

**BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA**

Re: Nonresident	}	
Pharmacy License of	}	
NATIONAL PHARMACIES, INC.	}	COMPLAINT
License No. 3028	}	AND
John Paxos, R.Ph.,	}	STATEMENT OF CHARGES
Pharmacist in charge,	}	AND
Respondent	}	NOTICE OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 13th day of October, 1994, and files this Complaint and Statement of Charge and Notice of Hearing against National Pharmacies, Inc., a nonresident pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Jay J. Cayner; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a nonresident pharmacy at 491 Edward H. Ross Drive in Elmwood Park, New Jersey, and holds nonresident pharmacy license number 3028.

3. Nonresident pharmacy license number 3028, issued in the name of National Pharmacies, Inc., with John Paxos as pharmacist in charge was issued on January 6, 1994, and is current until December 31, 1994.

4. On October 7, 1994, the Board received a complaint from "Jane Doe" who alleged that Respondent had dispensed the incorrect prescription medication to her husband (John Doe). The complaint alleges the following:

a. On September 23, 1994, "Jane Doe" contacted Respondent to request a refill (a three month supply) of her husband's (John Doe's) prescription medication, Capoten®. On October 3, 1994, "Jane Doe" received a 30-day supply of the prescription medication, Prinivil®. The prescription label indicated the prescriber as Rene M. Staudacher, D.O., of Indianola, Iowa.

b. The prescriber, as indicated on the label, was incorrect. "John Doe's" physician is Jerry W. Lehr, D.O., of Indianola, Iowa.

c. The prescription medication which was dispensed to "John Doe" was a therapeutic substitute. "John Doe's" prescription was for the drug captopril (Capoten®). Respondent dispensed the drug lisinopril (Prinivil®) to "John Doe."

d. A nurse from Dr. Staudacher's office indicated that she had received a telephone call from Respondent on September 28, 1994, asking if "John Doe's" prescription could be changed from Capoten® to Prinivil®. "John Doe's" patient progress notes (medical record) from Dr. Staudacher's office indicates the following: "9/28/94 -- Call from National Pharmacy in New Jersey 1-800-762-8681 Ext. 3927 -- stating pt. on Capoten -- would like to try less expensive med -- OK per Dr. Lehr to try Prinivil 10mg daily #30."

e. Sometime after September 28, 1994, Dr. Staudacher received an unsigned letter from "Olu Akinyosoye, R.Ph.," who was identified as a "National" pharmacist. The letter sought to confirm Dr. Staudacher's authorization for the change in "John Doe's" prescription from Capoten® to Prinivil®.

f. Dr. Staudacher did *not* authorize any change in "John Doe's" prescription for Capoten®. Dr. Staudacher is not and has never been "John Doe's" physician. Dr. Staudacher or her nurse consulted with Dr. Lehr and related the incident concerning "John Doe's" medication. Dr. Lehr indicated that he had agreed to change "John Doe's" medication from Capoten® to Prinivil® if that was what the patient wanted.

g. Sometime after September 28, 1994, "John Doe" received an unsigned letter from "Olu Akinyosoye, R.Ph.," who was identified as a "National" pharmacist. The letter informed "John Doe" of the following:

Because you participate in your drug benefit Formulary program, we make every effort to save as much money as possible on your prescription medications. One of the ways we do this is to let your physician know when he or she has written a prescription for which we can provide another brand medication that has the same effect on your body, but at less cost.

In your case, Dr. Staudacher has authorized a new prescription for Prinivil Tabs instead of the originally prescribed Capoten Tabs. Prinivil Tabs is equally appropriate and effective for your condition.

h. "Jane Doe" has stated, in writing, that Respondent's substitution of the drug Prinivil® for the drug Capoten®, for her husband "John Doe", took place "without our knowledge, consent or approval."

i. "Jane Doe" has reported having other problems with Respondent's company regarding prescriptions for "Jane Doe" and "John Doe."

j. The therapeutic substitution which occurred for "John Doe" was initiated by Respondent "to save as much money as possible." It was done "without the knowledge, consent or approval" of the patient or his representative. Respondent falsely represented that Dr. Staudacher had authorized the substitution. This incident was emotionally harmful to "Jane and John Doe."

5. Respondent is guilty of violations of 1993 Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(h), 155A.23(2), and 155A.23(4) by virtue of the allegations contained in paragraph 4.

1993 Iowa Code section 155A.15 provides, in part, the following:

2. ...The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

d. Delivered without legal authorization prescription drugs or devices to a person other than one of the following:

(1) A pharmacy licensed by the board.

(2) A practitioner.

(3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.

(4) A manufacturer or wholesaler licensed by the board.

...

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

1993 Iowa Code section 155A.23 provides, in part, the following:

A person shall not:...

2. Willfully make a false statement in any prescription, report, or record required by this chapter.

...

4. Make or utter any false or forged prescription or written order.

6. Respondent is guilty of violations of 657 Iowa Administrative Code sections 8.5(1), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), and 9.1(4)(u) by virtue of the allegations contained in paragraph 4.

657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

b. Professional incompetency. Professional incompetency includes but is not limited to:...

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

...

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful to the public. Proof of actual injury need not be established.

...

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

7. 1993 Iowa Code section 155A.13A provides, in part, the following:

3. Discipline. The Board may deny, suspend, or revoke a nonresident pharmacy license for any violation of this section, section 155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g", "h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

The Iowa Board of Pharmacy Examiners finds that paragraphs 5, 6, and 7 constitute grounds for which Respondent's Iowa Nonresident Pharmacy License can be disciplined.

WHEREFORE, the undersigned charges that Respondent National Pharmacies, Inc., has violated 1993 Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(h), 155A.23(2), and 155A.23(4) and 657 Iowa Administrative Code sections 8.5(1), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), and 9.1(4)(u).

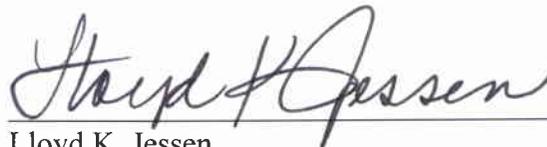
IT IS HEREBY ORDERED, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that John Paxos appear on behalf of National Pharmacies, Inc., before the Iowa Board of Pharmacy Examiners on Tuesday, November 15, 1994, at 10:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend, revoke, or not renew the nonresident pharmacy license issued to National Pharmacies, Inc., on January 6, 1994, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision, including disciplinary action, may be rendered.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for representation of the public interest in these proceedings. Information regarding the hearing may be obtained from Linn C. Emrich, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-3658). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen
Executive Secretary/Director

**BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA**

Re: Nonresident	}	
Pharmacy License of	}	
NATIONAL PHARMACIES, INC.	}	
License No. 3028	}	INFORMAL SETTLEMENT
Anthony Russo, R.P.h.,	}	
Pharmacist in Charge	}	
Respondent	}	

On this 9th day of July, 1996, the Iowa Board of Pharmacy Examiners and National Pharmacies, Inc., 399 Jefferson Road, Parsippany, New Jersey, each hereby agree with the other and stipulate as follows:

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Complaint and Statement of Charges and Notice of Hearing filed against Respondent on October 13, 1994, shall be resolved without proceeding to hearing, as the parties have agreed to the following Informal Settlement:

1. That Respondent was issued a license to operate a pharmacy on the 25th day of January, 1996, as evidenced by Nonresident Pharmacy License No. 3028, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That Iowa Nonresident Pharmacy License No. 3028 issued to and currently held by Respondent is current and in full force until December 31, 1996.
3. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.
4. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on October 13, 1994.

5. Respondent does not admit to the truth of the allegations set forth in the Complaint and Statement of Charges. This informal Settlement is executed as a compromise settlement of disputed claims.

6. Respondent agrees to accept a citation and warning for the alleged violations set forth in the Statement of Charges that was issued to the Respondent on October 13, 1994.

7. Respondent agrees to submit for board review and comment, within thirty (30) days of the effective date of the Informal Settlement, a written policy and procedure for therapeutic substitution or interchange of drugs by Respondent. The policy and procedure shall require safeguards designed to prevent unauthorized or inappropriate therapeutic substitution or interchange. The policy and procedure shall also require that any alterations in either the prescription drug order data or the patient record shall be completely documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist. The written policy and procedure shall include copies of any applicable forms or form letters utilized by Respondent to obtain prescriber authorization for therapeutic substitution or interchange, as well as copies of any forms or form letters utilized by Respondent to communicate with patients in regard to therapeutic substitution or interchange. Following review and comment by the Board, the Respondent agrees to adopt, implement, and adhere to this policy and procedure for all patient residing in Iowa. All written submissions by Respondent pursuant to this paragraph shall be considered confidential, proprietary and trade secret information by the Board and shall not be subject to public disclosure.

8. The Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy.

9. Within thirty (30) days of the date of approval of this Informal Settlement by the Board, the Respondent shall pay a civil penalty of \$5,000 by delivering a check made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The check shall be deposited into the general fund of the State of Iowa.

10. Should Respondent violate any of the terms of this Informal Settlement in any respect, the Board, after giving Respondent notice and an opportunity to be heard may take additional disciplinary action.

11. This Informal Settlement is subject to approval of a majority of the full Board. If the Board approves this Informal Settlement, it becomes the full and final disposition of this matter and the parties will be strictly bound by the terms set forth. If the Board fails to approve this Informal Settlement, it shall be of no force or effect to either party.

12. This Informal Settlement is voluntarily submitted by Respondent to the Board for its consideration on the 8th day July, 1996.



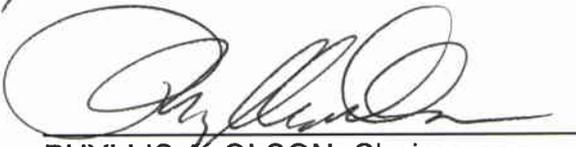
NATIONAL PHARMACIES, INC.
Anthony Russo, R.Ph.,
Pharmacist in Charge
Respondent

Subscribed and Sworn to before me on this 8th day of July, 1996.

YUDITA U YGLESIAS
Notary Public, State of New Jersey
No. 2098198
Qualified in Burlington County
Commission Expires March 13, 1997


NOTARY PUBLIC IN AND FOR THE
STATE OF NEW JERSEY

13. This Informal Settlement is accepted by the Iowa Board of Pharmacy
Examiners on the 9th day of July, 1996.


PHYLLIS A. OLSON, Chairperson
Iowa Board of Pharmacy Examiners
Executive Hills West
1209 East Court Avenue
Des Moines, Iowa 50319