

that Callahan's failed to provide information with respect to its list I chemical suppliers and customers. Similarly, with respect to factor five, other factors relevant to and consistent with the public safety, Callahan's failure to provide information necessary to the processing of its application for DEA registration supports the denial of its pending application. In addition, DEA investigators were unable to perform an on-site inspection of Callahan's to determine whether or not the company could adequately handle listed chemicals and the company provided incomplete information necessary to the processing of its DEA application. See, CHM Wholesale Co., 67 FR 9985 (2002).

In light of the above, and the absence of evidence to the contrary, the Acting Administrator is left with the conclusion that Callahan's cannot be entrusted with the responsibilities of a DEA registration. As a result, the Acting Administrator further concludes that it would be inconsistent with the public interest to grant the application of Callahan's Foods.

Accordingly, the Acting Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by Callahan's Foods be, and it hereby is denied. This order is effective August 25, 2003.

Dated: July 3, 2003.

William B. Simpkins,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

G & O Pharmacy of Paducah, Incorporated; Denial of Application

On April 19, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to G & O Pharmacy¹ (G & O) 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 practitioner pursuant to 21 U.S.C. 823(f). As a basis for the denial, the Order to Show Cause alleged that G &

O's registration would be inconsistent with the public interest. The Order to Show Cause also notified G & O that should no 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 G & O at its proposed registered location in Paducah, Kentucky, and was received on April 26, 2002. DEA has not received a request for hearing or any other reply from G & O or anyone purporting to represent the pharmacy in this matter.

Therefore, the Acting Administrator of DEA, finding that (1) thirty 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 G & O 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 Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Administrator finds that G & O previously possessed DEA Certificate of Registration AG2999691. On July 23, 1992, an Order to Show Cause was issued proposing to revoke that Certificate of Registration. The Order to Show Cause alleged in substance that (1) in July 1990, an individual had overdosed on Demerol received from the owner-manager pharmacist of G & O Pharmacy, Randall Lockhart, without the benefit of a prescription; (2) accountability audits conducted of G & O Pharmacy by DEA investigators in 1990 revealed shortages of Schedules II and III controlled substances; (3) G & O Pharmacy had filled at least 217 call-in prescriptions not authorized by the physicians whose names appeared on the pharmacy's records; and (4) at least one individual, on multiple occasions, had received controlled substances from Mr. Lockhart without seeing the physician listed on the call-in prescription.

Following prehearing procedures, a hearing was held in Louisville, Kentucky, on March 10 and 11, 1993. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. Subsequently, on December 16, 1993, counsel for the Government filed a motion to reopen the proceedings, alleging that Mr. Lockhart transferred ownership of G & O to AML Corporation (AML). The motion also alleged that AML had applied for and received DEA Certificate of Registration BA3838553 to operate G & O and that DEA had not been notified

pursuant to 21 CFR 1301.62 and 1307.14(b) (both sections presently designated as section 1301.52). The motion further alleged that G & O Pharmacy had ceased doing business under its previous ownership or that Mr. Lockhart had transferred ownership to another entity. When G & O failed to respond to the Government's motion, Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an order reopening the proceedings in Docket No. 92-78.

On March 11, 1994, an Order to Show Cause was issued to AML d/b/a G & O Pharmacy (containing the same allegations as those raised in the July 23, 1992, Order to Show Cause) alleging that its continued registration was inconsistent with the public interest. The Order to Show Cause further alleged that Mr. Lockhart had improperly transferred ownership of G & O without notifying DEA as required. Following the consolidation of the two cases, a hearing was conducted on November 17, 1994.

After finding that the continuance of a registration would be inconsistent with the public interest, the then-Deputy Administrator of DEA revoked DEA Certificate of Registration BA3838553 previously issued to AML Corporation d/b/a G & O Pharmacy. See, AML Corporation d/b/a G & O Pharmacy, and G & O Pharmacy, 61 FR 8973 (March 6, 1996). The Acting Administrator finds that the findings of fact and conclusions of law, which led to the revocation of AML/G & O's DEA Certificate of Registration, are set forth in great detail in the referenced final order. They will not be repeated in this final order, but are incorporated herein and will be referred to as necessary in rendering a decision in this matter.

G & O has a documented history of non-compliance with DEA laws and regulations. From 1989 to 1991 while registered under DEA registration number AG2999691, the pharmacy dispensed 24 vials of Demerol, a Schedule II controlled substance, to a dentist without a valid prescription. It was later determined that these drugs were dispensed for the dentist's personal use. Accountability audits conducted by DEA investigators of G & O's controlled substances revealed significant shortages of various Schedules II, III, and IV controlled substances and the pharmacy filled numerous prescriptions for controlled substances that were not authorized by physicians whose names appeared on the prescriptions. In addition, Mr. Lockhart improperly transferred ownership of G & O to AML without

¹ On the July 18, 2001 application for DEA registration, Mr. Lockhart listed the business address of the pharmacy as "G & O Pharmacy of Paducah Inc."

notifying DEA as required by the agency's regulations.

The Acting Administrator also finds that effective March 17, 1999, Mr. Lockhart and the Kentucky Board of Pharmacy (Board) entered into an Agreed Order with respect to Mr. Lockhart's license to practice pharmacy in that state. Among the factual findings agreed upon by the parties was that in September 1997, Mr. Lockhart made a false or fraudulent statement or misrepresentation of a material fact to the Board in securing renewal of his pharmacist license. As a result, Mr. Lockhart was ordered to pay a fine of \$1,000 and obtain ten hours of continuing education.

The parties entered into a second Agree Order on September 13, 2000, when it was determined that Mr. Lockhart failed to submit evidence of continuing education hours as required by the order of March 17, 1999. As a result, Mr. Lockhart was fined \$500, and ordered to obtain an additional 6.5 hours of continuing education within six months of the entry of the Agreed Order.

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

- (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 or safety.

These factors are to be considered in the disjunctive; the Acting Administrator may rely on any one or a combination of factors and may give each factor the weight he 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 16,422 (1989).

Regarding factor one, recommendation of appropriate state licensing board or professional disciplinary authority, in 1997 and again in 2000, Mr. Lockhart's license to practice pharmacy was subject to review and sanction by the Kentucky Board of

Pharmacy. These actions were based upon Mr. Lockhart's misrepresentations on a renewal application regarding his continuing education, and his failure to obtain continuing education as required by the Board.

Factors two and four, experience in dispensing controlled substances and compliance with applicable controlled substance laws are relevant in determining whether G & O's registration would be inconsistent with the public interest. The then-Deputy Administrator previously found that Mr. Lockhart's improperly dispensed Schedule II controlled resulting in the transfer of 24 dosage units of Demerol to a dentist for his personal use. 61 FR at 8976. Further, accountability audits conducted by DEA investigators revealed shortages of over 40,000 dosage units of various Schedules II through IV controlled substances with no evidence adduced by G & O to explain the shortages. In addition, DEA's previous investigation of G & O revealed that the pharmacy unlawfully dispensed controlled substances in which approximately 198 prescriptions retrieved from the pharmacy were not authorized by the physicians whose names appeared on the pharmacy records. Such conduct is grounds for denying G & O's pending application for DEA registration.

In addition, Mr. Lockhart and G & O demonstrated non-compliance with DEA regulations when Mr. Lockhart transferred ownership of G & O to AML. Pursuant to 21 CFR 1307.14(b) (since redesignated as 21 CFR 1301.52), Mr. Lockhart was required to provide the Special Agent in Charge in his area specific information at least 14 days in advance of the date of the proposed transfer of his ownership in G & O. The record before the Acting Administrator reveals that Mr. Lockhart failed to inform DEA of the transfer.

As to factor five, the Acting Administrator finds relevant a finding in the previous proceeding that the transfer of ownership from G & O to AML was not a bona fide transaction, but as Judge Bittner described, "a stratagem to obtain a new DEA registration." 61 FR at 8976. The apparent ruse designed to secure a DEA Certificate of Registration demonstrates a disturbing willingness on the part of Mr. Lockhart to engage in dishonest conduct, and further weighs in favor of denying G & O's pending application. Similarly, factor five is relevant to Mr. Lockhart's use of false information on the application for renewal of his pharmacist license. It is well settled that a registration of pharmacy may be revoked or application denied based on

the wrongdoing of its owner or officers, *Crosstown Drugs*, 54 FR 28521 (1989). See also, *Alexander Drug Company, Inc.*, 66 FR 18299 (2001).

It is clear that G & O's past experience in handling controlled substances is dismal at best. The pharmacy, through its owner Randall Lockhart improperly dispensed controlled substances, including instances where the pharmacy failed to obtain physician authorization and G & O also failed to account for shortages of large quantities of controlled substances. Mr. Lockhart further engaged in the deceptive transfer of his ownership interest in G & O to another entity for the purpose of securing a DEA registration.

The Acting Administrator acknowledges that most of these events took place more than ten years ago. However, in light of G & O's failure to request a hearing in this matter, and the absence of evidence to rebut the above allegations, the Acting 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. This conclusion is further supported by evidence that Mr. Lockhart has continued to engage in dishonest conduct by providing false information on a state professional application, resulting in fines and further conditions being placed on his pharmacist license. In view of the foregoing, the Acting Administrator concludes that G & O cannot be entrusted to handle controlled substances, and the granting of its application would not be in the public interest.

Accordingly, the Acting Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him 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 submitted by G & O Pharmacy of Paducah, Incorporated be, and it hereby is, denied. This order is effective August 25, 2003.

Dated: July 3, 2003.

William B. Simpkins,

Acting Administrator.

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