

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370) ...	I

The firm plans to bulk manufacture for product development.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than August 19, 2002.

Dated: June 7, 2002.

Laura M. Nagel,

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

[FR Doc. 02-15568 Filed 6-19-02; 8:45 am]

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registration is consistent with the public interest. This investigation included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. 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 classes of controlled substances listed above is granted.

Dated: June 7, 2002.

Laura M. Nagel,

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

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controlled substances may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than July 22, 2002.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import basic classes of any controlled substances in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: June 7, 2002.

Laura M. Nagel,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 21, 2001, and published in the **Federal Register** on January 8, 2002, (67 FR 920), OraSure Technologies, Inc., Lehigh University, Seeley G. Mudd-Bldg. 6, Bethlehem, Pennsylvania 18015, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Alphamethadol (9605)	I
Benzoylecgonine (9180)	II
Morphine (9300)	II

The firm plans to bulk manufacture the listed controlled substances to be used in-house to manufacture other controlled substances.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of OraSure Technologies, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated OraSure Technologies, Inc. to ensure that the company's

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on February 22, 2002, Penick Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application by renewal to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
Coca Leaves (9040)	II
Poppy Straw (9650)	II

The firm plans to import the listed controlled substances for the manufacture of bulk pharmaceutical controlled substances and non-controlled substance flavor extract.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of these basic classes of

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 01-6]

Vincent J. Scolaro, D.O.; Grant of Restricted Registration

By order dated October 23, 2000, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Vincent J. Scolaro, D.O. (Respondent), seeking to deny his application for a DEA Certificate of Registration as a practitioner, pursuant to 21 U.S.C. 823(f), because granting the application would be inconsistent with the public interest.

The Respondent, through counsel, timely filed a request for a hearing on the allegations raised by the Order to Show Cause. The requested hearing was held in Jacksonville, Florida, on February 27, 2001. At the hearing, both

parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law and Argument. Neither party filed exceptions to Judge Randall's opinion, and on September 7, 2001, Judge Randall transmitted the record of these proceedings to the Deputy Administrator for his final decision.

The Deputy Administrator has considered 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 Deputy Administrator adopts in full the recommended rulings, findings of fact, conclusions of law, and decision of the Administrative Law Judge. His adoption is in no way diminished by any recitation of facts, issues, or conclusions herein, or of any failure to mention a matter of fact or law.

Prior to medical school, the Respondent received a Bachelors degree in chemistry from Eckerd College in St. Petersburg, Florida, in 1984. The Respondent received his Doctorate in Osteopathic Medicine from Southeastern College in North Miami Beach, Florida, in 1988. The Respondent's medical education included training in the use and prescribing of controlled substances. Subsequent to medical school, the Respondent completed an internship in Family Medicine and a residency through Southeastern College of Osteopathic Medicine. After his residency, the Respondent relocated, started practicing with another physician, and then entered solo practice.

Currently, the Respondent is board certified in Family Medicine. For board certification, the Respondent was required to complete a family practice residency and to pass oral and written examination. Board certified physicians also face higher requirements for continuing medical education and must reapply every three years.

By DEA Form 224, dated March 6, 2000, the Respondent applied for a DEA registration as a practitioner to handle controlled substances in schedules II through V. On his application, the Respondent answered that he had been convicted of a crime in connection with controlled substances under state or federal law. He also disclosed that he had surrendered or had a federal controlled substance registration revoked, suspended, restricted, or denied. Furthermore, the Respondent indicated that he had had a state professional license or a controlled substance registration revoked,

suspended, denied, restricted, or placed on probation.

In the Respondent's written application, he succinctly and accurately described the dates and circumstances that surrounded the judgment against him and the surrender of his DEA registration and of his state license.

The Respondent was investigated by a DEA Diversion Investigator (D/I) and by a Special Agent (S/A) of the Florida Department of Law Enforcement. The record shows both individuals have various training, education, and experience relating to drug law enforcement, and were competent to testify as to the investigation of the Respondent.

In January 1998, a pharmacist working for Walgreen's in Deltona, Florida, contacted the D/I. The pharmacist told the D/I that the Respondent was picking up prescriptions, using fraudulent names. In light of DEA intelligence that the Respondent was getting fraudulent prescriptions, the D/I visited the Walgreen's pharmacy and obtained a pharmacy trace. A pharmacy trace, according to the D/I, comes from records that pharmacies are required to keep regarding prescriptions filled at the pharmacy. The DEA can ask a pharmacy for patient's names and the prescriptions actually filled at the pharmacy for that patient. The pharmacist can then search the database by patient name. The Walgreen's pharmacist also provided the D/I with the Respondent's vehicle license plate number and described the Respondent's vehicle as a white mini-van. Once the D/I had that information, the D/I contacted the S/A at the Belushi County Sheriff's Office. The investigators ran the license plate number given by the Walgreen's pharmacist and found that the vehicle was registered to the Respondent. The investigators together returned to the Walgreen's in Deltona to collect any prescriptions that were written by the Respondent for three individuals. As the Walgreen's pharmacist described to the investigators, the Respondent would either call in the prescription and pick it up through the pharmacy's drive-through, or he would drop off a prescription at the pharmacy and come back in one to three days. The prescriptions had the patient's name and the Respondent's signature. The Respondent would sign the patient's name on the claim log.

Upon further investigation of the three alleged patients, the D/I and S/A discovered that one of the patients was, in fact, the Respondent's wife. The

Walgreen's pharmacist was able to identify her from a photograph because she had picked up numerous prescriptions. Investigators did not talk to her in their investigation, however, because of her perceived conflict of interest.

Investigators found another alleged patient in Hollywood, Florida, and spoke to him. He told the investigators that he had never been seen by the Respondent, but did state his brother was a good friend of the Respondent. The Walgreen's Prescription Claim Logs did not indicate any insurance involvement for the prescriptions filled under this alleged patient's name.

When investigators talked with the third alleged patient, she was discovered to be the Respondent's eighty-four-year-old neighbor. When the investigators showed her the prescriptions attributed to her, this alleged patient stated that these prescriptions were not for her, although her late husband was a patient of the Respondent. This alleged patient stated that she had received prescriptions from another physician, but not the Respondent.

On May 15, 1998, pursuant to the issuance of an arrest warrant, the D/I and S/A arrested the Respondent at home. At the time of the arrest, the investigators searched the Respondent's vehicle and found prescription drugs. They also brought the Respondent to his offices and attempted to obtain his records on the three above-mentioned individuals; however, the Respondent had no such records. After the Respondent's arrest, and with his consent, the investigators had the Respondent tested for drug use. The Respondent tested positive for barbiturates, diazepam, and opiates.

After the Respondent's arrest, the investigators took him to the local DEA District office for an interview. At the interview, the Respondent signed a waiver of his rights. The Respondent confirmed that he did not have medical files or other records for the three alleged patients mentioned above.

All of the prescriptions in evidence were obtained from no more than five pharmacies. In May 1998, the DEA was contacted by another pharmacist at Target Pharmacy, regarding prescriptions written by the Respondent for one of the previously mentioned alleged patients. The pharmacist recognized the Respondent's name from a DEA press release. The DEA actually obtained the prescriptions from the pharmacy and found that they corresponded to the same period as the other prescriptions found at other pharmacies. All of the prescriptions

were issued prior to the Respondent's conviction.

Dr. Raymond Pomm is Medical Director for the Impaired Practitioners' Program for the State of Florida, also known as the Physician's Recovery Network (PRN), and is an expert in psychiatry and addiction medicine for professionals, including health care professionals. As Director, Dr. Pomm is directly responsible to the Department of Health for Florida and oversees interventions, evaluations, treatments, and the monitoring of impaired professionals. As Director of the PRN, Dr. Pomm has the authority to request an emergency suspension of license from a state agency if he knows a practitioner from the PRN has problems and if he believes that the practitioner cannot practice with the requisite skill and efficiency. The PRN had approximately 1100 professionals in treatment at the time of the hearing.

Dr. Pomm first came in contact with the Respondent's case when a representative from Florida's Agency for Health Care Administration called Dr. Pomm, seeking an evaluation of the Respondent. Dr. Kenneth W. Thompson conducted an inpatient evaluation of the Respondent on May 28, 1998. Dr. Pomm and Dr. Thompson found that the Respondent was not able to practice medicine with reasonable skill and safety. In addition to the inpatient evaluation, the Respondent also received psychiatric treatment. The Respondent's diagnosis was psychotic disorder.

Based on Dr. Pomm's and Dr. Thompson's recommendations, the Respondent voluntarily withdrew from practice immediately. Eventually, the Respondent officially entered a voluntary withdrawal from practice with the Agency of Healthcare Administration. On July 12, 1999, the Respondent also voluntarily surrendered his DEA registration. The Respondent entered treatment and evaluation.

Mr. Meagher is a certified addictions professional and is employed by Turning Point of Central Florida. Since 1979, he has worked in various counselor and managerial positions in the field of addiction. Specifically, Mr. Meagher has been with the PRN since 1987 or 1988. Mr. Meagher's role is to get involved should a PRN participant violate his or her PRN contract. Mr. Meagher also monitored and facilitated the Respondent's group therapy sessions. Mr. Meagher remembered the Respondent as entering the PRN in 1998. At first, Mr. Meagher believed that the Respondent seemed secretive, paranoid, and unsure whether people

were trying to help or hinder him. Slowly, however, the Respondent began to recognize that he was no different from anyone else in the group therapy sessions run by Mr. Meagher. Over time, the Respondent learned to trust others in the group, and recently had been able to assist others who have had difficult situations or problems. Respondent had become more willing to participate and speak about issues surrounding, *inter alia*, the DEA, the Florida Board of Osteopathic Medicine (State Board) and his family.

The Respondent underwent outpatient treatment for mental health and substance abuse at Turning Point. He initially saw a therapist every week and a psychiatrist every two weeks. Besides his two week inpatient evaluation, the Respondent did no other inpatient care. As of the date of the hearing, Mr. Meagher believed that the Respondent had been in total compliance with his PRN contract. If Mr. Meagher believed that the Respondent was not in compliance with his contract, he would notify Dr. Pomm and advise him to seek a second evaluation of the Respondent. Mr. Meagher also testified that the Respondent "would be an asset in the community [if he were able] to practice medicine to the full extent." He also stated that it would be a benefit to the Respondent's patients if the Respondent were granted a DEA registration.

The Respondent entered into a written contract with PRN. The contract details the type of treatment and monitoring recommended for the Respondent. A typical PRN contract lasts for five years. A contract generally stays in effect after an individual resumes his or her medical practice, to ensure continued progress. The program entails a high standard for urine screening that tests for a wider range of drugs than other screening processes used in similar programs in many other regions of the country. The standard is high in light of stringent observation and chain of custody rules and computer randomization. A participant must attend weekly support group sessions with other impaired professionals. Judge Randall found the Respondent thus far has been very compliant with the terms of his PRN contract.

The Respondent recalls that he last used drugs on May 15, 1998, his sobriety date. He characterized his drug use at the time of the intervention to be light to moderate. Pursuant to his contract, the Respondent's frequency of random substance abuse tests is, on average, every two weeks or twice a month. The Respondent must call a toll-

free number every day to see if he must provide a urine sample for testing. If the Respondent fails to so provide a requested urine sample, the PRN assumes that the failure is deliberate because the program participant knows that his or her test results would be positive if taken on that date. The Respondent also has urine testing twice a month pursuant to the terms of his probation. There is no evidence in the record that Respondent has ever had a positive result reported from PRN or his court-directed urinalysis.

Also, a PRN participant typically must attend a twelve-step program for recovery. At the Respondent's stage, Dr. Pomm believes that a person should be attending two to three times per week. Dr. Pomm testified that a participant should never attend less than one meeting a week after hitting the five-year mark.

The Respondent is not allowed to take mood altering drugs at all, even by prescription, without first informing the PRN. Thus, the Respondent has a primary care physician with knowledge of the Respondent's PRN contract and his chemical dependency diagnosis and treatment. The Respondent is also required to see a psychiatrist for ongoing medication of his condition. The Respondent participates in a weekly support group for the PRN, specifically for issues facing professionals. The Respondent attends group meetings in Orlando, Florida, monitored and facilitated by Mr. Meagher. As facilitator, Mr. Meagher reports problems whenever seen, and also gives a quarterly report to PRN about the Respondent's participation. The report contains the patient's attitudes, behaviors, attendance at group therapy, and signs or symptoms of relapse. Such signs might be the lack of attending meetings, avoidance of interaction with others in the group, and solitude or not participating in the group. The Respondent has missed group meetings five times, and each occasion was considered a justified absence. The Respondent reported his proposed absence before the meeting, rather than his missing a meeting and then offering an explanation.

The Respondent reports to the State board on a regular basis. The Respondent also signed a release, so the PRN can have access to records of his medical activities. The Respondent agreed that he would withdraw from practice immediately, if Dr. Pomm so instructed. Thereafter, Dr. Pomm would notify the State Board immediately, and investigators from PRN and the State Board would be looking for the Respondent, if necessary.

Dr. Pomm testified the PRN's primary goal is to protect the public, so that rehabilitation of an impaired physician is secondary to the public's protection. From 1995–2000, however, less than 10% of participants relapsed at all after having completed the five-year PRN program. The PRN has an 80% success rate, within the first two years of treatment. The rates of relapse in the Florida program are similar to the rates in other states' programs nationally. A relapse within the two-to-five-year mark is often due to a person's not practicing a recovery program.

He further stated that the type of drug is a factor for relapse in early recovery, but is not so significant once a person has hit the 5 year mark. Notably, the rate of relapse among pharmacists is the same as physicians, despite the former's contact with controlled substances on a regular basis. According to Dr. Pomm, the abuser does not stop abusing a controlled substance because of lack of access, but rather because he or she participates in a recovery and monitoring program. “[S]o, preventing [the Respondent's] impairment * * * is not done by preventing his prescribing.”

Since April 21, 1999, Dr. Pomm has found the Respondent safe to return to the practice of medicine. Dr. Pomm's opinion is based on another evaluation and a University of Florida Cares assessment, done on February 10 and 11, 1999. The University of Florida Cares assessment is an intense two-day evaluation of a practitioner's competence to practice. The program's recommendations for the Respondent were indirect supervision, chart audits, and Continuing Medical Education. Dr. Pomm testified that it is safe for the Respondent to prescribe controlled substances because the Respondent's disease is in remission, Respondent is maintaining recovery, Respondent is being monitored satisfactorily, and Respondent has confidence in his own skills, as evidenced by his passage of the University of Florida Cares course.

Dr. Pomm recommended that the Respondent be allowed to practice medicine with certain conditions. He suggested that the Respondent's prescribing needed to be monitored, though such monitoring would stem from the disciplinary process rather than any recovery process. But, Dr. Pomm does believe that monitoring would be needed for the safety of the public. Dr. Pomm's recommendation comes from this level of comfort that the Respondent would fit into normal statistics of success for PRN participants. He believes that the Respondent has successful in the PRN program and that there is no “medical

contraindication” to the Respondent's having a DEA registration. On the contrary, Dr. Pomm suggests that lacking a DEA registration has a negative impact on the Respondent's practice. Dr. Pomm testified to his belief that it is important for a doctor's recovery to engage in the full practice of medicine.

Additionally, Dr. Pomm noted that continuity of care is critical to a patient's well-being. Furthermore, he believes the Respondent is safe to practice medicine, under the same restrictions and protections for the public that exist under the State Board's probation. Dr. Pomm concluded that the Respondent should get a DEA registration with the same restrictions as are in the State Board's Order.

Mr. Meagher also testified that the Respondent would be an asset to the community as a physician and has no qualms about the Respondent's current safety in working with the public. Mr. Meagher stated his belief that a DEA registration would be a benefit to the Respondent's patients.

The Respondent voluntarily withdrew from the practice of medicine on July 9, 1998. The Respondent agreed to abstain from the practice of medicine until the State Board issued a final order in his case. The State Board's Order Reinstating License and Setting Terms of Probation was signed on December 15, 1999, and runs concurrently with the Respondent's contract with the PRN. The Order placed restrictions on the Respondent's medical practice. Among those restrictions are: (a) The Respondent shall issue no controlled substance prescriptions to family members, immediate or otherwise; (b) the Respondent shall keep a log of all Schedule II and III controlled substances that he prescribes, including the date prescribed, the patient's name, the drug name and quantity, and a brief description of reason for the prescription; (c) the log shall be made available for review by an investigator for Florida's Agency for Health Care Administration or by Florida's Department of Health at reasonable times and without prior notice; (d) the Respondent shall use sequentially numbered, triplicate prescriptions for all prescriptions of schedule II and III controlled substances, and the Respondents shall distribute a copy to his monitor, place a copy in the patient's file, and maintain a copy in his office for inspection; (e) if the Respondent leaves the State of Florida for thirty days or more, or if he does not actively engage in the practice of medicine in the State of Florida, certain provisions of his probation are tolled

until his return to active practice in Florida. The tolled provisions include the time period of the probation, provisions regarding supervision by a monitoring physician, and provisions regarding the reports that must be filed. If the Respondent leaves the active practice of medicine in the State of Florida for a year or more, the Board may require a demonstration that the Respondent is still qualified to practice with reasonable skill and safety before the Respondent resumes practice. The Board also requires the Respondent to comply with all terms and conditions of his criminal probation, and imposes various costs upon him for the administration of the agreement and for drug testing.

On April 28, 1999, the Circuit Court for the Seventh Judicial Circuit in Volusia County, Florida, entered an Order of Drug Offender Probation in *State of Florida v. Vincent J. Scolaro*, Case No. 97-2146CFAWS and 98-0739CFAWS. The Respondent pleaded nolo contendere to Resisting Arrest with Violence and to Unlawfully Obtaining/Attempting to Obtain a Controlled Substance. Both offenses are third degree felonies in Florida.

Pursuant to the conditions of the court's Order, the Respondent served a ninety-day jail term with credit for two days of time served. Having pleaded guilty to felonies, the Respondent was required to register at the Sheriff's Office in the County where he resides. The Order withholds adjudication and imposes a five-year Drug Offender Probation upon the Respondent under the supervision of the Florida Department of corrections. The Respondent must report monthly to his probation officer, and procure his officer's consent before changing his residence or employment, or before leaving the county. Additionally, the Respondent must totally abstain from consuming excess amounts of alcohol, or any drugs or controlled substances, unless they are prescribed by a physician.

The Order prohibits the Respondent from going to business establishments whose primary purpose is to sell or to encourage the consumption of alcohol, and from going to areas in the community where illegal drugs are bought, sold, or used. He must submit to alcohol and drug testing at any time that his probation officer requests. Generally, the Respondent is tested once or twice a month as part of his criminal probation, in addition to the two to three times a month he is tested as part of his PRN contract.

In addition to the PRN contract requirements, the Respondent had to

complete the Department of Corrections' Drug Offender Program, during this program he also had to attend at least two recovery meeting per week in either Narcotics Anonymous or AA, and to provide documentary evidence of his participation to his probation officer. Pursuant to the court's Order, the Respondent also had to complete outpatient and/or inpatient mental health counseling as directed by the PRN program.

The court order also requires that the Respondent not violate the law or associate with a person who is engaged in any criminal activity. A conviction is not necessary for the Respondent to have violated this term of his probation. Also, he must maintain or actively seek employment and pay a number of fees for such things as the cost of his supervision and of the investigation and prosecution of his case by the state.

The Respondent's Probation Officer, Ronald Murray, has worked for the Probation and Parole services, Florida Department of Corrections, Seventh Judicial Circuit, Deland, Florida, for nine years. As of the date of the hearing, he was serving in the position of Correctional Probation Senior Officer. Mr. Murray served as the Respondent's probation officer from April 28, 1999, to January 16, 201. As a probation officer, Mr. Murray visited periodically with the Respondent in his office and in the Respondent's home. Additionally, Mr. Murray was responsible for monitoring the Respondent's compliance with random urine tests and the substance abuse treatment program, as ordered by the court.

Mr. Murray testified that the Respondent, in a consistently timely manner, has been totally compliant with everything required or requested of him. Mr. Murray believes that the Respondent is sincere in his desire to comply with his probation and the law.

The Respondent has a monitoring doctor at the medical center, Dr. Mark Webster. Dr. Webster is a Board Certified Family Physician who acts as the supervisory physician for the Respondent pursuant to the terms of the Respondent's probation from the Department of Health. He works in the same office as the Respondent, and, since April 1, 2000, they have seen each other regularly throughout the eight to ten hour work day. Dr. Webster also believes that the Respondent is doing well in his rehabilitation and is in full compliance with his PRN contract. Dr. Webster testified that the Respondent "is sincere about his recovery and has an excellent attitude towards recovery." Dr. Webster agrees that the Respondent can safely practice medicine and

responsibly exercise DEA prescribing privileges.

Judge Randall found that the Respondent's care for his patients is hampered by his lack of a DEA registration. For example, the Respondent, without a DEA certificate, cannot receive hospital privileges in Florida. Additionally, certain insurance carriers will not approve prescriptions for non-controlled substances, such as antibiotics, because the Respondent lacks a DEA number.

The Respondent acknowledged that he fraudulently wrote, for his own use, the prescriptions dated from November of 1994 through May 8, 1998, contained in the Government's exhibits. He further acknowledged that he was addicted to hydrocodone products at the time he wrote the prescriptions offered by the Government. The Respondent credibly described his past history of denial of his substance abuse problem and his withdrawal from other people around him. He contrasted that past with his current "normal life" and "normal interactions." Specifically, since the intervention, the Respondent has changed his life by exercising more, socializing more, and experiencing better personal relationships with his wife, his brothers, and his parents.

The Respondent and his wife previously had lost a baby. At the time of the hearing, however, the Respondent and his wife had a four-month old baby. The Respondent's 36-year old brother, Timothy Scolaro, lives in Coconut Creek, Florida, is married, and has a three-year-old daughter. The Respondent and his brother share a good relationship, talking approximately twice a month and seeing each other three to four times a year. Regarding the Respondent's rehabilitation, Timothy Scolaro also reports that the Respondent seems to be doing fine, appears to be much happier, is much more open and willing to talk, and is taking better care of himself. The Respondent's 37-year-old brother, Dan Scolaro, lives in Broward County, Florida. Dan Scolaro talks to the Respondent weekly on the phone and sees him around eight times a year. Dan Scolaro wrote that since undergoing his recovery, the Respondent has lost 40 pounds and exercises every day. He describes the change in the Respondent's attitude as being remarkable. He too finds that the Respondent is doing well in his rehabilitation, and that he is "open and communicative."

Currently, the Respondent is happy about being a new father. The Respondent is confident that, as long as he keeps doing fine, there would not be

a problem if he were again given a DEA registration. He continues to go to Narcotics Anonymous meetings two to three times a week and acknowledges that he will always consider himself an addict.

Pursuant to 21 U.S.C. 823(f), and subdelegations of authority thereunder found at 28 C.F.R. 0.100(b) and 0.104, the Deputy Administrator may deny an application for registration as a practitioner, if he determines that the issuance of such a registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in evaluating 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.

These factors are to be considered in the disjunctive. The Deputy Administrator may properly rely on any one or any combination of these factors, and may give each factor the weight he deems appropriate in determining whether an application for registration should be denied. See *Henry J. Schwarz, Jr., M.D.*, 54 FR 16,422 (1989). As an initial matter, the Government bears the burden of providing that registration of the Respondent is not in the public interest. See *Shatz v. United States Dep't of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989).

Regarding factor one, the recommendation of the State licensing board, Judge Randall found the State Board has not made any official recommendation regarding this proceeding's outcome. Judge Randall further noted, however, that the Deputy Administrator has considered facts surrounding state licensure under this factor. See *In the Matter of David M. Headley, M.D.*, 61 FR 39,469, 39,470-71 (1996).

In Headley, the ten-Deputy Administrator approved a physician's application for a DEA registration, subject to conditions. *Id.* at 39,471. There, the Deputy Administrator noted that the state board quickly responded to the situation after discovering the applicant's drug abuse, acknowledged the applicant's recovery, reinstated the applicant's license, and allowed the

Respondent to apply for a DEA registration. *Id.* at 39,470–71.

Similarly to Headley, in the instant case the appropriate state health care authority also acted quickly following the Respondent's arrest. The Respondent entered the PRN program and is following through with treatment, according to the PRN staff, the Respondent's monitoring physician, and his family who offered testimony. The individuals who are vested by the State Board with the Respondent's treatment all agree that he is safe to return to practice in light of the ongoing treatment and monitoring that is maintained pursuant to the State Board's Order. Furthermore, the Respondent is in compliance with his responsibilities to keep the State Board apprised of his progress. Judge Randall noted that the Respondent's steady progress was not disputed by the Government. Rather, the Government draws attention to the Respondent's voluntary withdrawal from practice and the State Board's decision to place the Respondent on probation. The Deputy Administrator concurs with Judge Randall's finding that while those facts are relevant and undisputed, also relevant is the Florida State Board's decision that currently authorizes the Respondent to prescribe Schedule II and III controlled substances, with restrictions and monitoring during the probationary period. Similarly to the state board in Headley, the Florida State Board has acknowledged the Respondent's continued recovery in the PRN and reinstated his license to practice medicine. While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, Judge Randall found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances. Such authority would be meaningless if the State Board did not believe that the Respondent should be granted a DEA registration.

In light of the State Board's quick response to the Respondent's situation and its decision to reinstate the Respondent's license to practice with restrictions, the Deputy Administrator concurs with Judge Randall's conclusion that the Florida State Board implicitly agrees that the Respondent is ready to maintain a DEA registration upon the terms set forth in the State Board's December 15, 1999 Order.

Regarding factors two and four, experience in dispensing controlled substances, and compliance with laws related to controlled substances, the

Deputy Administrator concurs with Judge Randall's finding that when looking at the Respondent's past experiences in handling controlled substances, one must consider his undisputed record of substance abuse and egregious misconduct in issuing fraudulent prescriptions, a record of numerous violations extending over a number of years. The Government asserts that the Respondent's conduct was proscribed by 21 U.S.C. 829 and 841(a)(1) and 21 C.F.R. 1306.04. Judge Randall concurred, and further concluded that the Respondent's conduct also violated Florida State law. Clearly, the Respondent's conduct was in direct violation of the State and Federal law relating to the handling of controlled substances, as well as in violation of DEA regulations. His multiple breaches of the law, brought on by his personal addiction to controlled substances, are no less serious merely because the Respondent did not unlawfully provide controlled substances to others. The Deputy Administrator concurs with Judge Randall's finding that Respondent's repeated violations were intolerable and would provide more than sufficient reason, if not addressed, to deny the Respondent's application for a DEA registration.

The Respondent's conduct has gone through a dramatic change since he entered the PRN program, however. The State Board's monitoring, the frequent and random drug testing, and the Respondent's consistent record of compliance with all terms of probation and PRN contract together constitute strong evidence that the Respondent is well on the way to rehabilitation, and does not pose a threat to the public interest. The Respondent did not gain any further experience in dispensing controlled substances since his arrest, but he did demonstrate that he no longer illegally obtains controlled substances, and that he actively manages his addiction. The Deputy Administrator further concurs with Judge Randall's significant that the State Board decided to reinstate the Respondent's state authorization to handle controlled substances, subject to the restrictions set out in its December 15, 1999 Order.

Regarding factor three, convictions under Federal or State laws relating to controlled substances, the Deputy Administrator finds the Respondent entered a plea of *nolo contendere* in the Circuit Court for the Seventh Judicial Circuit in Volusia County for Unlawfully Obtaining/Attempting to Obtain a Controlled Substance. The offense is a third degree felony in

Florida, and imposed jail time, probation, and the costs inherent in the management of the Respondent's probation. The Respondent's probation officer also attested to the Respondent's progress and compliance with the Court's probation. Although the Court's order withheld adjudication of guilt during the Respondent's participation in five years of probation, the Deputy Administrator concurs with Judge Randall's finding that the DEA has found such a judicial action satisfies the "conviction" component of this factor. See, e.g., *Yu-To Hsu*, M.D., 62 FR 12,840 (1997) ("DEA has consistently held that a deferred adjudication of guilt following a plea of guilty is a conviction within the meaning of the Controlled Substances Act.") (quoting *Harlan J. Borcherding*, D.O., 60 FR 28,796 (1995)).

Regarding factor five, other conduct which they may threaten the public health or safety, the Government notes the Respondent's past abuse of controlled substances, prior to his entry into rehabilitation. The Government admits, however, that the Respondent's agreement with the Florida State Board to monitor his recovery provides mitigating circumstances. Despite the Respondent's evidence of his continuing strong recovery, the Government concludes that the Respondent is in the early stages of rehabilitation, and that he has not shown that he is ready for the responsibilities of a DEA registration. Considering all of the facts and circumstances in evidence, Judge Randall did not concur with the Government's assessment.

Judge Randall found the Respondent began his career with excellent prospects, as evidenced by his board certification, which he has maintained. It is true that the Respondent's conduct during his addiction included unlawful prescribing of controlled substances, unlawful consumption of controlled substances, and deception of his colleagues, family, and friends. Such behavior, absent rehabilitation, would support a decision to deny his pending application. The Deputy Administrator concurs with Judge Randall's finding that the Respondent has succeeded outstandingly in a well established, aggressive rehabilitation program, however. The program's treatment and assessments are rigorous, yet all of the Respondent's evaluators agree that he is performing with excellent results. The Deputy Administrator concurs with Judge Randall's conclusion that the Respondent has returned to a safe and healthy practice of medicine, due to the initial intervention of the State Board and the PRN, the monitoring he has received through the PRN, has new

employment with monitoring by Dr. Webster, and his probation with the Circuit Court.

The Deputy Administrator finds the Respondent has complied with the Court's terms of probation without incident. Unlike the Respondent in the Headley case, the Respondent has maintained a change in his lifestyle and has encountered no incidences of relapse since his reinstatement. See Headley at 39,469 (noting Dr. Headley's relapse). The experts agree that the Respondent's current condition indicates that he will continue to progress in a positive direction, drug-free and committed to his family and profession.

Further, the Respondent enjoys a support network in addition to the PRN, his family. His marriage and relationships with his siblings and his parents have changed to become stronger, which is in no small part due to the recent birth of his daughter. Judge Randall noted the Respondent's demeanor and testimony during the hearing were consistent with the remarks of the professionals who monitor him and his family. The Deputy Administrator concurs with Judge Randall's conclusion that the Respondent understands and has accepted responsibility for his past actions and sees his recovery from his addiction as a multifaceted and ongoing process. The network of family and interested colleagues, in light of the testimony of the Respondent's colleague and PRN staff, lends firm support to granting the Respondent's application.

The Deputy Administrator concurs with Judge Randall's finding that the Government has met its burden of proof for denial of the Respondent's pending application for registration. As Judge Randall correctly notes, however, the Deputy Administrator must consider all of the facts and circumstances of a particular case when deciding the appropriate remedy. See Martha Hernandez, M.D., 62 FR 61,145, 61,147 (1997).

After a review of the totality of the circumstances, the Deputy Administrator concurs with Judge Randall's conclusion that it would be in the public interest to grant the Respondent's application. The Deputy Administrator further concurs with Judge Randall's finding that the Respondent has demonstrated sufficient evidence of rehabilitation to warrant granting his application. See Jimmy H. Conway, Jr., M.D., 64 FR 32,271 (1999); see also Robert G. Hallermeier, M.D., 62 FR 26,818 (1997). The Respondent should be allowed the opportunity to demonstrate that he can now handle the

responsibilities of a DEA registrant. He has accepted responsibility for his past offenses and for his recovery. The record amply supports the conclusion that the Respondent will not repeat past misconduct, and relapse is extremely unlikely.

The Deputy Administrator further concurs with Judge Randall's conclusion that further monitoring by the DEA is appropriate, however. Given the aggressive monitoring by the PRN program, and the continuing supervision of the Respondent's conduct by Florida's probation system, federal oversight may seem redundant. Yet the DEA is also charged with protecting the public interest through its registration process. Here, given the evidence of less than five years of recovery time, monitoring by the DEA is warranted to protect the public interest. See Roger Lee Kinney, M.D., 64 FR 42,983 (1999).

Accordingly, the Respondent's application for a DEA Certificate of Registration in Schedules II through V is hereby granted, subject to the following restrictions:

(1) The Respondent, the PRN monitoring professionals, and the Respondent's probation officer shall file with the local DEA office copies of the status reports of the Respondent's progress that are already being filed with the Florida State Board;

(2) The Respondent shall agree to random warrantless inspections of his office, files, and prescription logs by DEA employees in addition to the terms set forth for random inspections under the Florida State Board's Order;

(3) The Respondent shall inform the DEA, within 30 days of the event, of any action taken by any state upon his medical license or upon his authorization to handle controlled substances within that state;

(4) These conditions shall extend through the three-year registration period.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for registration submitted by Vincent J. Scolaro, D.O., be, and it hereby is, granted subject to the above described restrictions. This order is effective upon the issuance of the DEA Certificate of Registration, but no later than July 22, 2002.

Dated: June 11, 2002.

John B. Brown III,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(I)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on November 27, 2001, Wildlife Laboratories, Inc., 1401 Duff Drive, Suite 600, Ft. Collins, Colorado 80524, made application by renewal to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
Etorphine Hydrochloride (9059)	II
Carfentanil (9743)	II

The firm plans to import the listed controlled substances to produce finished products for distribution to its customers.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than (30 days from publication).