

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

Re:) Case No. 2003-71
Pharmacy Technician Registration of)
PATRICIA K. WILLIAMS) **STATEMENT OF CHARGES**
Registration No. 6566)
Respondent)

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 147, 155A and 272C (2003).
3. In 2001 the Board first issued a pharmacy technician registration to Respondent, Patricia K. Williams, as evidenced by registration number 6566, subject to the laws of the State of Iowa and the rules of the Board.
4. Respondent's pharmacy technician registration was most recently renewed on April 14, 2003, and is current and active until February 28, 2005.
5. Respondent's current address is 1267½ Jackson Street, Apartment #2, Dubuque, Iowa 52001.
6. Respondent was employed as a pharmacy technician at Union Family Pharmacy, Dubuque, Iowa, and was employed as such during all times relevant to this statement of charges.

COUNT I

Respondent is charged under Iowa Code §§ 155A.6(7) (2003) and 657 Iowa Administrative Code § 3.23 with failing to comply with board rules pertaining to pharmacy technician tasks while employed at Union Family Pharmacy.

COUNT II

Respondent is charged under Iowa Code § 155A.6(7) (2003) and 657 Iowa Administrative Code § 3.28 with unethical conduct or practice while employed at Union Family Pharmacy.

COUNT III

Respondent is charged under Iowa Code § 155A.4(1) with unlawful dispensing of prescription drugs while employed at Union Family Pharmacy.

COUNT IV

Respondent is charged under Iowa Code § 155A.33 with performing inappropriate dispensing functions and performing appropriate dispensing functions without appropriate supervision by a pharmacist.

COUNT V

Respondent is charged under 657 I.A.C. § 36.1(4)(j) and 21 C.F.R. § 1306.04 with participating in the filling of Internet prescriptions for controlled substances at Union Family Pharmacy that were not issued in the usual course of professional treatment and as such were not prescriptions within the meaning and intent of § 309 of the Controlled Substances Act (21 U.S.C. 829).

COUNT VI

Respondent is charged under 657 I.A.C. § 36.1(4)(j), 21 C.F.R. § 1306.05 and 657 I.A.C. 10.21(1) with participating in the filling of Internet prescriptions at Union Family Pharmacy that were not prepared in the form prescribed by Federal regulations.

THE CIRCUMSTANCES

On or about September 9, 2003, an investigation of Union Family Pharmacy was commenced, which produced the following information:

1. An accountability audit of controlled substances at Union Family Pharmacy has revealed shortages of certain controlled substances.
2. An investigation of Union Family Pharmacy has revealed that it became a fulfilling pharmacy for an Internet website known as buymeds.com. As a fulfilling pharmacy for buymeds.com, Union Family Pharmacy retrieved prescription drug orders from an online location, filled the orders, and shipped medication to consumers throughout the United States.
3. Union Family Pharmacy shipped medication for buymeds.com to consumers located in at least 47 U.S. states. Union Family Pharmacy was not registrationed as a pharmacy in any state except Iowa. Currently, approximately 43 of 53 U.S. states and jurisdictions require licensure of nonresident pharmacies such as Union Family Pharmacy.

4. The Internet website, buymeds.com, is registered to Pharmacom LLC, PMB 365 9100 Port of Sale, Suite 2, St. Thomas, Virgin Islands 00802. Pharmacom LLC is not a pharmacy and is not registrationd as such in any state, including Iowa. Pharmacom LLC recruits registrationd pharmacies to fulfill orders that they solicit over the Internet. Neither Pharmacom LLC or buymeds.com are VIPPS-certified. VIPPS stands for Verified Internet Pharmacy Practice Site. Currently there are only 14 VIPPS-certified pharmacies in the United States.
5. Pharmacom LLC is a processor of prescriptions. It represents itself to the public on its website homepage as "Your Private, Secure, and Convenient Online Pharmacy for FDA approved prescription medications." The website offers "Free Medical Consultancy."
6. Pharmacom LLC recruits "affiliates" who agree to provide sponsoring websites that help drive business for the company. Such links direct potential customers to Pharmacom's website. The buymeds.com affiliate agreement program pays affiliates a fee for every new customer plus a percent of all sales, including product refills.
7. On or about August 19, 2003, Union Family Pharmacy became a fulfilling pharmacy for buymeds.com and began shipping prescription drugs, including controlled substances, to customers throughout the U.S. Union Family Pharmacy has indicated to the Board that the reason for the change to this vendor was "to be able to dispense a larger volume of prescriptions."
8. Beginning August 19, 2003, Union Family Pharmacy dispensed approximately 4,750 Internet prescriptions as follows:

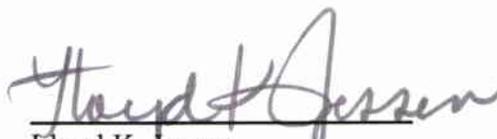
• August 19, 2003: 82	• September 2, 2003: 241
• August 20, 2003: 440	• September 3, 2003: 200
• August 21, 2003: 284	• September 4, 2003: 197
• August 24, 2003: 463	• September 5, 2003: 289
• August 27, 2003: 105	• September 6, 2003: 425
• August 28, 2003: 102	• September 7, 2003: 584
• August 29, 2003: 190	• September 8, 2003: 489
• September 1, 2003: 354	• September 9, 2003: 205

Some of the Internet prescriptions filled between August 20, 2003 and August 29, 2003, originated from another website known as "Medical Web Services," Union Family Pharmacy first began filling Internet prescriptions for Medical Web Services in March 2003. Medical Web Services is the parent company to a conglomeration of online sites that offer prescription drugs. The domain address for Medical Web Services is 440 Sawgrass Corporate Parkway, Suite 210, Sunrise, Florida 33325. Union Family Pharmacy filled prescriptions for Medical

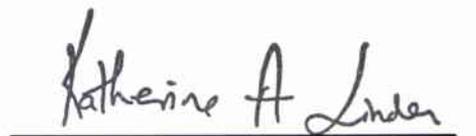
Web Services in a manner similar to the way in which it filled prescriptions for Pharmacom LLC and buymeds.com. On May 21, 2003, the Board received a complaint from a consumer who alleged that Union Family Pharmacy refused to provide her with a receipt for an Internet prescription that she had received from Union Family Pharmacy via Medical Web Services.

9. Four of the buymeds.com Internet prescriptions were filled for residents of Iowa: #60 Hydrocodone/APAP 7.5/750 for "BJ" of Davenport, Iowa; #60 Hydrocodone/APAP 5.0/500 for "RT" of Nevada, Iowa; #60 Diazepam 10mg for "IP" of Ames, Iowa; and #60 Acetaminophen with Codeine 60mg for "RB" of LeClaire, Iowa.
10. Nearly all of the Internet prescriptions were for Schedule III and Schedule IV controlled substances. The most commonly dispensed Schedule III controlled substance was Hydrocodone. The most commonly dispensed Schedule IV controlled substance was Phentermine. Quantities dispensed were typically 60 or more per prescription.
11. Most, if not all, of the buymeds.com prescriptions were approved electronically by four physicians registered in Florida: Armando Angulo, MD, Hialeah, Florida; Mario R. Avello, MD, Coral Gables, Florida; Carlos M. Barrera, MD, Miami, Florida; and Mario A. Diaz, MD, Hialeah, Florida. None of these prescriptions identified the date the prescriber approved them.
12. To the Complainant's information and belief, all of these Internet prescriptions were based solely upon an electronic questionnaire. There was no pre-existing patient-prescriber relationship between the purchasers and these four prescribers. There was no in-person physical examination of any of the purchasers prior to the prescribing of any of the medications. Purchasers were not seen or contacted by the prescribers. To the Complainant's information and belief, there was no telephone consultation between any of the purchasers and the prescribers. As a result, there was no valid patient-prescriber relationship for any of the Internet prescriptions for controlled substances which were dispensed by Union Family Pharmacy between August 19 and September 9, 2003.
13. Union Family Pharmacy utilized pharmacy technicians to dispense these Internet prescriptions and other prescriptions. Pharmacists at the pharmacy delegated inappropriate functions to the technicians and failed to properly supervise the appropriate functions they performed. Pharmacists at the pharmacy also failed to ensure that pharmacy technicians verified filled prescriptions before dispensing the prescriptions to purchasers.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.


Lloyd K. Jessen
Executive Secretary/Director

On this 6th day of November 2003, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.


Katherine A. Linder, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

RE:)	CASE NO. 2003-71
Pharmacy Technician Registration of:)	DIA NO: 04PHB010
Patricia K. Williams)	FINDINGS OF FACT,
Registration No. 6566)	CONCLUSIONS OF LAW,
Respondent)	DECISION AND ORDER

TO: Patricia K. Williams

On November 6, 2003, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file a Statement of Charges against Patricia K. Williams (Respondent), a registered pharmacy technician. The Statement of Charges alleged six counts of violations of state and federal statutes and board rules:

Count I: Failing to comply with board rules pertaining to pharmacy technician tasks while employed at Union Family Pharmacy, in violation of Iowa Code section 155A.6(7)(2003) and 657 IAC 3.23;

Count II: Unethical conduct or practice while employed at Union Family Pharmacy, in violation of Iowa Code section 155A.6(7)(2003) and 657 IAC 3.28;

Count III: Unlawful dispensing of prescription drugs while employed at Union Family Pharmacy, in violation of Iowa Code section 155A.4(1);

Count IV: Performing inappropriate dispensing functions and performing appropriate dispensing functions without appropriate supervision by a pharmacist, in violation of Iowa Code section 155A.33;

Count V: Participating in filling of Internet prescriptions for controlled substances at Union Family Pharmacy that were not issued in the usual course of professional treatment and as such were not prescriptions within the meaning and intent of §309 of the Controlled Substance Act (21 U.S.C. 829);

Count VI: Participating in the filling of Internet prescriptions at Union Family Pharmacy that were not prepared in the form prescribed by Federal regulations, in

violation of 657 IAC 36.1(4)(j), 21 C.F.R. 1306.05 and 657 IAC 10.21(1).

An Amended Notice of Hearing was issued on July 23, 2004 setting the hearing for December 14, 2004 at 1:00 p.m. The Amended Notice of Hearing was served on the Respondent by certified mail, return receipt requested. The Respondent failed to appear for the hearing.

The hearing on the Statement of Charges was held on December 14, 2004 at 1:15 p.m. The following members of the Board presided at the hearing: Michael J. Seifert, Chairperson; Katherine A. Linder; Paul Abramowitz; Leman Olson; Vernon Benjamin; Barbara Ellen O'Roake; and Kathleen Halloran. The Respondent did not appear for the hearing. Scott Galenbeck, Assistant Attorney General, represented the state. The hearing was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1)(2003).

After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate its decision. The administrative law judge was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with the Board's deliberations.

THE RECORD

The record includes the testimony of the witnesses and State Exhibits 1-5.

FINDINGS OF FACT

1. In 2001, the Board issued the Respondent pharmacy technician registration number 6566, subject to the laws of the state of Iowa and the rules of the Board. Pharmacy technician registration number 6566 is current and active until February 28, 2005. (State Exhibit 1)

2. On or about August 25, 2003, the Board received information from the Dubuque Drug Task Force that a user/informant had received large quantities of OxyContin 20mg and 40mg and Hydrocodone products from the Respondent, while she was working as a pharmacy technician at the Union Family Pharmacy in Dubuque, Iowa. The informant also claimed that he took a

minimum of 12 Hydrocodone tablets per day over a two-year period, all supplied illegally by the Respondent. According to the informant, the Respondent handled the paperwork and ordering of pills for the pharmacy and was able to manipulate the books and the orders. (Testimony of Debbie Ringgenberg; State Exhibits 3, 5)

3. In addition to the complaint of drug diversion that was filed against the Respondent, there was also a separate complaint concerning the Union Family Pharmacy's involvement in filling Internet prescriptions. The Union Family Pharmacy had entered into an agreement with buymeds.com to fill Internet prescriptions and ship medications to customers throughout the United States. The buymeds.com website is registered to Pharmacom LLC, in the Virgin Islands. Buymeds.com is not a licensed pharmacy in any state.

On September 9, 2003, three Board investigators conducted a complete inspection, inventory, and controlled substances audit at the Union Family Pharmacy in Dubuque, Iowa. The inspection revealed that the majority of the Internet prescriptions were for Schedule III and Schedule IV controlled substances. Union Family Pharmacy filled prescriptions from two dispensing areas within the store: one area dispensed drugs for Internet prescriptions, the second area dispensed drugs for "traditional" prescriptions. However, the pharmacy operated under one general pharmacy license, one Controlled Substance Registration, and one Drug Enforcement Agency Registration. One controlled substance inventory was maintained and stock was co-mingled within the pharmacy. Prescriptions were numbered sequentially and disbursement records included prescriptions filled in both areas of the pharmacy.

Union Family Pharmacy was dispensing large quantities of controlled substances to customers who were unknown to the pharmacy and for whom the pharmacy did not have adequate patient histories. From August 19, 2003 to the date of the inspection, Union Family Pharmacy had dispensed approximately 4,750 Internet prescriptions to consumers in 47 states. 43 of the 53 states and jurisdictions require licensure for nonresident pharmacies, but the Union Family Pharmacy was only licensed in Iowa.

Four Florida physicians approved most, if not all of the Internet prescriptions. None of the prescriptions identified the required date that the prescriptions were approved. The prescriptions were based upon an "online medical questionnaire" completed by the purchaser without a preexisting patient-

prescriber relationship and without an in-person physical examination. Prescriptions were dispensed without proper pharmacist verification. Pharmacy security was inadequate, and the dispensing area for Internet prescriptions was readily accessible to the public. A large number of Schedule III and Schedule IV controlled substances were stored in the area, and it was not locked when a pharmacist was not present. The pharmacists delegated inappropriate functions to the pharmacy technicians and failed to appropriately supervise the appropriate functions that the technicians performed. The pharmacy technicians in the Internet area were inadequately trained and were allowed to counsel patients on the telephone after conferring with the pharmacist. Many other violations were also noted. On September 12, 2003, the Board issued an Emergency Order suspending the Union Family Pharmacy's Controlled Substance Registration. The Board later accepted the surrender of the licenses for the pharmacy and its two pharmacists. (Testimony of Debbie Ringgenberg; State Exhibits 3-5)

4. The Respondent had been employed by the Union Family Pharmacy as a pharmacy technician in the "traditional" dispensing area of the pharmacy from approximately March 2001 until July 2003. The Respondent had moved to Colorado and was no longer employed by Union Family Pharmacy when the investigators arrived to conduct the inspection and audit.

On September 24, 2003, one of the Board's investigators interviewed the informant. The informant explained that he became acquainted with the Respondent several years earlier when they lived in the same building. The Respondent offered the informant, who had back pain, a pharmacy stock bottle of Lortab 7.5 (Hydrocodone) and told him that she had an "inside connection." The Respondent later started charging the informant \$100 for a bottle of Lortab. Sometimes the informant bought the pills at the Respondent's house and sometimes he bought them outside the pharmacy. Eventually the Lortab pills were not working for the informant's pain. When the Respondent wanted to buy his van, which was worth approximately \$1,000, the informant asked the Respondent for OxyContin, Morphine, and Hydrocodone. The Respondent gave the informant 3 bottles of 10mg Hydrocodone (100 tablets each); 1 bottle of 20mg OxyContin (100 tablets), 1 bottle of 40mg OxyContin (100 tablets), two bottles of 30 mg Morphine Sulfate (100 tablets), and 200-400 tablets of Hydrocodone in exchange for his van. When the informant was nearly out of pills, he sought help for his

addiction and was advised to report the Respondent to law enforcement.

The Board's investigator also interviewed Bobby Jo Rooney, the Respondent's niece and a former employee of Union Family Pharmacy. Rooney worked with the Respondent in the "traditional" dispensing area of the pharmacy and corroborated some of the informant's information. In early 2003, Rooney drove the Respondent and her boyfriend to various addresses in Wisconsin, Illinois, and East Dubuque several times a week. Rooney confirmed that one of the addresses she drove to was the informant's home in Wisconsin. The Respondent and her boyfriend were always gone for 20 minutes or so and then returned to Rooney's car with money. Rooney later saw stock bottles of Vicodin in the Respondent's house and in her purse. The Respondent told Rooney that she could get \$50 for the Vicodin when she needed rent money. According to Rooney, the pharmacy reported some of the missing drugs as shortages in their daily orders. If the drugs were replaced by the wholesalers, some of the thefts would not appear as shortages in the audit.

The Dubuque Drug Task Force detectives eventually interviewed the Respondent but she denied any involvement with drug shortages at the pharmacy and refused to answer questions about the alleged drug diversion. (Testimony of Debbie Ringgenberg; State Exhibit 5)

5. The audit of the Schedule II Controlled Substances at Union Family Pharmacy documented shortages of OxyContin 20mg and 40mg and the Morphine Sulfate IR 30mg in amounts that matched the drugs that the informant claimed to have received from the Respondent. Discrepancies were also noted between hard copy prescription records and computer-generated disbursement records. The Schedule III and IV controlled substances were re-inventoried on October 1, and October 17, 2003, due to the chaotic circumstances in the Internet area of the pharmacy when the initial audit was conducted. (Testimony of Debbie Ringgenberg; State Exhibits 3-5)

6. The Statement of Charges and Amended Notice of Hearing were served on the Respondent by certified mail, return receipt requested in late July 2004. The Respondent signed for the certified mail but failed to appear for the hearing. (Testimony of Debbie Jorgenson; State Exhibits 1-2)

CONCLUSIONS OF LAW

I. Failure to Appear

657 IAC 35.5(1)"b" provides that delivery of the notice of hearing may be executed by certified mail, return receipt requested. 657 IAC 36.5(5) provides that the notice shall be delivered at least 30 days before the time set for the hearing.

The notice of hearing was delivered to the Respondent by certified mail, return receipt prior to July 29, 2004. (State Exhibit 2) The Respondent personally signed the return receipt card. She was properly served with the notice of hearing but failed to appear.

If a party fails to appear or participate in a contested case hearing after proper service of notice, the presiding officer may, if no adjournment is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party. 657 IAC 35.21(1). When the Respondent failed to appear, the Board was authorized to proceed with the hearing.

II. The Violations

Iowa Code section 272C.3(1)(e) and (f)(2003) authorizes licensing boards to initiate and prosecute disciplinary proceedings and impose licensee discipline, including revocation of the license. See also 657 IAC 3.30.

Iowa Code section 155A.6(7)(2003) provides that the Board may deny, suspend, or revoke a pharmacy technician registration for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, 124B, 126, 147, or 205, or any rule of the board.

Iowa Code section 155A.4(1)(2003) provides that a person shall not dispense prescription drugs unless that person is a licensed pharmacist or is authorized by section 147.107 to dispense or distribute prescription drugs.

Iowa Code section 155A.33(2003) provides that a pharmacist may delegate technical functions to pharmacy technicians, but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the

delivery of the prescription to the patient or the patient's representative...

657 IAC 3.28 provides, in relevant part:

657-3.28(147,155A) Unethical conduct or practice.

Violation by a pharmacy technician of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 3.30(155A).

...

3.28(4) Unethical conduct or behavior. A pharmacy technician shall not exhibit unethical behavior in connection with the pharmacy technician's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts:...theft.

The preponderance of the evidence established that the Respondent removed controlled substances from the Union Family Pharmacy and dispensed them to the informant in exchange for money and a van. The informant did not have a valid prescription for the controlled substances. The Respondent's actions were unethical, constituted theft, and violated Iowa Code section 155A.6(7) and 657 IAC 3.28(4) [Count II]. By providing controlled substances to the informant, the Respondent also violated Iowa Code section 155A.4(1) [Count III] and Iowa Code section 155A.33 [Count IV] because a pharmacy technician is not authorized to dispense prescription drugs without a valid prescription and pharmacist supervision and verification.

The preponderance of the evidence failed to establish the Respondent's direct involvement in filling Internet prescriptions for Union Family Pharmacy. The Respondent primarily worked in the "traditional" area of Union Family Pharmacy and was no longer working at the pharmacy when the investigators performed their inspection. While the Board's investigators were told that all of the pharmacy technicians would help to fill Internet orders if the pharmacy was very busy, the Board's investigator could not recall any specific information about the Respondent's involvement in filling Internet orders. For this reason, Counts I, IV, and V, all of which relate to the filling of illegal prescriptions via the Internet, are hereby DISMISSED.

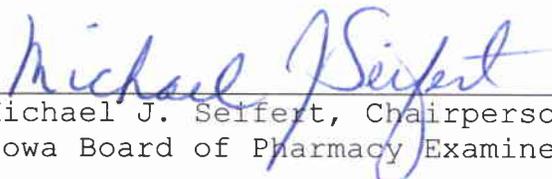
DECISION AND ORDER

IT IS THEREFORE ORDERED that pharmacy technician registration no. 6566, issued to Patricia K. Williams, shall be REVOKED, effective immediately upon service of this order.

IT IS FURTHER ORDERED, that the Respondent shall immediately return her pharmacy technician registration to the Iowa Board of Pharmacy Examiners, 400 SW 8th St., Suite E, Des Moines, Iowa 50309-4688.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that the Respondent shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board may bill the Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. The Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 15th day of february , 2005.


Michael J. Seifert, Chairperson
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Attorney General

Default decisions or decisions rendered on the merits after a party has failed to appear or participate in a contested case proceeding become final agency action, unless, within 15 days after the date of notification or mailing of this decision, a motion to vacate is filed and served on all parties or an appeal of the decision on the merits is timely initiated within the time frame provided by rule 657-35.26... A motion to vacate shall state all facts relied upon by the moving party which establish that good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated must be substantiated by at least one sworn affidavit or a person with personal knowledge of each such fact attached to the motion. 657 IAC 35.21. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate. 657 IAC 35.21(4).