Xtreme Enterprises, Inc., 67 FR 76195 (2002).

With regard to factor five, other factors relevant to and consistent with the public safety, the Deputy Administrator finds this factor weighs heavily against granting the application. Unlawful methamphetamine use is a growing public health and safety concern throughout the United States and Southeast. Ephedrine and pseudoephedrine are precursor products needed to manufacture methamphetamine and operators of illicit methamphetamine laboratories regularly acquire the precursor products needed to manufacture the drug from convenience stores and gas stations which, in prior DEA decisions, have been identified as constituting the grey market for list I chemical products. It is apparent that CWK intends on being a participant in this market.

While there are no specific prohibitions under the Controlled Substances Act regarding the sale of listed chemical products to these entities, DEA has nevertheless found these establishments serve as sources for the diversion of large amounts of listed chemical products. *See, e.g., ANM Whilesale, supra,* 69 FR 11652; *Xtreme Enterprises, Inc., supra,* 67 FR 76195; *Sinbad Distributing,* 67 FR 10232 (2002); *K.V.M. Enterprises,* 67 FR 70968 (2002).

The Deputy Administrator has previously found that many considerations weighed heavily against registering a distributor of list I chemicals because, ''[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are considered part of the grey market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine.'' *Xtreme Enterprises, Inc., supra,* 67 FR at 76197. As in *Xtreme Enterprises, Inc.*, lack of a criminal record and intent to comply with the law and regulations are far outweighed by CWK's lack of experience and the company's intent to sell ephedrine and pseudoephedrine exclusively to the gray market. The Deputy Administrator is further troubled by CWK's providing DEA investigators misleading information, indicating the company cannot be trusted to handle the responsibilities of a registrant.

Based on the foregoing, the Deputy Administrator concludes that granting the pending application would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders the pending application for DEA Certification of Registration, previously submitted by CWK Enterprises, Inc., be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–26309 Filed 11–26–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02–40]

Dan E. Hale, D.O., Denial of Registration

On March 21, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Dan E. Hale, D.O. (Respondent) notifying Respondent of an opportunity to show cause as to why DEA should not deny his application for a DEA Certificate of Registration as a practitioner pursuant to 21 U.S.C. 824(a)(1) and (a)(5) and on grounds that his registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

The Order to Show Cause alleged in sum that on March 21, 1995, Respondent had been convicted by a jury in United States District Court, Eastern District of Kentucky, of 21 felony counts related to wrongful billing under Medicaid, Medicare and TennCare programs from 1980 to 1993. On June 20, 1995, Respondent surrendered his DEA Certificate of Registration AH7753709 and was subsequently sentenced to a total of 57 months confinement, followed by two years of supervised release.

It was also alleged that on March 18, 1994, the Tennessee Department of Health, Board of Osteopathic Medicine (Board), issued a Notice of Charges alleging, among other things, that Respondent improperly allowed a physician assistant to dispense and prescribe controlled substances without supervision and that in several instances Respondent and the physician assistant, dispensed and prescribed controlled substances in violation of established treatment protocols. On November 8, 1995, he entered into an Agreed Order with the Board, whereby the Board ordered that he surrender his osteopathic medical license and in the event his conviction was upheld on appeal, his license would be automatically revoked. After the conviction was affirmed by the Sixth Circuit Court of Appeal on January 28, 1997, the Board revoked Respondent's medical license. That license was subsequently reinstated on May 25, 2001.

It was further alleged that on January 26, 1996, as a result of Respondent's convictions, the United States Department of Health and Human Services notified him that he was mandatorily excluded from the Medicare program pursuant to 42 U.S.C. 1320a–7(a).

Finally, it was alleged that on June 18, 2001, Respondent materially falsified an application for DEA registration by failing to disclose the voluntary surrender of his previous DEA registration and the revocation of his State osteopathic medical license.

Respondent requested a hearing on the issues raised by the Order to Show Cause and following pre-hearing procedures, a hearing was held in Arlington, Virginia, on January 7 and 8, 2003. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted written proposed findings of fact, conclusions of law, and argument.

On November 26, 2003, Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (Opinion and Recommended Ruling) in which she concluded that grounds existed to deny Respondent's application for DEA registration and recommended the application be denied. On January 14, 2004, Respondent filed exceptions to Judge Bittner's Opinion and Recommended Ruling and on January 15, 2004, Judge Bittner transmitted the record of these proceedings to the then-Acting Deputy Administrator of DEA.

By his counsel's letter dated March 22, 2004, Respondent asked the Deputy Administrator to consider the impact of recent changes implemented by the State of Tennessee, Bureau of TennCare. Counsel for the Government had no objection and the submission has been considered as a part of the administrative record.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. As set forth below, the Deputy Administrator adopts in whole, the recommended findings of

fact and conclusions of law of the Administrative Law Judge. Her adoption is in no manner diminished by any recitation of facts, issues, or conclusions herein, or of any failure to mention a matter of fact or law.

The record before the Deputy Administrator sows that on October 7, 1977, Respondent, an osteopathic physician, was issued DEA Certificate of Registration AH7753707, as a practitioner. At that time, Respondent had recently opened a practice in Morristown, Tennessee, had two employees and shared office space with another physician, Doctor L., at the Boulevard Center clinic. Respondent later purchased Doctor L.'s practice, hired him as an employee and began to expand operations. By the early 1990's, Respondent had over 100 employees and his clinic was seeing between 225 to 250 patients per day.

Around 1989, Respondent opened a second clinic in Bean Station, Tennessee, about eleven miles from Morristown. It was primarily staffed by Mr. Dean B., a physician assistant. Respondent later added a pharmacy and dental office to his Bean Station operations. Respondent testified that he never intended to go to the Bean Station clinic on a daily basis to see patients and it was overseen by the Rural Health Consortium, a government agency which oversees clinics run by physician assistants. He testified that he had consulted with attorneys who advised him it was permissible for Mr. B., to staff the Bean Station clinic.

From about 1991 to 1994, respondent made four trips to Benin, Africa, where he and his team provided humanitarian medical assistance to hundreds of patients every day. During an early 1991 trip, he asked Dr. L. to cover for him at Bean Station. While Dr. L. discussed patients with Mr. B., he did not sign medical charts and Respondent signed them upon his return. Respondent testified he thought it did not make any difference whether he or Dr. L. signed the charts and that based on his review of those charts, all controlled substances prescribed at the clinic were appropriate.

On March 18, 1994, the Tennessee Division of Health Related Boards, Department of Health (Department of Health), issued a Notice of Charges against Respondent. It alleged, in sum, that: Respondent had been improperly using physician assistants to supervise his clinics since at least 1985, even though State legislation authorizing osteopathic physicians to utilize and supervise physician assistants was not enacted until 1992 and it had no retroactive effect; that he allowed his physician assistants to see, treat and diagnose conditions in new patients and previously undiagnosed conditions in regular patients; that the allowed Mr. B. to improperly see patients and render treatment that was inappropriate for the diagnosed conditions; allowed Mr. B. to provide treatment and medications that were inconsistent with written protocols and allowed him to diagnose conditions outside the scope of those protocols without first consulting Respondent; that between January 1991 until April 1992, he continuously improperly dispensed or prescribed controlled substances to numerous patients without adequate attempts to diagnose their need for the controlled substances or attempt alternative methods of therapy; and allowed his patients to refer to Mr. B. as ''doctor.''

While Respondent was afforded a right to a hearing on the allegations, on November 8, 1995, through counsel, he entered into an Agreed Order with the Tennessee Board of Osteopathic Examination (Tennessee Board). However, the Agreed Order did not specifically address the allegations in the Notice of Charges but was, instead, based on Respondent's felony convictions of March 21, 1995.

At the DEA hearing, Respondent contested the allegations in the Notice of Charges. He testified, in sum, that he was appropriately vigilant in prescribing controlled substances and in supervising Mr. B. Respondent's son, an attorney and medical student who worked in the clinic, testified Respondent saw Mr. B. each morning and they talked on the phone eight to ten times a day. The son further testified that during 1992 and 1993, the Bean Street clinic saw an average of 45 to 55 patients per day and, while not every patient was a subject of discussion between Respondent and Mr. B., Respondent would review all patient notes and ask questions.

Dr. Maurice R., an osteopath who had known Respondent for 26 years, testified on Respondent's behalf. He had worked in Respondent's clinic briefly as part of his training and considered Respondent his mentor. He testified he never saw Respondent over-prescribe controlled substances and described the difficulties facing doctors in East Tennessee in determining patients' legitimate needs for controlled substances. He described Respondent as providing care to a medically underserved community by accepting Medicaid patients.

With regard to the allegations in the Notice of Charges, Dr. R. testified in order to determine whether the standard of care was met with regard to any patient, it would be necessary to review the patient's charts, which were unavailable. However, from what was contained in the Notice of Charges, he saw no deviation from the standard of care. With regard to the allegation that Respondent utilized a physician's assistant prior to enactment of legislation permitting such a practice, Dr. R. testified that the Tennessee Legislature frequently forgot to include physicians with Doctor of Osteopathy degrees in legislation addressing physicians with Medical Doctor degrees.

A pharmacist who worked at the pharmacy next door to Respondent's Morristown office testified that from 1985 to 1995, prescriptions issued by Respondent made up about thirty percent of the pharmacy's prescription business. He further testified Respondent did not issue prescriptions for controlled substances in greater proportions than other area physicians or issue prescriptions for abnormal quantities of drug. The pharmacist had also accompanied Respondent on a humanitarian trip to Benin and described the good work they performed. The pharmacy's owner, who co-owned the building with Respondent, testified Respondent issued the ''vast majority'' of prescriptions filled at the pharmacy and that he prescribed drugs in Schedules III, IV and V, but rarely those in Schedule II.

On November 17, 1994, Respondent was indicated in the United States District Court for the Eastern District of Kentucky on 21 felony counts of racketeering, conspiracy to engage in racketeering, insurance fraud, and Medicare and Medicaid fraud. A 22nd count contained forfeiture allegations.

The indictment alleged, in substance, that Respondent and his associates ordered and performed diagnostic tests on patients that were unnecessary, but for which medical insurers would pay; personnel working for Respondent put computer-generated medical histories in patient charts to justify diagnostic tests; providers at Respondent's clinic treated Medicare and Medicaid patients differently from others by, for example, requiring them to come to the clinic in person to obtain prescription refills, thus affording the clinic more opportunities to run reimbursable tests; although some Medicaid patients abused addictive medications, providers repeatedly gave such medications to those patients because the patients were a good source of business and did not object to being given numerous diagnostic tests as long as they received the drugs they wanted; that Respondent and Dr. L. had admitted to hospital personnel that certain individuals were

engaged in an on-going insurance fraud to collect on multiple hospital supplemental insurance policies and were rewarded for this assistance by receiving payment for medical services and unnecessary diagnostic tests; the clinic gave numerous new patients complete electrocardiograms, blood tests, and X-ray tests before the patients saw a physician and without regard for medical necessity; clinic personnel injected patients with certain drugs because there was an abundant supply of the drug in the clinic, not because the drug was medically necessary; injectable medications were diluted below the therapeutic dosages to increase profits; and when Medicaid patients were switched to TennCare in January 1994, they were given unnecessary comprehensive examinations solely because TennCare would reimburse the clinic for these tests.

On March 21, 1995, a jury found Respondent guilty of all 21 counts. On March 21, 1995, Respondent entered into an Agreed Order of Forfeiture with the United States. On July 3, 1995, the court sentenced Respondent to 57 months of incarceration, followed by two years of supervised release and ordered him to comply with the Agreed Order of Forfeiture and pay a special assessment of $1,050.00.

Respondent appealed the judgment to the United States Court of Appeals for the Sixth Circuit, which affirmed the convictions on January 28, 1997. *See, United States* v. *Hale,* No. 95–5915 (6th Cir. January 28, 1997). The Court of Appeal described the hospital admission aspect of the case as follows:

> The fraud worked simply. Participants would buy numerous hospital indemnity policies that paid a sum certain in the event of a hospital admission. They would then fake injuries, present themselves to a ''sympathetic'' doctor, and gain admission to a hospital, typically for a soft tissue injury. The participants then filed claims for coverage with numerous insurance companies. *Id.*

The Court stated that the issue on appeal was whether Respondent knew of the fraud. It concluded he did, relying on testimony from Russell R., who had directed many of the scheme's participants, that Respondent had advised that patients should ''bend over in pain, use a wheelchair, and request pain medication.'' Respondent ''also discouraged [Russell R.'s] fondness for staging car accidents because they involved police; rather, 'a bathtub was a good place to have an accident.' '' The court also relied on the testimony of a hospital administrator that he had been warned his hospital was being used to perpetuate fraud, the he discussed the fraud with Respondent, and Respondent indicated he knew about it. *Id.*

With respect to overbilling, the court noted testimony that Respondent's ''goal was to see as many patients and perform as many tests as the government would pay for'' and that Respondent used an egg timer to time himself and challenged the staff to increase the number of tests they performed. In sum, the court found, ''the testimony at trial from former employees, including doctors, nurses, and staff about the unnecessary testing and dubious billing was overwhelming.'' *Id.*

During the DEA hearing, Respondent testified about the conduct leading to his convictions. He testified that several patients came to him ''faking injuries'' and ''wanting to be put into the hospital for physical therapy,'' and that these patients used supplemental insurance to pay for their hospitalization and had bribed one of Respondent's insurance clerks to stamp forms for multiple (as many as 25) different companies, and would then collect on all of their policies. According to Respondent, ''I was guilty of participating in that because I was the physician.''

Respondent testified that ''I know that there were things going on that shouldn't be there and I should have taken action to have changed it.'' He admitted to the conduct alleged in various counts of the indictment, but denied providing addictive medications to patients who abused them in return for the patients agreeing to undergo diagnostic tests and that he felt they needed the diagnostic tests he ordered for them.

Notwithstanding the allegations in the indictment relating to providing drugs to persons who abused them and likewise, notwithstanding the jury's verdicts, Respondent also testified at the DEA hearing that he had never been charged with any crime relating to the unlawful prescribing or dispensing of controlled substances.

On June 20, 1995, Respondent surrendered his DEA Certificate of Registration AH7753709 and signed a DEA form preprinted with language that he was surrendering the registration ''[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part.''

As previously noted, on November 8, 1995, Respondent entered into an Agreed Order with the Tennessee Board. The Agreed Order cited the Tennessee Board's policy of disciplining osteopathic physicians convicted of felonies and ordered Respondent to surrender his license to practice osteopathic medicine in Tennessee. It did not address the specific allegations in the Notice of Charges.

The Agreed Order further stated that if Respondent's conviction was upheld on appeal, his license would be automatically revoked and if the conviction was reversed, the Tennessee Board would hear the matters in the Notice of Charges on their merits.

Respondent commenced his sentence on July 24, 1995. On January 26, 1996, the Director, Health Care Administrative Sanctions, U.S. Department of Health and Human Services, wrote Respondent advising him that because of his felony convictions, he was excluded from participating in Federal health care programs, including Medicare and Medicaid, for a period of fifteen years.

Respondent was released from incarceration on May 19, 1998. In early 2000, he applied to the Tennessee Board for relicensure. After taking and passing a Board ordered national examination, Respondent's medical license was reinstated on May 25, 2001.

On June 18, 2001, Respondent executed the application for DEA registration at issue in this matter. The form included several standard liability questions asking about prior convictions or adverse actions being taken against Federal or State licenses. Question 4(c) asked, ''Has the applicant ever been convicted of a crime in connection with controlled substances under State or Federal law?'' Question 4(d) asked, ''Has the applicant ever surrendered or had a Federal controlled substance registration revoked, suspended, restricted or denied?'' Question 4(e) asked, ''Has the applicant ever had a State professional license or controlled substance registration revoked, suspended, restricted, or placed on probation?'' The application further directs the applicant to explain any affirmative answers. Respondent answered ''no'' to all three questions and left the explanation section blank.

A DEA Diversion Investigator was assigned to investigate the application after a routine check of the NADDIS system indicated he had surrendered a previous DEA registration. The investigator testified at the hearing that Respondent's answer to question 4(d) was false because he had surrendered his DEA registration in 1995 and that his answer to question 4(e) was also false because he was ordered to surrender his State license as a result of his felony conviction and when the conviction was affirmed on appeal, the license was automatically revoked.

Respondent testified that while his answer to question 4(d) was false, he had simply forgotten he had surrendered his previous DEA registration and his answer had not been an intentional misrepresentation. He attributed the error to stress, anxiety and depression he was suffering at the time of the surrender emanating from the criminal proceedings and loss of his practice. Respondent's son also testified regarding the stress his father had been suffering at the time and the possibility that he had genuinely forgotten about surrendering the registration when he executed the application.

With regard to the answer pertaining to revocation of his State license, Respondent testified that his then-counsel had signed the Agreed Order, as Respondent had begun serving his prison sentence. He testified he answered question 4(e) in the negative because he knew he had surrendered his license and in his mind, at the time, he thought it was ''gone'' and thus not revoked.

Two months after applying for registration, Respondent called a diversion investigator to inquire as to its status. When told he had falsified the application, he did not claim he had simply forgotten surrendering the prior registration. Instead, he argued with the investigator that he had never surrendered his prior registration. Respondent testified that when he had made that phone call, he still believed he had never surrendered the registration.

Following Respondent's State relicensure, he was certified as a Medical Review Officer and passed examinations for certifications in pediatric acute life support and acute cardiac life support. He was designated a Civil Surgeon by the United States Immigration and Naturalization Service, authorizing him to perform medical examinations of aliens seeking permanent residence in the United States.

A pastor of a local church, whose congregants are mostly Spanish speakers from Central and South America, testified in Respondent's behalf. He described Respondent's close involvement with the church, its humanitarian assistance efforts and missions and Respondent's practice of conducting health fairs for congregants where he screened and treated them at no charge. He described Respondent as one of the few local physicians fluent in Spanish and that with his ability to communicate to Spanish speaking patients and his low fees, Respondent's contribution to the Latino community was invaluable. When questioned on cross-examination as to the reasons for the fraud convictions, the pastor attributed them to the size of Respondent's practice and his lack of management skills to ''stay on top of the bookkeeping and reports that were made.''

An assistant plant manager for a local poultry plant, whose employees are mostly Latino, testified for Respondent. He described how the company sends employees covered by workman's compensation to Respondent, which is cost effective and where they receive good medical treatment. He would like to send employees covered by the company's health insurance to Respondent, but the carrier requires that all covered physicians be able to prescribe any requisite medications, including controlled substances.

A reverend who was a missionary to Benin submitted a declaration describing Respondent and his wife's humanitarian efforts in Africa during 1991 through 1994, where they brought medical supplies and treated patients on four two-week trips, which were performed at their own expense. These activities were further testified to by a Licensed Practical Nurse who had worked for Respondent and accompanied him on the humanitarian missions.

In letters of support, a local doctor who had been the chief of the family practice service at the local hospital, described Respondent as a compassionate, hard working and competent general practitioner whose practice fills ''a necessary niche.''

Respondent's head nurse between 1985 and 1994 testified she was aware of the circumstances behind the convictions and that Respondent, Mr. B. and Dr. L. had all prescribed narcotics ''in a careful and responsible manner'' and that his registration should be granted.

Respondent testified that he now has a small practice, where his wife works as the receptionist and there is only one nurse. He sees about 20 patients per day and very few are covered by insurance. He testified that he needs a DEA registration in order to be a provider for various insurance plans, but that he had little need to prescribe controlled substances. However, he did have some patients suffering from pain and without registration, he has to send them to a pain clinic which is very expensive for the mostly low income patients. He further testified that whenever he calls a prescription into a pharmacy, he is asked for a DEA registration number, even when it is not a prescription for a controlled substance. Because the local pharmacy computer systems use DEA registration numbers for tracking purposes, whenever he writes any prescription, the pharmacy has to override its program in order to fill a prescription issued by Respondent.

Regarding acceptance of responsibility for his misconduct, Respondent testified he is not the same person as before and that he had made a number of errors in judgment, including turning management of his practice over to other people instead of ''keeping my hand on the pulse.''Asked if he took ''full responsibility for the actions, your actions, that led to the indictment and conviction,'' Respondent replied, ''Absolutely, I mean, * * * it was plain old outright horrible mistakes, and I take full responsibility. That's one thing that the prison did teach me, is that I can't pass it off on anyone else. It was me.''

Respondent also noted the conviction on his resume, which he prepared in 2001. In it he stated: ''I was convicted of insurance fraud. I lost my license to practice medicine. I *steadfastly assert my innocence,* but I readily accept responsibility for what happened. The crime occurred in my office under my nose and I did not take appropriate steps to correct the situation (emphasis added).''

Respondent also testified that ''*I did not have a criminal intent to commit a crime,* but I did commit a crime. So I'm guilty. I'm guilty of committing a crime. I accept full responsibility for it, and I agree with the Government and everything that they did to me. I have no bad feelings at all about anything that happened to me (emphasis added).''

He further testified that the had no intent to build his practice like he previously had and that if he received a DEA registration, he would treat it as a privilege and not abuse it.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny any pending applications for renewal of DEA registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health or safety.

The Controlled Substances Act further specifies in 21 U.S.C. 824(a), that the Deputy Administer may revoke a DEA Certificate of Registration if the registrant:

(1) has materially falsified any application for a DEA registration;

(2) has been convicted of a felony under Federal or State law relating to a controlled substance;

(3) has had his State license or registration suspended, revoked, or denied and is no longer authorized to handle controlled substances in the State in which he maintains a DEA registration;

(4) has committed acts that would render his registration inconsistent with the public interest as determined pursuant to 21 U.S.C. 823(f); or

(5) has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

As a theshold matter, Judge Bittner noted that although the grounds listed under 21 U.S.C. 824(a) pertain to revocation or suspension of a registration, ''[t]he agency has consistently held that the Administrator may also apply these bases to the denial of a registration, since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it the next.'' *See Kuen H. Chen, M.D.*, 58 FR 65,401, 65, 402 (1993) (citing *Sterling Drug Co. and Detroit Prescription Wholesaler, Inc.*, 40 FR 11918 (1975).

Further, the factors specified in section 823(f) 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 she deems appropriate in determining whether a registration should be revoked or an application for registration *See Henry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Administrative Law Judge found three grounds to deny Respondent registration under section 824(a). First, pursuant to 21 U.S.C. 824(a)(1), Judge Bittner found he materially falsified his application for registration and rejected Respondent's assertions to the contrary, primarily on credibility grounds. DEA has previously held that in finding that there has been a material falsification of an application, it must be determined that the applicant knew or should have known that the response given to the liability question was false. *See Merlin E. Shuck, D.V.M.*, 69 FR 22566 (2004); *James C. LaJavid, D.M.D.*, 64 FR 55962 (1999); *Martha Hernandez, M.D.*, 62 FR 61145 (1997).

The Deputy Administrator agrees with Judge Bittner's finding, made after observing Respondent's demeanor, that, ''In the instant case, and contrary to Respondent's assertions, I do not find that his misstatements were unintentional. Although Respondent did not sign the Agreed Order, he did sign the DEA form surrendering his previous Certificate of Registration and I do not credit his testimony that he did not know he had done so. I therefore find that Respondent materially falsified his application for registration and that under 21 U.S.C. 824(a)(1) this conduct is grounds to deny his application.''

Respondent was also convicted of a felony relating to controlled substances and the Deputy Administrator agrees with Judge Bittner's conclusion that Respondent's convictions for mail fraud and racketeering were based, in part, on his conduct in providing controlled substances to patients who were abusing them, so that those patients would acquiesce to unnecessary diagnostic tests. While Respondent denied this activity at the hearing, it is a long standing principle that facts established by criminal convictions are res judicata and cannot be relitigated in a DEA administrative forum. *See, e.g., Robert A. Leslie, M.D.*, 64 FR 25908–25910 (1999); *Shahid M. Siddiqui, M.D.*, 61 FR 14818 (1996). Respondent's convictions constitute grounds for denying the application under 21 U.S.C. 824(a)(2).

The Deputy Administrator further agrees that Respondent has been excluded by the United States Department of Health and Human Services from participating in Medicare, Medicaid and Maternal and Child Health Services Block Grants to States for Social Services programs for a period of fifteen years. This constitutes an independent ground for denying the application under 21 U.S.C. 824(a)(5).

The Deputy Administrator further finds, in agreement with Judge Bittner, that under 21 U.S.C. 823(f), granting Respondent's application would not be in the public interest.

As to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, the Deputy Administrator finds that Respondent has regained his license to practice osteopathic medicine in Tennessee and this weighs in favor of registration. However, as noted by Judge Bittner, inasmuch as State licensure is a necessary but not sufficient condition for DEA registration, this factor is not determinative. *See Edson W. Redard, M.D.*, 65 FR 30616, 30619 (2000); *James C. LaJevic, D.M.D.*, 64 FR 55962, 55964 (1999).

As to factor two, the Administrative Law Judge noted that despite Respondent's assertions that he always properly handled substances, he was convicted of charges that he provided controlled substances to drug abusers because those persons were willing to undergo unnecessary diagnostic tests if they received the drugs they wanted. Additionally, Respondent permitted his physician assistant to provide controlled substances to patients prior to the effective date of legislation permitting such activity. The Deputy Administrator agrees with Judge Bittner that his factor weighs in favor of a finding that Respondent's registration would not be in the public interest.

As to factor four, his compliance with applicable laws relating to controlled substances, his unauthorized utilization of a physician assistant to provide controlled substances and his provision of controlled substances to drug abusing patients so they would submit to unnecessary medical tests, violated laws relating to controlled substances. The Deputy Administrator also agrees with Judge Bittner that this factor weighs against registration.

As to other conduct that may threaten the public health and safety, the Administrative Law Judge found that Respondent's felony convictions for racketeering and mail fraud fall within this factor. The Deputy Administrator also agrees that the jury in Respondent's criminal case found that as a part of the racketeering scheme, Boulevard Center patients were given injections of drugs based on the abundance of the drug at the clinic, rather than medical necessity and that some injectable medications were diluted below their therapeutic dosages. The Deputy Administrator agrees that this factor also weighs in favor of denying registration.

The Administrative Law Judge concluded that the record established grounds to deny the application for registration. However, as Judge Bittner notes in her Opinion and Recommended Ruling, the governing statute is discretionary. *See Mary Thomson, M.D.* 65 FR 75969 (2000). In exercising her discretion in determining the appropriate remedy in any given case, the Deputy Administrator should consider all the facts and circumstances of the case. *See Martha Hernandez, M.D.*, 62 FR 61145 (1997).

In recommending against Respondent's application, Judge Bittner took particular note that,

> As discussed above, Respondent claims that he has taken ''full responsibility'' for the actions that led to his convictions. This assertion is, however, belied by the evidence. For example, and as also noted above,

Respondent denied that he engaged in some of the conduct for which he was convicted, including providing addictive medications to patients who abused them, and also testified that he felt that the patients needed the diagnostic examinations he ordered for them. I also note that in his resume Respondent ''steadfastly assert[s]'' his innocence, and that he testified that although he was guilty, he had no ''criminal intent to commit a crime.''

Based on the record, Judge Bittner could not ''find that Respondent recognizes his own misconduct, or that he is yet in a position to accept the responsibilities inherent in a DEA registration.'' She therefore concluded that granting Respondent's application for DEA registration would not be consistent with the public interest and recommended that the application be denied. The Deputy Administrator agrees.

Respondent filed exceptions to the Opinion and Recommended Ruling. First, he asserted the ruling was arbitrary and capricious in comparison to prior decisions in which grants of restricted registration were recommended by the Administrative Law Judge and approved by the agency. However the facts and circumstances of the five cases cited by Respondent are distinguishable from the facts and circumstances of this matter. *See, Mark Binette, M.D.*, 64 FR 42977 (1999); *Michael Alan Patterson, M.D.*, 65 FR 5682; *Robert M. Golden, M.D.*, 65 FR 5663; *Nick M. Higgins, D.D.S.*, 54 FR 53388 (1989); *Jane W. Wuchinich, M.D.*, 56 FR 4081 (1991).

As opposed to several cases cited by Respondent, he engaged in his criminal misconduct for pecuniary gain, not because he suffered from an addiction or dependency which was later demonstrated to have been successfully mitigated by rehabilitation, therapy or careful monitoring. While neither is desirable, depending on the facts, greed can be viewed as a more serious personal motivator for criminal activity than addiction or dependency. Respondent's reasons for violating the law and risking reputation and his growing livelihood also reflect a cavalier attitude toward his responsibilities as a physician and DEA registrant.

As opposed to other cases relied upon by Respondent, he has also failed to adequately acknowledge personal responsibility for the actions leading to his convictions and lengthy prison sentence. He also knowingly made material misrepresentations on his DEA application and was excluded from participating in Federal health care programs for 15 years, both of which are additional independent grounds for denying registration.

Finally, DEA has previously revoked registrants for actions and on grounds comparable to Respondent's. *See, Johnnie Melvin Turner, M.D.*, 67 FR 71203 (2002) (revocation based on exclusion from Medicare program after Federal fraud conviction); *Stanley Dubin, D.D.S.*, 61 FR 60727 (1996) (revocation for exclusion from Federal health programs after State fraud conviction).

In sum, the facts of this matter are unique and the cases cited by Respondent simply do not demonstrate that the recommended action is a departure from agency practice and policy or was rendered either arbitrarily or capriciously.

Respondent also contends in numerous exceptions that the Administrative Law Judge's ruling ''failed to take into account'' or ''ignores'' or ''disregards'' or ''erroneously discounted'' or ''failed to credit'' or ''refused to consider'' or ''placed improper emphasis'' on certain evidence in reaching her findings and recommendations. These include: Respondent's degree of contrition and acceptance of responsibility; the opinions of several witnesses as to Respondent's prescribing activities; his monitoring of the physician assistant at the secondary clinic; his post-incarceration medical education; his value to the local, humanitarian efforts and opinions of charter witnesses; his professed intended limited use of the registration were it to be granted; the nature of his current and intended medical practice; and the adverse impact denying registration will have upon Respondent and his practice.

The Opinion and Recommended Ruling clearly demonstrates that the Administrative Law Judge admitted and carefully considered Respondent's evidence on all of the foregoing issues. While Respondent would prefer Judge Bittner arrived at a different outcome, his objectives are really just a re-argument as to the weight which should be assigned certain testimony and documentary evidence introduced during the hearing and the credibility which the fact finder should give Respondent's explanations for his misrepresentations, the extent and sincerity of his remorse and his acceptance of personal responsibility. Given the record supporting Judge Bittner's conclusions, these arguments are insufficient to alter the outcome.

Finally, in the letter received by the Deputy Administrator after the Opinion and Recommended Ruling was transmitted to this office by Judge Bittner, Respondent notes recent changes in TennCare Products which will have the effect of limiting his ability to prescribe even non-controlled substances for TennCare patients, should DEA registration be denied. He submits this ''hardship could neither have been intended, nor anticipated by Judge Bittner's Report.''

However, while this particular consequence was not addressed at the hearing, when Judge Bittner recommended denial she was well aware of the multiple hardships befalling any physician denied DEA registration. She was also aware of numerous specific hardships that would impact Respondent and practice, were the application denied. Nevertheless, these consequences were insufficient for Judge Bittner to warrant recommending the application be granted and the Deputy Administrator does not consider the additional information on adverse collateral consequences sufficient to alter the conclusion that registration would not be in the public interest.

The Deputy Administrator has examined the record and finds that the facts and credibility determinations of Judge Bittner are well supported by the evidence. Respondent materially falsified his application for DEA registration and has been excluded from participating in Federal health care programs for fifteen years, both of which constitute independent grounds for denying registration. It has also been sufficiently established that Respondent's registration would not be in the public's interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b), and 0.104, hereby orders the Respondent's pending application for registration be, and it hereby is, denied. This order is effective December 29, 2004.

Dated: November 10, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Prachi Enterprises, Inc.; Denial of Registration

On July 23, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Prachi Enterprises, Inc. (Prachi) proposing to deny its September 9, 2003, application for DEA