

FINAL

**NEW JERSEY STATE BOARD OF PHARMACY MINUTES OF
THE OPEN SESSION OF MAY 11, 2005**

I. CALL TO ORDER

The Open meeting of the New Jersey State Board of Pharmacy was called to order by Board President Pamela Allen in the Monmouth Room, 7th Floor at 124 Halsey Street, Newark, New Jersey on May 11, 2005 at 9:00 a.m. All members were duly notified of the time and place and all pertinent materials had been provided.

II. SUNSHINE LAW ANNOUNCEMENT

Pamela Allen read a statement that newspapers and appropriate elected officials had been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A. Chapter 231, PL 1975, /C. 10:4-18.

III. ROLL CALL

Pamela Allen, R.Ph. President
Edward McGinley, R.Ph Vice-President
Jennifer Barron Government Member
Mona Doyle Public Member (Arrived at 9:06 a.m.)
Thomas F. Egan, Pharm. D. (Arrived at 9:06 a.m.)
Ira Katz R.Ph
Margherita R. Lafragola, R.Ph
Sy Larson, Ph.D Public Member
Elvy Paiva, R.Ph
Richard Palombo, R.Ph.
Marc Sturgill, Pharm. D.

OTHERS IN ATTENDANCE:

Marianne Greenwald Deputy Attorney General
Joanne Boyer, R.Ph. Executive Director
Shonnette Messiah Clerk Stenographer
Kiran Shamlall Clerk Stenographer

**IV. SECRETARY'S REPORT AND RECOMMENDATION FOR REGISTRATION BY RECIPROCITY,
EXAMINATION and GRADE TRANSFER**

Elvy Paiva moved, seconded by Margherita R. Lafragola to accept the Secretary's Report and Recommendation for Registration by Reciprocity, Examination and Grade Transfer. The motion passed unanimously.

V. CONTINUING EDUCATION REPORT

Elvy Paiva moved, seconded by Richard Palombo to accept the Continuing Education Report for May 11, 2005. The motion passed unanimously.

VI. VIOLATIONS PAID FOR THE MONTH OF APRIL

Edward McGinley moved, seconded by Ira Katz to accept the Violations Paid for the Month of April. The motion passed unanimously.

VII. OLD BUSINESS

1) Medco Health, Franklin Lakes, NJ – Four month status report on the Work at Home pilot program

Elvy Paiva moved, seconded by Mona Doyle to accept the extension of the Work at Home pilot program with an every 6 month report until rules are promulgated and pending a satisfactory inspection of the scanned NJPBs. The motion passed unanimously.

Richard Palombo was recused due to his affiliation with Medco Health.

2) Thomas Privett, CDC Senior Public Health Advisor, Tuberculosis Program manager, NJ Dept Health & Senior Services – Requesting an update on the UMDNJ proposal regarding providing service to TB clinics in 4 counties.

At 9:53 a.m., Marc Sturgill moved, seconded by Edward McGinley to move into executive session for advice of counsel regarding the UMDNJ proposal. The motion passed unanimously.

At 10:40 a.m., Edward McGinley moved seconded by Mona Doyle to move back into the open session. The motion passed unanimously.

Edward McGinley moved, seconded by Elvy Paiva that based on the Board's concern for public health and the State's desire to assure patient compliance, the Board shall grant a specialized retail permit to UMDNJ University Hospital as allowed in N.J.A.C. 13:39-4.15, provided that the permit application includes a policy and procedures manual which details how the retail pharmacy will accommodate the statewide tuberculosis (TB) initiative which the board deems to be a limited and specialized public need, designation of an RPIC who shall be different than the institutional pharmacy RPIC, and a statement of the weekly hours necessary for the retail RPIC to adequately fulfill his or her responsibilities. The retail facility requirements listed in N.J.A.C. 13:39-4.10, 13:39-5.2, 13:39-5.3, 13:39-5.4, 13:39-5.8, 13:39-5.11, and 13:39-6.2(f) shall be specifically waived. The motion passed unanimously.

VIII. NEW BUSINESS

1) Review of Senate Bill No. 1943 – Requires prescription drug label for brand name to include generic name of the drug dispensed

Ira Katz moved, seconded by Edward McGinley to support this bill if it is amended to require that the generic name be provided to the patient but to allow the pharmacist the option of providing the generic name either on the label or on a separate patient instruction sheet. The Board of Pharmacy believes that requiring the inclusion of the generic name of a brand drug on the prescription label will generate more confusion for consumers. The Board's existing labeling regulation already requires numerous pieces of information to be included on all dispensed prescription containers. The Board believes that requiring the label to contain the generic name of a brand name dispensed drug could make all the information on the label more difficult to read, given the fact that the font size will likely have to be decreased in order to fit this additional piece of information. The Board also notes that the generic equivalent of a brand drug could have multiple names, leading to even smaller type and even greater confusion. The Board believes that the decision as to whether to include the information on the label should be left to the discretion of the pharmacist. The Board believes that pharmacists should be allowed to provide the name of the generic drug to most consumers on a form other than the label, and believe that most pharmacies would choose to include the generic name in the monograph that is currently provided to consumers with each prescription. The motion passed with a vote of 8 to 3.

2) Review of Senate Bill No. 1884 – requires fee for service prescription drug benefits for NJ FamilyCare

Edward McGinley moved, seconded by Ira Katz to oppose Senate Bill No. 1884 based upon the fact that the purpose and value of the bill is unclear, yet the reporting requirements are burdensome for affected providers and the State. The benefits of providing patient-specific information by the Commissioner of Health to each insurer is not evident in the bill or the bill statement. The Board also opposes that the Commissioner of Health is being required to supply a prescriber's DEA number as part of the reporting requirements. Rather than misuse of the

DEA number the Board feels that if a provider needs to be specifically identified then the State registration number should be adequate. The motion passed unanimously.

3) Memorandum regarding Advanced Practice Nurse (APN) prescribing

The Board recommends putting this item in a future newsletter.

4) Request from NABP regarding committee volunteers

Richard Palombo discussed reasons for volunteering to serve on the Association's committees and task forces in 2005-2006. Executive officers and members of the state boards of pharmacy who wish to volunteer, may send a written request and current vitae to the attention of Carmen A. Catizone, Executive Director/Secretary of the NABP; with a copy to the Executive Director, Joanne Boyer by May 31, 2005.

5) Information from DEA regarding a final rule which permits the use of digital signature and Public Key Infrastructure technology to sign and transmit orders for Schedules I and II controlled substances, and to archive records of those orders

The DAG will research this item to assure that it is consistent with the current state statutes and regulations. In addition, this item will be placed on a future agenda.

6) Kathleen Hartner, R.Ph. – Requesting a waiver of N.J.A.C. 13:39 –3A.1(a) Edward McGinley moved, seconded by Marc Sturgill to allowing Ms. Hartner a waiver requirement for live Continuing Education credits. The motion passed unanimously.

7) NABP Proposed Resolutions- NABP's 101st Annual Meeting, May21-24, 2005 Edward McGinley will be attending this meeting as the voting delegate. In the event of Mr. McGinley's absence, Richard Palombo will attend as the alternate.

District I

I. Edward McGinley moved, seconded by Elvy Paiva to support this proposed resolution regarding the current communication provisions of the ACPE standards for Accreditation. The motion passed unanimously.

District IV

I. Edward McGinley moved, seconded by Thomas F. Egan to support this proposed resolution regarding revising the Model Rules to reflect changes related to sterile compounding as set forth in USP 797. The motion passed unanimously.

District V

I. Ira Katz moved, seconded by Elvy Paiva to support this proposed resolution if the results are stated in an aggregated manner by the Colleges and Schools of Pharmacy. The motion passed unanimously.

II. Elvy Paiva moved, seconded by Ira Katz to approve this proposed resolution pertaining to establishment of a centralized reporting system to collect data relating to the relationship of importation and reimportation of pharmaceuticals and the clinical health outcomes of individuals engaged in such practices. The motion passed unanimously.

III. Ira Katz moved, seconded by Thomas F. Egan to support this proposed resolution on replacing the current manufacturer's subsidized access programs with voucher or card systems. The motion passed unanimously.

District VI

I. Thomas F. Egan moved, seconded by Marc Sturgill to approve this proposed resolution requiring pharmacies to

report terminations of licensed individuals to the Board of Pharmacy. The Board suggests that the resolution be amended to also include registered individuals. The motion passed unanimously.

II. Elvy Paiva moved, seconded by Thomas F. Egan to support this proposed resolution for NABP to work with the FDA to study the feasibility of allowing the repackaging of medications by other hospitals under common ownership. The motion passed unanimously.

District VII & District VIII

I. Marc Sturgill moved, seconded by Mona Doyle to support this proposed resolution that the state boards and NABP support an electronic data structure for uniquely identifying pharmaceutical products and their distribution. The Board suggest that the resolution be modified to support methods, not just electronic data structures. The motion passed with a vote of 10 to 1.

8) FDA notification regarding an illegal drug diversion operation involving pharmacies in New Jersey Edward McGinley moved, seconded by Ira Katz to forward this notice to the Department of Health and Senior Services, since it involved a New Jersey distributor/wholesaler. In addition, the Board will send a letter to each New Jersey pharmacy listed on the notice and request a response from each pharmacy regarding whether they were notified by the FDA, what action they took, what products they purchased and if they notified the affected patients and/or prescribers. NABP will be copied on the letters. The motion passed unanimously.

9) Board of Pharmacy committee assignments for 2005-2006 Edward McGinley distributed the committee assignments. In addition, the Collaborative Practice Committee will consist of Thomas F. Egan, Margherita R. Lafragola, Elvy Paiva , Ira Katz and Marc Sturgill with Pamela Allen as an ex-officio member. Elvy Paiva will be the chair for this Committee.

The Immunization Practice Committee will be combined with the Collaborative Practice Committee.

The Licensing Permits and Practice Sites Committee will consist of the Executive Director, Joanne Boyer and Elvy Paiva in addition to Margherita Lafragola.

10) Central Fill Application – Medco Health and Rite Aid

Mona Doyle moved, seconded by Ira Katz to approve Medco Health's and Rite Aid's joint application to Conduct a Centralized Prescription Handling Pharmacy Service. The motion passed unanimously.

Margherita R. Lafragola was recused due to her affiliation with Rite Aid Pharmacy. Richard Palombo was recused due to his affiliation with Medco Health.

11) Request for Internship Waivers

a) Meghaben D. Patel

Ira Katz moved, seconded by Elvy Paiva to deny Meghaben D Patel's request for a waiver of an internship since there is no waiver provision. The motion passed unanimously.

b) Denise Dennie

Elvy Paiva moved, seconded by Richard Palombo to deny Ms. Dennie's request for a waiver of an internship since there is no waiver provision. The motion passed unanimously.

c) Amy Nathan

Mona Doyle moved, seconded by Marc Sturgill to grant Ms. Nathan an extension to complete 500 hours of internship within 2 years. The motion passed by a vote of 10 to 1.

d) Arthur Shin

Ira Katz moved, seconded by Elvy Paiva to deny Mr. Shin's request for a waiver of an internship since there was no bona fide hardship. The motion passed unanimously.

e) Nirmeen Ibrahim

Edward McGinley moved, seconded by Richard Palombo that this item will be tabled until Ms. Ibrahim can provide the Board with an affidavit that lists her work experience and rotations. The motion passed by a vote of 10 to 1.

12) Review of Senate Bill No. 3997 - Establishes New Jersey Prescription Drug Retail Price Registry in DHSS; requires pharmacies to compile drug retail price lists.

Ira Katz moved, seconded by Elvy Paiva to oppose Senate Bill No. 3997, because the Board does not believe that the Drug Retail Price Registry is necessary. The Board estimates that more than 90% of filled prescriptions in the State are paid for by third-party payers. The prices charged for these filled prescriptions are established by third-party payers pursuant to the contracts they enter into with consumers and/or the discount cards the third-party payers provide to consumers. The prices for such prescriptions are not tied in any way to the retail prices of the prescription drugs. Therefore, the retail price of prescribed drugs is not a relevant piece of information for an overwhelming majority of consumers in the State. Consumers who pay cash for their prescriptions, which the Board estimates to be less than 10% of the prescription filling population, would also not benefit from this type of price registry because of the dynamic nature of retail drug prices in the State. It is very likely that the drug price information provided to the DHSS by individual pharmacies would become outdated before the information is ever posted on the DHSS website. In addition, the Board believes that providing drug price information for so many drugs will result in consumers being inundated with too much information that is not relevant to their particular needs. Consumers would generally be seeking information on a handful of medications. The Board believes that it would be far easier for consumers to call their local pharmacies and inquire about the prices of their particular prescription drugs. Consumers would, therefore, be guaranteed to obtain price information that is specific to the particular medications they are taking, and this information would allow them to more easily compare prices charged by pharmacies in their particular geographic area. The Board notes that its licensees are already required to provide consumers with this information pursuant to Board rule N.J.A.C. 13:39-7.14(e), which provides that upon a consumer's request, a pharmacist must provide the usual and customary price information for a cash paying customer over the telephone, including the effective period of the price quotation. The motion passed with a vote of 10 to 1.

13) Elections for officers of the Board Mona Doyle moved, seconded by Margherita R. Lafragola to have the nominations on June 8, 2005 and the election of President and Vice President on June 22, 2005. The motion passed unanimously.

IX. CONFERENCES

1) ASAP 2005 Midyear Industry & Technology Issue Conference, June 16-18, 2005, Galloway, NJ The Board has no interest in attending the 2005 Midyear Industry & Technology Issue Conference, at this point without financial support from the state of N.J.

X. COMMITTEE REPORTS

1) Pharmacy Practice Act –Immunization/Collaborative Practice Workgroups At this time there is no new information on this item.

XI. APPROVAL OF MINUTES

1) April 27, 2005

Richard Palombo moved, seconded by Mona Doyle, to accept the draft minutes of April 27, 2005 as amended. The motion passed unanimously.

XII. ADJOURNMENT

At 1:22 p.m., Mona Doyle moved, seconded by Richard Palombo to enter into the Executive Session to review eleven (8) complaints, (24) inspection reports, and (11) retail and institutional permits. The motion passed unanimously.