

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

Re:

Pharmacy License of)	COMPLAINT
TRAVIS PHARMACY)	AND STATEMENT
License No. 156)	OF CHARGES
Patrick J. Travis,)	AND
Pharmacist in charge,)	NOTICE
Respondent)	OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary-Director of the Iowa Board of Pharmacy Examiners, on the 8th day of March, 1993, and files this Complaint and Statement of Charges and Notice of Hearing against Travis Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Alan M. Shepley, Chairperson; Marian L. Roberts, Vice Chairperson; Donna J. Flower; Phyllis A. Miller; Phyllis A. Olson; Ronald B. Reiff; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 616 West Sheridan Avenue in Shenandoah, Page County, Iowa 51601, and holds license number 156.

3. General pharmacy license number 156, issued in the name of Travis Pharmacy, with Patrick J. Travis as pharmacist in charge, was renewed on November 23, 1992, and is current until December 31, 1993.

4. The Board has received investigative reports from Pharmacy Investigator Morrell A. Spencer dated October 8, 1992, and November 6, 1992, and other investigative information which allege the following:

a. Information was received from the FDA on September 30, 1992, which alleged that Patrick J. Travis "had obtained bulk Cromolyn Sodium by use of a false statement, and had imported the drug from an unapproved source." Information from the FDA further alleged the following:

Concerning the use of a false statement, this firm [Travis Pharmacy] purchased bulk Cromolyn Sodium in July 1992 from...Corporation [A], Gardena, California. The product obtained was labeled "CAUTION: For research purposes only." The firm [Travis Pharmacy] used a false statement in order to obtain this drug chemical for the purpose of filling prescriptions.

Concerning the importation of a drug from an unapproved source, this firm [Travis Pharmacy] imported bulk Cromolyn Sodium in December 1991 from a firm in Canada. The product had originated from...[company B], Milano, Italy. The only approved source of Cromolyn Sodium at this time is Fisons Corp., Cheshire, England.

Our investigator verbally warned Mr. Patrick J. Travis...about the use of bulk drug substances from unapproved sources, the use of misbranded bulk drug substances, and the use of false statements to obtain bulk drug substances. Mr. Travis appeared to understand the situation and exhibited a willingness to comply.

b. On July 7, 1992, Patrick J. Travis had ordered bulk Cromolyn Sodium from a Texas supplier. In his letter to the supplier, Patrick J. Travis stated that he wanted the Cromolyn Sodium "for use in an ongoing research project."

c. Prescription records maintained at Travis Pharmacy by Patrick J. Travis reveal that between December 17, 1991, and October 6, 1992, a total of 68 compounded Cromolyn Sodium prescriptions (15,533 dosage units) were dispensed to patients by Patrick J. Travis at Travis Pharmacy.

d. Pharmacy Investigator Morrell A. Spencer found two lots of bulk Cromolyn Sodium powder at Travis Pharmacy on October 6-7, 1992:

Lot number HD127, which had been purchased by Patrick J. Travis on July 8, 1992, from corporation "A" (the California firm). Lot number HD 127 was labeled "CAUTION: For Research Purposes Only" ; and

Lot number F907, which had been purchased by Patrick J. Travis on December 18, 1991, from company "B" (the Italian firm). Company "B" was not approved by the FDA as a source of bulk Cromolyn Sodium.

e. An FDA investigator stated that at the end of his investigation of Travis Pharmacy on August 12, 1992, Patrick J. Travis agreed to return lot number HD127 to the supplier and that the remaining 190 grams of lot number F907 would not be used to compound prescriptions.

f. Patient medication records maintained by Patrick J. Travis at Travis Pharmacy revealed that approximately 124 grams of Cromolyn Sodium powder from lot number F907 were dispensed to patients between August 4, 1992, and October 5, 1992.

g. Compounding records maintained by Patrick J. Travis at Travis Pharmacy revealed that approximately 32 grams of Cromolyn Sodium powder from lot number F907 were used to compound prescriptions between August 7, 1992, and September 28, 1992.

h. Approximately 52 grams of Cromolyn Sodium powder (lot number F907) were released by Patrick J. Travis to Pharmacy Investigator Morrell A. Spencer on October 7, 1992.

i. Approximately 500 grams of Cromolyn Sodium powder (lot number HD127) were released by Patrick J. Travis to Pharmacy Investigator Morrell A. Spencer on October 16, 1992.

5. Respondent is guilty of violations of 1993 Iowa Code sections 126.3(1), 126.9(2), 126.9(3), 126.10(1), 126.10(9)(a), 126.10(9)(b), 126.10(9)(c), 155A.15(2)(c), and 155A.15(2)(h) by virtue of the allegations contained in paragraph 4.

1993 Iowa Code section 126.3 (formerly 1991 Iowa Code section 203B.3) provides, in part, the following:

The following acts and the causing of the acts within this state are unlawful:

1. The introduction or delivery for introduction into commerce of any drug, device, or cosmetic that is adulterated or misbranded.

1993 Iowa Code section 126.9 (formerly 1991 Iowa Code section 203B.9) provides, in part, the following:

A drug or device is adulterated under any of the following circumstances:...

2. If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the official compendium...

3. If it is not subject to subsection 2 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

1993 Iowa Code section 126.10 (formerly 1991 Iowa Code section 203B.10) provides, in part, the following:

A drug or device is misbranded under any of the following circumstances:

1. If its labeling is false or misleading in any particular.

....

9. a. If it is a drug and its container is so made, formed, or filled as to be misleading.

- b. If it is an imitation of another drug.

- c. If it is offered for sale under the name of another drug.

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.

....

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

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), 9.1(4)(j), 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.

....

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

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.

The Iowa Board of Pharmacy Examiners finds that paragraphs 5 and 6 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent has violated 1993 Iowa Code sections 126.3(1), 126.9(2), 126.9(3), 126.10(1), 126.10(9)(a), 126.10(9)(b), 126.10(9)(c), 155A.15(2)(c), and 155A.15(2)(h) and 657 Iowa Administrative Code sections 8.5(1), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(j), and 9.1(4)(u).

IT IS HEREBY ORDERED pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Patrick J. Travis appear on behalf of Travis Pharmacy before the Iowa Board of Pharmacy Examiners on Friday, April 9, 1993, 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 license to operate a pharmacy issued to Travis Pharmacy on November 23, 1992, 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 may be rendered. The failure of Respondent to appear could result in the permanent suspension or revocation of its license.

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 the public interest in these proceedings. Information regarding the hearing may be obtained from Lynette A. F. Donner, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-8760). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS

A handwritten signature in cursive script, reading "Lloyd K. Jessen". The signature is written in dark ink and is positioned above a horizontal line.

Lloyd K. Jessen, Executive Secretary/Director

APR 26 1993

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

Re: Pharmacy License of TRAVIS PHARMACY License No. 156 Patrick J. Travis, Pharmacist in charge, Respondent	} } } } } }	STIPULATION AND INFORMAL SETTLEMENT
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COMES NOW the Iowa Board of Pharmacy Examiners (the Board) and Travis Pharmacy (Respondent) and, pursuant to Iowa Code sections 17A.10 and 258A.3(4), enter into the following Stipulation of the contested case currently on file:

1. Respondent is licensed to operate as a pharmacy at 616 West Sheridan Avenue, Shenandoah, Iowa 51601, and holds license number 156.

2. Respondent's license is current until December 31, 1993.

3. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on March 8, 1993.

4. The Board has jurisdiction of the parties and the subject matter.

5. Respondent shall follow and adhere to the attached "Good Compounding Practices" guideline (or a successor rule as may be adopted by the Board) whenever engaging in the compounding of drugs and drug products.

6. Respondent shall not order or use any substances

designated or labeled for research use only.

7. Stipulation and Informal Settlement is subject to approval of the Board. If the Board approves this Stipulation and Informal Settlement, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Informal Settlement, it shall be of no force or effect to either party.

8. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 22nd day of April, 1993.



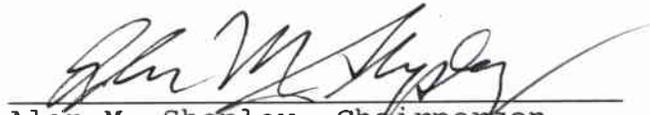
TRAVIS PHARMACY
Patrick J. Travis,
Pharmacist in charge,
Respondent

Signed and sworn to before me this 22nd day of April, 1993.



NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

9. This Informal Settlement is accepted by the Iowa Board of Pharmacy Examiners on the 22nd day of April, 1993.



Alan M. Shepley, Chairperson
Iowa Board of Pharmacy Examiners

**Iowa Board of Pharmacy Examiners
Good Compounding Practices
Guideline**

The following Good Compounding Practices (GCPs) are meant to apply to compounding of drugs by Iowa-licensed pharmacists and pharmacies.

Introduction.

In situations where there is no commercially available therapeutically suitable product, in the dose prescribed, it is appropriate for the pharmacist to compound in order to meet the needs of the prescriber and the patient. The compounding of specialty products by a pharmacist for drug products that are not commercially available is clearly authorized and desirable.

General Provisions.

The recommendations contained herein are considered to be the minimum current good compounding practices for the preparation of drug products except parenteral preparations for dispensing and/or administration to humans or animals.

The following definitions from Board rules contained in 657 Iowa Administrative Code chapter 8 apply to these Good Compounding Practices:

657-8.23(155A) Compounding. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

1. As a result of a practitioner's prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice, or
2. For the purpose of, or as an incident to, research, teaching, chemical analysis, and not for sale or dispensing.

Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

657-8.24(155A) Manufacturing. "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container. Manufacturing also includes the preparation, promotion, and marketing of commercially

available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

In addition, the following definition applies to these Good Compounding Practices:

Component. "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, in reasonable quantities, drug products which meet the therapeutic needs of the patient as ordered by the prescriber.

The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis is manufacturing. The distribution of compounded products without a prescriber/patient/pharmacist relationship is manufacturing.

Pharmacists shall receive, store, or use drug substances for compounding that have been made in an FDA-approved facility. If unobtainable from an FDA-approved facility, pharmacists shall receive, store, or use drug components in compounding prescriptions that meet current USP/NF requirements.

Pharmacists shall not offer compounded drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a prescriber to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products which cannot be substantiated. All advertisements shall meet the requirements contained in 657 Iowa Administrative Code section 8.6.

Organization and Personnel.

As in the dispensing of all prescriptions, the pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling, and has the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

All pharmacists who engage in compounding of drugs shall be

proficient in the art of compounding and shall maintain that proficiency through current awareness and training. Also, every pharmacist who engages in drug compounding must be aware of and familiar with all details of the Good Compounding Practices Guideline.

While non-pharmacist personnel may assist in the compounding of drug products, the supervising pharmacist remains responsible for all work performed by the non-pharmacist.

Personnel engaged in the compounding of drug products shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s) being compounded. All personnel who normally assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

Drug Compounding Facilities.

Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to compound medications. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding or dispensing of non-sterile drug products. The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

Bulk drugs and other materials used in the compounding of drug products must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

Adequate lighting and ventilation shall be provided in all drug compounding areas. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-source towels.

The area(s) used for the compounding of drug products shall

be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

Sterile Products.

If sterile (aseptic) products are being compounded, the requirements contained in 657 Iowa Administrative Code section 8.12 shall be met.

If radiopharmaceuticals are being compounded, the requirements of 657 Iowa Administrative Code chapter 16 shall be met.

Special Precaution Products.

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

Equipment.

Equipment used in the compounding of drug products shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in 657 Iowa Administrative Code section 8.12 must be followed.

Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that will perform a function satisfactorily may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

Control of Components and Drug Product Containers and Closures.

Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drug products shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area, (e.g., floors) and inspection.

Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest approval stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, stored, etc., in keeping with the requirements of 657 Iowa Administrative Code section 8.12. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals, if these processes are performed by the pharmacist, or under the pharmacist's supervision, following the requirements of 657 Iowa Administrative Code section 8.12.

Drug Compounding Controls.

There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component addition, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug product, shall be listed. These written procedures shall be followed in the execution of the drug

compounding procedure.

Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is removed from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the: (a) component name, and (b) weight or measure.

To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product being compounded (e.g., compounding of capsules). Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate): (a) capsule weight variation; (b) adequacy of mixing to assure uniformity and homogeneity; and (c) clarity, completeness, or pH of solutions.

Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

Labeling Control of Excess Products.

In the case where a quantity of a compounded drug product in excess of that to be initially dispensed in accordance with the general provisions described above is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned expiration date based upon professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.

At the completion of the drug finishing operation, the product shall be examined for correct labeling. Labeling shall conform with the label information requirements contained in 657 Iowa Administrative Code section 8.4.

Records and Reports.

Any procedures or other records required to be maintained in

compliance with these Good Compounding Practices shall be retained for at least two years from the date of such procedure or record.

All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection.

Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Records shall conform with the control and production record requirements contained in 657 Iowa Administrative Code section 8.4.

Summary.

Due to risks associated with compounded drug products, if a pharmacist has a choice between a commercially available product and a compounded product, the best interests of the patient require that the commercially available product be used. The cost of the commercially available product may be higher, because of the rigorous FDA requirements for approval. However, patient safety and well being are the first priorities, and a less safe or effective drug should not be chosen solely for economic reasons.

The compounding of specialty products by a pharmacist for drug products that are not commercially available is clearly authorized and desirable. But pharmacists should not compound a drug product when there is a commercially available FDA-approved drug product which is suitable for the patient. Given the risks associated with non FDA-approved drug products, i.e., their safety and effectiveness are unproven, it is incompetent and unethical for a pharmacist to dispense them for purely economic reasons, when there is a safe and effective commercially available product. The pharmacist who does so is purporting to offer a generic drug without complying with the requirements of Iowa Code section 155A.32(1) (1993).

END.