

of the circumstances, the Defendant's request for an extension was reasonable.

Documents relative to the Decree, including the proposed Amendment, can be accessed at www.cleanwateratlanta.org.

See, specifically, City of Atlanta, First Amended Consent Decree, 1:98-CV-1956-TWT, Financial Capability-Based Amendment & Schedule Extension Request. Further information pertaining to the Defendant's water system can be accessed at www.atlantawatershed.org.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Amendment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and either emailed to pubcomment-ees.enrd@usdoj.gov or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States and State of Georgia v. City of Atlanta*, D.J. Ref. 90-5-1-1-4430. During the public comment period, the Amendment may also be examined on the following Department of Justice Web site, http://www.usdoj.gov/enrd/Consent_Decrees.html. A copy of the Amendment may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or emailing a request to "Second Amendment to First Amended Consent Decree Copy" (EESCDCopy.ENRD@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-5271. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$4.750 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Pharmboy Ventures Unlimited, Inc., Decision and Order

On August 26, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to

Show Cause to Pharmboy Ventures Unlimited, Inc., d/b/a Brent's Pharmacy and Diabetes Care (Applicant), of St. George, Utah. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a retail pharmacy, on the ground that its "registration would be inconsistent with the public interest." Show Cause Order, at 1 (citing 21 U.S.C. 823(f)).

The Show Cause Order alleged that on February 28, 2011, Applicant submitted an application for a DEA Registration as a retail pharmacy and that while applicant is owned by Caroline McFadden, her husband Brent McFadden is Applicant's pharmacist-in-charge and sole pharmacist. The Show Cause Order then alleged that in 2010, Brent McFadden, while working as a pharmacist at Lin's Pharmacy, had unlawfully taken phentermine, a schedule IV controlled substance, from the pharmacy's stock and ingested it; the Order also alleged that Brent McFadden had failed to document the disposition of the phentermine he had taken. *Id.* at 1-2 (citing 21 U.S.C. 844; 827; 21 CFR 1304.22(c); 1306.06; 1306.21). The Order also alleged that while working as a pharmacist at Lin Pharmacy, Mr. McFadden had, on four or more occasions when it was open to the public, left the pharmacy unattended by a pharmacist, in violation of Utah Admin. Code R156-1-102a. *Id.* at 2.

Next, the Show Cause Order alleged that based on the various acts set forth above, on October 27, 2010, the Utah Division of Occupational and Professional Licensing (DOPL) issued a consent order to Mr. McFadden placing his pharmacist's license on probation for three years. *Id.* The Order also alleged that on January 20, 2011, Mr. McFadden had pled no contest to seven state law counts of making or altering a false prescription based on his conduct in taking phentermine from Lin's Pharmacy, and that he had been sentenced to eighteen-months' probation, fined, and ordered to undergo a substance abuse evaluation. *Id.* (citing Utah Code Ch. 58, § 37(3)(a)(iii)). Finally, the Order alleged that Mr. McFadden had engaged in such other conduct which may threaten public health and safety because he "took and consumed legend drugs and food items" from his former employer without paying for them, and that because of the aforementioned acts, he was terminated from his employment. *Id.* (citing 21 U.S.C. 823(f)(5)).

The Show Cause Order, which also notified Applicant of its right to request a hearing on the allegations or to submit

a written statement in lieu of a hearing, the procedures for electing either option, and the consequences for failing to do either, *id.* at 2-3 (citing 21 CFR 1301.43); was served on Applicant by certified mail, return receipt requested, addressed to it at the address of its proposed registered location. GX C. As evidenced by the signed return receipt card, service was accomplished on September 2, 2011. Since that date, more than thirty days have now passed, and neither Applicant, nor anyone purporting to represent it, has either requested a hearing or submitted a written statement in lieu of a hearing. Accordingly, I find that Applicant has waived its right to a hearing and issue this Decision and Order based on relevant evidence contained in the investigative record submitted by the Government. I make the following findings of fact.

Findings

On February 28, 2011, Applicant filed an application for a DEA Certificate of Registration as a retail pharmacy. GX A. Applicant's application was signed by Ms. Caroline McFadden. *Id.* In response to one of the application's liability questions, Applicant noted that "Brent McFadden, corporate owner, charges of unprofessional conduct and unlawful conduct for leaving the pharmacy unattended for thirty minutes and for taking 7 phentermine tablets from pharmacy stock and ingesting [sic] them." GX A.

Upon reviewing the application, a DEA Diversion Investigator (DI) noticed Applicant's statement regarding the action taken by the State of Utah against Brent McFadden. GX D, at 1. The DI learned that Applicant has a state pharmacy license and that Caroline McFadden was listed as the applicant and owner of the pharmacy. *Id.* at 1-2. The DI also obtained a report by a DOPL Investigator regarding an August 17, 2010 interview she did of Mr. McFadden, who had previously worked at the pharmacy in Lin's Supermarket, a grocery store located in St. George, Utah. *Id.*; GX F, at 1.

During the interview, Mr. McFadden admitted that he had taken both phentermine, a schedule IV stimulant, and Maxzide (Triamterene-HCTZ), a non-controlled legend drug used as a diuretic, from the store's pharmacy, where he had been employed for sixteen years. GX D, at 2. With respect to his use of phentermine, Mr. McFadden initially claimed that the drug had been prescribed to him by J.R.M., a physician's assistant and neighbor of his. *Id.* However, Mr. McFadden later admitted that J.R.M. had not treated him

and that he had taken the phentermine on his own. *Id.* Mr. McFadden admitted that he had taken a total of thirty phentermine pills over the preceding two to three months. *Id.* In a written statement he made on August 17, 2010, Mr. McFadden asserted that he had taken the 30–35 phentermine tablets “over a [two] month period” based “upon a verbal recommendation from a doctor.” GX G, at 2. Mr. McFadden further stated that he paid for the drugs “but an RX was never written.” *Id.* Finally, McFadden claimed that he had repaid the twelve to fifteen tablets of Maxzide by taking them out of his subsequent prescription. *Id.* at 1.

In addition, Mr. McFadden admitted that he had left the pharmacy unattended “for a few minutes,” on three or four occasions “during the past two to four years,” to get lunch or take a break because store policy did not allow for the pharmacy to close for lunch. GX F, at 2. However, upon being told by the State Investigator that it was reported that he had recently left the pharmacy for about 45 minutes, Mr. McFadden admitted that the week before, he had left the pharmacy, when no other pharmacist was in attendance, for 30 to 45 minutes to get lunch and run an errand. *Id.* Mr. McFadden denied, however, tampering with, or altering, the pharmacy’s records when he removed tablets from the dispensing machine. *Id.*

On October 20, 2010, Mr. McFadden entered into a Stipulation and Order with the DOPL; the Order was subsequently approved by the DOPL’s Director. GX M, at 10–11. Among the Order’s findings were that “[o]n or about August 17, 2010[,] [Mr. McFadden] admitted to a Division investigator that [he] had, on multiple occasions, taken Maxide [sic], a prescription only medication, and [p]hentermine, a Schedule IV controlled substance, from pharmacy stock for Respondent’s own use. Respondent did not possess a valid prescription for the [p]hentermine.” *Id.* at 3. Of note, the DOPL did not find that Mr. McFadden lacked a prescription for the Maxzide.

Mr. McFadden further stipulated that he “recently left the pharmacy unattended for 30 to 45 minutes to run an errand and pick up lunch. [He] also admitted to the Division investigator that the practice of leaving the pharmacy unattended had occurred on three or four occasions in the past four years.” *Id.* Mr. McFadden agreed that these (and other findings) constituted unprofessional conduct under Utah law and regulations, as well as unlawful conduct under Utah criminal law. *Id.* at 3–4.

The DI also developed evidence that Mr. McFadden was observed on the store’s security cameras occasionally taking various food items, including bagels and fountain drinks, without paying for them. GX D, 3–4. Subsequently, based on his expropriation of drugs, the bagels, and fountain drinks, as well as his having left the pharmacy unattended, Lin’s terminated Mr. McFadden. GX J.

In addition, Mr. McFadden was charged with seven felony counts of violating Utah Code § 58–37–8(3)(A)(III), which prohibits “mak[ing] any false or forged prescription or written order for a controlled substance, or * * * utter[ing] the same, or * * * alter[ing] any prescription or written order” for a controlled substance. GX H, at 5. However, Mr. McFadden was allowed to plead no contest, with his plea being held in abeyance, to seven misdemeanor counts of Utah Code § 58–37–8(3)(A)(III), as well as a single count of retail theft (also a misdemeanor), in violation of Utah Code § 76–6–602. *Id.* The court ordered that his pleas be held in abeyance for eighteen months, fined him \$1,000, and ordered him to both undergo a substance abuse evaluation and to successfully complete any treatment program and provide proof of completion to the court. *Id.* at 6.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner’s registration may be denied upon a determination “that the issuance of such registration would be inconsistent with the public interest.” 21 U.S.C. 823(f). In making the public interest determination in the case of a practitioner, which includes a retail pharmacy, *see id.* § 802(21), Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing * * * controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety. *Id.*

“[T]hese factors are considered in the disjunctive.” *Robert A. Leslie*, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may

give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, while I “must consider each of these factors, [I] ‘need not make explicit findings as to each one.’” *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009)); *see also Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005) (citing *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005)).

Having considered all of the factors,¹ I conclude that the Government’s evidence with respect to Applicant’s (more specifically, its pharmacist-in-charge’s) experience in dispensing controlled substances (factor two), his conviction record under laws relating to the distribution or dispensing of controlled substances (factor three), his compliance with applicable laws related to controlled substances (factor four), and his having engaged in other conduct which may threaten public health and safety (factor five), makes out a *prima facie* case to conclude that granting Applicant’s application would be “inconsistent with the public interest.” 21 U.S.C. 823(f). Because Applicant has waived its right to a hearing and present evidence refuting this conclusion, its application will be denied.

Factors Two—The Applicant’s Experience in Dispensing Controlled Substances, Factor Three—The Applicant’s Conviction Record Under Federal or State Laws Relating to the Distribution or Dispensing of Controlled Substances, Factor Four—Applicant’s Compliance With Applicable Laws Related to Controlled Substances, and Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

As found above, the Utah DOPL found that Mr. Brent McFadden, Applicant’s pharmacist-in-charge,² expropriated

¹ It is acknowledged that Applicant holds a state pharmacy license. However, the Agency has repeatedly held that while the possession of a state license is an essential condition for obtaining (and maintaining) a registration issued under 21 U.S.C. 823(f), it is not dispositive of the public interest inquiry. *Sun & Lake Pharmacy, Inc.*, 76 FR 24523, 24530 n.15 (2011).

² DEA has long held that it can look behind a pharmacy’s ownership structure “to determine who makes the decisions concerning the controlled substance business of a pharmacy.” *Carriage Apothecary*, 52 FR 27599, 27599 (1987) (citing cases); *cf. Unarex of Plymouth Road, et al.*, 50 FR 6077, 6079–80 (1985) (revoking registration of pharmacy, whose pharmacist, transferred his ownership interest to his wife following his conviction for conspiracy to unlawfully distribute controlled substances; “Pharmacists do not operate by themselves. They require human intervention to operate”); *Big-T Pharmacy, Inc.* 47 FR 51830, 51831

phentermine, a schedule IV controlled substance, from the stock of his former employer, which he ingested. The DOPL further found that Mr. McFadden did not have a prescription for the phentermine. These findings are entitled to preclusive effect in this proceeding. *See Robert L. Dougherty*, 76 FR 16823, 16830 (2011) (collecting cases).

Under the CSA, a controlled substance may only be dispensed “pursuant to the lawful order [such as a prescription] of, a practitioner.” 21 U.S.C. 802(21).³ Mr. McFadden did not, however, have a prescription for phentermine. Thus, he unlawfully distributed phentermine to himself, which he then ingested. *See id.* § 829(b) (“Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act * * * may be dispensed without a written or oral prescription * * *.”); *id.* § 841(a)(1) (prohibiting the knowing distribution or dispensing of a controlled substance “[e]xcept as authorized by” the CSA). *See also* Utah Code § 58–17b–501(12) (prohibiting pharmacist from “using a prescription drug or controlled substance for himself that was not lawfully prescribed for him by a practitioner”); *id.* § 58–37–6(7)(c)(i) (“A controlled substance may not be dispensed without the written prescription of a practitioner, if the written prescription is required by the federal Controlled Substances Act.”).

Mr. McFadden also violated 21 U.S.C. 844(a), which makes it “unlawful for

any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice,” except as otherwise authorized by the CSA. *See also* Utah Code § 58–37–8(2)(a)(i) (same).

In addition, the DOPL found that Mr. McFadden violated the Utah Pharmacy Practice Act Rule, when he left the Lin’s Pharmacy unattended on various occasions. *See* Utah Admin Code R156–17b–614(7). GX M, at 3. While this rule is applicable to pharmacy practice in general, given the evidence that controlled substances were dispensed (and obviously stored) at the pharmacy, the violations have a sufficient connection to the CSA’s core purpose of preventing the diversion of controlled substances to be considered as “such other conduct which may threaten public health and safety,” 21 U.S.C. 823(f)(5), and are thus within the Agency’s authority to consider under factor five.

Finally, the evidence also shows that Mr. McFadden pled no contest to seven misdemeanor counts of making a false or forged prescription or written order for a controlled substance or uttering the same, in violation of state law. Notwithstanding that his pleas are being held in abeyance, and thus the charges may eventually be dismissed, DEA has repeatedly held that a plea of no contest which is subject to deferred adjudication, nonetheless constitutes a conviction for purposes of the CSA. *See Kimberly Maloney, N.P.*, 76 FR 60922, 60922 (2011) (collecting cases). Nor does the fact that the charges were reduced to misdemeanors preclude consideration of his convictions under factor three, which, in contrast to 21 U.S.C. 824(a)(2), is not limited to felony offenses. *See* 21 U.S.C. 823(f)(3).

I thus conclude that the evidence with respect to factors two, three, four, and five⁴ establishes that granting

(1982) (“Pharmacies must operate through the agency of natural persons, owners or stockholders, pharmacists or other key employees. When such persons misuse the pharmacy’s registration by diverting controlled substances obtained thereunder, and when those individuals are convicted as a result of that diversion, the pharmacy’s registration becomes subject to revocation under section 824, just as if the pharmacy itself had been convicted.”); *S & S Pharmacy, Inc.*, 46 FR 13051, 13052 (1981) (“In a retail pharmacy, * * * the registered pharmacist in charge of the pharmacy is responsible for ordering controlled substances; for keeping and maintaining the required records and inventories; for taking all necessary measures to prevent the loss and diversion of controlled substances; and for dispensing such substances only in accordance with applicable State and Federal laws. The corporate pharmacy acts through the agency of its * * * pharmacist in charge.”).

³ Cf. 21 CFR 1306.03 (prescription may only be issued “by an individual practitioner * * * authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession”); *id.* 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of * * * professional practice.”).

⁴ The Government seeks several additional findings that Mr. McFadden engaged in “such other conduct which may threaten public health and safety.” 21 U.S.C. 823(f)(5). More specifically, the Government alleges that “[w]hile working as a pharmacist for Lin’s Pharmacy, * * * Mr. McFadden took and consumed legend drugs and food items from the pharmacy without compensating the store for the use of such items,” GX B, at 2, and that “[i]n August 2010, Lin’s Pharmacy terminated Mr. McFadden from working as a pharmacist there because he unlawfully took and consumed drugs and food items and left the pharmacy unattended by a pharmacist.” Gov. Req. for Final Agency Action, at 10.

As for his former employer’s termination of his employment, that decision is not conduct on his part but rather a response to his conduct. Moreover, his former employer’s findings that he engaged in

Applicant’s application would be “inconsistent with the public interest.” 21 U.S.C. 823(f). And because Applicant waived its right to a hearing, there is no evidence to the contrary. Accordingly, I will deny Applicant’s application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Pharmboy Ventures Unlimited, Inc., for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This order is effective immediately.

Dated: May 4, 2012.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Voluntary Fiduciary Correction Program

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, “Voluntary Fiduciary Correction Program,” to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before July 9, 2012.

misconduct are not entitled to preclusive effect in this matter. Accordingly, an employer’s termination decision clearly does not fall within the scope of factor five.

As for his expropriation of store property, there is no evidence refuting Mr. McFadden’s claim that he paid for the phentermine or that he “reimbursed” the pharmacy by taking the Maxzide out of his subsequent refill, and the evidence regarding his plea to misdemeanor retail theft does not identify what items were involved. To be sure, Mr. McFadden admitted in a statement to having taken bagels and fountain drinks from his employer without paying for them. However, his acts have no apparent relationship to controlled substances, and the Government offers no explanation as to why being a bagel bandit constitutes a threat to public health and safety, let alone one that is of such a degree as to “create reason to conclude that a person will not faithfully adhere to [his] responsibilities under the CSA.” *Terese, Inc., d/b/a/ Peach Orchard Drugs*, 76 FR 46843, 46848 n.11 (2011).