Dated: December 10, 1998.

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. 97–25]

Mary M. Miller, M.D.; Grant of Restricted Registration

On July 8, 1997, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mary Margaret Miller, M.D. (Respondent) of Louisville, Kentucky, notifying her of an opportunity to show cause as to why DEA should not deny her application for registration as a practitioner pursuant to 21 U.S.C. 823(f) and 824(a)(2).

By letter dated July 16, 1997, Respondent requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Frankfurt, Kentucky on December 10, 1997, 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 June 25, 1998, Judge Randall issued her Opinion and Recommended Ruling, recommending that Respondent be granted a DEA Certificate of Registration subject to several conditions. Neither party filed exceptions to the Opinion and Recommended Ruling of the Administrative Law Judge and on July 28, 1998, Judge Randall transmitted the record of these proceedings to the then-Acting Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts the Opinion and Recommended Ruling of the Administrative Law Judge, but includes an additional condition on Respondent's registration. 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 of law.

The Deputy Administrator finds that Respondent graduated from medical school in 1962 and obtained her first DEA registration in approximately 1963 while practicing in Colorado. In 1981, Respondent also became licensed to practice medicine in Kentucky.

In 1983, DEA noted that pharmacies in the Fort Collins, Colorado area were ordering large quantities of Schedule II controlled substances. Further investigation revealed that Respondent's name repeatedly came up as a large prescriber of Schedule II substances. As a result, DEA initiated an investigation of Respondent. An undercover DEA agent went to Respondent's office on five occasions to attempt to obtain controlled substance prescriptions for no legitimate medical purposes.

The first undercover operation was conducted on August 16, 1983, during which the undercover agent received prescriptions for Biphetamine and Seconal, both Schedule II controlled substances, from Respondent. Initially, the undercover agent told Respondent that she needed to lose weight, but later stated that she was a prostitute and that she needed Biphetamine to stay up all night and Seconal to allow her to sleep during the day. Respondent did not perform any physical examination and told the undercover agent not to fill the prescriptions in the Fort Collins area. Neither Biphetamine nor Seconal were acceptable for weight loss treatment in Colorado in 1983. Respondent later said that the prescribed substances were for narcolepsy and narcolepsy was noted on the prescriptions. However, there was no discussion regarding narcolepsy during this visit.

The undercover agent returned to Respondent's office on August 23, 1983, however she was unable to see Respondent on that day. The third undercover operation was conducted on September 15, 1983, during which the undercover agent obtained prescriptions from Respondent for Biphetamine, Seconal and Valium, a Schedule IV controlled substance. The undercover agent received the prescription for Valium after telling Respondent that she needed something to ''smooth her out'' between the Biphetamine and the Seconal. The undercover agent did not assert any medical complaints during this visit.

The undercover agent returned to Respondent's office on October 4, 1983. She obtained prescriptions for Biphetamine, Seconal and Valium from Respondent even though she did not give any medical reasons for needing the drugs. Respondent told the undercover agent to fill the prescriptions at different pharmacies and not to fill them at pharmacies in Fort Collins.

The final visit occurred on November 1, 1983, during which the undercover agent again obtained prescriptions for Biphetamine, Seconal and Valium from Respondent without giving any medical reason. Respondent again told the undercover agent not to have the prescriptions filled in Fort Collins. On this occasion the undercover agent asked for a prescription for another amphetamine and also asked for a prescription for a friend. Respondent refused both of these requests.

As a result of this investigation, Respondent was ultimately convicted on October 22, 1984, in the United States District Court of Colorado of 15 counts of distribution of controlled substances and prescriptions not issued for a letigimate medical purpose in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). Respondent was sentenced to 30 months imprisonment followed by 5 years probation and fined $75,000. She served 10 months in prison during which time she inactivated her Kentucky medical license.

As a result of her conviction, in October 1984 the Colorado Board of Medical Licensure (Colorado Board) suspended her medical license. Her license was reinstated in 1986.

According to Respondent, she abused alcohol during her criminal trial and again after her release from prison. After being confronted by her family about her alcohol abuse she entered an in-patient treatment facility for three months. Respondent testified that she has not consumed any alcohol since January 29, 1990. While in treatment, the Colorado Board suspended her medical license and on September 28, 1990, Respondent's Colorado medical license was revoked based upon her ''habitual intemperance'', referring to her abuse of alcohol.

Thereafter, Respondent applied for reinstatement of her Kentucky medical license which was denied by the Kentucky Board of Medical Licensure (Kentucky Board) in November 1992. The Kentucky Board recommended that Respondent get involved with the Kentucky Impaired Physicians Program (Kentucky Program). Respondent became involved with the Kentucky Program in 1993 and was required to attend four to six Alcoholics Anonymous (AA) meetings per week.

In December 1992, Respondent also became involved with an outpatient facility that treats alcohol and drug addiction. Respondent participated in the physicians' therapy group for approximately two years and agreed to

undergo random urine screens. Respondent still has monthly individual sessions with the executive director of the facility. The executive director testified at the hearing in this matter that he does not have any concern about Respondent relapsing, as long as she continues to attend to herself as a recovering alcoholic.

In March 1994, Respondent applied for and received Kentucky institutional medical license so she could work as a resident in family practice at the University of Louisville. Beginning on April 1, 1994, she worked in the residency clinic for six months and then spent six months on assigned rotations. During her residency training, Respondent continued to participate in the Kentucky Program.

In March 1995, the Kentucky Board granted Respondent a full Kentucky license with conditions. Respondent was placed on probation for five years, was required to maintain her contractual relationship with the Kentucky Program, and was required to have all controlled substance prescriptions co-signed by another physician.

On May 1, 1995, Respondent submitted the application that is the subject of these proceedings for registration in Schedules III narcotic, III non-narcotic, IV and V. On the application, Respondent fully disclosed her prior conviction, sentencing and rehabilitation information.

Thereafter, on September 22, 1997, the Kentucky Board entered an Amended Order of Probation striking the co-signature requirement and replacing it with a requirement that Respondent maintain a log of her controlled substance prescriptions. The log must include the date, patient name, patient complaint, medication prescribed, date it was last prescribed and the amount last prescribed.

In the meantime, Respondent applied for recertification by the American Board of Family Practice, since such certification is a requirement for hospital privileges. Respondent was advised that she was not eligible for recertification due to the revocation of her Colorado medical license. Consequently, Respondent applied for reinstatement of her Colorado medical license. On February 15, 1996, the Colorado Board reinstated Respondent's medical license with the condition that she never practice medicine in Colorado. The Colorado Board's action was taken solely to enable Respondent to sit for recertification with the American Board of Family Practice. At the time of the hearing, Respondent was still attempting to be recertified.

Since August 1996, Respondent has been working at a family heath care clinic with two locations in Kentucky. Respondent is one of three physicians affiliated with the clinics. One of the clinics is the only medical provider in the city and is approximately a thirty minute drive from the nearest hospital. Four out of five days a week, Respondent is the only physician at this location. The head and senior partner of the clinics testified at the hearing that he reviews the charts of the other physicians. He further testified that Respondent is very professional, responsible, ethical, hard-working and has a good medical judgment.

A physician and professor in the Family Practice Residency at the University of Louisville provided an affidavit stating that Respondent demonstrated good medical judgment and good ethical standards during her residency, and that she did not exhibit any signs of substance abuse. He recommended that Respondent be granted a DEA registration provided that she ''be followed by an appropriate organization who can monitor her continued recovery from alcoholism.''

Respondent testified that she takes full responsibility for her actions that led to her conviction and that she does not attribute her prior misconduct to her alcoholism. However, since 1990, Respondent's urine screens have never tested positive for alcohol or any other substance of abuse. At the time of the hearing, she was still enrolled in the Kentucky program, participating in monthly sessions with the executive director of the outpatient facility, attending AA meetings on a regular basis, and participating in health care professional meetings.

The medical director of the Kentucky Program testified that nationally, physicians involved in impaired physicians programs have a 90–95% recovery rate. He further testified that he does not believe that Respondent will relapase as long as she remains involved with her recovery efforts, and in his opinion, Respondent can handle the responsibilities of a DEA registrant.

Respondent testified that she needs a DEA registration to be able to treat acute trauma patients and patients with chronic pain with controlled substances. She also wants her registration because she has been denied privileges at area hospitals and her current employer has been denied participation in various insurance plans due to her lack of a registration.

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 such registration would be inconsistent with the public interest. In determining the public interest, the following factors are considered:

(1) The recommendation of 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 be denied. See *Henry J. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

Regarding factor one, it is undisputed that Respondent is currently licensed to practice medicine in Colorado and Kentucky. However, when Colorado granted Respondent a license in January 1996, it did so with the stipulation that Respondent never practice medicine in the state. In addition, Respondent's Kentucky medical license is currently on probation and she is required to maintain a log of her controlled substance prescribing.

As to factors two and four, Respondent's experience in dispensing controlled substances and her compliance with applicable laws relating to the handling of controlled substances, Respondent does not dispute that she issued controlled substance prescriptions to the undercover agent for no legitimate medical purpose in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). In addition, as Judge Randall noted, ''her instructions to [the undercover agent] not to fill all of the prescriptions at the same pharmacy demonstrate an understanding that she was acting improperly, as well as an effort to avoid detection.'' This egregious conduct by Respondent raises serious concerns about her ability to responsibly handle controlled substances.

However, the Deputy Administrator notes that Respondent's misconduct occurred 15 years ago, and there is no evidence of any wrongdoing since that time. In fact, during the ensuing years, Respondent has attempted to rehabilitate her career by participating in the family practice residency at the

University of Louisville and by working at the family health care clinics since 1996. However, as Judge Randall noted, ''since she has not been registered by the DEA to handle controlled substances for the past fifteen years she has lacked the opportunity to demonstrate that she can responsibly handle controlled substances.''

Regarding factor three, it is undisputed that in 1984, Respondent was convicted in the United States District Court for the District of Colorado of 15 counts of distributing controlled substances and issuing prescriptions for other than a legitimate medical purpose in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04.

As to factor five, the Deputy Administrator is concerned with Respondent's history of alcohol abuse. However, Respondent's sobriety date is Janaury 29, 1990. In addition, she has taken tremendous steps toward rehabilitating herself, and there was credible evidence presented at the hearing that Respondent is unlikely to relapse if she continues to attend to her recovery.

The Deputy Administrator concludes that Respondent's actions in 1983 were clearly contrary to the public interest and raise serious concerns regarding her fitness to be registered with DEA. However, the Deputy Administrator finds that there is evidence in the record that supports granting Respondent's application. Respondent's criminal conduct occurred 15 years ago. As has been previously determined, ''[t]he paramount issue is not how much time has elapsed since [Respondent's] unlawful conduct, but rather, whether during that time Respondent has learned from past mistakes and has demonstrated that [she] would handle controlled substances properly if entrusted with DEA registration.'' *Leonardo V. Lopez, M.D.,* 54 FR 36,915 (1989). Here, the Deputy Administrator finds it significant that Respondent has accepted responsibility for her past misconduct and fully disclosed her history on her application for registration. In addition, she has recently participated in a family practice residency program and has continued to practice medicine at the family health care clinics in Kentucky. Also, if granted a DEA registration, Respondent's controlled substance prescribing will be monitored by the Kentucky Board.

Concerning her alcoholism the Deputy Administrator agrees with Judge Randall's finding ''that the significant steps the Respondent has taken to rehabilitate herself demonstrate her commitment to her continuing recovery and to her profession.'' The Deputy Administrator also finds it noteworthy that according to the medical director of the Kentucky Impaired Physicians Program, the chance of Respondent relapsing is 90–95% if she continues with her recovery efforts.

Therefore, the Deputy Administrator agrees with Judge Randall's conclusion that Respondent should be given the opportunity to demonstrate that she can responsibly handle controlled substances. But in order to protect the public health and safety, some controls are warranted given her illegal prescribing of controlled substances, her conviction and her alcohol abuse. Imposing controls upon Respondent's registration ''will allow the Respondent to demonstrate that [she] can responsibly handle controlled substances in [her] 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).

Judge Randall recommended that Respondent's application be granted, provided that for three years Respondent must provide the local DEA office with a log of her controlled substance handling; she must maintain her contractual relationship with the Kentucky Impaired Physicians Program; and she must inform DEA of any action taken by any state upon her license or authorization to practice medicine or handle controlled substances. The Deputy Administrator agrees with Judge Randall's recommended restrictions, but concludes that Respondent should also be required to consent to periodic inspections by DEA without requiring an Administrative Inspection Warrant.

Therefore, the Deputy Administrator concludes that Respondent's application for registration in Schedules III, IIIN, IV and V should be granted subject to the following restrictions for three years from the date of issuance of the DEA Certificate of Registration:

1. On a quarterly basis, Respondent must provide the DEA Louisville Resident Office with a log, which at a minimum, should indicate: (1) the date that the controlled substance prescription was written, or such substance was administered or dispensed; (2) the name of the patient for whom the prescription was written, or to whom the substance was dispensed or administered; (3) the patient's complaint; (4) the name, dosage, and quantity of the substance prescribed, dispensed or administered; and (5) the date that the medication was last prescribed, dispensed or administered to that patient, as well as the amount last provided to that patient.

2. Respondent must maintain her contractual relationship with the Kentucky Impaired Physicians Program and abide by their recommendations.

3. Within 30 days, Respondent must inform the DEA Louisville Resident Office of any action taken by any state upon her medical license or upon her authorization to handle controlled substances.

4. Respondent shall consent to periodic inspections by DEA personnel based on a Notice of Inspection rather than an Administrative Inspection Warrant.

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 May 1, 1995 application for registration in Schedules III, IIIN, IV and V submitted by Mary M. Miller, M.D., be, and it hereby is, granted subject to the above described restrictions. This order is effective no later than January 21, 1999.

Dated: December 16, 1998.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 26, 1998, Noramco of Delaware, Inc., Division of McNeilab, Inc., 500 Old Swedes Landing Road, Wilmington, Delaware 19801, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below.

Drug	Schedule
Codeine (9050)	II
Oxycodone (9143)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Thebaine (9333)	II

The firm plans to manufacture the listed controlled substances for distribution to its customers as bulk product.

Any other such applicant and any person who is presently registered with