

admitted to “regularly taking” had been lawfully prescribed to him. Finally, while the Government alleged in the Show Cause Order that Respondent had refused to take a drug test upon being challenged to do so by the State inspector, Respondent asserts that he did so.

Here again, the Government offered no evidence to rebut Respondent’s contention. Indeed, the Government produced no evidence showing that it demanded that Respondent produce the test results and that he failed to do so. I therefore conclude that the allegations that Respondent was personally abusing controlled substances at the time of the December 2005 interview and thereafter are not proved by substantial evidence.²

While I reject the allegations of personal abuse, Respondent’s numerous violations of Federal law in prescribing controlled substances to his wife make out a *prima facie* case for the denial of his application. Where the Government has made out a *prima facie* case, the burden shifts to the applicant to show why granting the application would nonetheless be in the public interest. See *Gregory D. Owens*, 67 FR 50461, 50464 (2002).

As this Agency has repeatedly held, a proceeding under section 303 “is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused * * * their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration.” *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). In short, Respondent must prove by a preponderance of the evidence that he can be entrusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not re-occur.

While Respondent admitted in response to Show Cause Order that he violated Federal law by prescribing controlled substances to his wife, he has

² There is also some evidence suggesting that Respondent admitted to the Intake Coordinator at Rush that some of the prescriptions he wrote for his wife were for his personal use. This conduct would also violate Federal law. See 21 U.S.C. 843(a)(3) (“It shall be unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.”). The letter which reports these admissions was not included in the record. Moreover, this evidence does not establish that Respondent was abusing controlled substances at the time of the December 2005 interview and thereafter.

offered no evidence to establish that he will not engage in similar acts in the future.³ Respondent has therefore failed to rebut the Government’s *prima facie* showing that granting him a new registration “would be inconsistent with the public interest.” 21 U.S.C. 823(f). Accordingly, Respondent’s application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the application of Jon K. Dively, D.D.S., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective January 30, 2008.

Dated: December 13, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7-25347 Filed 12-28-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05-24]

The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy; Denial of Application

On March 4, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy (Respondent) of Cheverly, Maryland. The Show Cause Order proposed the denial of Respondent’s application for a DEA Certificate of Registration as a pharmacy on various grounds.

More specifically, the Show Cause Order alleged that in October 1999, the Prince George’s County, Maryland, Police Department received information that Ms. Tina M. Hart-Lawson, Respondent’s chief pharmacist, was filling fraudulent prescriptions. Show Cause Order at 1. The Show Cause Order further alleged that on multiple occasions between November 11, 1999,

³ I acknowledge that the State has allowed Respondent to retain his dental license and placed him on probation. The consent order, however, merely recites that “[t]he Department alleges that Respondent engaged in improper medication prescribing practice,” and does not contain the specific allegations that were made against Respondent. Consent Order at 1. It is thus not even clear what evidence the State had obtained and, in any event, there are a number of reasons why the State may have decided to settle the case. I thus decline to defer to the State’s decision. See *John Kennedy*, 71 FR 35708 (2006) (declining to defer to State board’s restoration of medical license; a “state license is a necessary, but not [a] sufficient condition for [a DEA] registration”).

and February 9, 2000, two undercover officers had presented fraudulent prescriptions for Percocet, a schedule II controlled substance, and Vicodin, a schedule III controlled substance, to Ms. Lawson, who filled the prescriptions without first verifying them. *Id.* at 1-3. The Show Cause Order alleged that all of the prescriptions presented by the undercover officers “had indicia of fraud” and “were written in the name of a fictitious doctor and DEA registration,” and that Ms. Lawson did not report any of the fraudulent prescriptions to the police. *Id.* at 3.

The Show Cause Order also alleged that on February 4, 2000, Ms. Lawson told one of the undercover officers that she knew that the prescriptions presented by the officer two days earlier were forged, but then proceeded to partially fill one of them anyway. *Id.* at 2. The Show Cause Order alleged that Ms. Lawson had told the undercover officer that a local police officer was present when the undercover officer presented the prescriptions and had asked Ms. Lawson about them. *Id.* at 2-3. Ms. Lawson allegedly told the undercover officer that because she did not want the latter “to get in trouble,” she told the local police officer that the undercover officer “was a cancer patient.” *Id.* at 3.

Next, the Show Cause Order alleged that on February 9, 2000, the other undercover officer presented a fraudulent prescription for Percocet. *Id.* The Show Cause Order alleged that Ms. Lawson filled the prescription, and after being paid for it, told the undercover officer that she “knew the prescription was fraudulent,” but “would not call the police” because the undercover officer was “a sister.” *Id.* The Show Cause Order further alleged that Ms. Lawson was subsequently arrested, and on March 8, 2002, pled guilty to having unlawfully distributed oxycodone in violation of 21 U.S.C. 841(a)(1). *Id.*

Finally, the Show Cause Order alleged that on September 13, 2003, Samuel L. Lawson, M.D., filed an application on behalf of Respondent for a new DEA registration. *Id.* The Show Cause Order alleged that in support of its application, Respondent had attached a signed statement of Ms. Lawson which contained several material falsehoods and omissions. *Id.* at 3-4. The Show Cause Order thus concluded by alleging that because Ms. Lawson ‘has a felony conviction and made false statements in the Medicine Shoppe’s application, granting a DEA registration to [Respondent] would not be consistent with the public interest.’ *Id.* at 4.

Respondent, through its counsel, requested a hearing. The matter was

assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Arlington, Virginia, on April 18, 2006. At the hearing, both parties introduced documentary evidence and called witnesses to testify. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On November 6, 2006, the ALJ issued her initial Opinion and Recommended Decision (ALJ 1). In this decision, the ALJ concluded that granting Respondent's application "would not be inconsistent with the public interest." ALJ 1, at 19. The ALJ further noted, however, that Respondent did not currently hold a Maryland controlled dangerous substances license and therefore recommended the denial of its application. *Id.* at 20. The ALJ further stated that in the event Respondent obtained the state license before the record was submitted to my office, she would change her recommendation. *Id.*

Thereafter, on November 27, 2006, the Government filed exceptions to the ALJ's decision, ALJ Supplemental Decision at 2 (hereinafter, ALJ Dec.). The next day, Respondent moved for reconsideration on the ground that it had received a state controlled-substance license. *Id.* On January 10, 2007, the ALJ granted Respondent's motion, and on February 12, 2007, the ALJ issued her supplemental decision which recommended that Respondent's application be granted. The record was then transmitted to me for final agency action.

Having considered the entire record, I hereby issue this Decision and Final Order. For reasons set forth below, I reject the ALJ's conclusion that "granting Respondent's application . . . would not be inconsistent with the public interest." ALJ Dec. at 19. In so holding, I adopt the ALJ's finding "that Dr. Lawson made substantial misrepresentations in the letter she attached to Respondent's . . . application." *Id.* I also note that the ALJ found credible Ms. Lawson's "acknowledgments at the hearing that she made mistakes . . . and her expressions of remorse for those mistakes." *Id.* at 19–20. But as the ALJ also found, Ms. Lawson "provided no testimony as to why she" made several materially false statements in connection with the application. *Id.* at 19. Thus, even if Ms. Lawson has acknowledged her wrongdoing in filling fraudulent prescriptions, she entirely failed to address her later misconduct in submitting a false statement in connection with her application. Because I conclude that the

falsifications cannot be attributed to mere carelessness or negligence, I conclude that Ms. Lawson (and Respondent) cannot be entrusted with a registration. I make the following findings.

Findings

Respondent, a franchise of The Medicine Shoppe International, Inc., is a retail pharmacy located in Cheverly, Maryland, GX 1, RX 14. Respondent is owned by Samuel Lawson, M.D., and Tina Hart-Lawson, Ph.D. and R.Ph., who are married to each other. ALJ at 2. Ms. Hart-Lawson began practicing as a pharmacist in 1981, Tr. 193, and was Respondent's Chief Pharmacist in the fall of 1999 when Ms. Lawson and the pharmacy first came to the attention of the Prince George's (P.G.) County Police Department when the latter received information that Ms. Lawson was knowingly filling fraudulent prescriptions. GX 14, at 1.

During the initial phase of the investigation, a DEA Diversion Investigator (DI) went to Respondent and retrieved the prescriptions that it had filled for a person that the P.G. County police had recently arrested. Tr. 19. During the visit, the DI noticed that when Respondent's customers dropped off their prescriptions, Ms. Lawson did not verify them with their physicians. *Id.* at 20.

Thereafter, the DI suggested to the P.G. County Police that further investigation of Ms. Lawson and Respondent was warranted. *Id.* at 20–21. Accordingly, the investigators decided to create fictitious prescriptions using the name of Deleon E. Ambrozewicz, M.D., and a false DEA registration number. *Id.* at 21. The prescriptions also included a telephone number, which if called, would result in the caller hearing that the number was not available. *Id.* The investigators also decided to use two persons to fill out the prescriptions and to leave out essential information necessary to fill a prescription such as the date, the quantity to be dispensed, and the number of refills. *Id.* at 47.

Between October 18, 1999, and February 9, 2000, two P.G. County detectives carried out a total of 10 undercover visits to Respondent during which they presented fraudulent prescriptions to Ms. Lawson. ALJ at 4. Using the undercover name of Amber Johnson, the first detective (hereinafter, Detective I) visited Respondent on October 18, November 11, November 16, December 1, and December 7, 1999, as well as on February 9, 2000. *Id.* Using the undercover name of Colleen Talliver, the second detective (hereinafter, Detective II) visited

Respondent on January 7, January 12, February 2, and February 4, 2000. *Id.*

On October 18, 1999, Detective I visited Respondent and presented to Ms. Lawson prescriptions for Percocet and Soma,¹ which were "issued" under the name of Dr. Ambrozewicz. Tr. 76, GX 15. Ms. Lawson called the telephone number on the prescription, determined that it was not a "good number," and refused to fill the prescription. Tr. 75–76.

On November 11, 1999, Detective I returned to Respondent and presented to Ms. Lawson another fraudulent prescription for Percocet "issued" by Dr. Ambrozewicz. *Id.* at 78–80. According to the Detective, Ms. Lawson asked her only if she had insurance. *Id.* at 82–83. Ms. Lawson then filled the prescription. *Id.* at 81–82; see also GX 10, at 2–3.

Five days later, Detective I returned to Respondent and presented to Ms. Lawson another fraudulent Percocet prescription "issued" by Dr. Ambrozewicz. Tr. 84; GX 11. On this occasion, Ms. Lawson asked the Detective whether she had been to the pharmacy before. Tr. 84. The Detective told Ms. Lawson that she had been there the week before to which Ms. Lawson responded: "Oh, you must be in pain." *Id.* The Detective answered affirmatively and Ms. Lawson filled the prescription. *Id.* at 84–85; see GX 11, at 2.

On December 1, 1999, Detective I returned to Respondent and presented to Ms. Lawson fraudulent prescriptions for both Percocet and Vicodin "issued" by Dr. Ambrozewicz. *Id.* at 86. According to the Detective, Ms. Lawson may have asked her whether she had been there before but did nothing to verify whether the prescriptions were valid. *Id.* at 86–87. Moreover, while these drugs are contraindicated, *id.* at 217, Ms. Lawson filled both prescriptions. *Id.* at 87–88; GX 7 & 8.

Six days later, Detective I returned to Respondent and again presented to Ms. Lawson fraudulent prescriptions for Percocet and Vicodin "issued" by Dr. Ambrozewicz. Tr. 88–89. According to the Detective, Ms. Lawson asked only whether she had insurance and had been to the pharmacy before; the Detective affirmatively answered the latter question. *Id.* at 89. Ms. Lawson did nothing to verify the validity of the prescriptions and filled both of them. *Id.* at 89–90; see also GXs 5 & 6.

Detective I did not return to Respondent until February 9, 2000, when she presented to Ms. Lawson another Percocet prescription "issued" by Dr. Ambrozewicz. GX 9; Tr. 90–91.

¹ Soma (carisoprodol) is not a controlled drug.

On this occasion, Ms. Lawson told the Detective that she knew that the prescription was "fake," because she had another customer who had used the same doctor's name and had determined that the "doctor did not exist." GX 14, at 2. After telling the Detective that she would let it go this time because she had already filled the prescription, Tr. 91, Ms. Lawson placed her telephone on its speaker-phone function and dialed the phone number listed on the prescription. GX 14, at 2-3. Ms. Lawson then stated: "I will let you go this time, and I'm not going to call the police because you're a sister." *Id.* at 3; Tr. at 91. The Detective paid cash for the Percocet and left Respondent. Tr. at 91.

On January 7, 2000, Detective II visited Respondent and presented to Ms. Lawson a fraudulent Soma prescription "issued" by Dr. Ambrozewicz. *Id.* at 26. The prescription did not include the quantity, *id.*; Ms. Lawson proceeded to ask the Detective if thirty tablets "would be enough?" *Id.* at 27. After the Detective told Ms. Lawson that thirty tablets "would be fine," Ms. Lawson filled the prescription. *Id.* at 27.

On January 12, 2000, Detective II returned to Respondent and presented to Ms. Lawson a fraudulent prescription for Percocet. *Id.* at 28. The prescription, which was "issued" by Dr. Ambrozewicz, was undated and left blank the number of refills. GX 12. According to the Detective, who remained present upon tendering the prescription, Ms. Lawson filled the prescription without verifying it. Tr. 30-31; GX 12, at 2-3.²

On February 2, 2000, Detective II returned to Respondent and presented to Ms. Lawson fraudulent prescriptions for Vicodin and Percocet. Tr. 32. The Vicodin prescription, which was "issued" by Dr. Ambrozewicz, was again undated and left blank the number of refills.³ GX 13, at 1. Ms. Lawson informed Detective II that because of a bad snowstorm two days earlier, a shipment had not come in, and therefore, she was unable to fill the Percocet prescription and could only fill

² On April 3, 2000, the police executed a search warrant at Respondent and seized the various prescriptions. This prescription bore the handwritten notation "fraudulent." GX 12, at 1. According to the Detective, the notation was not on the prescription when she tendered it to Ms. Lawson. TR. 29.

³ The record does not include a copy of the Percocet prescription which Detective II presented to Ms. Lawson. The Vicodin prescription bears the notations "forged" and "Called 911." GX 13. It also included information describing the Detective's physical appearance and automobile. See *id.* at 2. Ms. Lawson did not, however, testify regarding this information. ALJ at 8.

half of the Vicodin prescription. Tr. 32. Ms. Lawson then dispensed tablets of generic Vicodin to the Detective. GX 13, at 2-3.

On February 4, 2000, the Detective returned to Respondent in an attempt to obtain the remaining half of the Vicodin prescription and the Percocet prescription which had not been filled. Tr. 36. Ms. Lawson pulled the Detective aside and told her that she knew the prescriptions were fraudulent, and that Dr. Ambrozewicz did not exist. *Id.* at 36-37. Ms. Lawson also told the Detective that during her previous visit, a local police officer was in the store. *Id.* at 37. Ms. Lawson told the Detective that "she did not say anything in front of the police officer" because she did not want the Detective to get in "trouble." GX 14, at 2; *see also* Tr. 37. Ms. Lawson then told the Detective that she had only given her half the Vicodin prescription because she wanted the Detective to leave. Tr. 37. Ms. Lawson also told the Detective that she knew the latter needed help and hoped she would get it. *Id.*

Thereafter, the United States Attorney indicted Ms. Lawson. Tr. 122. Ms. Lawson pled guilty, and, on April 29, 2002, the United States District Court convicted her of the unlawful distribution of oxycodone on February 9, 2000, in violation of 21 U.S.C. 841(a)(1). GX 3. Ms. Lawson was sentenced to five months imprisonment and three years of supervised release, which also included a five-month term of home detention. GX 3, at 2-4. Prior to entering her plea, Ms. Lawson met with P.G. County Detectives and submitted to an interview. Tr. 56. Moreover, at some point not specified in the record, Respondent surrendered its DEA registration. Tr. 134.

On September 13, 2003, Respondent submitted an application for a new registration which was completed by Respondent's husband. GX 1. On the application, Respondent answered "yes" to the question whether it had "ever surrendered or had a federal controlled substance registration revoked * * * or denied?" GX 1, at 1. Respondent also answered "yes" to the question which asks a non-publicly traded corporate entity whether "any officer, partner, stockholder, or proprietor [has] been convicted of a crime in connection with controlled substances under state or federal law?" *Id.* In explaining its answer to the latter question, Respondent referred to the attached statement of Ms. Lawson regarding the events surrounding her conviction. GX 1, at 2.

In this statement, Ms. Lawson wrote:

Approximately 3 years ago (March 2000), a female patient exhibiting excruciating pain, came to the pharmacy with a prescription for a scheduled drug (percocet). Inspite (sic) of the fact that this patient was extremely conniving, I followed my usual professional protocol of verifying and authenticating the said prescription. My finding lead me to believe that, this was a fraudulent prescription. My professional judgment at the time on a very busy day, was to inform the police of this occurrence. However, in order to substantiate my finding, I decided to partial (sic) fill so that the police will apprehend the patient with the item in hand.

For the past 20 years as a licensed pharmacist, I have turned away several such prescriptions. On this busy day in question, I was trying to perform my civic duty by involving the police. No sooner had I made this professional judgement (sic), than I was later informed that this was a set up by an agent.

Upon further investigation, it was concluded that I had performed my duties in the past with distinction and without prior criminal record, but the professional judgment made by me on this day in question was in error and uncharacteristic.

Id. at 3. Upon receipt of Respondent's application, DEA commenced this investigation.

Based on Ms. Lawson's guilty plea, on March 25, 2005, the Maryland Board of Pharmacy charged Ms. Lawson with violating Md. Health Occ. Code Ann. § 12-313, a provision which authorizes the Board to discipline a licensee upon a conviction or guilty plea "to a felony or to a crime involving moral turpitude." RX 16, at 1. On the same day, the Board also charged Respondent with a violation of Maryland law based on Ms. Lawson's criminal conduct. *See* GX 17.

On August 1, 2005, "over the objection of the [State's] prosecutor," GX 16 at 2, the Board and Ms. Lawson agreed to a settlement under which her license was "suspended for three years, with all three years immediately [s]tayed." *Id.* at 3. The Board also placed Ms. Lawson on "probation for a minimum of three years," and ordered her to complete an ethics course. *Id.* at 4. Relatedly, the Board also suspended Respondent's pharmacy permit for three years with all three years stayed and imposed a fine of \$2,500. *See* GX 17, at 4.

Both Mr. and Mrs. Lawson testified at the hearing. Mr. Lawson testified that he and his wife "met on several occasions with the agents that * * * testified" in the proceeding, and that during these meetings, he "was able to find out a lot of things that had happened in terms of all the different incidents." Tr. 156. Mr. Lawson further testified that the various investigations had concluded that Ms. Lawson had received "negligible"

financial gain from her misconduct. *Id.* at 157. Mr. Lawson stated that when the Lawsons went before the Maryland Board “the incidents that had been put forward by DEA and also by the prosecuting attorney during the first adjudication process, all that information was relayed * * * to them.” *Id.* at 162. Mr. Lawson also testified that to his knowledge, his wife had not received any further complaints regarding her dispensing of controlled substances. *Id.* at 172–73.

Mr. Lawson testified that a DEA diversion investigator was aware that his wife had pled guilty to the criminal charge. *Id.* at 174. Mr. Lawson also testified that another diversion investigator had “objected” to the answers that Respondent had provided to the liability questions (in section 4) of the application because they did not reflect his wife’s conviction; the DI then sent him a new application and instructed him to “fill [it] out correctly.” *Id.* at 178; *see also id.* at 188–89. Mr. Lawson testified that he did so, *id.* 179 & 189, and that the information in his wife’s statement:

was constructed by me after listening to [her] years later as to what may have happened when the particular application that she pled guilty to, that one count, what had transpired in my absence based, on her best recollection. * * * I put those words together, not to mean those were the exact things that this agent might have purported before Tina. It was based on her physical appearance and whatever other demeanors that she may have had on that particular day.

Id. at 179.

Mr. Lawson testified that his wife had taken continuing education courses and completed the ethics course mandated by the Maryland Board. *Id.* at 183. Mr. Lawson further testified that since the events that led to her conviction, his wife “has been extremely cautious and she does her best to follow all the regulations.” *Id.*

Ms. Lawson testified that in the past, she “used to take [her customer’s] word,” but that since her arrest, she had become “more careful” and “more suspicious of anybody that comes into the pharmacy.” *Id.* at 195. Ms. Lawson further stated that while taking the required ethics course, she recognized that she had not been “dealing with [her customers] on a professional basis” because she would talk to them about “their private life and everything,” but now she keeps her interactions “short and simple” and only “deal[s] with them professionally.” *Id.* at 197.

Ms. Lawson testified that even when she fills pain medications which are not controlled substances, she now verifies the prescription with the prescribing

physician. *Id.* at 198. Ms. Lawson added that she also takes more time to fill the prescription and tells her customers that “if they cannot wait, they can go to another pharmacy.” *Id.* Ms. Lawson further testified that she had attended a number of continuing education courses. *Id.* at 200–01. Finally, Ms. Lawson testified that she “should have done things differently and * * * I made a big error,” and wanted a second chance “to show [DEA] that I’m a changed person.” *Id.* at 201.

Ms. Lawson offered no testimony, however, regarding the statement she signed and submitted in support of Respondent’s application. *See generally id.* 191–203. Moreover, when asked by her counsel whether there was “anything else” she wanted the ALJ to know as to why it would be “in the public interest to” grant the application, Ms. Lawson answered: “I can’t think of anything right now.” *Id.* at 203.⁴

On cross-examination, Ms. Lawson testified that she did not recall the Detective who presented the prescription which led to her indictment having ever been in her store. *Id.* at 211. She also testified that she did not recall the other Detective having been in her store until meeting the Detective during a de-briefing after her arrest. *Id.* Ms. Lawson further testified that she did not remember to which Detective she had given the partial prescription, that it had “been a very long time [since] all these things happened,” and that she had only a “vague recollection of any of these prescriptions being presented to me.” *Id.* at 212. Moreover, when asked whether she knew on December 7, 1999, whether “DeLeon Ambrozewicz was a legitimate doctor?,” Ms. Lawson answered: “I really don’t remember. It’s been a long time.” *Id.* at 215.

Ms. Lawson admitted that Percocet and Vicodin are contraindicated, but then testified that she did not remember whether she had advised Detective II of this fact when she dispensed both drugs to her on December 1, 1999. *Id.* at 216–17. Ms. Lawson also could not explain why her pharmacy’s computer-generated prescription printout indicated that one refill was authorized for the February 2, 2000 Vicodin prescription issued to Det. II when the initial script had left this blank. *Id.* at 218; *see also GX 13 at 1–2.* Ms. Lawson testified that she “should have * * * checked” the prescription and “done things differently.” Tr. 218. Ms. Lawson further maintained that “[i]n those days,

it used to be very busy at the pharmacy” and that she “did not have any help,” but that she now “double-checks” prescriptions, “scrutinizes anything that leaves the pharmacy,” and doesn’t “rush.” *Id.* at 219.

Discussion

Section 303(f) of the Controlled Substances Act 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, the CSA requires the consideration of the following factors:

- (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.

“These factors are * * * considered in the disjunctive.” *Robert A. Leslie, M.D.*, 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 * * * an application for registration [should be] denied.” *Id.* Moreover, I am “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005).

Furthermore, under Section 304(a)(1), a registration may be revoked or suspended “upon a finding that the registrant * * * has materially falsified any application filed pursuant to or required by this subchapter.” 21 U.S.C. 824(a)(1). Under agency precedent, the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. § 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See Anthony D. Funches*, 64 FR 14267, 14268 (1999); *Alan R. Schankman*, 63 FR 45260 (1998); *Kuen H. Chen*, 58 FR 65401, 65402 (1993). Thus, the allegation that Respondent materially falsified its application is properly considered in this proceeding. *See Samuel S. Jackson*, 72 FR 23848, 23852 (2007).

In this case, I agree with the ALJ that Respondent and Ms. Lawson materially

⁴Ms. Lawson also produced several letters of recommendation including one from her probation officer. *See RX 5.*

falsified its application for registration. ALJ Dec. at 19. While noting that Ms. Lawson "provided no testimony as to why she" made these "significant misrepresentations," the ALJ apparently treated the material falsification as just "other conduct" to be considered under Factor Five of the public interest analysis and recommended that the application be granted. *Id.* at 19–20.

The ALJ's approach gave insufficient weight to Ms. Lawson's separate act of misconduct in making several false statements in connection with Respondent's application. Just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, see 21 U.S.C. § 824(a)(1), it also provides an independent and adequate ground for denying an application. *Cf. Bobby Watts, M.D.*, 58 FR 46995 (1993).

Ms. Lawson's statement was offered as an explanation of the events which surrounded her dispensing of Percocet to Detective I on February 9, 2000. With respect to that statement, the ALJ concluded that Dr. Lawson made several "false statements in the letter." ALJ at 19. In particular, Ms. Lawson attempted to portray herself as the victim of deception stating that she filled the prescription in part because the Detective was "extremely conniving" and exhibited "excruciating pain." GX 1, at 3. The Detective—whom the ALJ found credible (ALJ at 19)—testified, however, that Ms. Lawson told her that she knew that Dr. Ambrozewicz "was a fictitious doctor," Tr. 91, but would "let this one go because she had already filled the prescription" and "was looking out for her." *Id.*

Moreover, while Ms. Lawson represented that it was "very busy" when she filled the prescription, GX 1, at 3; DI Valentine testified that both Detectives told her that "each time they went in there, it was not busy." Tr. 114. Indeed, Ms. Lawson's statement to the Detective that she knew the prescription was fraudulent but filled it because she was looking out for her, implicated her in the criminal act of unlawful distribution of a controlled substance. See 21 U.S.C. 841(a). This is not the type of conversation that one would expect to occur in a "very busy" pharmacy.

The evidence thus establishes that Ms. Lawson was neither duped into filling the prescription nor harried by the demands of a "very busy" work environment. I thus find that her representations that the Detective was "conniving" by exhibiting "excruciating pain" and that the pharmacy was "very busy" were false.

Ms. Lawson further asserted that her "professional judgment at the time * * * was to inform the police of this occurrence," and that "to substantiate [her] finding" that the prescription was fraudulent, she "decided to partial[ly] fill [the prescription] so that the police will apprehend the patient with the item in hand." GX 1, at 3. As the ALJ found, there is no evidence that Ms. Lawson contacted the police on the date in question, February 9, 2000.⁵ Indeed, as recounted in the police report, Ms. Lawson put her telephone on its speaker function so that the Detective could hear, dialed the number for Dr. Ambrozewicz (to show that she knew that there was no such doctor) and stated: "see, I will let you go this time, and I'm not going to call the police because you're a sister." GX 14, at 3. I thus find that Ms. Lawson's representations that it was her judgment "to inform the police" and that she filled the prescription "so that the police [would] apprehend the patient with the item in hand" were both false.

Having found that these various statements were false does not, however, close the inquiry because it must also be determined whether they were material. "The most common formulation" of the concept of materiality "is that a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.'" *Kungys v. United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock v. United States*, 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); *see also United States v. Wells*, 519 U.S. 482, 489 (1997) (quoting *Kungys*, 485 U.S. at 770). The evidence must be "clear, unequivocal, and convincing." *Kungys*, 485 U.S. at 772. However, "the ultimate finding of materiality turns on an interpretation of substantive law." *Id.* at 772 (int. quotations and other citation omitted).

DEA has previously held that "[t]he provision of truthful information on

applications is absolutely essential to effectuating [the] statutory purpose" of determining whether the granting of an application is consistent with the public interest. *See Peter H. Ahles*, 71 FR 50097, 50098 (2006). As the Sixth Circuit recently observed: "Candor during DEA investigations * * * is considered by the DEA to be an important factor when assessing whether a * * * registration is consistent with the public interest." *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005).

An applicant's answers to the various liability questions are material because this Agency "relies upon such answers to determine whether an investigation is needed prior to granting the application." *Martha Hernandez, M.D.*, 62 FR 61145, 61146 (1997). The explanation given by an applicant who has affirmatively answered a liability question is likewise material because the public interest inquiry under section 303(f) requires, *inter alia*, that the Agency examine "[t]he applicant's experience in dispensing * * * controlled substances," its "conviction record * * * relating to the * * * dispensing of controlled substances," and its "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. § 823(f). Moreover, even where, as here, an applicant (or its related person) has been convicted of a controlled-substance related offense, that conviction does not impose a *per se* bar to the granting of a new registration. *See, e.g., Scott H. Nearing, D.D.S.*, 70 FR 33200 (2005). Rather, in evaluating such applications, the Agency looks at several factors including the egregiousness of the applicant's criminal conduct, its mitigating evidence, and whether the applicant has accepted responsibility for its prior criminal conduct. *See id.; see also Jackson*, 72 FR at 23853.

While Ms. Lawson's misrepresentations were somewhat inconsistent in that they depicted her as a victim of a "conniving" customer and the circumstance of a "very busy" store, while then claiming that she filled the prescription so that police could apprehend the customer with the drugs in hand, I conclude that the statements were made to present her criminal conduct as less serious than it actually was. The statements were material because they had "a natural tendency to influence," or were "capable of influencing" the Agency's evaluation of several of the public interest factors and the ultimate decision as to whether the Agency should grant Respondent's

⁵ In discussing this part of Ms. Lawson's statement, the ALJ also noted that "Detective Muldoon testified to Dr. Lawson's statement that she partially filled the prescription so that Detective Muldoon would not get in trouble with the police." ALJ at 19. Detective Muldoon's statement was, however, in reference to the February 2 and 4, 2000 undercover visits, and not to Ms. Lawson's criminal conduct on February 9, 2000. Ms. Lawson was indicted for, and convicted of, only her conduct on February 9, 2000; her written statement was offered only in explanation of the events pertaining to her conviction. Detective Muldoon's statements are therefore not probative of the events occurring on this date. Accordingly, I reject the ALJ's reasoning to the extent it relied on the statement to Detective Muldoon in finding that Ms. Lawson's statement was false.

application.⁶ *Kungys*, 485 U.S. at 770 (internal quotations and other citations omitted).

That the Agency did not rely on Ms. Lawson's false statements and grant Respondent's application does not make the statements immaterial. As the First Circuit has noted with respect to the material falsification requirement under 18 U.S.C. § 1001, “[i]t makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.” *United States v. Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985). See also *United States v. Norris*, 749 F.2d 1116, 1121 (4th Cir. 1984) (“There is no requirement that the false statement influence or effect the decision making process of a department of the United States Government.”).⁷

I further conclude that Ms. Lawson's material falsifications cannot be attributed to mere negligence or carelessness, and that she either “knew or should have known” that the statements were false. *Dan E. Hale, D.O.*, 69 FR 69402, 69406 (2004); *The Drugstore*, 61 FR 5031, 5032 (1996). The circumstances surrounding the February 9, 2000 visit, in which Ms. Lawson indicated that she knew the prescription was fraudulent and proceeded to dial the phone number of Dr. Ambrozewicz to demonstrate to the Detective that she knew that the doctor did not exist, are sufficiently different from the typical filling of a prescription that one should accurately recall them. Furthermore, the experience of being indicted and pleading guilty in a federal district court to the unlawful distribution of Percocet on the above date are of such significance that one should have a fairly accurate recollection of the underlying circumstances. Moreover, only three and a half years had elapsed between her criminal conduct in filling the fraudulent prescription and her

⁶ My decision in *Jackson* is not to the contrary. In *Jackson*, I found that the respondent provided a factually accurate disclosure of his conviction; this act thus rendered immaterial the respondent's “no” answer to question of whether he had been convicted of a controlled substance offense. 72 FR at 23852–53. Similarly, respondent's statement that he had voluntarily surrendered his registration when it had actually been revoked was not consequential in light of fact that no regulation defines the difference between the terms and the respondent had provided an accurate disclosure of the conduct that led to the loss of his registration. *Id.* In addition, I also adopted the ALJ's finding that the respondent had not intentionally falsified his application. *Id.* at 23852.

⁷ The fact that a DEA Diversion Investigator from a local field office may have been present when Ms. Lawson entered her plea, Tr. 174, also does not render her representations immaterial. As the ALJ found, Respondent's application was submitted to a different section of the Agency, ALJ at 11, where it was initially reviewed.

submission of the statement. Significantly, Respondent provided the statement to DEA after the rejection of an earlier application.

I further note that Ms. Lawson did not testify regarding the circumstances surrounding the preparation of the statement. Ms. Lawson's failure to testify on the issue supports an adverse inference that she knew the statements were false. *See William M. Knarr*, 51 FR 2772, 2773 (1986). Cf. *Baxter v. Palmigiano*, 425 U.S. 308, 319 (1976). Both the circumstantial evidence and Ms. Lawson's silence thus support the conclusion that she knowingly made false statements in an attempt to obtain a favorable decision from the Agency on Respondent's application.

I recognize that the ALJ found that Ms. Lawson credibly acknowledged “that she made mistakes” and expressed “remorse for those mistakes.” ALJ Dec. at 19–20. But because Ms. Lawson did not address the issues surrounding the material falsification of her statement, the ALJ's findings are relevant only with respect to the issues related to Respondent's dispensing's of controlled substances to the two Detectives.

Because Ms. Lawson failed to offer any explanation as to why she submitted her statement, I further conclude that she has not accepted responsibility and expressed remorse for the separate act of misconduct that she committed in submitting her written statement. Her failure to do so precludes a finding that granting Respondent a new registration would be consistent with the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b) & 0.104, I order that the application of The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy, for a DEA Certification of Registration as a pharmacy, be, and it hereby is, denied. This order is effective January 30, 2008.

Dated: December 13, 2007.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E7-25346 Filed 12-28-07; 8:45 am]

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DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

December 17, 2007.

The Department of Labor (DOL) hereby announces the submission the following public information collection

requests (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at <http://www.reginfo.gov/public/do/PRAMain> or by contacting Darrin King on 202-693-4129 (this is not a toll-free number)/e-mail: king.darrin@dol.gov.

Comments should be sent to the Office of Information and Regulatory Affairs, Attn: Carolyn Lovett, OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202-395-7316/Fax: 202-395-6974 (these are not a toll-free numbers), E-mail: OIRA_submission@omb.eop.gov within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment Standards Administration.

Type of Review: Extension without change of currently approved collection.

Title of Collection: Request for Information on Earnings, Dual Benefits, Dependents and Third Part Settlements.

OMB Control Number: 1215-0151.

Agency Form Number: CA-1032.

Estimated Number of Annual Respondents: 50,000.