

the publication of this notice. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *Northwest Pipe & Casing Co. v. United States*, D.J. Ref. No. 90-11-3-1557. Commenters may request an opportunity for public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The proposed Consent Decree may be examined at the Office of the United States Attorney for the District of Oregon, 888 S.W. 5th Ave., Suite 1000, Portland, OR 97204-2024; the Region 10 Office of the United States Environmental Protection Agency, 1200 Sixth Ave., Seattle, WA 98101; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005 (202-624-0892). A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy of the proposed Consent Decree, please enclose a check in the amount of \$24.75 (25 cents per page for reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96-28]

Robert G. Hallermeier, M.D. Continuation of Registration With Restrictions

On March 27, 1996, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Robert G. Hallermeier, M.D., (Respondent) of Boothwyn, Pennsylvania, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certification of Registration, AH6871049, and deny any pending applications for registration as a practitioner under 21 U.S.C. 823(f), for reason that pursuant to 21 U.S.C. 824(a)(4), his continued registration would be inconsistent with the public interest.

By letter dated April 29, 1996, Respondent, through counsel, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Philadelphia, Pennsylvania on October 23 and 24, 1996, before Administrative Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, counsel for both parties submitted proposed findings of fact, conclusions of law and argument. On February 27, 1997, Judge Randall issued her Opinion and Recommended Ruling, recommending that Respondent's registration be continued subject to several temporary conditions. No exceptions were filed to her Opinion and Recommended Ruling, and on March 27, 1997, Judge Randall transmitted the record of these proceedings to the Acting Deputy Administrator.

The Acting 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 Acting Deputy Administrator adopts, in full, the opinion of the Administrative Law Judge, and adopts, with several modifications, the recommended ruling of the Administrative Law Judge. 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 Acting Deputy Administrator finds that Respondent received his medical degree from Temple University. While in medical school, Respondent observed a physician assistant write orders and prescriptions for medications without direct supervision of a physician. In 1977, Respondent joined an internal medicine group where there was a nurse practitioner who saw patients, and wrote orders and prescriptions for medication also without direct supervision of a physician.

In October 1988, Respondent began working, on a trial basis, for Joseph Kurtz, a physician assistant who operated three medical facilities, and in January 1989, Respondent was hired by Mr. Kurtz as an independent contracting physician. There was a written agreement between the Respondent and Mr. Kurtz, stating that one of Respondent's responsibilities was to act as a supervisor for the physician assistant, however there were no details provided as to the nature and extent of the supervision, and the agreement was not submitted for approval to the State Board of Medicine, Commonwealth of

Pennsylvania as required by state law. In addition, Respondent was not registered with the Pennsylvania Board of Medicine to use the services of a physician assistant as required by state law.

When he first began working for Mr. Kurtz, Respondent was concerned about the number of controlled substance prescriptions that were issued at the facilities and that a number of the patients appeared to be drug seekers. Respondent began reducing the number of controlled substance prescriptions issued and patients indicated that they felt safer coming to the facilities. After he was hired in 1989 and pursuant to Mr. Kurtz' request, Respondent provided three copies of his signature for the purpose of making a rubber stamp of his signature to be used for billing purposes and for writing prescriptions. Respondent and Mr. Kurtz had very little contact since they alternated working at the various facilities and would never work at the same facility at the same time. Respondent was told by another physician who had worked for Mr. Kurtz that the level of physician supervision used with Mr. Kurtz, including Mr. Kurtz working at a different facility, was permitted. Respondent testified at the hearing in this matter that pursuant to his agreement with Mr. Kurtz, Mr. Kurtz could only issue prescriptions for refills of earlier prescriptions and could not issue any new prescriptions. However, during previous interviews, Respondent did not mention this restriction on Mr. Kurtz' prescribing.

In 1990, the Pennsylvania Office of the Attorney General, Medicaid Fraud Section initiated an investigation of Respondent. As a result of this investigation, it was determined that Mr. Kurtz had been billing the medical assistance program using the provider identification number of Respondent, who was an approved provider under the program. Pursuant to the medical assistance program regulations, services by a physician assistant are permissible, providing that there is direct supervision of the physician assistant by the supervising physician and that the supervising physician is registered as such with the Board. Since the prescriptions discovered during the investigation were written by Mr. Kurtz, and not Respondent, they were not legitimately billed to the medical assistance program. As a result, criminal charges were filed against Mr. Kurtz and Maureen Clark, his wife, who owned Clark Family Pharmacy where the prescriptions were filled, which is located adjacent to one of the medical

facilities. Both Mr. Kurtz and his wife were each convicted in 1994 of three counts of Medicaid fraud.

In January 1992, after Respondent had testified before the grand jury in the state criminal proceedings against Mr. Kurtz and Ms. Clark, he became concerned and asked Mr. Kurtz to return his signature stamps. Mr. Kurtz provided Respondent with several photocopied pages from the **Federal Register** and the Pennsylvania Medical Board rules with portions highlighted by Mr. Kurtz and represented by Mr. Kurtz to be the law regarding the supervision of physician assistants. Respondent testified that he was afraid to confront Mr. Kurtz for fear of losing his job, and therefore, without further inquiry, Respondent continued to permit Mr. Kurtz to use his signature stamp and DEA registration number. According to Respondent, he did however begin going to the pharmacy on a weekly basis to review and initial the prescriptions issued by Mr. Kurtz to be certain they were not for "outrageous" amounts. However, this review was conducted after the controlled substances had already been dispensed. Respondent admitted at the hearing in this matter that he had not reviewed Mr. Kurtz' patient charts to see if the prescribed controlled substances were medically appropriate.

In May 1992, DEA initiated its investigation of Clark Family Pharmacy after receiving reports that the pharmacy was purchasing excessive quantities of controlled substances. Previously, while at the pharmacy to witness the destruction of drugs, a DEA investigator had noticed prescriptions that appeared to have rubber stamped signatures, and was told by the pharmacist that the prescriptions were written by Mr. Kurtz using the rubber stamp signature of Respondent. Pursuant to an administrative inspection warrant, DEA obtained controlled substance records from the pharmacy. A DEA investigator then entered into a database all of the prescriptions with Respondent's rubber stamped signature obtained from the pharmacy by DEA pursuant to the administrative inspection warrant, and by the Pennsylvania Attorney General's Office during its earlier investigation. It was determined that Respondent's signature was rubber stamped on a total of 2,545 prescriptions for controlled substances in Schedules III and IV between November 1990 and November 1992, for a total of 92,281 dosage units. These prescriptions were issued by Mr. Kurtz and were original prescriptions, and not refills.

During the course of DEA's investigation, on April 23, 1993, an

investigator interviewed the pharmacist at Clark Family Pharmacy who indicated that when he began working at the pharmacy in April 1989, he was told by Ms. Clark that Mr. Kurtz would hand carry patient files over to the pharmacy. The pharmacist was instructed to reduce the notes from these files to writing on Clark Family Pharmacy prescription pads and to sign Respondent's name to the prescriptions. In 1990, the pharmacy was visited by a state inspector who advised the pharmacist to cease the practice of reducing the information from patient files to writing on the pharmacy's prescription pads because that was the procedure for call-in prescriptions. The inspector advised the pharmacist that instead, the prescriptions should be generated by the medical facility on its own prescription pads and then filled at the pharmacy. Consequently, the medical facility and the pharmacy began a new procedure whereby Mr. Kurtz would write the prescription on the facility's prescription pad and rubber stamp it with Respondent's signature. The prescription would then be hand carried to the pharmacy by either Mr. Kurtz or one of the facility's employees. The patient would pick up the medication from the pharmacy without ever seeing the actual prescription. The pharmacist related that 90 percent of the pharmacy's business came from Mr. Kurtz' clinic.

Respondent was aware that Mr. Kurtz was not a licensed physician, that he was not registered with DEA, and that he treated patients and wrote controlled substance prescriptions without physician supervision. Respondent knowingly permitted Mr. Kurtz to use his DEA registration number to authorize controlled substance prescriptions. A letter from Respondent to DEA dated March 11, 1993, indicated that Mr. Kurtz told Respondent that he had destroyed the signature stamps in January of 1993. Respondent stopped working for Mr. Kurtz in August 1993. The last stamped prescription in evidence in this proceeding is dated November of 1992.

According to Respondent, one cause of his failure to adequately supervise Mr. Kurtz and to allow him to use Respondent's DEA registration number was his ignorance of the responsibilities of a supervising physician of a physician assistant. Respondent testified that based upon representations made by Mr. Kurtz and his previous experience with physician assistants and nurse practitioners, he did not know that allowing Mr. Kurtz to independently practice medicine was not permissible. Respondent

acknowledged that he made no further inquiries regarding the acceptable scope of practice for a physician assistant nor did he attempt to verify whether the prescriptions issued by Mr. Kurtz were refills of earlier prescriptions or new prescriptions.

In addition, Respondent testified that his actions were also caused by his abuse of alcohol. Respondent has a family history of alcoholism and started abusing alcohol in 1979. Following his first attempt to commit suicide in 1988, Respondent was admitted to the hospital for several weeks, where he was treated for depression, rather than alcoholism. In July 1988, he voluntarily signed up with the Physician's Health Program (PHP), an arm of the State Medical Society. Pursuant to this program, among other things, Respondent underwent urine screens, attended professional support group meetings and met with his psychiatrist. Respondent followed the program for approximately six months, when he began drinking again, and ultimately attempted suicide a second time in 1992.

Following his second suicide attempt, Respondent was hospitalized for two weeks and then was transferred to the Strecker Institute in November 1992 where for four weeks he received group and individual counseling from a psychiatrist specializing in addiction counseling, and attended alcoholics anonymous and narcotics anonymous meetings. Upon his release from inpatient treatment, Respondent participated in extensive aftercare for two years including regular attendance at AA meetings, random drug and alcohol screening, continued therapy with his psychiatrist and regular contact with the PHP. When his contract with the PHP expired in December 1995, Respondent voluntarily signed up for an additional five years of monitoring by the PHP, which he was still participating in at the date of the hearing in this matter. The Assistant Medical Director at the PHP testified that he had seen Respondent two to three times per month for the few years prior to the hearing; that Respondent met all of the requirements of his contract with the PHP; that Respondent's urine screens were negative for alcohol and controlled substances; and that Respondent's prognosis for continued recovery and sobriety is excellent.

In describing Respondent's behavior in 1992, Respondent's psychiatrist noted in a treatment summary dated July 26, 1996, that "He stated that he never looked into the regulations of working as a physician's assistant, and

in retrospect it is clear that he was mentally obtunded and not thinking clearly and coherently due to his active alcoholism." Respondent's psychiatrist further noted that "[t]he recommendation is that if Dr. Hallermeier continues to do as he currently is doing and follow [sic] his current regime which is that of attending many AA meetings every week and working his program as he is doing the prognosis for continuing successful outcome is quite optimistic."

Respondent's wife testified at the hearing in this matter that the family was supportive of Respondent's treatment efforts. She also stated that they have "an abstinence based home," in which no alcoholic beverages are kept or consumed.

Also testifying at the hearing were the administrators of three medical facilities where Respondent had been employed for the two to three years prior to the hearing. Each administrator stated that Respondent had refused a request for a signature stamp, and instead personally signs all comments requiring his signature. There are no physician assistants employed at any of these facilities. The administrators testified that Respondent is a professional and caring physician.

Respondent testified that he has progressively become more "stingy" in his handling of controlled substances. He further testified that although he has not frequently needed to prescribe controlled substances recently, he believed that such prescribing might be necessary in the future. He also stated that he has become a better doctor as a result of his recovery and that there is no question that the situation that occurred with Mr. Kuntz would never happen again.

The Government contends that Respondent's continued registration would be inconsistent with the public interest in light of the fact that he allowed Mr. Kurtz to use his DEA registration to issue over 2,000 controlled substance prescriptions, and in so doing, violated numerous provisions of both state and Federal laws and regulations. The Government also argues that Respondent's conduct is all the more egregious since he felt that a number of the patients of the facility were drug seekers; he was concerned over the number of controlled substance prescriptions being issued at the facility; and he was called to testify before a grand jury regarding the prescribing and billing practices of the facility. The Government questions Respondent's credibility, his lack of remorse, and his explanation that alcoholism was the cause of his problems.

The Respondent contends that the Government has not met its burden of proof and that his continued registration is not inconsistent with the public interest. Respondent argues that the Government's case focused entirely on Respondent's past misconduct and that Respondent does not deny this misconduct. However, Respondent contends that there was uncontroverted evidence presented at the hearing that his continued registration is in the public interest in light his recovery from alcohol addiction, his current responsible use of his DEA registration, his refusal to give new employers a signature stamp, his responsible practices regarding the prescribing of controlled substances, and the testimony of his present employers who think highly of his medical judgment and professionalism. Respondent further argues that the causes of his past misconduct, ignorance of the laws regarding physician assistants and his alcoholism, have now been remedied.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications, 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 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. Schwarz, Jr., M.D., Docket No. 88-42, 54 **Federal Register** 16,422 (1989).

Regarding factor one, there is no evidence that any action has been taken against Respondent's license to practice medicine or handle controlled substances by any State licensing board or disciplinary authority.

As to factors two and four, it is undisputed that Respondent allowed an unsupervised physician assistant to

prescribe large quantities of controlled substances. This is extremely troubling given that Respondent admitted that he did not trust Mr. Kurtz; that he thought that too many controlled substance prescriptions were being issued by Mr. Kurtz' medical facility; that he thought that some of the people receiving these prescriptions were drug seekers; and that he was subpoenaed to testify before the grand jury regarding Mr. Kurtz' prescribing and billing practices. Any one of these circumstances should have caused Respondent to be more vigilant in his supervision of Mr. Kurtz. Instead, Respondent continued to allow Mr. Kurtz to use his DEA registration number and the rubber stamp of his signature, thereby causing the unauthorized dispensing of over 92,000 dosage units of controlled substances over a two year period. Respondent's actions permitted the prescribing of controlled substances by an unauthorized individual in violation of numerous provisions of Federal and state laws and regulations, including 21 U.S.C. 829(b) and 841 and 21 C.F.R. 1306.03 and 1306.04(a), as well as, 63 P.S. 422.13 and 49 Pa. Code 18.144, 18.152, and 18.153 (1988-1992 version).

As Judge Randall noted, "[s]uch violations clearly raise questions as to the Respondent's fitness to possess a DEA Certificate of Registration." The Acting Deputy Administrator finds that Respondent's lack of control and supervision over the dispensing of controlled substances through the use of his DEA registration from 1989 to 1992 is reprehensible. However, like Judge Randall, the Acting Deputy Administrator notes that Respondent offered evidence that his behavior was caused by his alcoholism, and that he has taken numerous steps towards recovery and has remained alcohol-free since October 1992. The Acting Deputy Administrator also finds significant that there is no evidence that Respondent has improperly dispensed controlled substances or allowed the improper dispensing of controlled substances since November 1992.

As Judge Randall noted regarding factor three, "[t]he record contains no evidence that the Respondent has been convicted of any Federal or State laws relating to the manufacture, distribution or dispensing of controlled substances."

The Acting Deputy Administrator concurs with Judge Randall that "[t]he Respondent's lack of responsibility in dealing with Mr. Kurtz bears on factor five." While Respondent testified that he has never frequently prescribed controlled substances, he exhibited an extremely cavalier attitude towards the potentially dangerous nature of these

drugs by allowing an unsupervised and unauthorized physician assistant to prescribe these substances at will. As a DEA registrant, Respondent was entrusted with the responsibility to ensure that controlled substances are only dispensed for a legitimate medical purpose. While working for Mr. Kurtz, Respondent miserably failed to carry out his responsibilities as a DEA registrant.

Nevertheless, as Judge Randall notes, "the record contains no evidence that the Respondent has engaged in similar conduct since beginning treatment for his alcohol addiction." In addition, "Respondent has maintained his DEA registration [since 1992] and acted without incident." The Acting Deputy Administrator finds that while passage of time alone is not dispositive, it is a consideration in assessing whether Respondent's continued registration is inconsistent with the public interest. See Norman Alpert, M.D., 58 F.R. 67,420 (1993).

Judge Randall found, and the Acting Deputy Administrator concurs that "[t]he Government has proven by a preponderance of the evidence that the Respondent's past conduct would justify revocation of his DEA Certificate of Registration. Further, the Respondent has taken no remedial courses to enhance his knowledge of the proper prescribing practices related to controlled substances." However, Respondent has admitted and accepted responsibility for his past misconduct, and there is no evidence of any wrongdoing since November 1992, when he began extensive treatment for his alcoholism. Following the expiration of his treatment contract with the PHP, Respondent voluntarily signed up for an additional monitoring program. In addition, it is the opinion of the Assistant Medical Director at the PHP and Respondent's psychiatrist that Respondent's prognosis is excellent for continued recovery and sobriety provided that he continues to actively participate in his treatment program. Respondent's family is extremely supportive of his recovery efforts. Further, Judge Randall found Respondent's testimony credible that he has been sober since October 1992. Respondent's assertion is supported by the reports in evidence of Respondent's negative urine screens for the presence of alcohol or drugs. Finally, it appears that Respondent has learned from his past mistakes as evidenced by the fact that he has refused the requests of his subsequent employers to provide a signature stamp and considers it highly unlikely that he will ever work with physician assistants again.

Judge Randall concluded that "based upon the Respondent's hearing testimony and demeanor, and the fact that he has practiced medicine with his DEA registration for over four years without incident, I find it highly unlikely that he will engage in this type of misconduct again." However, she further concluded that "Respondent's misconduct warrants future monitoring of his prescribing practices and some remedial training." Judge Randall recommended that Respondent's continued registration subject to the following conditions would be in the public interest:

(1) For two years after the date of the final order, Respondent shall be required quarterly to submit a controlled substance prescription log to the local DEA office, with the type of log entries to be determined by the Special Agent in Charge or a designated representative. However, at a minimum the log should record the name of the patient, the date the prescription was issued, and the name, dosage and quantity of the controlled substance prescribed.

(2) By not later than two years after the date of the final order, Respondent shall submit to the local DEA office evidence of successful completion, after October of 1992, of formal training in the proper prescribing of controlled substances.

(3) If Respondent's current PHP contract requires urine screens, then Respondent shall keep these urine screen results on file in his office for two years, and shall allow DEA to review them upon reasonable request.

The Acting Deputy Administrator agrees with Judge Randall that in light of Respondent's rehabilitative efforts, his acceptance of responsibility for his past misconduct, his current employment situation, and the lack of any wrongdoing since November 1992, revocation of Respondent's DEA Certificate of Registration is not appropriate, but that some monitoring of his controlled substance handling and remedial training is appropriate to protect the public health and safety. The Acting Deputy Administrator agrees with Judge Randall that Respondent should receive some remedial training within two years of this final order. However, given the nature and extent of Respondent's previous misconduct, the Acting Deputy Administrator finds it appropriate to impose several additional restrictions than those recommended by the Administrative Law Judge and to require that these restrictions remain on Respondent's registration for three years, the period of one full registration cycle.

Therefore, the Acting Deputy Administrator finds that Respondent's DEA Certificate of Registration should be continued subject to the following restrictions:

(1) For the years after the effective date of this final order, Respondent shall submit at the end of every calendar quarter, a log of all controlled substances he has prescribed, administered or dispensed during the previous quarter to the Special Agent in Charge of the nearest DEA office or his designee. The log shall include the name of the patient, 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.

(2) For three years after the effective date of this final order, Respondent shall notify in writing the Special Agent in Charge of the nearest DEA office of his designee, if he assumes responsibility for the supervision of a physician assistant or any other mid-level practitioner.

(3) For three years after the effective date of this final order, Respondent is to continue his association with the PHP, and if for any reason, the PHP no longer requires random urine screens, Respondent shall continue these screens at his own expense. Respondent shall provide copies of the reports of the results of the screens upon reasonable request by DEA personnel.

(4) Within two years after the effective date of this final order, Respondent shall submit to the local DEA office evidence of successful completion, after October of 1992, of formal training in the proper handling of controlled substances.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AH6871049, issued to Robert G. Hallermeier, M.D., be continued, and any pending applications be granted, subject to the above described restrictions. This order is effective June 16, 1997.

Dated: May 8, 1997.

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