shall attend Alcoholic Anonymous meetings or an equivalent program for recovering professionals, upon a frequency as recommended by the supervising physician or therapist, but not less than one meeting per week. Attendance of Respondent at such meetings shall be verified and reported monthly to the supervising physician or therapist.

(4) Drug Screening. Respondent's rehabilitation program shall include and Respondent shall participate in a program of random, witnessed collection of breath, urine and/or blood specimens for monitoring for the presence of alcohol and its metabolites, on the following schedule:

- (a) Eight times per month for the first year following the effective date of the Interim Order, or once per week if not practicing pharmacy.
- (b) Six times per month for the second year following respondent's resumption of practice.
- (c) Four times per month for the third through fifth years following resumption of practice.

At least once per month (included in the above schedule), respondent shall have either a blood or urine test for the following substances and their metabolites: tetrahydrocannabinols, alcohol, amphetamines, cocaine, opiates, and benzodiazepines. All urine screens shall include testing and reporting of the specific gravity of the urine specimen, and shall be conducted by a NIDA-certified facility.

The random drug and alcohol screening program shall include all hours of the day and evenings, and include weekends and holidays, for collection of specimens. Failure of the drug and alcohol screening program to be conducted on a random basis shall be deemed a violation of this Order and may result in denial of extension of Stay of Suspension, disapproval of the monitoring facility or program, or other action as deemed appropriate by the Board.

Respondent shall appear and provide a specimen not later than 5 hours following a request for a specimen, and forthwith if requested to provide a breath sample.

If the physician or therapist supervising the Respondent's plan of care, Respondent's employer, the Pharmacy Examining Board or the Department of Regulation and Licensing, Division of Enforcement deems that additional breath, blood or urine screens are warranted, respondent shall submit to such additional screens as requested or recommended. The supervising physician or therapist shall exceed the above stated minimum frequency for obtaining drug and alcohol screens to prevent ability of respondent to predict that no further screens will be required for a given period because the minimum frequency for that period has been met.

Respondent is responsible for obtaining a monitoring facility and reporting system acceptable to the Board. Respondent shall immediately provide a copy of this Order to the monitoring facility conducting the collection of specimen and/or chemical analyses upon specimens for the random witnessed drug and alcohol screening program.

To be an acceptable program, the monitoring facility and supervising physician and therapist shall agree to provide random and gatherings of specimens for analysis for the specified substances and alcohol under NIDA collection guidelines. Any specimen that yields a positive result for any controlled substance or alcohol shall be immediately subjected to a gas chromatography-mass spectrometry (hereinafter, "GC-MS") test to confirm the initial positive screen results. The monitoring facility and supervising physician and therapist shall agree to immediately file a written report directly with the Pharmacy Examining Board, the supervising physician or therapist, and the respondent's supervising pharmacist upon any of the following occurrences: if the respondent fails to appear for collection of a specimen as requested; or if a drug or alcohol screen and confirmatory GC-MS test prove positive; or if the specific gravity of a urine specimen is below 1.008; or if respondent refuses to give a specimen for analysis upon a request authorized under the terms of this Order. Respondent shall arrange for quarterly reports from the monitoring facility directly to the Board and to Respondent's supervising physician or

therapist providing the dates and results of specimen analyses performed. Such reports shall be due on dates specified in paragraph 1.d. above.

The monitoring facility shall further agree to keep a record of the custody of all specimens collected and subjected to analysis. The facility shall further agree to preserve any specimens which yielded positive results for any controlled substance or alcohol, or specific gravity below 1.008, pending further written direction from the Board (not to exceed one year).

Respondent understands and agrees that the accuracy of the monitoring facility obtained is respondent's responsibility. For purposes of further board action under this order, it is rebuttably presumed that all confirmed positive reports are valid. Respondent has the burden of proof to establish by a preponderance of the evidence an error in testing or fault in the chain of custody regarding a positive monitoring report.

If a breath sample is requested, it shall be analyzed with a device approved by the Wisconsin Department of Transportation. It is intended that the department may call upon law enforcement officers to assist the department in this matter, and that such officers shall perform breath tests in a manner similar to tests performed upon persons suspected of operating a vehicle while influenced by an intoxicant. The results of such tests shall be presumed to be valid, if performed in the manner

approved by the WisDoT (except for the reading of the warnings which would be read to a motor vehicle operator).

(5) Quarterly Reports. Respondent shall arrange for quarterly reports from his supervising physician or therapist directly to the Board evaluating and reporting:

- (a) A summary of Respondent's progress in his rehabilitation program to date, and all recommendations for continuing rehabilitation treatment,
- (b) Respondent's attendance in NA/AA meetings,
- (c) Respondent's participation in and results of his random witnessed urine and/or blood screening program.

Such quarterly reports shall be due on the dates specified under paragraph 1.d. of this Order.

(6) Immediate Reports. Respondent shall arrange for agreement by his supervising physician or therapist, and his employer, to report immediately to the Board any conduct or condition of respondent that may constitute a danger to the public in his practice of pharmacy, and any occurrence that constitutes a failure on the part of respondent to comply with the requirements of this Order or treatment recommendations by the supervising physician or therapist, including any indications of consumption of alcohol or unauthorized use of any controlled substances, failure to appear for a urine or blood screening, notice of any positive blood and/or urine screen for alcohol or controlled substances, and any urine specimen that is below a specific gravity of 1.008.

c. Practice of Pharmacy: Limitations and Conditions. Any practice of Pharmacy by respondent during the pendency of this Order shall be subject to the following terms and conditions:

(1) Full Compliance with Order Required. Respondent shall not practice as a pharmacist in any capacity unless he -is -in full compliance with the rehabilitation and treatment programs as specified and approved under this Order.

(2) No Managing Pharmacist. Respondent shall not be employed as or work in the capacity of a "managing pharmacist" as defined in § Phar 1.02 (6), Wis. Adm.

Code.

(4) Provision of Copy of Order to Employers. Respondent shall provide his employer and any prospective employers with a copy of this Stipulation and Final Decision and Order immediately upon issuance of this Order, and upon any change in employment.

(5) Quarterly Reports. Respondent shall arrange for his supervising pharmacist to provide directly to the Board quarterly written reports evaluating Respondent's work performance, which shall include reports or information required under subparagraph (6) and (7) hereunder. Such reports shall be due on the dates specified in paragraph 1.d. of this Order.

(6) Monitoring of Access to Drugs. Respondent shall obtain agreement from his supervising pharmacist to monitor Respondent's access to and accountability for handling of controlled substances and other abuseable prescription drugs in order to

reasonably detect loss, diversion, tampering, or discrepancy relating to controlled substances and other abuseable prescription drugs. Respondent's supervisor shall include in the quarterly reports a description of Respondent's access to controlled substances and other abuseable drugs and the monitoring thereof Any loss, diversion, tampering, or discrepancy shall be immediately reported to the Board.

(7) Controlled Substances Audits. In addition to the foregoing subparagraph (6), Respondent shall obtain from his supervising pharmacist agreement to conduct a full and exact (not estimated) count of the following controlled substances in inventory immediately, and accountability audits of the following controlled substances every six months for the duration of this Order: all narcotics and all stimulants. The audit shall be conducted by and certified by a licensed pharmacist other than respondent, who shall be approved by the Board. A summary of all audits required under this subparagraph shall be included in the quarterly report following the audit, however, any discrepancy or missing drugs indicated by the audits shall be immediately reported in writing to the Board.

(8) Immediate Reports. Respondent shall arrange for agreement by his supervising pharmacist to immediately report to the Board and to the supervising physician or therapist any conduct or condition of Respondent that may constitute a violation of this Order or a danger to the public.

d. Consents for Release of Information. Respondent shall provide and keep on file with his supervising physician/therapist and all treatment facilities and personnel current releases which comply with state and federal laws, authorizing release of all his medical and drug and alcohol counseling, treatment and monitoring records to the Pharmacy Examining Board and the Department of Regulation and Licensing, Division of

Enforcement, and permitting his supervising physician/therapist and treating physicians and therapists to disclose and discuss the progress of his treatment and rehabilitation and all matters relating thereto with the Pharmacy Examining Board or its duly authorized representatives or agents. Copies of these releases shall be filed simultaneously with the Pharmacy Examining Board and the Division of Enforcement. Respondent shall also provide and keep on file with his current employer(s) current releases authorizing release of all employment records and reports regarding Respondent to the Pharmacy Examining Board and the Division of Enforcement, and authorizing his employer to discuss with the Board or its authorized agents and representatives Respondents employment history, progress and status and all matters relating thereto. Copies of these employment records releases shall be filed simultaneously with the Board and the Division of Enforcement.

e. Notification of Change of Address and Employment. The Respondent shall report to the Board any change of employment status, residence address or phone number within five (5) days of any such change.

3. COSTS AND RESTITUTION. Respondent shall pay partial COSTS of this investigation and prosecution under §440.22, Wis. Stats., in the amount \$639, to the Department of Regulation and Licensing, within 45 days of this Order.

4. PHARMACY OWNERSHIP PROHIBITED. Respondent shall not own in whole or in part any interest in a pharmacy during the period of time this Order remains in effect.

5. **TERMS FOR MODIFICATION OF ORDER.** Following successful compliance with and fulfillment of the provisions of paragraph 2. of this Order for a period of two years, the Respondent may petition the Board, in conjunction with an application for extension of the stay of suspension, for modification of the conditions or limitations for stay of suspension. Any such

petition shall be accompanied by a written recommendation of respondent's supervising physician or therapist expressly supporting the specific modifications sought. A denial of such a petition for modification shall not be deemed a denial of license under §§227.01(3), or 227.42, Wis. Stats., or Ch. RL 1, Wis. Adm. Code, and shall not be subject to any right to further hearing or appeal.

6. RESPONDENT RESPONSIBLE FOR COSTS AND EXPENSES OF COMPLIANCE. Respondent shall be responsible for all costs and expenses of complying with this Order and For arranging any alternative means for covering such costs and expenses.

7. BOARD/DEPARTMENT INSPECTIONS. The Board or the Department in its discretion may conduct unannounced inspections and/or audits, and make copies, of pharmacy records and inventory where respondent is employed as a pharmacist.

8. VIOLATIONS OF ORDER. Violation of any of the terms of this Order or of any law substantially relating to the practice of pharmacy may result in a summary suspension of the Respondent's license; the denial of an extension of the stay of suspension or the termination of the stay; the imposition of additional conditions and limitations; or the imposition of other additional discipline, including revocation of license.

9. EFFECTIVE DATE. This Order shall become effective immediately upon issuance by the Pharmacy Examining Board, except for provision 2.a., which is effective the date of signing by respondent.

Dated this June 16, 1999.

PHARMACY EXAMINING BOARD

By: Daniel F. Luce, R.Ph

A Member of the Board

