

Registration is not warranted. The Deputy Administrator does not find that the patients at issue in this proceeding were prescribed controlled substances for no legitimate medical purpose.

While Respondent may not have been as careful in prescribing controlled substances and in documenting the reasons for his prescribing, the Deputy Administrator does not believe that revocation is appropriate given the dispute within the medical community as to when it is proper to use controlled substances in weight control.

However, Respondent clearly violated state law by ignoring the 12-week rule and by failing to properly document the treatment of his patients. The Deputy Administrator does not condone Respondent's defiance of state law, but the Deputy Administrator finds it noteworthy that the state is currently monitoring Respondent's treatment of patients and documentation of this treatment; that the state did not restrict Respondent's ability to handle controlled substances based upon the same patient charts in evidence in this proceeding; and that Respondent has taken remedial steps to ensure that he practices in compliance with the law.

But given Respondent's admitted defiance of state law by ignoring the 12-week limitation on prescribing controlled substances for weight control that was in effect at the time of the events at issue, the Deputy Administrator finds that some controls are necessary to ensure that Respondent properly handles controlled substances in the future. Therefore, for two years from the effective date of this final order Respondent shall: (1) Forward to the DEA Salt Lake City office copies of the reports of the physician reviewing his charts pursuant to the Consent Order with the State of Utah; and (2) consent to unannounced inspections by DEA personnel without requiring 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 DEA Certificate of Registration AH1650248, previously issued to Wesley G. Harline, M.D., be and it hereby is continued, subject to the above described restrictions. This order is effective March 6, 2000, and is the final agency action for appellate purposes pursuant to 21 U.S.C. 877.

Dated: January 18, 2000.

Donnie R. Marshall,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98-16]

Judy L. Henderson, D.V.M.; Grant of Restricted Registration

On February 3, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Judy L. Henderson, D.V.M. (Respondent) of Corinth, Mississippi, 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), for reason that her registration would be inconsistent with the public interest.

By letter dated March 3, 1998, Respondent requested a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Memphis, Tennessee on November 18, 1998, and April 20, 1999, before Administrative Law Judge Mary Ellen Bittner. At the hearing, the Government called witnesses and introduced documentary evidence and Respondent testified on her own behalf. After the hearing both parties submitted proposed findings of fact, conclusions of law and argument.

On September 21, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (Opinion), recommending that Respondent's application for registration be granted limited to four specific substances and subject to two conditions. Neither party filed exceptions to Judge Bittner's Opinion, and on October 25, 1999, 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 findings of fact and conclusions of law of the Administrative Law Judge in their entirety, and adopts with several modifications, as noted below, the conclusion and recommended 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 is a veterinarian. At various times during her career she suffered

from serious medical conditions which prevented her from practicing veterinary medicine.

In March 1987, a local pharmacist advised the Mississippi Bureau of Narcotics (MBN) that Respondent had used prescriptions and DEA order forms to obtain a large amount of Demerol, a Schedule II narcotic controlled substance, from the pharmacy. A subsequent pharmacy survey revealed a total of six prescriptions and eight order forms written by Respondent. The prescriptions were for a total of 30 dosage units of Ionamin, a Schedule IV controlled substance, 30 dosage units of diazepam, a Schedule IV controlled substance, six ampules of Demerol, one ounce of liquid Demerol, and 20 dosage units of Mepergan Fortis, a Schedule II narcotic controlled substance. The Ionamin and diazepam prescriptions listed Respondent as the patient, the prescription for six ampules of Demerol listed the clinic where Respondent worked and had the notation "clinic use only," the Mepergan Fortis prescription was made out to Respondent's then-husband, and the prescription for one ounce of Demerol was made out in a dog's name. Each of the order forms was for one 30 cc. vial of Demerol.

On March 26, 1987, MBN agents interviewed Respondent who told the agents that she had obtained the various narcotics for her own use because she suffered from extremely painful medical conditions. The agents subsequently confirmed with Respondent's physician that he was treating Respondent for the medical conditions. However, the physician indicated that he did not know that Respondent was self-prescribing and that he would help her. No charges were filed against Respondent as a result of this investigation.

Respondent testified at the hearing in this matter that she was treated with intravenous Demerol for a painful kidney disorder. Following surgery for this disorder, Respondent experienced withdrawal from the Demerol. Respondent testified that she was ashamed that she had become dependent on the Demerol and attempted to wean herself off by taking oral Demerol intended for the animals she treated. This attempt was unsuccessful and in fact Respondent was taking more Demerol than she had before her surgery. According to Respondent she then began injecting herself with Demerol. Finally, at or about the end of November 1997, Respondent entered a 28-day treatment program and stopped using controlled substances.

As to the other prescriptions discovered during this investigation, Respondent testified that she purchased Ionamin to treat an obese dog, and that the Valium was for use in a clinic where she worked. Respondent further testified that she did not prescribe Mepergan Fortis for her then-husband, but that the prescription was for her then-mother-in-law's dog, who Respondent was treating for cancer.

The Government alleged that Respondent surrendered her DEA Certificate of Registration in 1987. However, the investigator who testified at the hearing indicated that she could not locate a copy of the surrender form. Respondent testified that at some point in 1987 the attorney for the Mississippi State Board of Veterinary Medicine (Veterinary Board) wrote to her recommending that she surrender her DEA registration, but that she did not respond to this letter since she was very ill and not working at the time. It was Respondent's recollection that she simply let her DEA registration expire. She testified that she still had the registration certificate in her possession the next time that she applied for a DEA registration. Judge Bittner found Respondent's testimony to be credible and therefore found that the evidence does not support a finding that Respondent's surrendered her DEA Certificate of Registration in 1987.

Respondent was issued DEA Certificate of Registration BE2196687 on March 20, 1990.

In October 1992, DEA was advised by Respondent's then-husband that Respondent was abusing controlled substances. A subsequent pharmacy survey did not reveal any controlled substance prescriptions issued by Respondent. DEA then contacted Respondent's drug distributor and discovered that Respondent had ordered 500 dosage units of lorazepam 2 mg., a Schedule IV controlled substance, and 2200 dosage units of hydrocodone with APAP, a Schedule III controlled substance, between March 4 and October 19, 1992.

A DEA investigator contacted two physician who had treated Respondent. One physician treated Respondent for painful medical conditions from 1989 until June 1992, and prescribed her Lortab 7.5 mg., a Schedule III controlled substance. The other physician indicated that he treated Respondent from February 1987 until March 1991, also for painful medical conditions. There is no indication in the record whether this physician prescribed Respondent any controlled substances.

On October 21, 1992, DEA agents met with Respondent at her home.

Respondent told the agents that she had not been practicing veterinary medicine for a period of time because she was ill. She further told the agents that rather than filling the prescriptions that her physician issued to her, she was ordering the drugs using her DEA registration because it was less expensive to obtain the drugs that way. At this meeting, Respondent surrendered her DEA Certificate of Registration, order forms, and controlled substances in her possession.

Respondent testified at the hearing that in 1990 she developed an extremely painful medical condition that rendered her unable to work. She acknowledged that she ordered controlled substances during this period, and that at one point she bought Demerol from a hospital pharmacy. Respondent further testified that her physician did not know that she was ordering hydrocodone, and that although she knew that ordering the drug for herself was an unethical use of her DEA registration, she had not thought that it was criminal conduct. Respondent testified that she ultimately recovered from this illness following radical surgery.

On March 1, 1996, Respondent executed an application for a new DEA Certificate of Registration. DEA sought a recommendation from the Veterinary Board as to whether this application should be granted. On June 10, 1996, the Veterinary Board responded, stating in pertinent part:

While the granting or denial of [a DEA registration] is a determination to be made by your agency, the Mississippi Board of Veterinary Medicine cannot recommend unrestricted approval by your agency. While the Board is happy that [Respondent] has returned to practice, nevertheless, the Board feels that, at most, [Respondent's] purchases of controlled drugs should be limited to the purchase of euthanasia solutions and a limited number of purchases for anesthetics.

As a result of this letter, Respondent wrote to the Veterinary Board asking for its approval for her to use ketamine, at the time a non-controlled substance; Socumb, brand name for a product containing sodium pentobarbital, a Schedule II non-narcotic controlled substance; Valium, brand name for a product containing diazepam; Sodium Pentothal, trade name for thiopental, a Schedule III non-narcotic controlled substance; phenobarbital, a Schedule IV controlled substance; testosterone, a Schedule III controlled substance; and Winstrol-V, Telazol, and Tussigon, all controlled substances. By letter to Respondent dated October 28, 1996, the Veterinary Board recommended that she use ketamine, Rompun, acepromazine (or other tranquilizers), gas anesthesia,

lidocaine (for local use), Torbutral, and Sodium Pentothal as a pre-anesthetic. Rompun, acepromazine, and lidocaine are not controlled substances. Ketamine was previously noncontrolled but was placed in Schedule III effective August 12, 1999. Torbutral is a controlled substance.

During the course of investigating Respondent's application for a DEA registration, DEA contacted the local sheriff. The local sheriff indicated that in 1993, Respondent was caught stealing ketamine from another veterinarian.

In explaining why she stole the ketamine, Respondent testified that after her radical surgery, she went through a very bitter divorce and custody proceeding, that she "lost everything," and that her ex-husband made allegations about her to other veterinarians in the area that effectively prevented her from obtaining work. She further testified that her ex-husband was physically abusive and had threatened to kill her if she did not stop attempting to regain custody of their child. Respondent testified that upon the recommendation of a local police officer, she obtained a gun to protect herself from her ex-husband. According to Respondent, she ultimately realized that she would not be able to shoot her ex-husband if threatened and instead decided to obtain ketamine to use as a chemical immobilizer. Respondent testified that shortly before stealing the ketamine, her ex-husband had attacked her with a hammer, resulting in her being admitted to an emergency room.

Respondent testified that she stole ketamine from the other veterinarian twice. The first time, she took a total of two cc. of ketamine, but then decided that that would not be a sufficient quantity to subdue her ex-husband. Respondent testified that she then took a bottle that had held 10 cc. of ketamine and had about one cc. of the drug left in it, and she then added small quantities of ketamine that she took from other bottles, substituting saline in those bottles. Respondent acknowledged that what she did was wrong.

The other veterinarian decided not to press charges against Respondent provided that Respondent seek treatment. As a result, Respondent entered a treatment program to be treated for depression and tested for ketamine. According to Respondent, she stayed in that program for two weeks and then went to a program that treated health care professionals where she stayed for three to four months. Thereafter she moved to an outpatient facility. Respondent testified that she spent a total of five months in treatment for clinical depression and hydrocodone

addiction. According to Respondent, her treatment ended in February 1994. She testified that she has not taken any narcotic drug, except during surgery, since October 1993.

On November 5, 1996, a DEA investigator asked Respondent to send information regarding her rehabilitation and aftercare treatment. According to the investigator, Respondent did not send any such information. Respondent acknowledged that the DEA investigator had asked her to provide records of her treatment, but that she had substantial difficulty obtaining these records from the facilities.

Respondent testified that she eventually started her own veterinary practice, and that she was the only veterinarian in her town who was always available. According to Respondent, the majority of her practice is trauma emergency medicine, unlike other veterinarians.

In June 1997, Respondent contacted the DEA investigator and advised that the only drug she was using at that time was Socumb. The investigator asked Respondent how she obtained the Socumb since she was not registered with DEA to handle controlled substances at that time. Respondent indicated that she received a partial bottle from another veterinarian. The DEA investigator contacted the other veterinarian who indicated that he provided the sodium pentobarbital to Respondent after Respondent showed him a letter from the Veterinary Board stating that she could use the drug. Respondent told the other veterinarian that she had an animal in distress, so he gave her 10 to 20 cc. to euthanize the animal.

Respondent testified at the hearing that the dog she was treating had been poisoned, that the incident occurred late at night on a weekend, and that the dog was in intense pain. She contacted the other veterinarian who refused to put the dog to sleep himself, but offered to prescribe enough of the drug so Respondent could euthanize the dog. Respondent testified that because she was working under the other veterinarian she did not realize that she had done anything wrong. It is undisputed that after speaking to the DEA investigator, Respondent returned the remaining sodium pentobarbital to the other veterinarian.

Respondent asserted that since she is the only veterinarian in the area who handles emergencies after hours, she needs a DEA registration in order to care for her patients. Respondent testified that she needs to use sodium pentobarbital, butorphanol, and Valium in her practice. The sodium

pentobarbital would be used to euthanize animals, the butorphanol to relieve pain in the animals, and the Valium to control seizures and treat sick cats that refuse to eat. According to Respondent, she would be willing to install security measures, maintain whatever records are required, and be subject to random drug testing.

Respondent has acknowledged her mistakes. Respondent testified that she has "suffered greatly because of this. And I expect to the rest of my life. This will be a great humiliation to me. But I truly—I truly don't believe it will ever happen again. I never have a desire to. I never had before these two instances and I never have since."

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).

As to factor one, the Veterinary Board recommended that Respondent not be given an unrestricted registration, however the Veterinary Board did recommend that Respondent be authorized to handle thiopental and ketamine, Schedule III controlled substances, and butorphanol, a Schedule IV controlled substance. Although Respondent has indicated that she also needs to be able to use sodium pentobarbital for euthanasia, the Veterinary Board did not mention this substance in its June 10, 1996 letter. The Deputy Administrator agrees with Judge Bittner that while the Veterinary Board's recommendations are not dispositive, they certainly weigh in favor of at the

very least granting Respondent a DEA registration restricted to certain substances.

Regarding factor two, the evidence supports a finding that prior to 1987, Respondent abused her DEA registration by issuing prescriptions and using DEA order forms to obtain controlled substances for her own use. In 1992, Respondent again used her DEA registration to obtain controlled substances for her own use. Respondent also handled sodium pentobarbital in 1997, when she was not authorized to do so.

As to factor three, there is no evidence that Respondent has been convicted of any criminal charges relating to the manufacture, distribution or dispensing of controlled substances.

Regarding factor four, Respondent's compliance with applicable laws relating to controlled substances, it is undisputed that Respondent used DEA order forms in violation of 21 U.S.C. 828(e) to obtain controlled substances for her own use. In addition, Respondent issued prescriptions to obtain Demerol for her own use in violation of 21 U.S.C. 829 and 21 CFR 1306.04. The Deputy Administrator notes however that these violations occurred when Respondent was suffering from painful medical conditions and had become addicted to narcotic controlled substances. According to Respondent, these conditions are now under control, she has undergone treatment for her addiction, and she has not improperly obtained or personally used controlled substances, except as a result of surgery, since October 1993. As recently as 1997, Respondent handled sodium pentobarbital when she was not registered with DEA to do so in violation of 21 U.S.C. 841(a). While not condoning this violation, the Deputy Administrator does not find under the circumstances that this isolated incident warrants denying Respondent's application for registration.

As to factor five, the Deputy Administrator is troubled by Respondent's theft of ketamine in 1993. Although ketamine was not a controlled substance at the time, her stated purpose of immobilizing her ex-husband with the drug raises serious concerns about her fitness to handle controlled substances. However, the Deputy Administrator notes that this incident occurred in 1993, that Respondent has since undergone extensive treatment for depression and drug addiction, that Respondent has acknowledged the wrongfulness of this behavior, and that there is no evidence

of any similar type behavior since that time.

The Deputy Administrator also finds it relevant under this factor that Respondent was previously addicted to narcotic controlled substances. Respondent has acknowledged her past problems and appears to be remorseful. However, while Respondent asserts that she has undergone treatment and that she has not improperly used controlled substances since 1993, the Deputy Administrator is troubled by the lack of evidence in the record, other than Respondent's own testimony, regarding Respondent's treatment for her addiction. The record is also devoid of evidence of any continued monitoring of Respondent and any support network in place to help prevent a relapse.

The Deputy Administrator agrees with Judge Bittner that the Government has presented a prima facie case for the denial of Respondent's application for registration based upon Respondent's use of her previous DEA registrations to obtain controlled substances for her own use, her abuse of controlled substance, her violation of laws relating to controlled substances, her handling of sodium pentobarbital in 1997 when not authorized to do so, and her theft of a non-controlled substance in 1993 to be used to temporarily immobilize her ex-husband. However, Judge Bittner found credible Respondent's testimony that she has not used controlled substances since 1993 except as prescribed lawfully by a physician. Judge Bittner also found credible Respondent's testimony regarding the circumstances surrounding her theft of ketamine in 1993 and her 1997 handling of sodium pentobarbital, and that she regrets her misconduct, is willing to accept restrictions on her registration, and will not abuse her registration or controlled substances in the future.

Therefore, Judge Bittner concluded that it would not be inconsistent with the public interest to grant Respondent a DEA Certificate of Registration limited to the Schedule II controlled sodium pentobarbital, the Schedule III controlled substances ketamine and thiopental, and the Schedule IV controlled substance butorphanol subject to the following conditions:

(1) Respondent shall maintain accurate records showing all purchases, administering and dispensing (including prescribing) of all controlled substances; and

(2) Respondent shall submit copies of all such records to the Special Agent in Charge of DEA's New Orleans Office, or his designees, quarterly, for five years from the effective date of her registration.

The Deputy Administrator agrees with Judge Bittner that it is not in the public interest to deny Respondent's application for registration and basically agrees with Judge Bittner's recommended restrictions. However, the Deputy Administrator is extremely reluctant to grant Respondent the authority to handle ketamine, the very substance she admitted stealing in 1993 to potentially use to incapacitate her ex-husband. Nonetheless, the Deputy Administrator will do so given that the Veterinary Board recommended that Respondent be authorized to handle ketamine and the recommendation of the appropriate state licensing authority is one of the factors to be considered by the Deputy Administrator in determining the public interest. The Deputy Administrator is also troubled by the lack of evidence in the record, other than Respondent's own testimony, regarding her treatment and rehabilitation. Consequently, the Deputy Administrator finds it necessary to have safeguards in place to be certain that Respondent does not abuse controlled substances once she is issued a limited registration.

Therefore, the Deputy Administrator concludes that Respondent should be issued a DEA Certificate of Registration in Schedules II non-narcotic, III and IV subject to the following restrictions for three years from the date of issuance of the DEA Certificate of Registration:

(1) While Respondent shall be registered in Schedules II non-narcotic, III and IV, she shall only handle sodium pentobarbital, ketamine, thiopental, and butorphanol.

(2) Respondent shall send copies of records documenting all of her purchases of controlled substances to the Special Agent in Charge of the DEA New Orleans office, or her designee, on a quarterly basis.

(3) Respondent shall submit, on a quarterly basis, a log of all of the controlled substances she has prescribed, administered, or dispensed during the previous quarter, to the Special Agent in Charge of the DEA New Orleans office, or his designee. The log shall include: the patient's name; the date that the controlled substance was prescribed, administered or dispensed; and the name, dosage and quantity of the controlled substance prescribed, administered or dispensed. If no controlled substances are prescribed, administered or dispensed during a given quarter, Respondent shall indicate that fact in writing, in lieu of submission of the log.

(4) Respondent shall submit to random urinalysis, at her own expense, not less than one time per month.

Within 30 days of the effective date of this order, Respondent shall notify the Special Agent in Charge of the DEA New Orleans office, or his designee, in writing, as to the identity of the laboratory or hospital that will be conducting the random urinalysis. Reports documenting the results of these tests shall be forwarded to the Special Agent in Charge of the DEA New Orleans office, or his designee.

(5) Respondent shall consent to random, unannounced inspections without the need for 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 application for registration submitted by Judy L. Henderson, D.V.M., be, and it hereby is, granted in Schedules II non-narcotics, III and IV, subject to the above described restrictions. This order is effective upon the issuance of the DEA Certificate of Registration, but no later than March 6, 2000.

Dated: January 18, 2000.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Archibald W. Hutchinson, M.D.; **Revocation of Registration**

On July 28, 1999, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Archibald W. Hutchinson, M.D., of Marietta, Ohio, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BH2898053 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 Ohio. The order also notified Dr. Hutchinson 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. Hutchinson at his registered location. DEA received a signed receipt indicating that it was received and signed for by an individual on November 3, 1999. The Order to Show