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Minutes Of The Meeting

Ohio State Board of Pharmacy
Columbus, Ohio
February 9, 1999

TUESDAY, FEBRUARY 9, 1999

10:12 a.m. ROLL CALL

The State Board of Pharmacy convened in Room 1914, Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio with the following members present:

Joseph J. Maslak, R.Ph. (President); Robert B. Cavendish, R.Ph. (Vice-President); Ann D. Abele, R.Ph.; Paul F. Lamping, R.Ph.; Suzanne L. Neuber, R.Ph.; and Nicholas R. Repke, Public Member.

RES. 99-124 Mr. Winsley discussed the Optometry Board's proposed rules that were to be filed with a tentative public hearing date of March 10, 1999. After a review of the proposed rules, with specific attention to Proposed Rule 4725-16-02 (Additional oral therapeutic pharmaceutical agents), the Board members present had no concerns about the rules and affirmed that no testimony would be needed at the public hearing.

RES. 99-125 Mr. Winsley next requested that the Board approve the payment of \$250.00 for the 1999 dues for membership in the National Association of Boards of Pharmacy. Mr. Cavendish moved that the Board approve the continuing membership and authorize payment of the dues. The motion was seconded by Mr. Repke and approved by the Board (Aye-5/Nay-0).

10:19 a.m.

Mr. Littlejohn and Mrs. Adelman arrived and joined the discussion of items requiring the Board's attention.

10:22 a.m.

RES. 99-126 The Board then considered two requests for approval to be providers of continuing pharmacy education (CPE). Mrs. Neuber moved that the Board approve the application of Wooster Community Hospital Pharmacy Department; Wooster, Ohio to be a provider of CPE. The motion was seconded by Ms. Abele and approved by the Board (Aye-7/Nay-0).

RES. 99-127 Mrs. Neuber then moved that the Board approve the application of VHA Central Inc.; Worthington, Ohio to be a provider of CPE. The motion was seconded by Ms. Abele and approved by the Board (Aye-7/Nay-0).

Timothy Benedict, Assistant Executive Director, and David L. Rowland, Legal Affairs Administrator, joined the meeting to introduce two new employees to the Board members. Mr. Rowland introduced Teri Turner, Administrative Assistant I, who will be working in the Board office with Mr. Rowland. Mr. Benedict then introduced Robert Burdick, R.Ph., who will be the Board's Compliance Specialist in the Dayton area.

10:30 a.m.

Mr. Cavendish moved that the Board go into Executive Session for the purpose of the investigation of charges or complaints against licensees and registrants pursuant to Section 121.22(G)(1) of the Revised Code. Mr. Lamping seconded the motion. President Maslak then conducted the following roll call vote: Abele-Yes, Adelman-Yes, Cavendish-Yes, Lamping-Yes, Littlejohn-Yes, Neuber-Yes, and Repke-Yes.

11:45 a.m.

RES. 99-128 The Board came out of Executive Session and Mr. Cavendish moved that the Board accept the settlement offer presented in the matter of Donald Rettig, R.Ph., Toledo. Mrs. Neuber seconded the motion and it was approved by the Board (Aye-7/Nay-0).

RES. 99-129 Mr. Maslak stated that he must recuse himself from any discussion or consideration of the matter involving Joseph Rukse, R.Ph. and asked Mr. Cavendish, Vice-President, to assume the chair, lead the discussion, and conduct any votes that might be needed. After discussion, Mrs. Neuber moved that the Board deny the settlement offer presented in the matter of Joseph Rukse, R.Ph. and that the hearing proceed as scheduled. The motion was seconded by Mr. Lamping and approved by the Board (Aye-7/Nay-0).

RES. 99-130 Mr. Cavendish then relinquished the chair back to Mr. Maslak. Mr. Lamping then moved that Board staff be instructed to proceed with settlement agreements in the matters of Fairview Park Pharmacy; Lawrence Friedman, R.Ph.; and Stephen Dolin, R.Ph. according to terms as outlined by the Board. The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-7/Nay-0).

12:00 p.m.

The Board then recessed for lunch.

1:00 p.m.

RES. 99-131 All of the Board members, with the exception of Mrs. Plant, reconvened in Room 1919 for the purpose of meeting with the candidates for licensure by reciprocity. Following presentations by Board members and self-introductions by the candidates for licensure by reciprocity, Mr. Cavendish moved that the Board approve the following candidates for licensure. The motion was seconded by Mrs. Adelman and approved by the Board (Aye-7/Nay-0).

ASUMADU, SAMPSON A.	03-2-23434	MASSACHUSETTS
BOWLBY, JR., GILBERT FRANCIS	03-2-23360	MICHIGAN
BUCK, JEFFREY DONALD	03-2-23339	TEXAS
GARVIN, CORY GENE	03-2-23391	IOWA
KEYSER, KELLI SUZANNE	03-2-23416	WEST VIRGINIA
MALEK, ADAM	03-2-23233	TEXAS
MASHNI, JOSEPH ROBERT	03-2-23410	KENTUCKY
OVERSTREET, JOYCE HOPKINS	03-2-23417	VIRGINIA
PAPE, SCOTT ANTHONY	03-2-23418	ILLINOIS
REUTER, JAMESON PATRICK	03-2-23367	MICHIGAN
STIGELMAN, JR., WILLIAM HOWARD	03-2-23369	MASSACHUSETTS
VIGNEAULT, RICHARD ALEXANDER	03-2-23350	MASSACHUSETTS

1:30 p.m.

The Board was joined by Mr. James Henry, representing the Retail Merchants Association. Mr. Henry wished to express his organization's concerns with the Board's Proposed Rule 4729-7-02. After Mr. Henry finished his presentation, Mr. Maslak thanked him for his comments and Mr. Henry left the meeting.

1:45 p.m.

RES. 99-132 Mrs. Adelman moved that the Board appoint the following individuals to the 1999 Ad Hoc Committee on Rule Review:

William Armbrrecht, R.Ph.; Randall Myers, R.Ph.; James Turner, R.Ph.; Kent Zellner, R.Ph.; Karen Beard, R.Ph.; Diane Gary, R.Ph.; Betty Gregg, R.Ph.; Nick Barsan, R.Ph.; Laurie Loria, R.Ph.; Robert Wagonblott, R.Ph.; and Kevin Hornbeck, D.O.

The motion was seconded by Mr. Littlejohn and approved by the Board (Aye-7/Nay-0).

RES. 99-133 Ms. Abele then moved that the Board adopt the following three rules and instruct Board staff to file them with an effective date of March 1, 1999 for Proposed Rules 4729-5-29 and 4729-29-05 and an effective date of June 1, 1999 for Proposed Rule 4729-5-17. The motion was seconded by Mr. Lamping and approved by the Board (Aye-7/Nay-0).

4729-5-17 LABELING BY PRESCRIBERS WHO PERSONALLY FURNISH DANGEROUS DRUGS TO THEIR PATIENTS.

(A) WHENEVER A PRESCRIBER PERSONALLY FURNISHES A DANGEROUS DRUG, OTHER THAN A SAMPLE DRUG PURSUANT TO SECTION 3719.81 OF THE REVISED CODE, THE PRESCRIBER SHALL AFFIX TO THE CONTAINER A LABEL SHOWING:

- (1) THE NAME AND ADDRESS OF THE PRESCRIBER.
- (2) THE NAME OF THE PATIENT FOR WHOM THE DRUG IS INTENDED. IF THE PATIENT IS AN ANIMAL, THE NAME OF THE OWNER AND THE SPECIES OF THE ANIMAL.
- (3) NAME AND STRENGTH OF THE DANGEROUS DRUG.
- (4) DIRECTIONS FOR USE.
- (5) DATE FURNISHED.

(B) WHENEVER A PRESCRIBER PERSONALLY FURNISHES A DANGEROUS DRUG, LABELED AS A SAMPLE PURSUANT TO SECTION 3719.81 OF THE REVISED CODE AND WHERE THE DIRECTIONS FOR USE ARE DIFFERENT FROM THE DIRECTIONS ON OR IN THE SAMPLE CONTAINER, THE PRESCRIBER SHALL ALSO PROVIDE, IN WRITTEN FORMAT, THE FOLLOWING:

- (1) NAME OF THE PRESCRIBER.
- (2) NAME OF THE PATIENT. IF THE PATIENT IS AN ANIMAL, THE NAME OF THE OWNER AND THE SPECIES OF THE ANIMAL.
- (3) DIRECTIONS FOR USE.

4729-5-29 Confidentiality of patient records.

(A) ~~Records of dispensing~~ RELATING TO THE PRACTICE OF PHARMACY or administering of drugs are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

- (1) The patient for whom the prescription or medication order was issued.
- (2) The ~~practitioner~~ PRESCRIBER who issued the prescription or medication order.
- (3) Certified/licensed health care personnel who are responsible for the care of the patient.
- (4) A member, inspector, agent, or investigator of the STATE board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.
- (5) An agent of the state medical board when enforcing Chapter 4731. of the Revised Code.
- (6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.
- (7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

- (8) Any person, other than those listed in paragraphs (A)(1) to (A)(6)(7) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient. In an emergency, the pharmacist may disclose the prescription information when, in the professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.
- (B) ANY COMMUNICATION BETWEEN A PHYSICIAN, A PHARMACIST, AND A PATIENT, PURSUANT TO A CONSULT AGREEMENT, EXCEPT WHEN REQUESTED BY A FEDERAL, A STATE, OR A LOCAL GOVERNMENT ENTITY, IS PRIVILEGED FROM DISCOVERY OR OTHER USE AND DISCLOSURE IN CIVIL PROCESS.
- (C) ~~Records of dispensing~~ RELATING TO THE PRACTICE OF PHARMACY or administering drugs which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the STATE board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. ~~The IF THE RECORD IS A PRESCRIPTION, THE receipt shall list the records removed and shall include the following information:~~
- (1) Prescription identification number; or, if an order for medication, the name of the patient;
 - (2) The drugs prescribed;
 - (3) Quantity of drugs prescribed and dispensed;
 - (4) Name of the ~~prescribing practitioner~~ PRESCRIBER;
 - (5) Date, name of agency, and signature of person removing the records.
- ~~(C)~~ (D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(7)(8) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

4729-29-05 SIGNATURES REQUIRED ON A CONSULT AGREEMENT.

TO BE EFFECTIVE, A CONSULT AGREEMENT MUST BEAR THE SIGNATURES OF ONE PATIENT OR CAREGIVER, ONE PHYSICIAN, AND ONE PHARMACIST. THE CONSULT AGREEMENT MUST DEFINE THE DIAGNOSIS OR DIAGNOSES THAT AFFECT THE DRUG THERAPY THAT IS COVERED BY THE AGREEMENT. WHERE THERE IS A GROUP OF PHYSICIANS OR PHARMACISTS WHO MAY BE CARING FOR THE PATIENT, THE CONSULT AGREEMENT SHALL BE SIGNED BY THE PRIMARY PHYSICIAN AND THE PRIMARY PHARMACIST. IN THIS CASE, THE CONSULT AGREEMENT SHALL DESIGNATE ONE OTHER PHARMACIST WHO MAY BE COVERING FOR THE PRIMARY PHARMACIST. THIS DESIGNATION OF AN ALTERNATE PHARMACIST FOR COVERAGE PURPOSES MUST BE MADE PRIOR TO THE CONSULT AGREEMENT RECEIVING THE SIGNATURE OF THE PATIENT OR THE PATIENT'S CAREGIVER.

RES. 99-134 Ms. Abele then moved that Board staff be instructed to re-file Proposed Rule 4729-7-02 as originally written with the revised financial summary sheet presented by Mr. Winsley. The motion was seconded by Mr. Lamping. After discussion about the concerns raised by Mr. Henry and others, the Board voted to approve the motion (Aye-5/Nay-2).

2:50 p.m.

RES. 99-135 Mr. Winsley presented a letter from Cathi Clark of the American Pharmacy Services Corporation with an attachment regarding the Pharmacy Care Information Center's (PCIC) program of data collection. After discussion, Mrs. Neuber moved that as long as no

patient-specific information is able to be discerned by PCIC, the Board would not find this program, as outlined in the letter, to be a violation of the Board's Rule 4729-5-29 (Confidentiality of patient records). Mr. Lamping seconded the motion and the motion was approved by the Board (Aye-7/Nay-0).

RES. 99-136 Mr. Winsley next presented a letter received in the Board office from Mr. C. William Howe, Manager, State Government Relations for Pfizer, Inc. In his letter, Mr. Howe requested the Board's opinion as to the individuals who could properly prepare the written information required pursuant to the Board's new Rule 4729-5-17 (Labeling by prescribers who personally furnish dangerous drugs to their patients). Mr. Winsley also presented the draft copy of a proposed response. After discussion, Mr. Lamping moved that the Board approve the following letter of response. The motion was seconded by Mr. Littlejohn and approved (Aye-7/Nay-0).

C. William Howe
Manager, State Government Relations
Corporate Affairs Division
Pfizer Inc.
209 N. Walnut, Suite C
Lansing, MI 48933

Dear Mr. Howe:

You have written to me asking about the Board's intentions regarding Rule 4729-5-17. As you know, this rule has been filed and will be effective on June 1, 1999. In your letter, you asked who may prepare and distribute the written instructions for use for a dangerous drug that is labeled as a sample.

Paragraph (B) of Rule 4729-5-17 states that "the prescriber shall provide" the written instructions for use. You are correct in stating that the rule does not specify that the prescriber must prepare or distribute the written instructions and, therefore, this task may be delegated to another individual. You are also correct that the ultimate responsibility for this task would be the prescriber's. For that reason, the Board expects that the prescriber would, at a minimum, perform a final check on the finished product immediately prior to it being given to the patient.

To further clarify this, I would refer you to the Board's definition of dispensing as found in Rule 4729-5-01(B). The interpretation of this rule is consistent with the principles discussed above for Rule 4729-5-17. All technical functions relating to the dispensing of a dangerous drug may be performed by another, but the final check must be done by the individual authorized by law to "dispense" and the final responsibility for all of the dispensing functions rests with that individual.

I hope this explanation meets your needs. If you have any further questions about this issue, please don't hesitate to ask. This letter was reviewed by the Board at their February 9, 1999 meeting and will become part of the official minutes of that meeting.

Sincerely,
William T. Winsley M.S., R.Ph.
Executive Director

RES. 99-137 The Board next discussed the appointment of a Delegate and Alternate Delegate to the NABP Annual Meeting to be held May 22-26, 1999 in Albuquerque, New Mexico. Ms. Abele moved that the Board appoint President Joseph Maslak as the Ohio Pharmacy Board Delegate and Board member Diane Adelman as the Alternate Delegate. The motion was seconded by Mr. Cavendish and approved (Aye-7/Nay-0).

Ms. Abele reported that the Nursing Board's Formulary Committee did not meet in January.

The Licensing Report was distributed to the Board members by Mr. McMillen, Licensing Administrator, and discussed.

Mr. Winsley reported on his trip to Chicago at the end of January to attend the Committee on Law Enforcement and Legislation. The final committee report will be made during the NABP Annual Meeting in May.

Ms. Abele moved that the Minutes of the January 4, 5, 6, 1999 meeting be approved as amended. The motion was seconded by Mrs. Neuber and approved (Aye-7/Nay-0).

Mr. McMillen presented a request from CedarFairmount Pharmacy in Cleveland Heights for an exemption from the requirements of Rule 4729-5-10 (Prescription pick-up station). After discussion, the Board decided to table this request until the March meeting so that more information could be obtained.

3:33 p.m.

Mr. Cavendish moved that the Board receive Per Diem as follows:

PER DIEM	<u>2/9</u>	<u>Total</u>
Abele	1	1
Adelman	1	1
Cavendish	1	1
Lamping	1	1
Littlejohn	1	1
Maslak	1	1
Neuber	1	1
Plant	-	-
Repke	1	1

The motion was seconded by Mr. Repke and approved by the Board (Aye-7/Nay-0).

3:34 p.m.

Mr. Cavendish moved that the meeting be adjourned. The motion was seconded by Mr. Repke and approved (Aye-7/Nay-0).

/s/ Joseph J. Maslak
Joseph J. Maslak, President

/d/ 3/9/99
Date

/s/ W T Winsley
William T. Winsley, Executive Director