Dated: January 20, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02–24]

Karen A. Kruger, M.D.; Grant of Restricted Registration

On January 4, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Karen A. Kruger, M.D. (Respondent), proposing to deny her application for a DEA Certificate of Registration pursuant to 21 U.S.C. 823(f).

By letter dated April 9, 2002, the Respondent through her legal counsel requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held on December 10, 2002, in Chicago, Illinois. At the hearing, both parties called witnesses to testify, and the Respondent also testified on her behalf. Both parties also introduced documentary evidence. After the hearing, both parties submitted written proposed findings of fact, conclusions of law, and argument.

On April 23, 2003, Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (Opinion and Recommended Ruling), recommending that Respondent's application for registration be granted subject to certain conditions. Neither party filed exceptions to Judge Bittner's opinion, and on May 28, 2003, Judge Bittner transmitted the record of these proceedings to the then-Acting Administrator.

The Acting 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 Acting Deputy Administrator adopts in full the recommended ruling, findings of fact, conclusions of law and decision of the Administrative Law Judge. Her 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 record before the Acting Deputy Administrator shows that the Respondent received her medical degree from the Medical College of Wisconsin and is board certified in internal medicine and anesthesiology and board eligible in critical care medicine. The Respondent testified during the DEA hearing that she practiced as an anesthesiologist from 1986 until September 1999, and that during that period, there were no medical malpractice actions brought against her, nor did she lose staff privileges at any hospital.

The Respondent testified that in the early 1980s, she began taking diethylpropion, prescribing the drug to herself. Diethylpropion, a Schedule IV controlled substance, is used primarily for weight loss. Specifically, the Respondent testified that she called prescriptions into pharmacies under fictitious names, went to the pharmacies pretending to be the persons in whose names she had issued the prescriptions, and paid cash for and picked up the prescriptions. The Respondent further testified that while the recommended dosage for Tenuate (a brand name product containing diethylpropion) is one 75 mg. tablet daily, she developed a tolerance to the drug and eventually increased her use of the drug to as many as fifty tablets per day. The Respondent testified that she initially took Tenuate for weight control, but then began using it also for its properties as a stimulant.

The Government presented the testimony of a medical investigator and controlled substances inspector for the Illinois Department of Professional Regulation (IDPR). The inspector testified that an investigation of the Respondent was initiated in December 1999 as a result of information received from DEA regarding a pharmacist's concern over the Respondent's apparent prescribing of diethylpropion to three individuals at the same address.

In response to the above information, the IDPR inspector and a DEA diversion investigator interviewed the Respondent at her residence in Chicago on December 14, 1999. When informed of allegations that she had improperly prescribed controlled substances, the Respondent replied that as an anesthesiologist she rarely had occasion to prescribe, but she had prescribed Tenuate to six to ten friends. When asked by the IDPR inspector to identify these persons, the Respondent admitted that she had not prescribed to friends for about the last year, and instead, had issued prescriptions in fictitious names and then picked up the medications from the dispensing pharmacies herself.

During the interview, the Respondent also admitted during the interview that she telephoned bogus prescriptions to many chain and independent pharmacies in Chicago and its suburbs, using approximately forty different names, and that she took as many as 40 to 60 tablets per day for purposes of weight loss and to maintain alertness. The Respondent further admitted that she was probably psychologically addicted to diethylpropion, but willing to accept treatment for her addiction. The Respondent was then provided contact information for a physician involved with Illinois' Physician Assistance Program.

As part of its investigation of Respondent, DEA obtained from the Walgreens Company a printout of prescriptions that the Respondent called into various Walgreens pharmacies in the Chicago area. That printout, along with additional evidence presented at the hearing, revealed that between September 19, 1998 and September 4, 1999, Chicago-area Walgreens pharmacies filled more than 170 prescriptions that Respondent authorized for diethylpropion 75 mg. These unlawfully issued prescriptions resulted in the aggregate dispensing of approximately 5,500 dosage units of the controlled substance. The Respondent testified during the hearing that she also acquired diethylpropion from other area pharmacies.

On August 2, 2000, Respondent, represented by counsel, appeared at an Informal Conference with representatives of the IDPR. Following the conference, Respondent and the IDPR entered into a Consent Order, which the Director of the IDPR approved on March 22, 2001. The Consent Order specified, in substance, that Respondent's Illinois Controlled Substance License would be placed on probation for six months; she would comply with the terms of an aftercare agreement into which she entered on August 31, 2000, with the Illinois Professionals Health Program; Respondent would abstain from the use of alcohol and/or mood altering or psychoactive drugs except as prescribed by her primary care or treating physician; Respondent would attend Alcoholics Anonymous and/or Narcotics Anonymous meetings and Caduceus meetings at least twice per week; Respondent would undergo monitored random urine screens at least once per month within twenty-four hours of a request by the Illinois Professionals Health Program; and Respondent would continue therapy with her psychiatrist. The Consent Order further required various reports and provided that violation of any of its terms by the Respondent would constitute grounds for the IDPR to file

a complaint to revoke her medical license.

At the DEA hearing, the Respondent called as a witness the Chief of Investigations for IDPR's probation section. The witness testified that the probation on Respondent's Illinois controlled substance license terminated in compliance, i.e., that during the course of the probation the IDPR did not become aware of any violations of the terms of the March 22, 2001, Consent Order. The witness acknowledged however that although he recalled receiving required reports from the Respondent's aftercare program, he did not recall reviewing them. The Respondent later testified that her case manager and physician monitor were responsible for the quarterly reports, but that copies were not provided to her. Respondent also testified that she had brought to the hearing prepared quarterly reports of drug screens; however, these reports were not made a part of the record by either party.

The Respondent testified that she has not taken diethylpropion and has not written any controlled substance prescriptions at all since December 14, 1999. She also testified that she contacted her monitoring physician, who referred her to Elmhurst Medical Guidance Services in Elmhurst, Illinois, a suburb of Chicago, and that she underwent ''partial inpatient'' treatment there from August 2000 until January 2001. The Respondent further testified that she has continued to attend meetings at Elmhurst Medical Guidance Services on Wednesday nights.

On the date of the hearing in this proceeding, the Respondent's medical license and controlled substance license were ''non-renewed'' status. Subsequently, counsel for Respondent advised counsel for the Government and Judge Bittner that Respondent's licenses had been renewed and provided copies of the licenses. Finally, the Respondent testified that she intends to resume the practice of anesthesiology and needs a DEA registration in order to do so, and that if her application for registration is granted, she is willing to accept such conditions as submitting to drug screens, limiting her prescribing to drugs used in anesthesiology, and a prohibition on handling diet drugs.

Pursuant to 21 U.S.C. 823(f), the Acting Deputy Administrator may deny an application for a DEA Certificate of Registration if she determines that granting 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 or safety.

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

As to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, the Acting Deputy Administrator finds that while the Respondent's Illinois Controlled Substance License was placed on a six month period of probation pursuant to a consent order with the IDPR, the record in this proceeding demonstrates that the Respondent has satisfactorily complied with the terms of her probation. In addition, the Respondent is fully licensed as a physician and surgeon in Illinois with controlled substance handling privileges in that state. The Acting Deputy Administrator agrees with Judge Bittner's finding that while the Respondent's licensures to practice medicine and to handle controlled substances are not determinative in this proceeding, the Respondent's successful completion of probation and the renewal of her state professional licenses weigh in favor of granting her application for DEA registration.

Factors two and four, Respondent's experience in handling controlled substances and her compliance with applicable controlled substance laws, are also relevant in determining the public interest in this mater. Evidence was presented at the DEA hearing that the Respondent has prescribed diethylpropion to herself since the early 1980s. The record further established that these prescriptions were issued in the names of fictitious individuals.

In addition, the Respondent's use of fictitious names on the face of prescriptions was in violation of 21 CFR 1306.04 and 1306.05, in that these prescriptions were not issued for a legitimate medical purpose nor did the prescriptions bear the full name and address of a patient. As noted in Judge Bittner's Opinion and Recommended Ruling, the Respondent's use of fictitious prescriptions was also in violation of Illinois law prohibiting the acquiring or obtaining possession of controlled substances by misrepresentation, deception, or subterfuge. Like Judge Bittner, the Acting Deputy Administrator finds the Respondent's personal illicit use of controlled substances relevant under factors two and four, and weighs in favor of a finding that the Respondent's registration would be inconsistent with the public interest.

Factor three, the applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances, is not relevant for consideration here, since there is no evidence that the Respondent has ever been convicted of any crime related to controlled substances.

With respect to factor five, other conduct that may threaten the public health and safety, the Acting Deputy Administrator finds this factor relevant to the lack of detail surrounding the Respondent's rehabilitation, and the Respondent's conduct in unlawfully obtaining controlled substances. The Acting Deputy Administrator shares the concern of the Government regarding the scant nature of evidence involving the Respondent's recovery from drug abuse. The Acting Deputy Administrator is also deeply disturbed by the apparent long duration the Respondent's drug use, as well as her dishonest conduct in obtaining controlled substances. Therefore, the Acting Deputy Administrator finds the Respondent's history of drug abuse relevant under factor five, and further weighs in favor of a finding that the grant of her application for registration would be inconsistent with the public interest.

Based on the foregoing, adequate grounds exist for the denial of the Respondent's pending application for DEA registration. Having concluded that there is a lawful basis upon which to deny the Respondent's application, the question remains as to whether the Deputy Administrator should, in the exercise of his discretion, grant or deny the application. Ray Roya, 46 FR 45842 (1981). Like Judge Bittner, the Acting Deputy Administrator concludes that it would not be in the public interest to deny the Respondent's pending application.

The Acting Deputy Administrator finds significant the Respondent's ready willingness to cooperate with law enforcement authorities when

questioned about allegations of her improperly prescribing. During a December 1999 interview with DEA and IDPR investigators, the Respondent admitted that he used fictitious names on prescriptions to acquire controlled drugs and that she abused controlled substances for several years. With respect to the above referenced interview, the Acting Deputy Administrator also finds significant the Respondent's stated willingness to seek treatment for her drug abuse. It appears from the record that the Respondent demonstrated the same openness and resolve in confronting her problems with drug abuse during her testimony at the administrative hearing.

The Acting Deputy Administrator also finds significant the Respondent's participation in inpatient drug treatment and her continued participation in meetings at the Elmhurst Medical Guidance Services. The Respondent has also successfully completed the probationary terms imposed upon her state controlled substance license. There is no evidence in the record of any misuse of controlled substances by the Respondent since 1999, nor is there evidence of any further disciplinary action brought against the Respondent with respect to her handling of controlled substances. It appears from these positive developments that the Respondent has acknowledged her past problems with drug abuse and is willing to take steps to further insure her recovery.

However, given the concerns about the Respondent's past mishandling of controlled substances, a restricted registration is warranted. This will allow the Respondent to demonstrate that she can responsibly handle controlled substances. Accordingly, the Acting Deputy Administrator adopts the following restrictions upon the Respondent's DEA registration as recommended by Judge Bittner:

1. Respondent's controlled substance handling authority shall be limited to the administering and prescribing of controlled substances used in the practice of anesthesiology;

2. Respondent shall not write any prescriptions for herself, and shall not obtain or possess for her use any controlled substance except upon the written prescription of another licensed medical professional. In the event that another licensed medical professional prescribes a controlled substance for the Respondent, Respondent shall immediately notify the Special Agent in Charge of the DEA's nearest office, or his designee; (a) that she is about to obtain a specified controlled substance for her personal use, and (b) the reasons the controlled substance is being prescribed.

3. For at least two years from the date of the entry of a final order in this proceeding, Respondent shall continue to submit to random drug testing under the auspices of the Illinois Department of Professional Regulation or its designee and shall continue to participate in meetings at Elmhurst Medical Guidance Services or in an equivalent program.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b), hereby orders that the application for DEA Certificate of Registration submitted by Karen A. Kruger, M.D. be, and it hereby is, granted, subject to the above described restrictions. This order is effective March 15, 2004.

Dated: January 20, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mark Wade, M.D.; Revocation of Registration

On October 4, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mark Wade, M.D. (Respondent) at his registered location in Memphis, Tennessee. The Order to Show Cause notified the Respondent of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AW1747166, and deny any pending applications for modification or renewal of that registration, pursuant to 21 U.S.C. 824(a)(4) and 823(f), for reason that the Respondent's registration was inconsistent with the public interest.

The Acting Deputy Administrator's review of the investigative file reveals that the Order to Show Cause was received on behalf of the Respondent on October 17, 2002. By letter dated October 28, 2002, the Respondent directed a letter to the Hearing Clerk of the Office of Administrative Law Judges notifying of his desire to waive his right to a hearing in the matter. The Respondent also requested that the DEA Administrator forgo revocation proceedings based on the anticipated surrender of his DEA Certificate of Registration as part of a sentencing proceeding in Federal court scheduled for January 9, 2003. There is however, no information in the investigative file that the Respondent has surrendered his DEA registration.

Therefore, finding that the Respondent has requested the waiver of his right to a hearing and after considering material from the investigative file in this matter, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(e) and 1301.46.

A review of the investigative file reveals that on or about September 19, 1995, the Tennessee Board of Medical Examiners (Tennessee Board) adopted a policy statement titled, ''Management of Prescribing with Emphasis on Addictive and Dependence-Producing Drugs.'' Step One advises: ''First and foremost, before [prescribing any drug], start with a diagnosis which is supported by history and physical findings, and by the results of any appropriate tests'' and ''do a workup sufficient to support a diagnosis including all necessary tests.'' Step Three of the policy statement specifies that ''Before beginning a regimen of controlled drugs, [a determination should be made] through trial or a documented history that non-addictive modalities are not appropriate or they do not work.'' Step Four of the policy statement cautions prescribing physicians to make sure they ''are not dealing with a drug-seeking patient.''

On September 13, 2000, the Tennessee Board adopted a Position Statement titled, ''Prerequisites to Prescribing Drugs In Person, Electronically, Or Over the Internet.'' In its adoption of the position statement, the Board outlined its interpretation of Tennessee Code Annotated, Sections 63–6–214(b)(1), (4), and (12). The Tennessee Board's statement posits in relevant part, that ''it shall be a prima facie violation of T.C.A. 63–6–214(b)(1), (4), and (12) for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed, all of the following:

(a) Performed an appropriate history and physical examination;

(b) Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and

(c) Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatment options, a part of which might