

convicted of a controlled substance related crime, had ever surrendered a DEA registration or had one revoked, suspended, denied, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation. Thereafter, Respondent was issued a Notice of Hearing which alleged that Respondent had been charged with three felony violations of state law and that he had been found guilty of one count of possession of a controlled substance. As Judge Bittner correctly notes, "[a]s far as this record shows, the Notice of Hearing did not make any reference to Respondent's explanation on his application of his answer to the liability question."

Respondent then participated in an informal hearing with DEA personnel and a representative from the United States Attorney's Office. Again as Judge Bittner correctly notes, "there is no evidence about the discussion at that meeting and, more specifically, about whether any of the government personnel advised Respondent that his statements on his [1990] application for DEA registration were inadequate."

Respondent ultimately entered into a memorandum of understanding in August 1990 wherein he agreed to "answer fully and truthfully" the questions on renewal applications. However, there is nothing in the memorandum of understanding that documents that Respondent was told that his previous explanation on the 1990 application was inadequate, nor was there any testimony at the hearing as to whether the parties discussed the meaning of this provision of the memorandum of understanding.

Respondent was then issued a DEA registration. Given the lack of evidence in the record that Respondent was advised that his answer in 1990 was inadequate, it is reasonable to accept Respondent's explanation for giving the same answer on his 1993 renewal application. Respondent testified, "I figured if this was good enough the first time, it's good enough the second time." Therefore, the Acting Deputy Administrator concludes that while Respondent may have technically violated the memorandum of understanding by failing to provide full and truthful answers on future applications, such a violation is understandable given that he was apparently not told his earlier explanation was inadequate.

The Acting Deputy Administrator concurs with Judge Bittner's conclusion that the Government has not established by a preponderance of the credible evidence that Respondent's continued

registration would be inconsistent with the public interest. While Respondent handled controlled substances from 1982 to March 1984 without proper state authorization and failed to maintain the required records, these events occurred over 12 years ago, and there is no evidence in the record that Respondent has improperly handled controlled substances since being issued a DEA registration in 1990. In addition, there is no evidence in the record that Respondent was ever advised that the explanation on his 1990 application was not sufficient, and therefore his use of the same explanation on his 1993 application is understandable.

Judge Bittner recommended that Respondent's registration not be revoked, but that it be subject to the following restrictions:

(1) Respondent shall not prescribe, administer or otherwise dispense any controlled substances for any member of his family or himself.

(2) Respondent shall handle controlled substances only in treating podiatric patients, and not for any purpose outside the usual practice of podiatry.

Under the circumstances of this case, the Acting Deputy Administrator finds Judge Bittner's recommended restrictions to be reasonable. Therefore, the Acting Deputy Administrator concludes that Respondent's DEA registration should be continued in Schedules II through V subject to Judge Bittner's recommended restrictions. It should be noted that it is unclear from the record, which schedules Respondent is currently registered to handle. He applied for Schedule II through V in 1990, however, the memorandum of understanding executed in August 1990 states, "[t]hat Respondent's handling of controlled substances pursuant to his Federal controlled substances registration upon issuance of such registration by the DEA, shall be limited to controlled drugs in Schedules III through V and that Respondent not be allowed to handle any controlled substance found in Schedule II for a period of not less than one (1) year from the date of the execution of the agreement." His 1993 renewal application, which is the subject of this proceeding, indicates that Respondent wishes his registration to be renewed in Schedules II through V. Regardless of Respondent's current authorization, the Acting Deputy Administrator concludes that in light of all of the evidence, Respondent should be registered in Schedules II through V subject to the above-referenced restrictions.

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 BB2461604, issued to Mark J. Beger, D.P.M., be continued, and any pending applications be granted in Schedules II through V, subject to the above restrictions. This order is effective March 10, 1997.

Dated: January 30, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97-3082 Filed 2-6-97; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated July 25, 1996, and published in the Federal Register on July 31, 1996, (61 FR 39986), Guilford Pharmaceuticals, Inc., Attn: Ross S. Laderman, 6611 Tributary Street, Baltimore, Maryland 21224, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of cocaine (9041), a basic class of controlled substance listed in Schedule II.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. § 823(a) and determined that the registration of Guilford Pharmaceuticals, Inc. to manufacture cocaine is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. § 823 and 28 CFR §§ 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: January 9, 1997.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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BILLING CODE 4410-09-M

[Docket No. 95-20]

Joseph S. Hayes, M.D.; Grant of Restricted Registration

On January 25, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Joseph S. Hayes, M.D. (Respondent) of Bristol, Tennessee, 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), for reason that such registration would be inconsistent with the public interest.

By letter dated February 10, 1995, the Respondent, acting pro se, timely filed a request for a hearing, and following prehearing procedures, a hearing was held in Nashville, Tennessee on July 12, 1995, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both sides submitted proposed findings of fact, conclusions of law and argument. After the filing of the posthearing findings of fact and conclusions of law, Respondent submitted three letters requesting favorable consideration of his application for DEA registration, two from himself dated January 8 and March 15, 1996, and one from another doctor dated March 18, 1996. Judge Bittner did not consider these letters in rendering her decisions since they were submitted after the hearing record was closed and after the period for filing proposed findings of fact and conclusions of law had expired. On May 1, 1996, Judge Bittner issued her Opinion and Recommended Ruling, Finding of Fact, Conclusions of Law and Decision, recommending that the Respondent's application for a DEA Certificate of Registration should be granted subject to various restrictions. On May 15, 1996, Government counsel filed exceptions to the Recommended Ruling of the Administrative Law Judge, and on June 14, 1996, Judge Bittner transmitted the record of these proceedings, including the three letters not considered by her, to the Deputy Administrator.

The Acting Deputy Administrator concurs with Judge Bittner's decision not to consider the three letters submitted after the time for filing proposed findings of fact and conclusions of law. The Acting Deputy Administrator has considered the remainder of the record in its entirety, and pursuant to 21 C.F.R. 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 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 Acting Deputy Administrator finds that Respondent graduated from the University of South Carolina

medical school and is board certified in family practice. Since 1977, he practiced emergency medicine in various states, including Tennessee, without incident until 1988, when he began using drugs. Respondents testified that he began using controlled substance samples of Xanax and Halcion, Schedule IV controlled substances, to help him sleep after his then-wife was charged with Medicare and Medicaid fraud for forging his signature to claims without his knowledge. According to Respondent, he gradually increased his dosage to up to eight tablets a night, without realizing how addictive the drugs were or how they changed his personality and behavior.

In May 1988, the Tennessee Health Related Boards Division (Division) received an anonymous complaint that Respondent was prescribing and dispensing controlled substances not in the course of professional practice. As a result of this information, the Division surveyed area pharmacies and found that of 826 prescriptions issued by Respondent, 602 were for Percocet, a Schedule II controlled substance. Subsequently, in December 1988, a Division Investigator met with Respondent to discuss his prescribing of controlled substances to four individuals. Respondent indicated that three of the individuals had medical problems that required the use of controlled substances. Respondent however, could not justify prescribing and administering a number of different drugs to one individual over an approximately three year period, indicating that he thought that the individual was abusing drugs, but that he did not know what to do with the individual.

As a result of this investigation, on September 7, 1989, the Division issued a Notice of Charges against Respondent alleging, in substance, that Respondent maintained numerous patients on highly addictive and abusable narcotics over extended periods of time, that he prescribed Schedule II narcotics to himself and his wife, that he prescribed various controlled substances to a patient he knew was abusing drugs, and that he had not kept adequate records of the dispensing of drugs at his office.

In January 1991, the Fourth Judicial Drug Task Force (Task Force) initiated an investigation of Respondent after receiving information from several sources that Respondent was overprescribing controlled substances to his patients and would provide them with whatever drugs they wanted. On two occasions in early 1991, a cooperating individual who was a

patient of Respondent received 100 Xanax tablets, after a very cursory physical examination, however Respondent did talk to the individual about the individual's anxiety attacks. The Task Force did not pursue the investigation of Respondent at that time.

On April 10, 1991, as a result of continued investigation, the Division issued an Order of Summary Suspension of Respondent's license to practice medicine in the State of Tennessee. The Order asserted that Respondent was found guilty of assaulting a patient who had done to his office seeking medical treatment, slapped a waitress in a restaurant across the face during a dispute over the bill, held a gun to his wife's head during an argument at his medical office, was found in contempt of court for not complying with a court order in his divorce proceeding, was arrested for resisting arrest and unlawful possession of a deadly weapon, prescribed phentermine, a Schedule IV controlled substance, for non-legitimate purposes, and prescribed hydrocodone, a Schedule III controlled substance, to an individual complaining of headaches after only a cursory examination causing the individual to become chemically dependent. The Order further found that in January 1991, Respondent issued prescriptions for various controlled substances to an individual. After consuming some of these drugs the individual returned to Respondent's office and was injected with Demerol, a Schedule II controlled substance, and Phenergan, a non-controlled prescription substance, even though Respondent was aware that the individual had consumed alcohol and some of the prescribed controlled substance prior to the injections. After leaving Respondent's office, the individual collapsed, causing an automobile accident. Subsequently, the individual required emergency medical assistance for drug overdose and respiratory arrest.

On April 12, 1991, Respondent was personally served with a copy of the Order of Summary Suspension by a Division Investigator who told Respondent on two occasion that in light of the Order, he was to cease practicing medicine in the State of Tennessee. Also on April 12, 1991, Respondent surrendered his DEA Certificate of Registration and was told by a DEA Investigator that as a result of this surrender he could no longer handle controlled substance in Tennessee.

It was subsequently discovered that Respondent issued at least 10 controlled substance prescriptions and continued

to practice medicine after April 12, 1991, when he was no longer authorized to do either. Thereafter, on May 10, 1991, an undercover Task Force Agent visited Respondent's office complaining of elbow pain. Respondent performed a very cursory physical examination and squeezed the agent's elbow asking if it hurt, but did not perform any other sort of examination or take any x-rays. The agent asked for Valium, to which Respondent replied that he was waiting for a shipment. Respondent then gave the agent some non-controlled prescription drug tablets, and charged him \$30.00 for the visit. The undercover agent returned to Respondent's office on May 13, 1991, telling Respondent that his elbow still hurt. Respondent did not examine the agent on this occasion, but gave him 22 tablets of propoxyphene, a Schedule IV controlled substance. The agent paid Respondent \$10.00 for the visit and received a receipt marked "immunization".

On July 23, 1991, DEA received a telephone call from a pharmacist advising that on July 20, 1991, he had filled prescriptions for a Mr. Steven Hayes, issued by a Dr. George Mills. The pharmacist indicated that he later compared the signature on the prescriptions with prescriptions that had been issued by Respondent and realized that the signatures matched. The pharmacist then called Dr. Mills, who stated that he had not written any prescriptions for a Steven Hayes.

Further investigation revealed that Respondent had been placing orders for controlled substances with a Connecticut drug distributor using his surrendered DEA registration number. Respondent placed an order for controlled substances on July 16, 1991, and on July 20, 1991, a DEA agent, posing as a United Parcel Service employee, delivered the order to Respondent's residence. After Respondent signed for the package, search warrants were executed at Respondent's residence and office. The search of Respondent's residence revealed approximately 17,400 dosage units of various controlled substances, as well as syringes and other drug paraphernalia.

Consequently, on May 10, 1991, the Division issued a Supplemental Notice of Charges to Respondent regarding his license to practice medicine, and on July 23, 1991, the Board of Medical Examiners (Board) issued a Final Order revoking Respondent's license to practice medicine, retroactive to April 10, 1991, the date of the summary suspension of his license. The Board also prohibited Respondent from applying for reinstatement of his

medical license for a year from April 10, 1991, and directed him to participate in the Tennessee Medical Association's Overprescribing and Substance Abuse Program, cooperate in further aftercare, take and pass the Special Purpose Examination, and obtain the advocacy of the Tennessee Medical Association's Impaired Physicians Program.

On June 18, 1991, as a result of Respondent's dispensing of drugs to the undercover agent, Respondent was arrested and charged with the sale and delivery of a Schedule IV controlled substance and the sale and delivery of a legend drug. Thereafter, following the search of his residence in July 1991, Respondent was arrested, and eventually indicted in the State of Tennessee on several counts of unlawful possession with intent to deliver or sell controlled substances. On January 16, 1992, Respondent pled guilty to one misdemeanor count of delivery of a legend drug, one misdemeanor count of delivery of a Schedule IV controlled substance, and one felony count of unlawful possession of a Schedule IV controlled substance with intent to deliver. Respondent was sentenced to four years imprisonment, which was stayed in favor of 90 days imprisonment, four years supervised probation, and a fine.

According to Respondent, the conduct which led to his convictions and revocation of his medical license was caused by his abuse of controlled substances on a daily basis from 1988 until he entered treatment in 1991. Respondent further testified that during that period he was "totally in a panic and [his] mind was completely blurred due to the effects of benzodiazepines," and that he had "lost all sense of feeling, and [his] sense of honesty and ethics were gone, because of the effects of drugs." In addition, Respondent testified that after he recognized that he needed treatment for his drug abuse, he attempted to stop the order for controlled substances that was ultimately delivered on July 29, 1991, but was informed that the order had already been processed.

Beginning in late July 1991, under the direction of the Tennessee Medical Foundation's Impaired Physicians Program, Respondent spent four months at an inpatient treatment facility. He then moved to a halfway house to continue his recovery. In January 1992, he began serving his 90 day criminal sentence during which he continued his recovery efforts. After his release from jail, he voluntarily re-entered a halfway house. Respondent testified that he has continued attending group therapy and meetings of Alcoholics Anonymous and

Caduceus, a recovery program for medical professionals. In addition, in compliance with the conditions for reinstatement of his medical license, he passed the competency examination and participated in the Tennessee Medical Association's Overprescribing and Substance Abuse Program.

On February 23, 1993, Respondent appeared before the Board seeking reinstatement of his medical license. The Board found that Respondent had complied with the requirements of its July 1991 Order and restored Respondent's medical license without restrictions, finding that he was no longer a threat to the health and safety of the citizens of Tennessee. On November 17, 1993, Respondent was granted permission by the Board to reapply for a DEA Certificate of Registration.

Respondent had been subject to random drug screens for the two and one-half years preceding the hearing. A representative sampling of the results were introduced into evidence, all of which were negative. Respondent also introduced into evidence at the hearing a letter dated July 10, 1995, from the Medical Director of the Tennessee Medical Foundation's Impaired Physicians Program which documented Respondent's rehabilitative efforts, and stated that "we are pleased to present Dr. Hayes to you as a repaired physician."

Respondent testified that he has learned mechanisms to avoid and manage stress, such as discussions with Caduceus group members and his friends, attending Alcoholics Anonymous meetings, and writing in a journal. He also testified that he has seen the consequences of drug abuse and knows that he will lose everything he has worked to regain should he relapse.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration if he determines that such registration would be inconsistent with the public interest. In determining the public interest, the following factors are considered:

- (1) The recommendation of 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, FR 16,422 (1989).

As to factor one, the recommendation of the appropriate state licensing board, it is undisputed that in April 1991, Respondent's license to practice medicine in the State of Tennessee was summarily suspended and was revoked effective April 10, 1991. It is also undisputed that on February 23, 1993, the Board of Medical Examiners for the State of Tennessee reinstated Respondent's medical license without restrictions and on November 17, 1993, granted Respondent permission to apply for a DEA Certificate of Registration. The Acting Deputy Administrator agrees with Judge Bittner's conclusion that the finding of the Board that Respondent is no longer a threat to the health and safety of the citizens of Tennessee and that there is no reason to believe that he would again abuse his DEA registration privileges, weighs in favor of finding that Respondent's registration would not be inconsistent with the public interest.

As to factor two, the evidence presented clearly indicates that Respondent's experience in dispensing controlled substances from 1988 to mid-1991 was abysmal. Respondent dispensed controlled substances to himself, causing him to become addicted to the drugs. He exhibited extremely poor judgment in dispensing controlled substances to his patients as evidenced by his continued prescribing of drugs to an individual he knew to be addicted, and his injecting a patient with Demerol knowing that she had already taken some other controlled substances and had consumed alcohol. In addition, he continued to dispense and prescribe controlled substances after his license to practice medicine was suspended and he had surrendered his DEA registration. However, as Judge Bittner noted, Respondent testified that his behavior was caused by his drug addiction. Since 1991, Respondent has taken numerous steps towards recovery and has remained drug-free. Accordingly, the Acting Deputy Administrator concurs with Judge Bittner that "Respondent's past practices were reprehensible," however,

"his efforts at recovery weigh in his favor."

Regarding factor three, it is undisputed that Respondent pled guilty and was convicted of one felony count of possession of a Schedule IV controlled substance with intent to deliver and one misdemeanor count of delivery of a Schedule IV controlled substance. However, as discussed above, Respondent's actions, which resulted in these convictions, were caused by his abuse of controlled substances. There is no evidence that Respondent has engaged in such behavior since 1991, and as Judge Bittner states, "Respondent appears to have made substantial progress in his efforts at recovery."

As to factor four, the record is replete with instances of Respondent's violation of Federal and state laws and regulations relating to controlled substances. On numerous occasions, he prescribed controlled substances for non-legitimate medical purposes in violation of 21 U.S.C. 841(a)(1) 21 C.F.R. 1306.04(a), a Tenn. Code Ann. 63-6-214(b)(12). He continued to practice medicine after his license was summarily suspended, and continued to use his surrendered DEA registration to prescribe, dispense and order controlled substances in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.03. Finally, he forged another doctor's signature on a prescription in violation of 21 U.S.C. 843(a)(3). The Acting Deputy Administrator finds that violations such as these, clearly raise questions as to Respondent's fitness to possess a DEA Certificate of Registration. Again, however, the record supports a finding that Respondent committed these violations of the law because of his addiction to drugs, and he has been in extensive successful treatment for this addiction since 1991.

Finally, regarding factor five, Respondent's acts of physical violence, including assaulting a waitress at a restaurant, a patient in his office, and his wife at the medical office, as well as, his arrest for unlawful possession of a weapon and resisting arrest, are of tremendous concern to the Acting Deputy Administrator. However, there is no evidence in the record that Respondent has engaged in similar behavior since beginning treatment for his drug addiction in 1991.

Judge Bittner recognized that Respondent has exhibited in the past a disregard for the laws and regulations regarding the proper handling of controlled substances. However, he has not abused controlled substances since July 1991, and has undertaken considerable steps towards rehabilitation. Judge Bittner found that

"Respondent appears to accept responsibility for his drug addiction and actions resulting from it, and has testified that he knows the consequences of relapse." Consequently, Judge Bittner found that it would not be inconsistent with the public interest to issue Respondent a DEA registration subject to the following conditions for a period of three years after issuance of the Certificate of Registration: (1) Respondent is not to order or dispense controlled substances except in a medical clinic or hospital environment; (2) Respondent is to continue his association with the Tennessee Medical Foundation's Impaired Physicians Program, continue attending Caduceus group meetings, and continue attending Alcoholics Anonymous or a similar program; (3) Respondent is to continue random drug screening at this own expense; and (4) Respondent shall maintain a log of all prescriptions for controlled substances he issues, and is to submit that log for review to the Nashville DEA office at the end of each calendar quarter.

Government counsel filed exceptions to Judge Bittner's recommendations arguing that "Respondent's egregious conduct evidenced a lack of regard for the responsibilities inherent in a DEA registration; therefore, such conduct constitutes the basis for the denial of his application for DEA registration." In support of its position, the Government cited two previous cases where an application for DEA registration was denied. The Government argued that in the case of James W. Shore, M.D., 61 FR 6262 (1996), an application for DEA registration was denied even though "it was found that the applicant's misconduct occurred nearly ten years prior; that the applicant was found to have taken responsibility for past unlawful actions; successfully completed criminal probation; and, taken a course on prescribing practices * * *." The Government argued that this denial was based, in part, "upon the applicant's demonstrated 'cavalier attitude' toward controlled substances."

The Acting Deputy Administrator finds that the Shore case is distinguishable from this case since in Shore, it was found that the applicant was manipulated by patients and there was no explanation as to how he would avoid being manipulated in the future. In addition, in that case, it was found that the applicant exhibited a "cavalier attitude" at the hearing. In this case, Respondent's actions were caused by his self-abuse of controlled substances over more than five years ago. He has taken numerous steps towards continued recover and he provided

assurances at the hearing as to how he would avoid a relapse. It is without question that Respondent exhibited a cavalier attitude towards controlled substances from 1988 to mid-1991, but the evidence in the record supports a finding that Respondent has been diligent in his efforts to correct and control his problem and understands the severity of the consequences should he begin abusing controlled substances again.

In its exceptions, the Government also cites to David W. Bradway, M.D., 59 FR 6297 (1994), arguing that in that case the application was denied even though the applicant presented evidence regarding his rehabilitation from drug abuse, his ability to responsibly handle controlled substances, and the unlikelihood of his relapse into drug abuse. However, the Acting Deputy Administrator concludes that in that case, the underlying circumstances of the applicant's self-abuse were far more serious than the circumstances surrounding Respondent's abuse of controlled substances. In addition, in Bradway, it was determined that the applicant had "not demonstrated either ethical conduct nor trustworthy behavior to warrant the granting of a DEA Certificate of Registration." The Acting Deputy Administrator concludes that Respondent has shown, through this continued rehabilitative efforts even though no longer required by the State of Tennessee, that he can be trusted to responsibly handle controlled substances subject to the restrictions recommended by Judge Bittner.

The Government further argues in its exceptions that the Acting Deputy Administrator should not credit Respondent's explanation that his use of controlled substances caused him to exercise poor judgment. The Government contends that "[t]he granting of a DEA registration under such circumstances would open the door for future litigants to misuse the substance abuse defense in rationalizing flagrant violations of controlled substances laws and regulations." If the Acting Deputy Administrator accepted the Government's argument, no applicant who had abuse controlled substances in the past would ever be granted a DEA registration regardless of any rehabilitative efforts. Instead, the Acting Deputy Administrator is charged with evaluating the facts and circumstances surrounding each application to determine whether registration would be inconsistent with the public interest. In this case, the Acting Deputy Administrator concludes that the record supports a finding that Respondent's behavior was caused by

his abuse of controlled substances, and there is no evidence of any wrongdoing by Respondent since he entered treatment in 1991.

The Government alternatively argues in its exceptions that should a registration be issued to Respondent it should be restricted to schedules IV and V for a three year period, thereby allowing Respondent to demonstrate that he can "properly handle controlled substances in schedules with the least potential for addiction * * *." Given Respondent's past behavior, the Acting Deputy Administrator appreciates the Government's argument. However, the Acting Deputy Administrator does not believe that restricting Respondent's registration to Schedules IV and V would better protect the public interest, since the drugs that Respondents abused himself were in Schedule IV. The Acting Deputy Administrator concludes that the restrictions recommended by Judge Bittner are sufficient at this time to monitor Respondent's handling of controlled substances and to protect the public interest. Therefore, the Acting Deputy Administrator finds that it would not be inconsistent with the public interest at this time to grant Respondent's application for registration, provided that for three years after Respondent is granted a DEA registration: (1) Respondent is not to order or dispense controlled substances except in a medical clinic or hospital environment; (2) Respondent is to continue his association with the Tennessee Medical Foundation's Impaired Physicians Program, continue attending Caduceus group meetings, and continue attending Alcoholics Anonymous or a similar program; (3) Respondent is to continue random drug screening at his own expense; and (4) Respondent shall maintain a log of all prescriptions for controlled substances he issues, and is to submit that log for review to the Nashville DEA office at the end of each calendar quarter. The log shall include at a minimum, the name of the patient, the date the prescription is issued, and the name, dosage and quantity of the drug prescribed.

Accordingly, the Acting 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, submitted by Joseph S. Hayes, M.D., for a DEA Certificate of Registration in Schedules II through V, be and it hereby is granted subject to the above described restrictions. This order is effective March 10, 1997.

Dated: January 31, 1997.
James S. Milford,
Acting Deputy Administrator.
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Kenneth Kleiner, M.D.; Revocation of Registration

On October 20, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Kenneth Kleiner, M.D., of Woodside, New York, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AK1048203, pursuant to 21 U.S.C. 824(a)(3), and deny any pending applications for registration pursuant to 21 U.S.C. 823(f). Specifically, the Order to Show Cause alleged that the State Board for Professional Medical Conduct, State of New York, revoked his license to practice medicine in New York by Order dated December 15, 1994, and consequently, Dr. Kleiner is without state authorization to handle controlled substances in the State of New York.

The Order to Show Cause was ultimately served upon Dr. Kleiner, and by letter dated May 14, 1996, Dr. Kleiner requested "an adjournment of the hearing" pending the outcome of civil litigation concerning his state medical license. On May 21, 1996, the Office of Administrative Law Judges sent Dr. Kleiner a letter stating that it is unclear whether or not he is requesting a hearing and advising him to respond by June 5, 1996 to request a hearing, otherwise his right to a hearing will be deemed waived. Dr. Kleiner responded by letter dated June 4, 1996, stating, "I respectfully request neither a hearing nor a waiver of such hearing, but rather an adjournment until such time as the instant matter may be fairly and justly adjudicated," apparently referring to his pending civil action. Thereafter, on June 14, 1996, Administrative Law Judge Mary Ellen Bittner advised Dr. Kleiner that pursuant to 21 C.F.R. 1301.54(d) and (e), he is deemed to have waived his opportunity for a hearing, inasmuch as he has not requested a hearing. Judge Bittner further advised Dr. Kleiner that his letters dated May 14 and June 4, 1996, would be forwarded to the Deputy Administrator for consideration in rendering his decision in this matter.

The Acting Deputy Administrator concurs with Judge Bittner's conclusion that Dr. Kleiner has waived his opportunity for a hearing. Therefore, after considering relevant material from the investigative file in this matter, as