

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 DEA Certificates of Registration BC2335912 and BC5019395, previously issued to Bryant D. Chomiak, M.D., be, and they hereby are, revoked. The Deputy Administrator further orders that any pending applications for the renewal of such registrations, be, and they hereby are, denied. This order is effective September 7, 1999.

Dated: July 27, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99-20239 Filed 8-5-99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 26, 1999, and published in the **Federal Register** on May 7, 1999, (64 FR 24678), Dupont Pharmaceuticals, 1000 Stewart Avenue, Garden City, New York 11530, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Oxycodone (9143)	II
Hydrocodone (9193)	II
Oxymorphone (9652)	II

The firm plans to manufacture the listed controlled substances to make finished products.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Dupont Pharmaceuticals to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Dupont Pharmaceuticals on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.104, the Deputy Assistant Administrator, Office of Diversion

Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: July 22, 1999.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98-27]

Roger Lee Kinney, M.D.; Grant of Restricted Registration

On March 17, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Roger Lee Kinney, M.D. (Respondent) of Sapulpa, Oklahoma, notifying him of an opportunity to show cause as to why DEA should not deny his application for registration as a practitioner pursuant to 21 U.S.C. 823(f), for reason that his registration would be inconsistent with the public interest.

By letter dated April 15, 1998, Respondent, through counsel, requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Tulsa, Oklahoma on July 21, 1998, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. On January 22, 1999, Judge Randall issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, recommending that Respondent's application for registration be granted subject to various conditions. Neither party filed exceptions to Judge Randall's opinion, and on April 12, 1999, Judge Randall transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts in full the recommended rulings, findings of fact, conclusions of law and decision of the Administrative Law Judge. His adoption

is in no manner diminished by any recitation of facts, issues or conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that Respondent graduated from medical school in 1966, and entered private practice in Sapulpa, Oklahoma in 1967, as a general or family practitioner. He has been a staff member at the only local hospital for approximately 30 years. There are 14 active staff positions at the hospital and it serves a fairly rural area consisting of approximately 58,000 people.

During the early 1980s, Respondent purchased and ingested cocaine. The record is not clear as to the extent of Respondent's abuse of cocaine. However according to Respondent, he last ingested cocaine on August 8, 1985. There is also some evidence in the record that in 1981, Respondent dispensed and distributed Preludin, a Schedule II controlled substance, not in the usual course of his professional practice or for legitimate medical or research purposes.

In 1985, a federal grand jury charged Respondent with an 82-count indictment, which include counts for illegal distribution of a controlled substance, conspiracy to distribute cocaine, and income tax evasion. According to Respondent, he pled guilty to at least 14 felony counts, among them, conspiracy, illegal distribution, and tax evasion, and he was sentenced to four years incarceration. However, the Deputy Administrator is unable to determine exactly what charges Respondent was convicted of, since no judgment order was entered into evidence. Further, while Respondent pled guilty to some charges and he admitted in his 1990 application for a DEA Certificate of Registration that he has been convicted of illegal distribution of controlled substances "which stemmed from a problem of substance abuse," the Government did not present any evidence of the underlying fact of the investigation which led to Respondent's indictment and ultimate conviction. Therefore, the Deputy Administrator is unable to determine the extent and severity of Respondent's unlawful conduct.

Respondent consented to the suspension of his medical license during the period of his incarceration. Thereafter, on February 24, 1986, the Oklahoma State Board of Medical Examiners (Board) suspended Respondent's medical license. While incarcerated, Respondent participated in a drug rehabilitation program. His sentence was later reduced to three years incarceration because of his

cooperation with the Government, and he ultimately served approximately 20 to 22 months of his sentence before being released.

Upon his release, Respondent spent four months at a halfway house, where he was subject to random drug testing six times per month. Following his stay at the halfway house, Respondent was on court-ordered probation for four years, during which time he was randomly tested for drugs once or twice a month. According to Respondent, he never failed any of these drug tests, and the Government presented no evidence to the contrary. Following his incarceration, Respondent participated for several years in an impaired physicians group that met weekly. Respondent testified that he stopped participating in any drug rehabilitation programs or support groups in 1995, "because I didn't seem to have any inclination to do drugs anymore."

On May 19, 1987, the Board conditionally reinstated Respondent's medical license and placed it on probation for five years. Among the conditions imposed by the Board were that Respondent could not prescribe, administer or dispense controlled substances without specific approval from the Board; that he would submit to biological fluid testing at his expense; and that he would abstain from personally using alcohol or any controlled substance unless lawfully prescribed by his physician. Thereafter, on October 19, 1987, the Board modified its previous order, thereby allowing Respondent to prescribe, administer or dispense controlled substances "for emergency room in-patients under the conditions that a fully licensed physician countersign the order within 36 hours and * * * that no controlled dangerous substances may be taken off the premises of the emergency room by any patient." Respondent complied with these conditions.

As a result, the Board terminated Respondent's probation effective October 26, 1989. In its "Order Terminating Probation," the Board commended Respondent for his compliance with the terms and conditions of his probation. Once his probation was terminated, there were no restrictions on Respondent's ability to prescribe, dispense or administer controlled substances in the hospital, using the hospital's DEA registration number. The pharmacist at the hospital testified that Respondent has never asked her to fill a controlled substance prescription for one of Respondent's outpatients.

On January 31, 1990, the Oklahoma State Bureau of Narcotics and

Dangerous Drugs Control (OBN) found that Respondent was addicted to cocaine and had been convicted of a felony; denied Respondent's request for a state controlled substance registration at that time; but granted the registration with an effective date of June 1, 1990. There is no evidence that Respondent has misused his state controlled substance license since it was reinstated.

On June 8, 1990, Respondent submitted an application for a DEA Certificate of Registration. In investigating this application, a DEA investigator visited 16 area pharmacies to gather information Respondent's prescribing habits. During the course of this pharmacy survey, the investigator discovered a prescription written by Respondent on December 11, 1991, for Tussi-Organidin, a Schedule V controlled substance. Tussi-Organidin is a cough syrup that contains codeine phosphate. There is also a non-controlled substance called Tussi-Organidin DM, which contains dextromethorphan rather than codeine. Since Tussi-Organidin is a controlled substance, Respondent was not authorized at that time to issue a prescription for it for a clinic patient; but, he was authorized to prescribe Tussi-Organidin DM. Further, Respondent was authorized at that time to issue a prescription for Tussi-Organidin in a hospital setting. Therefore, is it possible that Respondent simply forgot to put the "DM" on the prescription for Tussi-Organidin. Had "DM" been written on the prescription, it would have been for a non-controlled substance and it would have been lawfully prescribed by Respondent for his clinic patient.

In investigating the origin of this prescription, the investigator was told by an unnamed person "to discount it being written by Dr. Kinney * * * [it] was going to be changed to another physician's name and DEA number." Respondent was not informed that the prescription as written was inaccurate, and DEA did not contact the patient as part of the investigation. According to Respondent, the individual had been a patient of his for a number of years.

As a result of this investigation, an order to Show Cause was issued proposing to deny Respondent's 1990 application for a DEA Certificate of Registration. Before the case could proceed to a hearing however, Respondent withdrew his application. DEA has not conducted any investigation of Respondent since this 1991 investigation.

At some point following his reinstatement by the Board, Respondent

practiced medicine part-time at a medical clinic owned by the local hospital. While there, Respondent prescribed injectable Nubain, a non-controlled substance, to his patients. At some point, the clinic manager told Respondent that she would no longer maintain a supply of Nubain because of Respondent's past licensing history. Because there are very few non-controlled analgesics that can be substituted for Nubain, Respondent began purchasing injectable Nubain from pharmacies to administer to his patients.

When Respondent left the clinic and only practiced at the hospital, he stopped purchasing Nubain, because the hospital pharmacy maintained a supply of it. In addition, the clinic where Respondent currently works also purchases Nubain for clinic use. According to Respondent, he has never self-administered Nubain, and the Government did not present any evidence that Respondent was using or abusing Nubain, or that he was unlawfully prescribing it for his patients.

Respondent submitted another application for registration with DEA dated October 16, 1996. According to Respondent, it is becoming increasingly difficult for him to treat patients, since he is unable to participate in many managed care programs without a DEA registration.

Currently, Respondent has staff privileges at the local hospital. At the hospital, Respondent also performs surgery, serves as anesthesiologist, works in the emergency room, and is the director of the Skilled Nursing Unit. Typically, Respondent is in surgery five days a week as the primary surgeon or the practicing anesthesiologist. Also, Respondent currently works at a clinic that is owned by the hospital.

Presently, Respondent tries to treat his clinic patients without the use of controlled substances. However, if a controlled substance is necessary, Respondent refers patients directly to another physician who is considered the "patriarch" of the hospital or Respondent asks him to consult on a case and to prescribe a controlled substance for the patient if necessary. However, this physician is 93 years old with significant health problems, and will likely not be practicing for too much longer. If Respondent does not have his own DEA registration and this other physician retires, Respondent will need to find another physician to examine his patients and prescribe controlled substances when necessary.

Respondent's handling of controlled substances at the hospital is subject to

several levels of review. Respondent's orders have never been questioned or reversed. Respondent has been "in good standing" with the hospital at all time.

The number of patients requiring medical care in the Sapulpa area has increased significantly in recent years. If Respondent is not granted a DEA registration, medical care in Sapulpa would suffer since he would be unable to treat a number of patients because he is not allowed to participate in managed care programs.

Based upon Respondent's testimony at the hearing, it is clear that he recognizes the unlawfulness of his prior conduct and appreciates the consequences of such activities.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration, if he determines that the 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 Deputy 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. Schwarz, Jr., M.D.*, 54 FR 16422 (1989).

Regarding factor one, it is undisputed that the Board suspended Respondent's medical license in 1986, but then conditionally reinstated it in 1987 and placed it on probation for five years. Then in 1989, the Board lifted the restriction from Respondent's medical license and terminated the probationary period. It is also undisputed that the OBN initially denied Respondent's application for a state controlled substance registration, but then granted him such a registration in June 1990. Thus, Respondent has had an unrestricted medical license in Oklahoma since 1989 and has been authorized to handle controlled

substances in that state since 1990. As Judge Randall stated, "[b]y reinstating both these licenses, over eight years ago, the Board and the OBN have asserted their belief that the Respondent is not a threat to the health or safety of the citizens of Oklahoma."

Factors two and four, Respondent's experience in handling controlled substances and his compliance with applicable controlled substance laws, are clearly relevant in determining the public interest in this matter. Respondent admitted that he purchased and abused cocaine in the early 1980's. However, according to Respondent he has been drug-free since 1985.

In addition, based upon his guilty pleas to a number of criminal charges, there is evidence that Respondent illegally distributed Preludin in the early 1980s. However, without any evidence of the underlying facts that led to Respondent's guilty pleas, the Deputy Administrator is unable to determine the extent and severity of this illegal activity. Nonetheless, the Government has established that at least to some extent, Respondent improperly handled controlled substances and violated relevant controlled substance laws in the early 1980s.

More recently, the Government presented evidence that in 1991, Respondent issued a prescription for the controlled substance Tussi-Organidin to a clinic patient, when he was not authorized to do so. As Judge Randall stated, "[c]onsidered alone, this assertion satisfies the Government's *prima facie* burden." However like Judge Randall, the Deputy Administrator finds Respondent's evidence concerning this allegation compelling. Respondent was authorized to prescribe Tussi-Organidin in a hospital setting using the hospital's DEA registration number. Further, he was authorized to prescribe Tussi-Organidin DM, a non-controlled substance, to his clinic patients. Since this was the only improper prescription found during the DEA investigator's survey of 16 pharmacies, Respondent's contention is credible that he simply forgot to write "DM" on the prescription for his clinic patients. As Judge Randall noted, "the seizure of only one prescription indicates that there was no pattern of unauthorized prescribing by the Respondent during this time frame." The Deputy Administrator agrees with Judge Randall that "the existence of this single prescription dated in 1991 for Tussi-Organidin lends little support to the Government's position that granting the Respondent's application in 1999 is inconsistent with the public interest."

The Deputy Administrator finds that while Respondent's behavior in the

early 1980s is troubling, it is also significant that other than the one prescription in 1991, there have been no allegations of any improper handling of controlled substances. In fact, Respondent has been handling controlled substances in a hospital setting using the hospital's DEA registration number for a number of years without any problems or questionable conduct.

As to factor three, it is undisputed that Respondent was convicted of charges related to the illegal distribution of a controlled substance and conspiracy. Respondent was incarcerated for 20 to 22 months, and after spending four months in a halfway house, he was placed on probation for four years. Respondent successfully completed his probation.

Regarding factor five, the Government argues that Respondent's purchase of Nubain during 1990 and 1991, is evidence of other conduct which may threaten the public health and safety. The Government contends that Respondent's explanation, that he purchased the Nubain to administer to his patients, was not credible. However, the Government has the burden of proof in these proceedings. The mere fact that Respondent purchased Nubain is not evidenced of any wrongdoing. The Government did not present any evidence that Respondent's purchase of this non-controlled substance was improper. To the contrary, Respondent was authorized to handle Nubain at that time. Respondent explained that he purchased the Nubain because the clinic where he was then employed stopped stocking the drug, and he ceased purchasing Nubain once it became available to him to dispense to his patients at the hospital.

Also relevant under this factor is Respondent's abuse of cocaine. While it is troubling that Respondent stopped actively participating in a recovery program in 1995, he has not illegally used drugs since August 1985.

The Deputy Administrator concludes that Respondent's conduct in the early 1980s and his lack of ongoing participation in a recovery program warrants concern as to whether Respondent can be trusted to responsibly handle controlled substances. However, Respondent has accepted responsibility for his past misconduct; he has complied with all of the terms of his criminal probation, as well as the restrictions placed on his medical license by the Board; there is only one instance of questionable prescribing since the early 1980s; and he has not abused controlled since 1985.

Additionally, the Deputy Administrator finds it significant that without a DEA registration, Respondent is unable to effectively contribute to the medical care of the Sapulpa community. There are only 14 active physicians employed by the sole hospital responsible for the care and treatment of approximately 58,000 people. Because Respondent cannot independently handle controlled substances and is unable to participate in managed care programs, the other physicians at the hospital must handle more than their share of the patients.

The Deputy Administrator concludes that based upon a review of the record, denial of Respondent's application is not warranted. However, the Deputy Administrator concurs with Judge Randall's conclusion that although, "the Respondent should be allowed the opportunity to demonstrate that he can now handle the responsibilities of a DEA registrant, * * * the public interest would best be served by monitoring the Respondent's handling of controlled substances during the first registration period." Imposing conditions upon Respondent's registration, "will allow the Respondent to demonstrate that he can responsibly handle controlled substances in his medical practice, yet simultaneously protect the public by providing a mechanism for rapid detection of any improper activity related to controlled substances." Steven M. Gardner, M.D., 51 FR 12576 (1986).

Therefore, the Deputy Administrator agrees with Judge Randall's recommendation that Respondent's application for registration be granted, pursuant to the following restrictions for three years from the date of issuance of the DEA Certificate of Registration:

(1) On a quarterly basis, Respondent shall provide the DEA Oklahoma City Resident Office with a log of his handling of controlled substances outside of the Bartlett Hospital setting. This log should include at a minimum the date the controlled substance was prescribed, administered, or dispensed; the patient's complaint; the name, dosage, and quantity of the controlled substance prescribed, administered, or dispensed; and the date that the medication was last prescribed, administered, or dispensed to that patient, as well as the amount last provided to that patient. If no controlled substance are prescribed, administered, or dispensed during a given quarter, Respondent shall indicate that fact in writing, in lieu of submission of the log.

(2) Respondent shall notify the DEA Oklahoma City Resident Office of any

action taken by any state upon his medical license or upon his authorization to handle controlled substance in any state. Such notification shall occur within 30 days of any state action.

(3) Respondent shall notify the DEA Oklahoma City Resident Office within 30 days of any change in his employment.

Accordingly, the Deputy 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 registration submitted by Roger Lee Kinney, M.D., be, and it hereby is, granted subject to the above described restrictions. This order is effective upon the issuance of the DEA Certificate of Registration, but no later than September 7, 1999.

Dated: July 27, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99-20231 Filed 8-5-99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lawson and Associations; Denial of Application

On November 5, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Lawson and Associates, of Nashville, Tennessee, notifying it of an opportunity to show cause as to why DEA should not deny its application for a DEA Certificate of Registration as a researcher pursuant to 21 U.S.C. 823(f), for reason that is not currently authorized to handle controlled substances in the State of Tennessee. The order also notified Lawson and Associates that should no request for a hearing be filed within 30 days of receipt of the Order to Show Cause, its hearing right would be deemed waived.

DEA received a signed receipt indicating that the Order to Show Cause was received on November 23, 1998. No request for a hearing or any other reply was received by the DEA from Lawson and Associates or anyone purporting to represent it in this matter. Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Lawson and

Associates is deemed to have waived its hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that DEA registers dog handlers as researchers pursuant to 21 U.S.C. 823(f). The Deputy Administrator further finds that there is a letter in the investigative file dated June 9, 1997, from the Tennessee Board of Pharmacy which indicates that Lawson and Associates was issued a license as a dog handler on November 15, 1995, but that the license expired on November 30, 1996, and has not been renewed. Lawson and Associates did not present any evidence to indicate that it was currently licensed in Tennessee as a dog handler.

The Deputy Administrator concludes that Lawson and Associates is not currently licensed as a dog handler in the State of Tennessee and therefore, it is reasonable to infer that it is not currently authorized to handle controlled substances in that state. The DEA does not have the statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without states authority to handle controlled substances in the state in which it conducts its business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See Romeo J. Perez, M.D., 62 FR 16193 (1997); Demetris A. Green, M.D., 61 FR 60,728 (1996); Dominick A. Ricci, M.D., 58 FR 51104 (1993).

Here it is clear that Lawson and Associates is not currently authorized to handle controlled substances in the State of Tennessee. As a result, it is not entitled to a DEA registration in that state.

Accordingly, the Deputy 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 registration submitted by Lawson and Associates, be, and it hereby is, denied. This order is effective August 6, 1999.

Dated: July 27, 1999.

Donnie R. Marshall,

Deputy Administrator.

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