

a licensed physician." The Judge accepted the plea agreement and sentenced him to probation for one year and to pay a \$500.00 fine.

After the plea agreement was entered, the DEA Investigator continued to notice that the Pharmacy still purchased large quantities of Demerol. Based on this information, investigators conducted a second audit of the Pharmacy of the period of May 21, 1993, through November 30, 1993, and this audit revealed that the Pharmacy had a shortage of 28 ampules of Demerol.

Pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of 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:

(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 Deputy Administrator may rely on any one or 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., Docket No. 88-42, 54 Fed. Reg. 16,422 (1989).

In this case, factors one through five are relevant in determining whether the Pharmacy's continued registration would be inconsistent with the public interest. As to factor one, "recommendation of the appropriate State licensing board," Judge Tenney found that there was "no evidence to indicate that [the Pharmacy] does not hold proper State authorization to operate a retail pharmacy and handle controlled substances."

As to factor two, the Respondent's "experience in dispensing * * * controlled substances," the Deputy Administrator agrees with Judge Tenney that the evidence of numerous photocopied prescriptions filled by the Pharmacy "clearly demonstrated poor dispensing experience under 21 U.S.C. § 823(f)(2) * * *. In addition, substantial weight must be given to

factor (2) in evaluating the public interest based upon the dangerous trend concerning Demerol." Specifically, the Deputy Administrator agrees with Judge Tenney's findings concerning the Pharmacy's dispensing of Demerol to individuals presenting altered and photocopied prescriptions and to individuals presenting prescriptions with instructions that were inconsistent with the nature of the substance prescribed. Further, the Pharmacy's inability to accurately account for its supply of Demerol as evidenced by the overage and shortage revealed during DEA audits, and its inability to track its supply of various Schedule III and IV controlled substances, are all relevant concerns under factor two. Finally, the Deputy Administrator agrees with Judge Tenney's conclusion that "the Government has proven poor dispensing experience under 21 U.S.C. § 823(f)(2), and this conduct warrants serious concern by the DEA."

As to factor three, "the applicant's conviction record * * * relating to the * * * distribution * * * of controlled substances," the evidence shows that the Owner-pharmacist working at the Pharmacy had a conviction record related to the dispensing of controlled substances, for in August 1993, he pled guilty to charges of violating Federal statutes; specifically, he admitted to accepting and filling photocopied prescriptions in violation of 21 U.S.C. §§ 829(a), 842(a)(1) and 842(c)(2)(A). He was placed on probation for one year and fined \$500.00.

As to factor four, the Respondent's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," there was some dispute as to the evidence presented. The record contains testimony that the pharmacy failed to maintain an initial and a biennial inventory as required by regulation, and yet the Owner testified that he maintained a "perpetual inventory," for the Puerto Rican authorities would not give him a license unless a yearly inventory was maintained. Judge Tenney found that the Owner's testimony on this point was credible and un rebutted, and he concluded "in light of the weight that is attached to other factors under 21 U.S.C. § 823(f), factor (4) is not considered critical in assessing the public interest."

As to factor five, "[s]uch other conduct which may threaten the public health or safety," Judge Tenney agreed with the Government's position, that "in light of [the Owner's] past conduct * * * potential future actions by [the Owner] may threaten the public health and safety * * * [for] considerable weight is attached to the alterations of

expiration dates on bottles of controlled substances seized at the [Pharmacy]." Although the Owner testified that he was unaware of the alterations made on the expiration dates, Judge Tenney found his testimony on this point lacked credibility. In the alternative, Judge Tenney also found that, as the owner and pharmacist at the Pharmacy, "it was his responsibility to assure that such alterations did not occur."

The Deputy Administrator agrees with Judge Tenney's findings and his conclusion that the Government proved, by a preponderance of the evidence, that continued registration of the Farmacia Ortiz by the DEA would be inconsistent with the public interest, and that any pending applications should be denied at the present time. See *Sokoloff v Saxbe*, 501 F. 2d 571, 576 (2d Cir. 1974) (stating that "permanent revocation" of a DEA Certificate of Registration may be "unduly harsh").

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 AF1619040, issued to Farmacia Ortiz, be, and it hereby is, revoked and any pending applications are hereby denied. This order is effective February 9, 1996.

Dated: December 28, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96-338 Filed 1-9-96; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 94-40]

Darrell Risner, D.M.D., P.S.C.; Granting of Restricted Registration

On March 18, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Darrell Risner, D.M.D., P.S.C., (Respondent) of Barbourville, Kentucky, notifying him of an opportunity to show cause as to why DEA should not deny his application for registration as a practitioner under 21 U.S.C. 823(f) as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that:

1. An investigation by the Kentucky State Police in 1989 revealed that in 1988 and 1989, [the Respondent] wrote numerous prescriptions for Percodan and Percocet, Schedule II controlled substances, using the names of fictitious individuals or individuals who did not receive the prescriptions.

2. On June 12, 1989, [the Respondent] surrendered [his] DEA Certificate of Registration, #AR1091482.

3. As a result of [his] unlawful prescribing practices, on July 13, 1992, [he] pled guilty in the Knox County (Kentucky) Circuit Court to one count of facilitation to obtain a Schedule II controlled substance, and [was] sentenced to 24 months unsupervised probation, fined court cost[s] and ordered to perform community service.

4. Effective August 15, 1989, [he] entered into an agreed order with the Kentucky Board of Dentistry in which [his] dental license was suspended for six months followed by three years probation, and [he was] prohibited from prescribing controlled substances during the probationary period.

On April 18, 1994, the Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Arlington, Virginia, on November 29, 1994, before Administrative Law Judge Mary Ellen Bittner. At the hearing both parties called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On May 31, 1995, Judge Bittner issued her Opinion and Recommended Ruling, recommending that the Respondent's application be granted with restrictions applicable for a period of two years commencing on the effective date of his registration. Neither party filed exceptions to her decision, and on July 5, 1995, 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, in full, the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, and 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 the Respondent is licensed to practice dentistry in Kentucky, where he has three offices and provides dental services to low income communities in Barbourville, Cumberland, and Hyden. Besides the Respondent's offices, these communities had available limited alternative dental care. The Respondent testified that his patients do not have access to fluoridated water and did not have training on how to care for their teeth. Consequently, many of his patients suffered serious and painful dental conditions. The Respondent further stated that because he did not have a DEA registration, he had to

prescribe non-controlled medication to his patients. However, these drugs sometimes were not as effective in alleviating pain as controlled substances, and in some cases, such drugs exacerbated his patients' other medical conditions. Consequently, the Respondent could not adequately treat some of his patients, and his only available alternative was to send them to an emergency room to obtain the needed medication. However, some patients had difficulty getting to a hospital with emergency facilities, because of the distances they would need to travel in this rural area of Kentucky.

A retired Kentucky State Police trooper (Trooper) testified before Judge Bittner, stating that he had been assigned to the state police Narcotics Division, and on January 20, 1989, he had opened an investigation in response to a complaint received from the Kentucky Board of Pharmacy. The complaint advised that the Respondent had obtained Schedule II drugs from a pharmacy in Barbourville, Kentucky. The Trooper testified that on February 28, 1989, he obtained approximately 29 prescriptions for Percocet or Percodan signed by the Respondent, and that many of these prescriptions were for "Dennis Smith." The parties stipulated that Percocet and Percodan contain oxycodone, a Schedule II controlled substance.

The Trooper then interviewed the Respondent, who said that "Dennis Smith" was a fictitious name, and that he had written the prescriptions and had had them filled himself in order to have the drugs on hand to dispense without charge to his patients in his Hyden office. The Respondent testified that he saw patients at that location in the evening, and that there were no local pharmacies open evenings where his patients could fill prescriptions for pain medication. He also testified: "I know it's wrong, and I realize it was a bad error in judgment; but I did it."

The Trooper then testified that he contacted Dr. Thompson of the Kentucky Board of Dentistry (Dental Board), and on March 24, 1989, he and Dr. Thompson met with the Respondent. During that interview, the Respondent denied using any of the Percocet or Percodan himself and offered to take a drug test. He also told the Trooper that he had written controlled substance prescriptions for his wife and her parents for pain relief, but that he had not kept any medical records for his wife. He produced a medical file for his mother-in-law, but it did not indicate that he had prescribed her controlled substances. The

Respondent testified before Judge Bittner that he also had failed to maintain a proper medical record for his father-in-law, and that he failed to maintain proper records for his family members because he usually treated them on weekends when staff members were not in the office to assist with recordkeeping.

On May 12, 1989, the Knox County Circuit Court grant jury indicted the Respondent on four felony counts of obtaining a Schedule II controlled substance by deception and fraud, and one felony count of failing to keep records of Schedule II controlled substances. On July 13, 1992, the Commonwealth's Attorney added an additional misdemeanor count of facilitation to obtain a Schedule II controlled substance by fraud. On that same day, the Respondent pled guilty to the misdemeanor count, and the court accepted the plea and sentenced him to 24 months unsupervised probation, costs, and community service consisting of accepting without charge all referrals for dental work from the Kentucky Department of Social Services. The Respondent testified that for two years, from July 13, 1992, to July 13, 1994, he provided free dental care to approximately 150 patients, at a value of approximately \$28,000.00.

In June of 1989, the Respondent appeared before the Dental Board, and on June 12, 1989, he voluntarily surrendered his DEA registration. On July 27, 1989, the Dental Board entered an Agreed Order suspending the Respondent's dental license for six months, placing his license on probation for three years following the suspension, and ordering him to pay a civil penalty of \$500.00. The conditions of probation included, among other things, that the Respondent would not prescribe any controlled substances and that he would submit to random drug screenings. During the third year of his probation, the Respondent underwent drug screenings, and the results were negative. The Respondent testified that he had complied with the Agreed Order, and that since the end of the probationary period on February 15, 1993, his dental license had not been subject to any restrictions.

On February 15, 1993, the Respondent applied for a new DEA registration in Schedule II non-narcotic and in Schedules III through V. One of the questions on that application asks whether the applicant has

Ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a Federal controlled substance registration revoked, suspended, restricted or

denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?

The Respondent had answered that question as "yes," and on the back of the application, in response to the requirement to explain an affirmative answer, he had written:

I surrendered my DEA license #AR1091482 to the Kentucky Board of Dentistry in July 1989. I was placed on three years probation which ended February 15, 1993. This was due to prescription irregularities.

However, the Respondent did not mention his conviction.

Finally, the Respondent testified before Judge Bittner, stating that he had learned his lesson and that he would not make the same "error judgments" again. He stated that if his DEA registration was restored, he would be willing to maintain a log of patients who received controlled substances, keep copies of prescriptions in patient charts, and undergo drug screening to provide assurances that he was handling controlled substances appropriately. He also testified that his application should be amended, for he was no longer requesting to be registered to handle Schedule II non-narcotic substances. He merely asked to be registered to handle controlled substances from Schedules III through V.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for registration if he determines that the registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered:

- (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 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., Docket No. 88-42, 54 FR 16,422 (1989).

In this case, the Deputy Administrator agrees with Judge Bittner that all five factors are relevant in determining whether the Respondent's registration

would be inconsistent with the public interest. As to factor one, "recommendation of the appropriate State licensing board," the Kentucky Dental Board, after reviewing the Respondent's conduct, suspended his license, and according to the terms of the Agreed Order, subsequently placed the Respondent on probation. Of equal significance, the Respondent served out the terms of his probation, and as of February 15, 1993, his probationary period ended, and his dental license has not been subject to any restrictions since that time.

As to factor two, the Respondent's "experience in dispensing * * * controlled substances," factor three, his "conviction record" as related to controlled substances, and factor four, the Respondent's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," it is undisputed that the Respondent obtained and handled Schedule II controlled substances in violation of State and Federal law and DEA regulations, and that he pled guilty to a criminal offense involving controlled substances. Further, DEA regulations levy recordkeeping requirements, such as a requirement that the Respondent use and maintain a DEA Form 222, order form, for each distribution of a Schedule II controlled substance per 21 CFR 1305.03, and maintain inventories and other dispensing records per 21 CFR 1304.03(b), 1304.04(g) and 1304.24. However, the Respondent failed to maintain records in compliance with these provisions.

As to factor five, "[s]uch other conduct which may threaten the public health or safety," the Government argued that "[w]hat is disturbing about the [Respondent's] conduct" is not only the dishonest and unlawful nature of falsifying prescriptions, but the fact that legitimate means were available to [the] Respondent to adequately and lawfully treat his patients." Further, the Government argued that as to future conduct, the Respondent continued to be less than forthright as evidenced by his 1993 DEA application wherein he failed to disclose his criminal conviction. However, Judge Bittner commented upon this allegation by noting:

In certain contexts, [the] Respondent's failure to state on his application form that he had been convicted of a drug-related crime might be sufficient grounds to * * * deny an application. In the instant case, however, I note that [the] Respondent stated that he had surrendered his DEA registration and that the Dentistry Board had put him on probation for "prescription irregularities," so the Government was clearly aware from the

application that he had engaged in some form of misconduct, and it does not appear that [the] Respondent attempted to conceal his conviction. In addition, it is also well established that the parameters of the hearing are determined by the prehearing statements, and although [the] Respondent's application was at all times available to the Government, the Government did not specify in its prehearing statement or indicate at any time prior to the hearing that [21 U.S.C.] § 824(a)(1) was at issue in this proceeding; and [the] Respondent therefore had no notice that this matter might be litigated. In these circumstances, I find that [the] Respondent's failure to mention his conviction on his application is not a basis for denying him a registration.

As to this point, the Deputy Administrator agrees with Judge Bittner's conclusion.

Further, the Deputy Administrator also agrees with Judge Bittner's conclusion that "[i]t is undisputed that Respondent's obtaining and handling of Schedule II controlled substances violated State and Federal law and DEA regulations, and I find that his falsification of prescriptions, using prescriptions to obtain controlled substances for general dispensing and failure to record dispensings of controlled substances constitute grounds for denying his application for DEA registration."

However, in mitigation, Judge Bittner also found the Respondent's testimony credible. Specifically, that the Respondent dispensed the improperly obtained controlled substances to patients for legitimate medical purposes, and that he credibly acknowledged his wrongdoing and was willing to accept the responsibilities inherent in a DEA registration. Finally, Judge Bittner noted that "although evidence that a DEA registration would assist a practitioner in caring for his patients does not, standing alone, establish that the registration would be in the public interest, such evidence should be considered, and it is clear from the record here that [the] Respondent's lack of a DEA registration adversely affects his ability to effectively treat his patients."

Therefore, the Deputy Administrator agrees with Judge Bittner that the public interest is best served by granting the Respondent's amended application, subject to restrictions. Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823, and 28 CFR 0.100(b) and 0.104, hereby orders that the application for a DEA Certification of Registration in Schedules III through V of Darrell Risner, D.M.D., P.S.C., be granted subject to the following restrictions: (1)

the Respondent shall not administer or dispense, other than by prescribing, any controlled substance; and (2) the Respondent shall maintain a log of all controlled substance prescriptions and submit such logs on a quarterly basis, to the Resident Agent in Charge of the DEA Louisville, Kentucky, Resident Office, or a selected designee. The restrictions will run for a period of two years commencing on the effective date of the Respondent's registration. It hereby is so ordered. This order is effective upon publication in the Federal Register.

Dated: December 28, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96-339 Filed 1-9-96; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Extension of Time for Response to a NIOSH Criteria Document

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice; Extension of time for response by the Mine Safety and Health Administration (MSHA) to the recommended standard on occupational exposure to respirable coal mine dust from the National Institute for Occupational Safety and Health (NIOSH).

SUMMARY: On November 7, 1995, MSHA received criteria for a recommended standard from the National Institute for Occupational Safety and Health (NIOSH). Under the Federal Mine Safety and Health Act of 1977, the Secretary of Labor must take one of the following three actions within 60 days of receipt of the NIOSH criteria: (1) Appoint an advisory committee; (2) publish a proposed rule; or (3) publish in the Federal Register his determination not to do so, and his reasons therefor. As a result of the lapse in funding for the U.S. Department of Labor and the partial government shutdown, MSHA has been unable to meet the 60-day statutory deadline for a response.

FOR FURTHER INFORMATION CONTACT: Patricia Silvey, Office of Standards, Regulations, and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203, (703) 235-1910.

SUPPLEMENTARY INFORMATION: The Federal Mine Safety and Health Act of 1977, 30 U.S.C. 801 *et seq.* (Mine Act), authorizes the National Institute for Occupational Safety and Health

(NIOSH) of the U.S. Department of Health and Human Services to recommend that the Secretary of Labor promulgate specific occupational safety and health standards to serve the objectives of the Mine Act. By means of criteria documents NIOSH notifies MSHA, as well as others with an interest in occupational safety and health, of its recommendations for health and safety standards. When the Secretary of Labor receives any such recommendation from NIOSH, Section 101(a)(1) of the Mine Act requires him to take one of three actions within 60 days: (1) Refer such recommendations to an advisory committee; (2) publish such recommendations as a proposed rule; or (3) publish in the Federal Register his determination not to do so, and his reasons therefor.

On November 7, 1995, NIOSH transmitted to MSHA the document entitled *Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust*, which examines the occupational health risks associated with exposures to respirable coal mine dust and crystalline silica over a working lifetime. In that document NIOSH makes a number of recommendations for reducing those risks, including reducing the permissible exposure levels for respirable coal mine dust and for respirable crystalline silica by 50 percent.

Because of the lapse in funding for the U.S. Department of Labor and the resulting shutdown, MSHA has been unable to meet the statutory deadline for a response to the NIOSH criteria document.

As soon as MSHA resumes normal operations, the agency will move as quickly as possible to respond to the criteria document, and will publish notice of its response in the Federal Register.

Dated: January 4, 1996.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 96-331 Filed 1-9-96; 8:45 am]

BILLING CODE 4510-43-M

NATIONAL CREDIT UNION ADMINISTRATION

Information Collection Under Review

January 10, 1996.

The National Credit Union Administration (NCUA) has submitted the following public information collection requests to the Office of Management and Budget (OMB) for

review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). The proposed information collections are published to obtain comments from the public. Public comments are encouraged and will be accepted for sixty days from the date listed at the top of this page in the Federal Register.

Copies of these individual information collection requests, with applicable supporting documentation, may be obtained by calling the NCUA Clearance Officer, Suzanne Beauchesne, at (703) 518-6412. Written comments and/or suggestions regarding the information collection requests listed below should be directed to Ms. Beauchesne, Office of Administration, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314 within 60 days from the date of this publication in the Federal Register. Comments should also be sent to the OBM Desk Officer indicated below at the following address: OMB Reports Management Branch, New Executive Office Building, Room 10202, Washington, DC 20530. Attn: Milo Sunderhauf.

National Credit Union Administration

OMB Number: 3133-0016.

Form Number: None.

Type of Review: Extension of currently approved collection of information.

Title: Letter of Understanding and Agreement.

Description: The Letter of Understanding and Agreement requires the credit union to submit financial and statistical reports to the NCUA on a monthly basis. The collection of financial information is used by the NCUA and the credit union to assess the credit unions' financial condition and to minimize potential losses to the National Credit Union Share Insurance Fund.

Respondents: Federally insured credit unions.

Estimated Number of Respondents/Recordkeepers: 219.

Estimated Burden Hours Per Response: 30 minutes.

Frequency of Response: Monthly.

Estimated Total Annual Burden

Hours: 1,314 hours.

Estimated Total Annual Cost:

\$19,552.32.

OMB Number: 3133-0024.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Title: Mergers of Federally Insured Credit Unions.

Description: As authorized by 12 U.S.C. § 1766 and Part 708b, of NCUA's