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Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

Issued: May 28, 1999.

By order of the Commission.

Donna R. Koehnke,
Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98-10]

Lawrence C. Hill, M.D.; Conditional Grant of Restricted Registration

On January 2, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Lawrence C. Hill, M.D. (Respondent) of Monroe, Louisiana, notifying him of an opportunity to show cause as to why DEA should deny his pending 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 January 30, 1998, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Monroe, Louisiana on May 6 and 7, 1998, before Administrative Law Judge Mary Ellen Bittner. 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 October 30, 1998, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's application for registration be granted. Neither party filed exceptions to the Administrative Law Judge's recommended decision, and on December 2, 1998, Judge Bittner 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 the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, except as specifically noted below. His adoption is in no manner diminished by any recitation of facts, issues and 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 1976 and entered private practice as a general practitioner in 1977. In 1976, Respondent was issued DEA Certificate of Registration AH7179725, which he allowed to expire on October 31, 1980. According to Respondent, he moved office locations without advising DEA of his new address, and as a result he did not receive the renewal application for his registration.

In July 1987, Respondent called DEA's New Orleans Field Division and requested that he be issued DEA order forms to enable him to purchase Schedule II controlled substances. Respondent was informed that his DEA registration had expired and that he would need to apply for and receive a new registration before he could again handle controlled substances. On July 16, 1987, Respondent executed an application for a new DEA registration. On that same day a DEA investigator visited Respondent at his office and reiterated that his previous DEA registration had expired and that he could no longer handle controlled substances until he received a new DEA registration. On July 20, 1987, Respondent contacted the investigator's supervisor to verify what he had been told. Respondent was again advised that he could not handle controlled substances until he received a new DEA registration.

On August 13, 1987, the investigator visited the pharmacy located across the street from Respondent's office. The investigator discovered that Respondent had issued 44 controlled substance prescriptions since July 17, 1987, when she had advised him that he was not authorized to handle controlled substances. A subsequent review of another pharmacy's records revealed that Respondent issued an additional 54 controlled substance prescriptions between July 17 and August 13, 1987.

The investigator questioned Respondent about these prescriptions. Respondent indicated that another physician had agreed to "cover" his prescriptions. Respondent was again advised that he could not handle controlled substances until he received

a new DEA registration. After the investigator left his office, Respondent telephoned DEA's New Orleans Field Division to confirm that he was not permitted to handle controlled substances.

On August 21, 1987, the owner of the pharmacy located across the street from Respondent's office called the DEA investigator and informed her that a friend of his had recently visited Respondent and was given a medication bottle filled with Lorcet, a Schedule III controlled substance, and Valium, a Schedule IV controlled substance, in exchange for \$5.00. During a subsequent interview, the individual confirmed this information and also indicated that Respondent had dispensed Vicodin, a Schedule III controlled substance, to the individual's wife on August 27, 1987.

As a result of this information, the DEA investigator contacted several pharmaceutical companies to determine whether Respondent had ordered any controlled substances since July 16, 1987. One company indicated that on September 16, 1987, Respondent had requested 100 dosage units of Lorcet and 100 dosage units of Lorcet Plus misrepresenting that his expired DEA registration AH7179725 would expire on October 31, 1987. A second company advised that since July 17, 1987, Respondent had requested and received controlled substances such as Valium, Dalmane and Limbitrol, all Schedule IV controlled substances. Finally, the records of a third company showed that Respondent used his expired DEA registration on July 28, 1987 to request 100 dosage units of Vicodin.

Based upon this information, several undercover visits were made to Respondent's office in an attempt to determine whether Respondent would prescribe, dispense or administer controlled substances to the undercover officers. No controlled substances were obtained by the undercover officers.

On December 9, 1987, a search warrant was executed at Respondent's office and investigators found, among other things, a small amount of controlled substances. Respondent told the investigators that he did not realize that there were still controlled substances in his office and that he thought that he had disposed of all of them. During execution of the warrant, records of patients who had received controlled substances from Respondent were seized. These records were then turned over to the Louisiana State Board of Medical Examiners (Medical Board) for its review.

In November 1988, Respondent withdrew his pending application for registration with DEA after he received

an Order to Show Cause proposing to deny the application.

Based upon its review of information received from DEA, the Medical Board filed an Administrative Complaint against Respondent alleging that Respondent prescribed, administered or dispensed controlled substances to 11 patients, "in amount, frequency, and duration, in excess of any legitimate justification." Rather than have these charges adjudicated at a hearing, Respondent entered into a Consent Order with the Medical Board on June 12, 1989, however he did not admit the accuracy of the allegations. Pursuant to the Consent Order Respondent's medical license was suspended for six months, and then placed on probation until June 1, 1999. Respondent was prohibited from handling controlled substances for the duration of his medical career; fined \$5,000; and ordered to attend at least 50 credit hours per year of continuing medical education.

The United States Attorney's Office contemplated criminally prosecuting Respondent for using an expired DEA registration to prescribe and order controlled substances. However, criminal prosecution was declined in light of Respondent's agreement to a lifetime suspension of his controlled substance authority as contained in the Consent Order with the Medical Board. For the same reasons, the United States Attorney's Office declined to pursue a civil complaint against Respondent.

However, on August 10, 1994, the Medical Board issued a letter to Respondent, notifying him that "the Board voted to grant your request for release from your probation and allow you to apply for your DEA privileges." As a result, Respondent submitted the application that is the subject of these proceedings.

At the hearing in this matter, the Government introduced a letter to DEA dated July 28, 1995, from the United States Attorney for the Western District of Louisiana objecting to Respondent being granted a DEA registration. According to the United States Attorney a "key factor" in the decision not to criminally prosecute Respondent in 1989 was his agreement to forfeit, for life, his privilege to handle controlled substances. He further stated that "had this office known [Respondent] would not live up to his word, this office would have vigorously prosecuted him."

Respondent testified at the hearing that as a result of the suspension of his medical license he closed his medical practice. He further testified that after the investigation, he "went through a

tremendous amount of self-directed anger for having been so wrong-headed and you might say willful, and anger was translated at one point into depression, and I became very depressed."

In 1989, Respondent entered the residency program at E.A. Conway Hospital, Louisiana State University Monroe Medical Center in Monroe, Louisiana (LSU Monroe Medical Center). Respondent was considered an impaired physician because according to the hospital's medical director, "he just frankly didn't believe that the rules applied to himself * * *." As a result, Respondent was closely monitored during his residency. During the final year of his residency, Respondent was elected chief resident.

After graduating from the residency program in 1992, Respondent was offered a position at the emergency room at LSU Monroe Medical Center, where he was still working as of the date of the hearing. Respondent administers and dispenses controlled substances using the hospital's DEA registration, however, he does not issue controlled substance prescriptions.

At the hearing, Respondent testified that following the lifting of his probation, he applied for and received his Louisiana controlled substance license, however he let it lapse since he did not have a DEA registration. Following the hearing, on July 7, 1998, Respondent introduced into evidence a copy of his Louisiana Controlled Dangerous Substance License with an expiration date of March 1, 1998.

After the Medical Board lifted his probation, Respondent became Board certified in family practice. To maintain his certification, he is required to attend at least 50 hours of continuing medical education each year.

A number of Respondent's supervisors and colleagues testified on his behalf at the hearing and/or wrote letters of recommendation for Respondent. Essentially it was the position of these physicians that Respondent does not pose a threat to the public health and safety; that he is a competent, hard working physician; that he is well respected by his peers; and that they have no hesitation in recommending that Respondent be issued a DEA registration.

Respondent testified that with respect to his handling of controlled substances in the 1980s he felt that he was "under-trained" and that he would do things differently now in light of all of his subsequent training. He further testified that he had learned from his mistakes and that although he has gone through difficult times because of those

mistakes, he feels that "it's been to (his) benefit." He stated that DEA "can take assurances that I will not break the rules again if I were to receive my DEA license again."

The Government contends that Respondent's application for registration should be denied because he continued to handle controlled substances after being told several times that he was not authorized to do so. Respondent contends that he made mistakes in his past, but he has been rehabilitated. He further asserts that he needs a DEA registration in order to better care for his patients.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if he determines that the continued 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. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

Regarding factor one, there is no dispute that in June 1989, the Medical Board issued a Consent Order that suspended Respondent's medical license for six months, placed him on probation for nine and one-half years, and prohibited him from handling controlled substances for life. It is also undisputed that in 1994, the Medical Board removed all restrictions from Respondent's medical license and permitted him to apply for a DEA Certificate of Registration.

However, what is in dispute is whether Respondent is currently authorized to handle controlled substances in Louisiana. Judge Bittner concluded that "Respondent also

received his Louisiana controlled substance license. Thus, Respondent is now fully licensed in Louisiana." The Deputy Administrator does not believe that such a conclusion can be drawn from the evidence in the record. At the hearing, Respondent testified that he allowed his state controlled substance permit to lapse since he was not registered with DEA. Judge Bittner kept the record open following the conclusion of the hearing to allow Respondent to present evidence that he is currently authorized to handle controlled substances in Louisiana, a prerequisite to DEA registration in that state. By letter dated July 7, 1998, counsel for Respondent forwarded a copy of Respondent's Louisiana controlled dangerous substance license. However, review of this license indicates that it expired on March 1, 1998. Therefore, there is a question as to whether Respondent is in fact currently authorized to handle controlled substances in Louisiana. This is significant because DEA does not have the statutory authority under the Controlled Substances Act to register a practitioner unless that practitioner is authorized by the state to handle controlled substances. See 21 U.S.C. 802(21) and 823(f).

As to factors two and four, Respondent's experience in handling controlled substances and his compliance with applicable laws relating to controlled substances, the evidence is clear that Respondent handled controlled substances, the evidence is clear that Respondent handled controlled substances in 1987 knowing that he was not authorized to do so. He used his expired DEA Certificate of Registration to prescribe, dispense, administer, and order controlled substances in violation of 21 U.S.C. 843(a)(2).

While there is some indication that Respondent may have excessively prescribed diet pills to 11 patients, the only evidence presented regarding this allegation is the Administrative Complaint filed by the Medical Board. As Judge Bittner noted, "[a]n Administrative complaint alone, however, fails to prove by a preponderance of the evidence that Respondent's DEA registration is not in the public interest." Like Judge Bittner, the Deputy Administrator does not rely on the allegations in the Medical Board's Administrative Complaint in rendering his decision regarding Respondent's application for registration.

There is also evidence in the record regarding Respondent's experience in handling controlled substances since

1987. Respondent has undergone extensive training in among other things, how to properly handle controlled substances. He has been working at LSU Monroe Medical Center since 1992 and has been administering and dispensing controlled substances under the hospital's DEA registration. There are no allegations that he has improperly handled controlled substances or failed to comply with controlled substance laws since 1987. In fact, Respondent's supervisors and colleagues are of the opinion that Respondent is a hard working, dedicated professional and that he is not a threat to the public health and safety.

Regarding factor three, there is no evidence that Respondent has ever been convicted under State or Federal laws relating to controlled substances.

Under factor five, the Government asserted that the only reason Respondent was not prosecuted for his use of his expired DEA registration to handle controlled substances was because he agreed with the Medical Board to the lifetime suspension of his ability to handle controlled substances. In his July 28, 1995 letter, the United States Attorney stated, "(Respondent) received the benefit of his agreement and now, when the statute of limitations prohibits (the United States Attorney's Office) from taking further action, he wants to 'renege' on the agreement." But as Judge Bittner noted "the only formal agreement that Respondent would not seek to handle controlled substances was between Respondent and the Medical Board, and neither the United States Attorney nor DEA has standing to assert any rights with regard to that agreement or to claim detrimental reliance on it."

Judge Bittner concluded that the Government presented a *prima facie* case for denying Respondent's application for registration based upon Respondent's use of his expired DEA registration to continue to handle controlled substances in the 1980s and the Medical Board's action against his medical license. Nonetheless, Judge Bittner concluded that Respondent's application should be granted. Respondent has admitted his mistakes, is remorseful, and has taken great steps to rehabilitate himself. He has the support of his supervisors and colleagues and has been handling controlled substances since at least 1992 using the hospital's DEA registration with no indication of any problems. Judge Bittner stated that "I am satisfied that Respondent now understands that the rules do apply to him and that there is little likelihood that his misconduct will recur."

The Deputy Administrator appreciates the concerns of the United States Attorney's Office. Respondent agreed with the Medical Board not to handle controlled substances for the duration of his medical career. In light of this agreement, the United States Attorney's Office declined to criminally or civilly prosecute Respondent for his wrongdoing. While it is true that there was no formal agreement with the United States Attorney's Office or DEA, Respondent clearly was aware that his agreement with the Medical Board was the reason that he was not criminally prosecuted. Then in 1994, Respondent sought to be released from his agreement with the Medical Board, and as a result, he is no longer prohibited from handling controlled substances.

However, the Deputy Administrator must look at the record as a whole to determine whether Respondent's registration is currently in the public interest. In light of Respondent's admission of wrongdoing and expressions of remorse; his training since 1989; and his handling of controlled substances since at least 1992 using the hospital's DEA registration with no problems, the Deputy Administrator agrees with Judge Bittner that it is in the public interest to issue Respondent a DEA Certificate of Registration.

But, given the egregious nature of Respondent's conduct in the 1980s and that he has not had his own DEA registration since 1980, the Deputy Administrator concludes that a restricted registration is appropriate. Respondent needs to demonstrate his ability to effectively and responsibly handle controlled substances with his own DEA registration. Imposing strict controls upon Respondent's registration "will allow 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 12,576 (1986), as cited in Michael J. Septer, D.O., 61 FR 53,762 (1996).

Therefore, for one year from the issuance of the DEA Certificate of Registration:

(1) Respondent shall maintain a log of all controlled substances that he prescribes. This log shall include at a minimum the name of the patient, the date of the prescription, and the name, strength and quantity of the controlled substance prescribed. This log shall be made available for inspection by DEA personnel.

(2) Respondent shall notify the Special Agent in Charge of the DEA New Orleans Field Division, or his designee, if he ceases to be employed at LSU Monroe Medical Center.

(3) If Respondent goes into private practice, he shall permit DEA personnel to conduct inspections of his registered location and of his controlled substance records without an Administrative Inspection Warrant.

However, having said that it is in the public interest to issue Respondent a restricted registration, DEA cannot issue him such a registration unless he is authorized to handle controlled substances by the state in which he practices. As discussed above, it is unclear whether Respondent possesses a current valid state controlled substance license. Therefore, the Deputy Administrator concludes that Respondent should be issued a DEA Certificate of Registration subject to the above described conditions once he provides evidence to DEA that he is authorized to handle controlled substances in Louisiana.

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 a DEA Certificate of Registration submitted by Lawrence C. Hill, M.D., be, and it hereby is granted subject to the above described conditions, upon receipt by the DEA New Orleans office of evidence of his state authorization to handle controlled substances. This order is effective June 4, 1999.

Dated: May 25, 1999.

Donnie R. Marshall,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Pablo E. Melgarejo, M.D.; Revocation of Registration

On November 17, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Pablo E. Melgarejo, M.D., of Orlando, Florida, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AM2026284 pursuant to 21 U.S.C. 824(a)(3), and deny any pending applications for renewal of such registration pursuant to 21 U.S.C. 823(f), for reason that he is not

currently authorized to handle controlled substances in the State of Florida. The order also notified Dr. Melgarejo that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent to Dr. Melgarejo by registered mail to his DEA registered address, but was returned with the notation "not deliverable as addressed, unable to forward." The Order to Show Cause was then sent to Dr. Melgarejo at another address in Florida. This time the order was returned to DEA with the notation that delivery had been refused. Information in the investigative file indicates that the records of the Florida State Attorney's Office in Orange County and the Florida Medical Board show that Dr. Melgarejo failed to appear at a criminal proceeding and has fled the United States.

The Deputy Administrator finds that DEA has made numerous attempts to locate Dr. Melgarejo and has determined that his whereabouts are unknown. It is evident that Dr. Melgarejo is no longer practicing medicine at the address listed on his DEA Certificate of Registration. The Deputy Administrator concludes that considerable effort has been made to serve Dr. Melgarejo with the Order to Show Cause without success. Dr. Melgarejo is therefore deemed to have waived his opportunity for a hearing. The Deputy Administrator now enters his final order in this matter without a hearing and based on the investigative file pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that on July 15, 1998, the Florida Board of Medicine issued an Order revoking Dr. Melgarejo's license to practice medicine effective July 21, 1998, based upon his sexual misconduct with patients.

The Deputy Administrator finds that Dr. Melgarejo is not currently authorized to practice medicine in Florida. It is reasonable to infer that he is also not 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 state authority to handle controlled substances in the state in which he conducts his business. 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 16,193 (1997); *Demetris A. Green, M.D.*, 61 FR 60,728 (1996); *Dominick A. Ricci, M.D.*, 58 FR 51,104 (1993).

Here it is clear that Dr. Melgarejo is not currently licensed to practice medicine or authorized to handle

controlled substances in the State of Florida. Therefore, Dr. Melgarejo is not entitled to a DEA registration in that state.

Accordingly, the Deputy Administration 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 DEA Certificate of Registration AM2026284, previously issued to Pablo E. Melgarejo, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for the renewal of such registration, be, and they hereby are, denied. This order is effective July 6, 1999.

Dated: May 25, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99-14101 Filed 6-3-99; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Neil Laboratories, Inc.; Suspension of Shipment

On August 7, 1998, the then-Acting Deputy Administrator of the Drug Enforcement Administration (DEA), issued an Order to Suspend Shipment to Neil Laboratories, Inc. of East Windsor, New Jersey, notifying it that a proposed shipment of 240 kilograms of pseudoephedrine to Oscar Barajas Gomez/Comercializadora Del Noroeste (Comercializadora) of Mexico was suspended pursuant to 21 U.S.C. 971 and 21 CFR 1313.41. The Order to Suspend Shipment stated that DEA believed that the listed chemical may be diverted. Specifically, the order provided Neil Laboratories, Inc.: (1) With the factual and legal basis for the suspension of the shipment; (2) with an opportunity to file a written request for a hearing within 30 days pursuant to 21 CFR 1313.51 through 1313.57; (3) with notice that, should it fail to request a hearing, it would be deemed to have waived the hearing; and (4) with notice that upon the expiration of the 30 day time frame, the Deputy Administrator may then enter his final order in this matter without a hearing.

The order was received by Neil Laboratories, Inc. on August 21, 1998. No request for a hearing has been received by DEA from Neil Laboratories, Inc., or anyone purporting to represent the company in this matter. Subsequently, the investigative file was transmitted to the Deputy Administrator for final agency action.