

**BEFORE THE IOWA BOARD OF PHARMACY**

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|                      |   |                                |
|----------------------|---|--------------------------------|
| Re:                  | ) | Case Nos. 2013-225 & 2014-37   |
| Pharmacy License of  | ) |                                |
| <b>DOWNTOWN DRUG</b> | ) | <b>STATEMENT OF CHARGES</b>    |
| License No. 1281,    | ) | <b>&amp; NOTICE OF HEARING</b> |
| Respondent.          | ) |                                |

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**COMES NOW** the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent was issued Iowa license 1281. Respondent's license is currently active.

**A. TIME, PLACE, AND NATURE OF HEARING**

Hearing. A disciplinary contested case hearing shall be held on June 30, 2014 before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S.W. 8<sup>th</sup> Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin  
Assistant Attorney General  
Iowa Attorney General's Office  
2<sup>nd</sup> Floor Hoover State Office Building  
Des Moines, Iowa 50319.

Ms. Gavin can also be reached by phone at (515)281-6736 or e-mail at [Meghan.Gavin@iowa.gov](mailto:Meghan.Gavin@iowa.gov).

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you

may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistance Attorney General Meghan Gavin at (515)281-6736.

## **B. LEGAL AUTHORITY AND JURISDICTION**

Jurisdiction. The Board has jurisdiction over this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 155A, and 272C and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

## **C. CHARGES**

### **Count I UNETHICAL BEHAVIOR OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC**

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code section 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(c).

### **Count II FAILURE TO REPORT CHANGE IN PHARMACIST IN CHARGE AND FAILING TO COMPLY WITH REQUIREMENTS FOR MAKING THE CHANGE**

Respondent is charged with failing to report change in pharmacist-in-charge and failing to comply with requirements for making the change in violation of Iowa Code sections 155A.15(2)(c) and 155A.19(1)(d) and 657 Iowa Administrative Code rule 8.35(6)(c) and 36.1(4)(u).

**Count III**  
**FAILURE TO MAINTAIN ADEQUATE CONTROL OVER AND ACCOUNTABILITY  
FOR CONTROLLED SUBSTANCES**

Respondent is charged with failing to maintain adequate control over and accountability for controlled substances in violation of Iowa Code section 155A.15(2)(c), (i) and 657 Iowa Administrative Code rule 36.1(4)(ac).

**Count IV**  
**FAILURE TO ESTABLISH ADEQUATE SECURITY AND EFFECTIVE  
CONTROLS AGAINST DIVERSION**

Respondent is charged with failing to establish adequate security and effective controls against diversion in violation of Iowa Code section 155A.15(2)(c), (i) and 657 Iowa Administrative Code rules 10.15 and 36.1(4)(u).

**Count VII**  
**FAILURE TO KEEP AND MAINTAIN RECORDS REQUIRED BY THE  
CONTROLLED SUBSTANCES ACT**

Respondent is charged with failing to keep and maintain records required by the controlled substances act in violation of Iowa Code sections 124.306 and 155A.15(2)(h) and Iowa Administrative Code rules 10.34 and 36.1(4)(u).

**D. FACTUAL CIRCUMSTANCES**

*Case 2013-225*

1. Respondent is a pharmacy in Cedar Rapids, Iowa.
2. On December 17, 2013, Chris Tuetken, owner and manager of Downtown Drug, informed pharmacist-in-charge Sara Hoskins that she would be laid off as of January 1, 2014.
3. That same day, Hoskins faxed her resignation as PIC to the Board and completed a controlled substances inventory.
4. Downtown Drug was without a PIC for several weeks following Hoskins resignation.

*Case 2014-37*

1. On February 28, 2014, pharmacy support person Katrina Lovan was reconciling invoices for Downtown Drug Pharmacy. She noticed that a long list of invoices had not been paid to Dakota Drug over the course of several years. She informed Amy Moet of the discrepancies.
2. Pharmacist-in-charge Amy Moet noticed that quantities of prescription drugs,

including controlled substances were being ordered from Dakota Drug in a pattern inconsistent with Downtown Drug's volume.

3. An investigation revealed that during pharmacy support person Chuck Long's shifts, items had been added to the invoices. These additions included eleven 500 count bottles of hydrocodone.

4. On Monday, March 3, Mr. Long was observed placing product from that morning's Dakota Drug shipment inside the front register counter under his coat.

5. Two bottles of hydrocodone and two boxes of ondansetron were discovered under the counter.

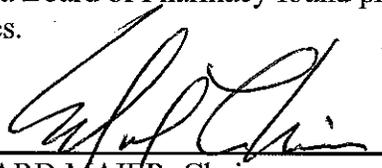
6. Subsequent investigation revealed that at least 18,000 tablets of hydrocodone were unaccounted for in 2013 & 2014. At least 3700 tablets of alprazolam 2mg tablets were missing over that same period. Hundreds of tablets of multiple products were unaccounted for in 2011 and 2012, but the pharmacy's records were insufficient for an accurate accounting.

#### **E. SETTLEMENT**

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

#### **F. PROBABLE CAUSE FINDING**

On this the 30th day of April, 2014, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



EDWARD MAIER, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Meghan Gavin  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa

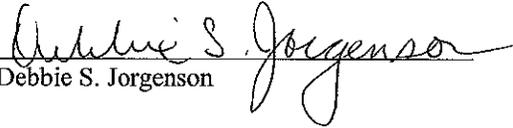
PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |  |   |
|--|---|
| <input type="checkbox"/> personal service                                    | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number <u>9171999991703239255189</u>                                 | <input type="checkbox"/> other _____      |

on the 12<sup>th</sup> day of May, 2014

I declare that the statements above are true to the best of my information, knowledge and belief.

  
Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

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|                               |   |                                |
|-------------------------------|---|--------------------------------|
| IN THE MATTER OF:             | ) |                                |
|                               | ) |                                |
| Pharmacist License of         | ) | Docket No. 2013-148, 2013-225, |
| <b>CHRISTOPHER P. TUETKEN</b> | ) | & 2014-37                      |
| License No. 19681             | ) | DIA No. 14PHB025               |
|                               | ) |                                |
| Pharmacy License of           | ) |                                |
| <b>DOWNTOWN DRUG</b>          | ) |                                |
| License No. 1281              | ) |                                |
|                               | ) | <b>FINDINGS OF FACT,</b>       |
| Respondents.                  | ) | <b>CONCLUSIONS OF LAW,</b>     |
|                               | ) | <b>DECISION, AND ORDER</b>     |

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**STATEMENT OF THE CASE**

On April 30, 2014, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges & Notice of Hearing against Respondents Christopher Tuetken, Downtown Drug, Chuck Long, and Amy Moet.<sup>1</sup> The Statement of Charges alleges five counts against Respondent Downtown Drug: 1) unethical behavior or practice harmful or detrimental to the public; 2) failure to report change in pharmacist-in-charge and failure to comply with requirements for making the change; 3) failure to maintain adequate control over and accountability for controlled substances; 4) failure to establish adequate security and effective controls against diversion; and 5) failure to keep and maintain records required by the Controlled Substances Act. The Statement of Charges alleges seven counts against Respondent Tuetken: 1) unethical behavior or practice harmful or detrimental to the public; 2) violation of Board order; 3) practicing pharmacy without an active license; 4) violating the duties of a pharmacist-in-charge; 5) failure to maintain adequate control over and accountability for controlled substances; 6) failure to establish adequate security and effective controls against diversion; and 7) failure to keep and maintain records required by the Controlled Substances Act. The Statement of Charge alleges two counts against Respondent Long.

The hearing was held on June 30, 2014. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratiias; Susan Frey; Judith Trumpy; and Edward McKenna. Respondent Christopher Tuetken appeared and represented himself and Respondent Downtown Drug. Respondent Long did not appear. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of Respondents Downtown Drug and Tuetken, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in

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<sup>1</sup> Prior to hearing, the State filed a Motion to Dismiss the charges against Amy Moet. There is a separate dismissal order pertaining to the charges against Moet.

conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

This Decision and Order relates only to Respondents Downtown Drug and Tuetken; a separate order is issued concurrently with regard to Respondent Long.

### **THE RECORD**

The record includes the Notice of Hearing and Statement of Charges with regard to all three Respondents. The record also includes hearing testimony of Mark Mather and Christopher Tuetken. The State introduced Exhibits 1 through 24, which were admitted as evidence.

### **FINDINGS OF FACT**

Respondent Downtown Drug, located in Cedar Rapids, Iowa, holds Iowa pharmacy license number 1281, which is currently active. Respondent Christopher Tuetken was the pharmacist-in-charge at Downtown Drug from 2011 to approximately October, 2013. Tuetken is also the owner of Downtown Drug, as well as four other pharmacies that are currently operational. Respondent Long began working at Downtown Drug sometime in 2011. (Mather testimony).

#### *Active License and Violation of Board Order*

Pursuant to an April 27, 2011 Stipulation and Consent Order, the pharmacist license of Tuetken was placed on probation for a period of three years. The terms of Tuetken's probationary license require that he obey all federal and state laws, rules, and regulations related to the practice of pharmacy. (Exh. 11).

Tuetken's pharmacist license expired on June 30, 2013, while the license was still subject to probationary terms. The Board received a renewal application from Tuetken on July 15, 2013, but the application was returned to Tuetken because he had not completed the correct number of continuing education hours; because his application was delinquent, Tuetken was required to complete one and one-half times the number of delinquent continuing education hours prior to reactivation of his license. In his case, Tuetken had 9.5 additional hours that were required before he could resubmit his renewal application. (Exh. 3).

On August 1, 2013, Tuetken resubmitted the application, but failed to resubmit his \$360 renewal fee. The Board returned Tuetken's application again with instructions to provide payment. On August 7, 2013, the Board received Tuetken's completed renewal application with \$360 payment. As of August 7, 2013, Tuetken's license was again active. (Exh. 3, pp. 22-23).

Dispensing records from Downtown Drug and Belle Plaine Pharmacy, another pharmacy where Tuetken worked, show that Tuetken filled prescriptions during the time between his license expiring on June 30 and being renewed on August 7. Tuetken

admitted that he could not find coverage for all his shifts during that time period. Tuetken also acknowledged at hearing that he had been through the renewal process before and was aware that he should not have been working prior to receiving the renewal certificate from the Board. (Exh. 3, p. 23, Exh. 7; Tuetken testimony).

*Delay in Appointing Replacement Pharmacist-in-Charge*

On December 17, 2013, Tuetken advised Sara Hoskins, the pharmacist-in-charge at Downtown Drug who began employment in October, 2013, that her employment would end as of December 31, 2013. Hoskins worked as a pharmacist at Downtown Drug until December 31, 2013. Hoskins faxed a statement to the Board on December 17 indicating that she had been laid off and was "terminating [her] position as Pharmacist in Charge at Downtown Drug, effective today." Hoskins informed Tuetken by text message on December 20 that she had faxed the Board her resignation as PIC and had completed the ending controlled substance inventory. (Tuetken testimony; Exh. 12, 13).

Board compliance officer Mark Mather visited Downtown Drug on January 7, 2014 to investigate the issue of whether a new PIC had been appointed at the pharmacy within the required 10-day window. As of that date, no temporary or permanent PIC had been appointed. At some point later in January, 2014, Tuetken appointed Amy Moet as the pharmacist-in-charge at Downtown Drug. (Exh. 12).

*Diversion of Controlled Substances*

On February 28, 2014, pharmacy support person (PSP) Katrina Lovan was reconciling invoices for the pharmacy. Lovan noticed that there was a long list of invoices that had not been paid to Dakota Drug, the pharmacy's drug wholesaler. Upon discovery, Lovan alerted pharmacist-in-charge Amy Moet to the unpaid invoices. (Exh. 17, p. 63).

After being alerted by Lovan, Moet reviewed the unpaid invoices from Dakota Drug and noticed that products had been ordered in amounts that the pharmacy would not normally utilize. Downtown Drug is a fairly low volume pharmacy, filling approximately 10 to 15 prescriptions per day. Moet noticed that there were numerous orders for 500 count bottles of hydrocodone tablets, which are larger than the pharmacy would typically order given its volume of business. Moet was certain that the 500-count bottles had never made it onto the shelves. (Exh. 17, p. 63).

On the same date, Moet checked the invoice history on the pharmacy's Dakota Drug website for items ordered on that day, February 28, 2014. Moet saw that someone had accessed the site and added one 500 count bottle of hydrocodone/APAP 10/325 tablets and one 500 count bottle of hydrocodone/APAP 7.5/325 tablets. Other prescription medications that Moet did not order or authorize were also on the invoice; these were not controlled substances. Moet checked with Tuetken and he indicated he did not order those items either. (Exh. 17, pp. 63-64).

Moet investigated further, reviewing invoices from Dakota Drug for hydrocodone/APAP 10/325 going back to mid-2012. During the time period Moet reviewed, 12 500 count

bottles of that product had been ordered. Moet was able to determine which products were ordered legitimately based on the purchase order number on the invoices. She determined that approximately 18,000 tablets of hydrocodone were ordered during 2013 and 2014 without authorization. (Exh. 17, p. 64; Exh. 21).

After discovering the fraudulent ordering, Moet went back and cross-referenced staff schedules with the dates that the unauthorized orders were made. Moet determined that the only person who was on duty on all of the dates when unauthorized orders were made was Chuck Long, a PSP and front end cashier. Moet contacted Tuetken with this information, and Tuetken in turn contacted Board compliance officer Mark Mather. The three made a plan to observe Long on Monday, March 3 when the Dakota Drug shipment containing the two unauthorized hydrocodone bottles arrived. (Exh. 17, p. 64).

After the Dakota Drug order arrived on March 3, Long was observed placing product from the order inside the front register counter under his coat. At 9:30 AM, Tuetken and Mather attempted to ask Long questions in Tuetken's office. Long denied any wrongdoing, started yelling and swearing, stormed out of the office, and went to the front counter to retrieve his coat before exiting the store. Long left the hydrocodone behind and Tuetken and Mather retrieved it from the area where Long's coat had been stored. (Exh. 17, p. 64).

Tuetken and Mather contacted the Cedar Rapids police department and a police report was taken. During the police investigation, the controlled substance invoice from Dakota Drug was found wadded up in the pharmacy's trash can, along with the product stickers. (Exh. 17, p. 64).

The typical practice at Downtown Drug was that when shipments were received from Dakota Drug, the pharmacy's wholesaler, Long would receive the shipment. Long was supposed to give the prescription drugs to a pharmacist, but he would keep the over-the-counter medications to put them into the inventory. (Tuetken testimony).

Long had access to the computer system the pharmacy used to order drugs from its wholesaler because he was responsible for inputting information regarding over-the-counter medications that were sold each day.<sup>2</sup> With that access, he was also able to place orders for controlled substances, though ordering controlled substances was not part of Long's job duties. The drugs that Long diverted were never entered into the pharmacy's inventory since Long diverted them before they could be logged. Nevertheless, the fraudulent orders were still reflected in the wholesaler's invoices to the pharmacy. (Tuetken testimony).

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<sup>2</sup> Although there is no evidence that anyone but Long made the fraudulent orders to the wholesaler, Tuetken acknowledged at hearing that any of the pharmacy support personnel who had access to the computer could have added drugs to the wholesaler's order the same way that Long did.

Tuetken downsized his business from 12 to 5 stores over the past few years and has let go of some nursing home pharmacy business. Tuetken admitted at hearing that while he was trying to be the owner, manager, and pharmacist-in-charge, he knew he was not taking good care in his role as PIC at Downtown Drug. (Tuetken testimony).

Around the beginning of 2013, Tuetken laid off his chief financial officer. She stopped reconciling invoices prior to her layoff. It was at the time Tuetken was attempting to get caught up in early 2014 that Lovan brought to Moet's attention that the invoices from Dakota Drug did not reconcile with the pharmacy's inventory records. Tuetken acknowledged at hearing that he takes full responsibility for this issue, as he should have figured it out before Moet brought it to his attention. While Long was discarding the paper invoices that came with the fraudulent orders, Dakota Drug did provide the pharmacy with electronic summaries of controlled substances that were shipped. Tuetken provided those to his CFO. From approximately 2012 on, those summaries were not reconciled with the pharmacy's inventory records to ensure that all of the drugs received were placed into the pharmacy's inventory. (Tuetken testimony).

### CONCLUSIONS OF LAW

#### Unethical Behavior or Practice Harmful or Detrimental to the Public

*Count I: Downtown Drug; Count I: Christopher Tuetken*

The Board is authorized to impose a disciplinary sanction on a licensee when the licensee knowingly makes misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engages in unethical conduct or practice harmful or detrimental to the public. It is not necessary that there be proof of actual injury for a violation to be found.<sup>3</sup>

The undisputed evidence in this case demonstrates that Tuetken was the pharmacist-in-charge at Downtown Drug during a time period when approximately 18,000 tablets of hydrocodone, a controlled substance, were diverted from the pharmacy's wholesale shipments without his awareness. While Long, the individual responsible for the diversion, destroyed the invoices and packaging stickers for the unauthorized drugs, the pharmacy's wholesaler periodically sent summaries to the pharmacy detailing the quantity of controlled substances that had been ordered and shipped. Since approximately 2012 or earlier, the pharmacy failed to reconcile these summaries with its invoices or inventory records. This failure to reconcile the summaries resulted in the diversion going undetected for two years or more.

Tuetken was the pharmacist-in-charge at Downtown Drug during the bulk of the time when Long was diverting large quantities of controlled substances. The pharmacy failed to reconcile its invoices with shipments, an easy method by which this diversion could have been avoided.

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<sup>3</sup> Iowa Code § 155A.12(2) (2013); 657 Iowa Administrative Code 36.1(4)(c).

Allowing the diversion of extremely large quantities of controlled substances is harmful and detrimental to the public. The preponderance of the evidence demonstrates that Tuetken and Downtown Drug committed a violation of 657 Iowa Administrative Code 36.1(4)(c).

Failure to Maintain Adequate Control over and Accountability for Controlled Substances  
*Count III: Downtown Drug; Count V: Christopher Tuetken*

The State alleges that both Tuetken and Downtown Drug failed to maintain adequate control over and accountability for controlled substances. In support of this allegation against Downtown Drug, the Statement of Charges references Iowa Code section 155A.15(2)(c) and (i) and 657 Iowa Administrative Code 36.1(4)(ac). In support of this allegation against Tuetken, the Statement of Charges references Iowa Code section 155A.12(1) and 657 Iowa Administrative Code 36.1(4)(ac).

Section 155A.12(1) provides that the Board may impose discipline on a pharmacist's license in the event that the licensee violates any provision of Chapter 155A or any rules of the Board adopted under Chapter 155A. Section 155A.15(2)(c) is a commensurate provision for pharmacies, allowing the imposition of discipline where a pharmacy violates any provision of Chapter 155A or any rule adopted under Chapter 155A or where any owner or employee of the pharmacy has committed such a violation. Section 155A.15(2)(i) allows a pharmacy to be disciplined where it has failed to establish effective controls against diversion of prescription drugs as provided for under Chapter 155A or any other Iowa or federal laws or rules. 657 Iowa Administrative Code 36.1(4)(ac) allows the Board to impose discipline where a licensee has failed to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the Board.

None of the citations referenced in the Statement of Charges against Tuetken or Downtown Drug create an affirmative obligation on the part of the licensee; rather, each of them allows the Board to impose discipline if the licensee fails to comply with laws or regulations set out elsewhere. There is no reference in either of these counts in the Statement of Charges to affirmative obligations the State argues Respondents have failed to uphold. Accordingly, the preponderance of the evidence does not support the conclusion that Tuetken or Downtown Drug have committed the violations alleged in this count.

Failure to Establish Adequate Security and Effective Controls Against Diversion  
*Count IV: Downtown Drug; Count VI: Christopher Tuetken*

Pursuant to Iowa Code sections 155A.12(1) and 155A.15(2), the Board is authorized to impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend the license of a pharmacy or pharmacist, or may place such license on probation, if the Board finds that the licensee has failed to establish effective controls against diversion of prescription drugs.<sup>4</sup> The Board's regulations set forth both physical security controls and operating

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<sup>4</sup> Iowa Code § 155A.15(2)(i) (2013).

procedures necessary to prevent diversion. These include, among other things, periodic review and adjustment of security measures based on changes or discrepancies in the quantity of substances in the possession of the pharmacy.<sup>5</sup> The Board may consider a number of factors in evaluating security controls, including the adequacy of supervision over employees having access to controlled substances and the adequacy of the licensee's system for monitoring the receipt, distribution, and disposition of controlled substances.<sup>6</sup>

There is no evidence that the pharmacy detected the 18,000-plus discrepancy in controlled substance inventory at any point prior to Moet assuming the pharmacist-in-charge position in early 2014. Within a relatively short time, Moet was able to discover the discrepancy as well as identify the employee responsible for diverting controlled substances. The fact that this did not happen during the two preceding years that Tuetken was pharmacist-in-charge points to serious holes in Tuetken's and the pharmacy's security controls.

The fact that Long had the degree of autonomy such that he could access the wholesale ordering system without the approval or assistance of any other personnel, change the order, receive the shipment, divert the controlled substances, and destroy the invoices points to inadequate supervision. Additionally, even knowing that Long had the degree of autonomy such that he was able to perform all of these functions, the pharmacy under Tuetken's direction failed to reconcile the invoices from the wholesaler for a long period of time, which – if it had been done – would have resulted in almost immediate detection of the diversion.

The preponderance of the evidence establishes a violation of 657 Iowa Administrative Code 10.15 by both Tuetken and Downtown Drug.

Failure to Keep and Maintain Records Required by the Controlled Substances Act  
*Count V<sup>7</sup>: Downtown Drug; Count VII: Tuetken*

Under Iowa law, the Board is authorized to impose disciplinary sanctions when a licensee fails to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the Board, including the Controlled Substances Act.<sup>8</sup> Pursuant to 657 Iowa Administrative Code 10.34, a pharmacy and pharmacist shall maintain controlled substances records in a readily retrievable manner that establishes the receipt and distribution of all controlled substances.

The evidence demonstrates that Long had engaged in a pattern over a period of years of systematically destroying invoices for unauthorized orders of controlled substances that he had placed with the pharmacy's wholesaler. The wholesaler's summaries, which were

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<sup>5</sup> 657 IAC 10.15(1).

<sup>6</sup> 657 IAC 10.15(2).

<sup>7</sup> This charge is actually listed as Count VII on the Statement of Charges against Downtown Drug; there are, however, only five counts alleged against Downtown Drug and this is the final count. Consequently, it has been renumbered to accurately reflect that it is Count V.

<sup>8</sup> Iowa Code §§ 155A.12(1); 155A.15(2)(c), (h) (2013).

sent to Downtown Drug and contained information regarding the quantity and type of controlled substances that had been ordered by and shipped to the pharmacy were systematically disregarded. Under these circumstances, a violation of 657 Iowa Administrative 10.34 has been established on the part of both Downtown Drug and Tuetken.

Failure to Report Change in Pharmacist-in-Charge and Failure to Comply with Requirements for Making the Change

*Count II: Downtown Drug*

Pursuant to 657 Iowa Administrative Code 8.35(6)(c), a pharmacy must identify a temporary pharmacist-in-charge if a permanent pharmacist-in-charge has not been identified at the time the position is vacated. The pharmacy owner or corporate officer must submit written notification to the Board, signed by the temporary pharmacist-in-charge, within 10 days following the vacancy.<sup>9</sup>

Sara Hoskins notified Tuetken on December 20 that she had submitted her resignation as pharmacist-in-charge to the Board on December 17, effective immediately. As of January 7, more than 10 days following the vacancy, Downtown Drug had still not appointed a temporary pharmacist-in-charge. While Tuetken testified that he believed the pharmacy had 90 days to replace the pharmacist-in-charge, Tuetken's misunderstanding of the Board's regulations is not a legitimate excuse for failure to follow those regulations. A violation has been established.

Practicing Pharmacy Without an Active License

*Count III: Christopher Tuetken*

The Board may impose disciplinary sanctions on any licensee who practices pharmacy without an active and current Iowa pharmacist license.<sup>10</sup> The undisputed facts here are that Tuetken's license to practice pharmacy expired on June 30, 2013, he failed to renew his license until August 7, 2013, and he practiced pharmacy, including dispensing prescriptions, in the intervening time period without an active and current license. Tuetken had gone through the license renewal process previously and was aware that his renewal would be effective once he received a renewal certificate from the Board. He practiced pharmacy without this renewal certificate for over a month. Under these circumstances, a violation has been established.

Violation of a Board Order

*Count II: Christopher Tuetken*

The Board is authorized to revoke, restrict, cancel, or suspend a license based on a licensee's failure to comply with a decision of the Board.<sup>11</sup> The April 27, 2011 Stipulation and Consent Order, which placed Tuetken's license on probation and which was still in

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<sup>9</sup> 657 IAC 8.35(6)(c)(1).

<sup>10</sup> 657 IAC 36.1(4)(v).

<sup>11</sup> Iowa Code §§ 155A.12(1); 272C.3(2)(a) (2013).

effect during the summer of 2013, required that Tuetken obey all federal and state laws, rules, and regulations related to the practice of pharmacy. As discussed above, Tuetken failed to comply with the Board's requirement of a current and active Iowa pharmacist license in order to practice pharmacy. Tuetken's testimony established that he was aware of the licensing requirements, but ignored them because he was unable to fill all of the shifts he was scheduled to work during the time period between when his license expired and when his renewal was effective. Under these circumstances, a willful violation has been established.

Violating the Duties of a Pharmacist-In-Charge

*Count IV: Christopher Tuetken*

Under the Board's regulations, a pharmacist-in-charge is required to, among other things: 1) train pharmacy technicians and pharmacy support persons; 2) maintain records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations; 3) establish and maintain effective controls against the theft or diversion of prescription drugs and records for such drugs; and 4) ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.<sup>12</sup>

As discussed at length above, Tuetken was pharmacist-in-charge at Downtown Drug during an approximately two-year period when over 18,000 doses of controlled substances were diverted by Long, a pharmacy support person. The discrepancy was not discovered until a new pharmacist-in-charge took over. That fact that Tuetken failed to implement controls to prevent such large-scale diversion constitutes a violation of 657 Iowa Administrative Code 6.2.

Sanction

The Board may consider a number of factors in determining the nature and severity of the disciplinary sanction to be imposed when a violation is established, including the relative seriousness of the violation as it relates to assuring a high standard of professional care; the facts of the violation; any extenuating circumstances; whether remedial action has been taken; and any other factors that reflect upon the competency, ethical standards, and professional conduct of the licensee.<sup>13</sup>

The Board has grave concerns about Tuetken's ability to safely practice pharmacy. Tuetken himself acknowledged at hearing that he deserves some sort of a penalty for these violations. The evidence demonstrates that Tuetken spread himself entirely too thin, as owner of up to 12 pharmacies at one point. Tuetken's vast business interests left him unable to manage the day-to-day requirements of being a pharmacist-in-charge at Downtown Drug. This practice of overextending himself seems to have led directly to the majority of the violations found here. Tuetken did not make time to properly

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<sup>12</sup> 657 IAC 6.2(9), (12), (13), (15).

<sup>13</sup> 657 IAC 36.1(3).

complete the requirements to renew his license, did not make time to appoint a temporary pharmacist-in-charge within the time frame required, and did not make time to perform the types of checks and balances that would have allowed him to discover the large-scale diversion of controlled substances by Long before two years had elapsed.

The Board likewise has serious concerns about Respondent Downtown Drug's compliance with the laws and regulations applicable to the practice of pharmacy. As previously noted, during Tuetken's tenure as pharmacist-in-charge over 18,000 doses of controlled substances were diverted over a period of approximately two years. Despite the fact that the diversion would not have been difficult to discover if accounts and inventory were being reconciled, the diversion was not discovered until a new pharmacist-in-charge took over.

While Tuetken testified that he has made changes to procedures at Downtown Drug, including installation of security cameras and a revised protocol for checking in medications received from the wholesaler, it is not clear that the pharmacy will be able to comply with applicable laws and regulations without more extensive monitoring.

### **DECISION AND ORDER**

IT IS THEREFORE ORDERED that Respondent Christopher Tuetken's license shall be suspended for a period of one year, effective 90 days from the date of this Order. Respondent Tuetken shall not engage in any aspect of the practice of pharmacy during this period of suspension.

IT IS FURTHER ORDERED that Respondent Tuetken shall have no involvement in the ownership, management, direction, or control of any business engaged in the practice of pharmacy. Respondent Tuetken shall have 90 days from the date of this Order to divest himself of any ownership, management, direction, or control of any business engaged in the practice of pharmacy.

IT IS FURTHER ORDERED that Respondent Tuetken shall not hold the position of pharmacist-in-charge in the future.

IT IS FURTHER ORDERED that Respondent Tuetken shall not serve as a pharmacy preceptor in the future.

IT IS FURTHER ORDERED that, after the expiration of the one year period of suspension, Respondent Tuetken's license shall be placed on probation for a period of five years, subject to the following terms:

- a. Respondent Tuetken shall submit quarterly reports to the Board. The reports shall be filed not later than December 5, March 5, June 5, and September 5 of each calendar year. These reports shall include Respondent Tuetken's place of employment; current address; a narrative discussing Respondent Tuetken's current compliance with the terms of this Decision and Order; and any further information requested by the Board;

- b. Respondent Tuetken shall ensure that he completes all of his continuing education requirements in a timely fashion;
- c. Respondent Tuetken shall ensure that he completes the license renewal process on time;
- d. Only the periods of time during which Respondent Tuetken is actively practicing as a pharmacist in Iowa shall apply to the duration of the probation, unless otherwise approved by the Board;
- e. Upon the Board's request, Respondent Tuetken shall appear informally before the Board for the purpose of reviewing his performance as a pharmacist and compliance with his probation. Respondent Tuetken shall be given reasonable notice of the date, time, and place for such appearances;
- f. Respondent Tuetken shall comply with all applicable Iowa pharmacy laws and rules and all related federal requirements for controlled substances.

IT IS FURTHER ORDERED that Respondent Downtown Drug's license shall be placed on probation for an indefinite period.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Downtown Drug shall not permit Respondent Tuetken to be involved in any aspect of ownership, management, direction, or control of the pharmacy. Respondent Downtown Drug shall have 90 days from the date of this Order to allow for Respondent Tuetken to divest himself of any ownership, management, direction, or control of the pharmacy.

IT IS FURTHER ORDERED that, as a condition of probation, within 15 days of the date of this Order, Respondent Downtown Drug shall enter into an agreement with a pharmacy consultant. This agreement shall be at Respondent Downtown Drug's expense. The pharmacy consultant shall be required for the Respondent Downtown Drug's probationary term.

- a. The pharmacy consultant shall be an Iowa-licensed pharmacist who is approved by the Board to serve as a pharmacy consultant.
- b. Upon approval of the pharmacy consultant, the pharmacy consultant shall meet with Board staff to review the requirements of this Order and related matters.
- c. The pharmacy consultant shall meet with Respondent Downtown Drug's pharmacist-in-charge on a weekly basis to ensure that Respondent Downtown Drug has fully complied with the terms of this Decision and Order and with the laws governing the practice of pharmacy in Iowa.
- d. Respondent Downtown Drug shall comply with all recommendations made by the pharmacy consultant.

- e. The pharmacy consultant shall file monthly reports with the Board by the fifth day of every month. The reports shall describe Respondent Downtown Drug's compliance with this Decision and Order and include any recommendations the consultant believes necessary to ensure Respondent Downtown Drug is in compliance with this Decision and Order and the laws governing the practice of pharmacy in Iowa. Respondent Downtown Drug is responsible for ensuring the pharmacy consultant's reports are timely filed.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Downtown Drug shall maintain a perpetual inventory of controlled substances with daily reconciliation. Respondent Downtown Drug shall submit monthly reports to the Board detailing compliance with this condition.

IT IS FURTHER ORDERED that Respondent Downtown Drug shall pay a civil penalty in the amount of \$10,000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa, and mailed to the executive director of the Board within 30 days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

IT IS FURTHER ORDERED pursuant to Iowa Code section 272C.6 and 657 Iowa Administrative Code 36.18(2), that Respondents Downtown Drug and Christopher Tuetken shall pay \$75 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board may bill Respondents for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondents shall remit for these expenses within 30 days of receipt of the bill.

Dated this 27<sup>th</sup> day of August, 2014



Susan Frey  
Acting Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General

*Any aggrieved or adversely affected party may seek judicial review of this decision and order of the Board, pursuant to Iowa Code section 17A.19.*

BEFORE THE IOWA BOARD OF PHARMACY

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|                                |   |                                       |
|--------------------------------|---|---------------------------------------|
| RE:                            | ) | Case No. 2013-148, 2013-225 & 2014-37 |
|                                | ) |                                       |
| Pharmacist License of          | ) | DIA No. 14PHB025                      |
| <b>CHRISTOPHER P. TUETKEN,</b> | ) |                                       |
| License No. 19681              | ) |                                       |
|                                | ) |                                       |
| Pharmacy License of            | ) | Modification to                       |
| <b>DOWNTOWN DRUG</b>           | ) | Findings of Fact,                     |
| License No. 1281               | ) | Conclusions of Law,                   |
| Respondent.                    | ) | Decision and Order                    |

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On August 27, 2014, the Iowa Board of Pharmacy (the Board) approved the Findings of Fact, Conclusions of Law, Decision and Order (Decision and Order). Respondent requested a limited modification to the Decision and Order on October 28, 2014, seeking an extension of time within which to divest himself of any ownership, management, direction, or control of any business engaged in the practice of pharmacy.

IT IS HEREBY ORDERED that the second unnumbered paragraph contained in the Decision and Order is hereby amended as follows:

IT IS FURTHER ORDERED that Respondent Tuetken shall have no involvement in the ownership, management, direction, or control of any business engaged in the practice of pharmacy. Respondent Tuetken shall have until January 31, 2015, to divest himself of any ownership, management, direction, or control of any business engaged in the practice of pharmacy.

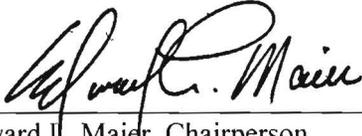
Respondent Tuetken is also reminded that all other requirements of the August 27 order must be complied with, including the requirement for a pharmacy consultant.

In addition, Respondent Tuetken shall:

1. Assure termination of all pharmacy practice at Downtown Drug in Cedar Rapids, Iowa, in compliance with 657 IAC 8.35(7) no later than November 25, 2014.
2. Submit to the Board staff, not later than December 1, 2014, an executed Asset Purchase Agreement with Hartig Drug Company or its affiliate or assignee relating to the pharmacies in Williamsburg, Monticello, and Belle Plaine.
3. Afford rights to Hartig Drug Company, pursuant to the Asset Purchase Agreement, or an ancillary agreement thereto, to inspect, access and monitor the pharmacy operations in Williamsburg, Monticello, and Belle Plaine during the interim period preceding the transfer of ownership.

4. Continue to engage in good faith efforts to identify and complete the terms of sale with a purchaser for the pharmacy of located in Wyoming.

Dated this 28<sup>th</sup> day of October, 2014.

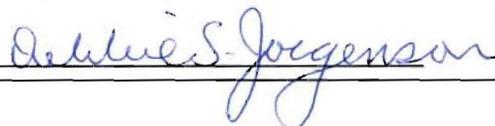


Edward L. Maier, Chairperson  
Iowa Board of Pharmacy

Copies to:

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Des Moines, IA 50319  
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BRADLEY & RILEY PC  
2007 First Avenue SE  
PO Box 2804  
Cedar Rapids, IA 52406-2804

| Proof of Service   |  |
|--|--|
| The undersigned certifies that the foregoing instrument was served in the following manner on the 29 <sup>th</sup> day of October, 2014. |  |
| <input type="checkbox"/> U.S. Mail   | <input type="checkbox"/> Fax               |
| <input type="checkbox"/> Hand Delivery   | <input type="checkbox"/> Overnight Courier |
| <input type="checkbox"/> Federal Express   | <input type="checkbox"/> Other             |
| <input checked="" type="checkbox"/> Electronically   |  |
| Signature:   |  |