

disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: January 6, 2004.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 04-444 Filed 1-6-04; 11:52 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jong H. Bek, M.D., Revocation of Registration

On August 16, 2002, the Deputy Administrator of the Drug Enforcement Administration (DEA), issued a Notice of Immediate Suspension of Registration and Order to Show Cause to Jong H. Bek, M.D. (Dr. Bek), notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AB5580243, as a practitioner, and deny any pending applications for renewal or modification, for reason that Dr. Bek's continued registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 824(a)(4). The Notice of Suspension, Order to Show Cause further informed Dr. Bek of the suspension of his DEA Certificate of Registration, as an imminent danger to the public health or safety pursuant to 21 U.S.C. 824(d).

The Notice of Suspension, Order to Show Cause alleged, in part, that Dr. Bek repeatedly prescribed controlled substances to undercover law enforcement personnel without a legitimate medical purpose, and was arrested on state felony murder charges after prescribing Xanax (a Schedule IV controlled substance) to two patients who subsequently overdosed on a combination of Xanax and heroin. It was further alleged that on July 25, 2002, the Indiana Medical Board issued a 90-day emergency suspension of Dr. Bek's medical license, thus, rendering him without authorization to practice medicine or handle controlled substances during the period of suspension. Finally the Notice of Suspension, Order to Show Cause further notified Dr. Bek that should no request for a hearing be filed within 30 days, her hearing right would be deemed waived.

The Order to Show Cause was personally served on Dr. Bek on August 21, 2002 at a detention facility in Lake County, Indiana, where Dr. Bek was awaiting trial on the above referenced

felony charges. DEA has not received a request for hearing or any other reply from Dr. Bek or anyone purporting to represent him in this matter.

Therefore, the Acting Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Notice of Suspension, Order to Show Cause to Dr. Bek, (2) no request for hearing having been received, concludes that Dr. Bek is deemed to have waived his hearing right. *See David W. Linder*, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Deputy Administrator finds that Dr. Bek currently possesses DEA Certificate of Registration AB5580243. A review of the investigative file reveals that on August 31, 2002, the Indiana State Medical Licensing Board (Board) issued an Order summarily suspending Dr. Bek's medical license in that state. While not outlining the specific basis for its action, the suspension order nevertheless alleged that Dr. Bek was "defending certain State of Indiana criminal charges" and that the matter was set for trial on April 28, 2003. The Acting Deputy Administrator has recently received information that on October 24, 2002, Dr. Bek and the Board entered into a Stipulation and Agreement to Extension of Summary Suspension, whereby the parties agreed that the suspension at issue would be extended "until the criminal charges against [Dr. Bek] are resolved and until the Board has an opportunity to take final action on his license."

The Acting Deputy Administrator has obtained a copy of a letter dated October 16, 2003, from the Director of the Indiana Medical Licensing Board, Health Professions Bureau to the Merrillville Resident Office of DEA notifying that Dr. Bek's Indiana state medical license remains suspended. The investigative file contains no evidence that the agreed extension of the Board's suspension order regarding Respondent's medical license has been lifted and the Acting Deputy Administrator has received no evidence that Dr. Bek's medical license has been reinstated. Therefore, the Acting Deputy Administrator finds that Dr. Bek is not currently authorized to practice medicine in the State of Indiana. As a result, it is reasonable to infer that he is also without authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to

issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See James F. Graves, M.D.*, 67 FR 70968 (2002); *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Here, it is clear that Dr. Bek's medical license is currently suspended and therefore, he is not currently licensed to handle controlled substances in the State of Indiana, the state where he maintains a DEA controlled substance registration. Therefore, Dr. Bek is not entitled to a DEA registration in that state. Because Dr. Bek is not entitled to a DEA registration in Indiana due to his lack of state authorization to handle controlled substances, the Acting Deputy Administrator concludes that it is unnecessary to address whether his registration should be revoked based upon the other grounds asserted in the Notice of Immediate Suspension of Registration and Order to Show Cause. *See Fereida Walker-Graham, M.D.*, 68 FR 24761 (2003); *Nathaniel-Aikens-Afful, M.D.*, 62 FR 16871 (1997); *Sam F. Moore, D.V.M.*, 58 FR 14428 (1993).

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AB5580243, issued to Jong H. Bek, M.D. be, and it hereby is, revoked. The Acting Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective February 9, 2004.

Dated: December 18, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04-341 Filed 1-7-04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

City Drug Company; Denial of Application

On November 19, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to City Drug Company (City Drug) notifying the applicant of an opportunity to show cause as to why DEA should not deny its pending

application for DEA Certificate of Registration as a retail-pharmacy pursuant to 21 U.S.C. 823(f). As a basis for the denial, the Order to Show Cause alleged that City Drug's registration would be inconsistent with the public interest. The Order to Show Cause also notified City Drug that should not request for a hearing be filed within 30 days, its hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to City Drug at its proposed registered location in Opp, Alabama and was received on November 26, 2002. DEA has not received a request for hearing or any other reply from City Drug or anyone purporting to represent the pharmacy in this matter.

Therefore, the Acting Deputy Administrator of DEA, finding that (1) 30 days having passed since the attempted delivery of the Order to Show Cause at the applicant's last known address, and (2) no request for hearing having been received, concludes that City Drug is deemed to have waived its hearing right. *See David W. Linder*, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Deputy Administrator finds that on February 8, 2002, a new application was submitted on behalf of City Drug for DEA registration as a retail pharmacy. The application was submitted and signed by Joseph G. Grimes, the President and owner of City Drug, and that application is the subject of the current proceedings.

The Acting Deputy Administrator finds that prior to the submission of its most recent registration application, City Drug previously possessed DEA Certificate of Registration AC5430450. On August 29, 1996, an Order to Show Cause was issued proposing to revoke that registration, and deny any pending applications for registration under 21 U.S.C. 823(f), for reason that City Drug's continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4).

Following an April 15, 1997, administrative hearing in Mobile, Alabama, the presiding Administrative Law Judge Gail A. Randall (Judge Randall) recommended that City Drug's DEA Certificate of Registration be revoked. Judge Randall further recommended however that favorable consideration be given to any future application for registration submitted by City Drug, should the pharmacy provide persuasive evidence of procedural

changes for the dispensing of controlled substances. While the then-Acting Deputy Administrator did not adopt the latter recommendation, he did adopt Judge Randall's recommendation with respect to revocation of City Drug's Certificate of Registration. Accordingly, City Drug's previous DEA registration was revoked, effective November 13, 1997. *See* 62 FR 53338 (October 14, 1997).

In revoking City Drug's DEA registration, the then-Acting Deputy Administrator relied upon evidence that in 1992, an investigation revealed that between January 1990 and January 1992, the pharmacy violated 21 U.S.C. 829 and 21 CFR 1306.04 by dispensing over 25,000 dosage units of controlled substances without a physician's authorization. The then-Acting Deputy Administrator based this conclusion on affidavits submitted by 11 physicians who reviewed prescriptions found at City Drug that were attributed to them, compared these prescriptions to their patient charts, and then swore that they had not authorized the prescriptions. The then-Acting Deputy Administrator found unpersuasive City Drug's argument that the physicians had forgotten to note the issuance of the prescriptions in the patient charts, stating that it was "highly unlikely that eleven different physicians forgot to note numerous prescriptions in the patient charts which accounted for the dispensing of over 25,000 dosage units of controlled substances." The then-Acting Deputy Administrator also found that the patients' affidavits submitted by City Drug were less reliable than the physicians' affidavits since the physicians' affidavits were "based upon a review of [their] patient records which were prepared and maintained during the relevant time period, whereas the patients' affidavits [were] based upon their recollection more than six years after the event."

The then-Acting Deputy Administrator further concluded that City Drug violated 21 U.S.C. 827, by failing to maintain complete and accurate records of controlled substances, as evidenced by the pharmacy's inability to account for more than 80,000 dosage units of Schedule III and IV substances, and to explain an overage of 859 dosage units of oxycodone 5 mg., the only Schedule II controlled substance that was audited. With respect to the failure of Joseph Grimes to accept responsibility for past improper conduct, the then-Acting Deputy Administrator found that:

(Joseph) Grimes has failed to acknowledge that he and his pharmacy have done anything

improper. An unexplained shortage of 80,000 dosage units and the unauthorized dispensation of over 25,000 dosage units of controlled substances are not merely minor technical violations. The egregious nature of the violations in this matter demonstrates that [City Drug] has failed miserably in its responsibility as a DEA registrant to protect against the diversion of controlled substances from the legitimate chain of distribution. Id. at 53343.

The Acting Deputy Administrator also finds that on November 13, 1997, City Drug submitted an application for a new Certificate of Registration as a retail pharmacy. The application was submitted on behalf of City Drug by Louie Grimes, a pharmacist and the nephew of Joseph Grimes. DEA again issued an Order to Show Cause on February 24, 1998, seeking the denial of City Drug's previous application, and a hearing was held in Mobile, Alabama on October 28, 1998, before Administrative Law Judge Mary Ellen Bittner (Judge Bittner). On June 30, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that City Drug's application for a DEA Certificate of Registration be denied. Accordingly, and effective November 2, 1999, DEA denied City Drug's previous application for registration. 64 FR 59212 (November 2, 1999).

In that final order, the then-Deputy Administrator found that on November 12, 1997, the day before the effective date of the revocation of City Drug's previous DEA Certificate of Registration, Joseph Grimes executed a Bill of Sale that transferred, "in consideration of ten dollars and other good and valuable consideration," a life estate in City Drug to Louie Grimes. The "other good and valuable consideration" noted in the Bill of Sale was an oral agreement that Joseph Grimes would continue to work at City Drug two days per week in return for \$1,500 per month, and that he would also receive rent of \$1,500 per month on the building in which the pharmacy is located. According to the attorney who drafted and notarized the Bill of Sale, Louie Grimes was authorized to transfer his life estate in city Drug but that the pharmacy would revert back to Joseph Grimes upon his nephew's death.

As noted in the November 2, 1999, final order, evidence was presented from the 1992 investigation concerning Louie Grimes' involvement in the operation of the pharmacy at that time, including his dispensation of 870 dosage units of controlled substances that had not been authorized by a prescribing physician. The then-Deputy Administrator also found that while Louie Grimes was the owner of City

Drug, he was also a pharmacist at City Drug working three days a week, during 1990 to 1992, when unlawful dispensing practices were documented. The then-Deputy Administrator further referenced evidence which revealed eight instances, when Louie Grimes refilled controlled substance prescriptions more than five times or more than six months after issuance of the original prescription in violation of 21 U.S.C. 829(b), for a total of 550 dosage units. The then-Deputy Administrator concluded that Louie Grimes was responsible for the unlawful dispensation of approximately 1,400 dosage units of controlled substances.

In addition, despite the apparent change of ownership of City Drug, the then-Deputy Administrator nevertheless found that Joseph Grimes continued to receive employment, salary and rent from City Drug, and he held a reversionary ownership interest in the pharmacy. The then-Deputy Administrator concluded that Joseph Grimes continued to derive a benefit from City Drug's operation. The then-Deputy Administrator further concluded that "Joseph Grimes' continued interest in Respondent, considered in conjunction with the Grimes' familial relationship and the nominal consideration for the life estate, lead * * * to the conclusion that the bonds linking Joseph Grimes with Louie Grimes and [City Drug] are too close to ensure that Joseph Grimes will have no influence in the operation of [City Drug]."

The Acting Deputy Administrator's review of the investigative file reveals that with respect to City Drug's most recent application for registration, DEA personnel from the Mobile, Alabama Resident Office (the Mobile R.O.) requested from Joseph Grimes information on whether he had attained any subsequent education with respect to the handling of controlled substances and whether any steps were taken towards improvement in recordkeeping. On March 22, 2002, the Mobile R.O. received from Joseph Grimes a five page facsimile consisting of a cover page, and accompanied by a photocopy of the Pharmacist's Manual, Certificate of Continuing Education Participation titled "Pain Management for the RPh.," Certificate of Continuing Education Participation titled "Pain Management for the Pharmacists," and Statement of Continuing Pharmaceutical Education Credit titled "Use of Opioids in Chronic Non-Cancer Pain."

On the face of the cover page was a handwritten index which listed the following: "(1) Continuing Education material, (2) Pharmacist Controlled

Substances Manual, (3) Proposal to keep accurate records for controlled drugs, [and] (4) Conscientious effort to comply with all requirements involved with DEA certificate." The index was signed "J.G. Grimes, RPh." Listed under heading number (3) "Proposal to keep accurate records," *et. al.*, were the following:

- (A) File prescriptions separately;
- (B) Careful control of order books;
- (C) Identify time and name of persons calling in prescriptions that are allowed by phone;
- (D) Careful scrutiny of controlled drug prescriptions in determining authenticity of prescriptions, and ,
- (E) Large red color "C" on each narcotic or controlled prescription.

Absent from the supplied materials was any information demonstrating Joseph Grimes' familiarity with controlled substance regulations, diversion prevention or recordkeeping. In addition, Joseph Grimes did not provide information on specific procedures that would be employed at City Drug for maintaining accurate controlled substances inventories and accountability.

Pursuant to 21 U.S.C. 823(f), the Acting Deputy Administrator may deny an application for a DEA Certificate of Registration if she determines that the granting of a registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to 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.

These factors are to be considered in the disjunctive; the Acting Deputy Administrator may rely on anyone or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. *See Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

Regarding factor one, there is no information before the Acting Deputy Administrator with respect to the State licensure status of City Drug. In prior DEA proceedings involving City Drug

however, the agency found that the pharmacy was in fact licensed to handle controlled substances in Alabama. But as Judge Bittner noted in the prior proceeding, "inasmuch as State licensure is a necessary but not sufficient condition for a DEA registration * * * this factor is not determinative." 64 FR at 59212.

Factors two and four, City Drug's experience in the dispensing of controlled substances and its compliance with applicable laws, are clearly relevant in this matter in determining the public interest. City Drug's previous DEA registration was revoked based upon the then-Acting Deputy Administrator's findings that City Drug could not account for over 80,000 dosage units of controlled substances and that the pharmacy had dispensed more than 25,000 dosage units of controlled substances without a physician's authorization. The then-Acting Deputy Administrator did not find City Drug's explanation persuasive regarding the unauthorized dispensing of controlled substances. The then-Acting Deputy Administrator's findings regarding the previous revocation are *res judicata* for purposes of this proceeding. *See Stanley Alan Azen, M.D.*, 61 FR 57893 (1996), *Liberty Discount Drugs, Inc.*, 57 FR 2788 (1992).

Factors two and four are also relevant to evidence presented at a prior DEA proceeding that Louie Grimes, the purported new owner of City Drug was responsible for the unlawful dispensation of approximately 1,400 dosage units of controlled substances. 64 FR 59212. Louie Grimes' prior contentions that physicians were mistaken, that they had in fact authorized the prescriptions in question, as well as others, were rejected by the then-Acting Deputy Administrator, and those conclusions remain binding for purposes of this proceeding. *Id.*

Regarding factor three, there is no evidence that City Drug or its owner or employees have ever been convicted under State or Federal laws relating to the manufacture, distribution, or dispensing of controlled substances. As to factor five, while not necessarily relying on such evidence, the then-Deputy Administrator nevertheless referenced evidence presented by the government at a prior proceeding questioning the legitimacy of the transfer of City Drug from Joseph Grimes to Louie Grimes and also the role that Joseph Grimes would play in City Drug's future management. *Id.* at 59212.

The Acting Deputy Administrator concludes that City Drug's registration would be inconsistent with the public

interest. As noted by my predecessors, from 1990 to 1992, City Drug could not account for over 80,000 dosage units of controlled substances and dispensed more than 25,000 dosage units of controlled substances without a physician's authorization. The Acting Deputy Administrator remains concerned that City Drug has yet to present any persuasive evidence of meaningful procedural changes since 1992 that would ensure that it will not again fail to account for controlled substances or dispense controlled substances without authorization.

The Acting Deputy Administrator however notes that Joseph Grimes has apparently directed his efforts toward educating himself on the proper handling of controlled substances, as evidenced by the information provided with his most recent DEA registration application. Such evidence may be given favorable consideration in conjunction with a future application for registration. However, without credible evidence of any procedural changes having taken place at City Drug, and the lack of acknowledgement or explanation for previous shortages of large quantities of controlled substances, the Acting Deputy Administrator remains unconvinced that the granting of the pending application of City Drug is consistent with the public interest.

The Acting Deputy Administrator acknowledges that many of the violations recited above took place more than 10 years ago. However, in light of City Drug's failure to request a hearing in this matter, and the absence of evidence to rebut the above allegations, the Acting Deputy Administrator is left with the conclusion that the applicant has not corrected the deficiencies which led to the revocation of its previous Certificate of Registration and the denial of a previous application for registration. City Drug, although given the opportunity to request a hearing or to submit a written statement, has failed to do either. Thus, the facts recited above stand uncontroverted. *See, Ruggero Angiolicchio, M.D.*, 58 FR 14426 (March 17, 1993). In view of the foregoing, the Acting Deputy Administrator reiterates that City Drug cannot be entrusted to handle controlled substances, and the granting of its application would not be in the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for DEA Certificate of Registration executed

by City Drug Company be, and it hereby is, denied. This order is effective February 9, 2004.

Dated: December 18, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02-11]

Marlou D. Davis, M.D.; Revocation of Registration

On October 12, 2001, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Marlou D. Davis, M.D. (Respondent). The show cause order proposed the revocation of DEA Certificate of Registration AD7084217 pursuant to 21 U.S.C. 824(a), and denial of any pending applications for renewal or modification of such registration for reason that such registration was deemed inconsistent with the public interest pursuant to 21 U.S.C. 823(f). The Order to Show Cause alleged in substantive part, the following:

1. On November 25, 2000, the Respondent notified the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") that he was moving his office/practice from his registered location in Bridgeton, Missouri to a new location in St. John, Missouri.

2. On December 7, 2000, BNDD notified the Respondent by certified mail that his Missouri controlled substance registration was valid only for his registered location in Bridgeton, Missouri. The letter referenced 19 CSR 30-1.030(1)(J), which states, in part, that "the registration of any person shall terminate if and when that person changes his/her address as shown on the certificate of registration." The Respondent was also notified in the letter that he did not currently have a registration and therefore did not have authority to order, stock, dispense, prescribe or administer controlled substances in the State of Missouri. Ref. 19 CSR 30-1.030(1)(E) 1 ("Any person who is required to be registered and who is not so registered shall not engage in any activity for which registration is required, until the application is granted and a certificate of registration is issued by the Board of Health").

3. Effective December 20, 2000, the Respondent's Missouri State Controlled Substances Registration was terminated. Therefore, the Respondent lacked

authority under Missouri state law to prescribe, dispense and/or administer controlled substances. Consequently, the Respondent was not authorized to possess a Federal controlled substances registration.

4. In addition, on October 18, 2000, the Respondent was arrested by the St. Louis Division Tactical Diversion Squad and charged at the state felony level with 14 counts of attempt to deliver a controlled substance and three (3) counts of delivery of a controlled substance. One of the conditions of the Respondent's release on bond by a St. Louis County Circuit Judge was that the Respondent would be prohibited from writing controlled substance prescriptions until his criminal case was concluded.

5. On April 27, 2001, DEA became aware that the Respondent wrote two (2) prescriptions for controlled substances for patient B.F. The first prescription, dated April 23, 2001, was for Triazolam, .25 mg #30, a Schedule IV controlled substance, and Fioricet, #100, a non-controlled substance. The second prescription, dated May 29, 2001, was for Triazolam, .25 mg, #30.

By letter dated November 12, 2002, the Respondent, acting *pro se*, timely requested a hearing. The matter was subsequently assigned to Administrative Law Judge Gail A. Randall (Judge Randall) and on January 11, 2002, Judge Randall issued to the Government and the Respondent an Order for Prehearing Statements.

In lieu of filing a prehearing statement, the Government filed Government's Request for Stay of Proceedings and Motion for Summary Judgment. The Government argued that the Respondent was without authorization to handle controlled substances in Missouri, and as a result, further proceedings in the matter were not required. Attached to the Government's motion was a copy of a letter dated December 7, 2000, from the Administrator of the Missouri Department of Narcotics and Dangerous Drugs ("BNDD") to the Respondent. The letter notified the Respondent that as a result of his changing the location of his medical practice, and because his controlled substance registration was valid only for his registered practice location, the Respondent's Missouri controlled substance registration was terminated. While the BNDD letter informed the Respondent that he lacked state authority to handle controlled substances in Missouri, the Respondent was nevertheless provided an opportunity to apply for a new Missouri state certificate of registration at his new business address.