

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 June 12, 2000.

This procedure is to be conducted simultaneously with an 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 the 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 1301.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: April 25, 2000.

John H. King,

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

[FR Doc. 00-11885 Filed 5-11-00; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on January 25, 2000, Mallinckrodt, Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine Hydrochloride (9059)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone-intermediate (9254) ...	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II

Drug	Schedule
Morphine (9300)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium powdered (9639)	II
Opium granulated (9640)	II
Levo-alphacetylmethadol (9648) ..	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The firm plans to manufacture the controlled substances for distribution as bulk products to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances 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, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than July 11, 2000.

Dated: April 21, 2000.

John H. King,

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

[FR Doc. 00-11889 Filed 5-11-00; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 98-34]

Edson W. Redard, M.D., Continuation of Registration With Restrictions

On June 12, 1998, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Edson W. Redard, M.D. (Respondent) of Sacramento, California, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BR1670012 and deny any pending applications for renewal of such registration as a practitioner pursuant to 21 U.S.C. 823(f), 824(a)(2) and (a)(4).

By letter dated June 26, 1998, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Sacramento, California on April

27 and 28, 1999, before Administrative Law Judge Mary Ellen Bittner. 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. On December 20, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's registration not be revoked subject to two restrictions. Neither party filed exceptions to Judge Bittner's Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, and on January 24, 2000, the record was transmitted to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, but includes additional restrictions on Respondent's continued registration. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that Respondent graduated from medical school in 1987, and in 1991 he began working as a family practitioner at a large multi-specialty clinic in Sacramento, California.

On August 27, 1997, a pharmacist called the California Department of Justice, Bureau of Narcotic Enforcement (BNE) and told an investigator that on May 20, 1997, Respondent had presented a prescription in the name of Donald Gram, for Vicodin ES, a Schedule III controlled substance. At that time, Respondent filled out a patient information form using the name Donald Gram. The pharmacist had previously met Respondent when she worked at another pharmacy, so she knew that this was not Respondent's name. Further investigation revealed that the address given to the pharmacist on the patient information form was Respondent's address.

The pharmacist told the investigator that Respondent had presented another prescription for Vicodin on July 25, 1997, which another pharmacist filled. The pharmacist further told the investigator that a pharmacy technician advised her that Respondent had presented controlled substance prescriptions in the name Carol Jordan.

Subsequently, the investigator obtained prescriptions issued to Carol Jordan on Respondent's prescription forms from three different pharmacies. These prescriptions accounted for 1,510 dosage units of Vicodin ES for the period February 27, 1995 to August 26, 1997.

Thereafter on October 20, 1997, the pharmacist again contacted the investigator and advised him that Respondent had just presented two prescriptions, one for 80 dosage units of Vicodin ES and the other for a non-controlled substance, in the name of Donald Gram. The investigator also learned that on October 17, 1997, one of the other pharmacies had filled a prescription issued to Carol Jordan on Respondent's prescription form for 80 dosage units of Vicodin ES. A check of Department of Motor Vehicle records revealed no matches for the purported names and dates of birth of Donald Gram or Carol Jordan.

On November 24, 1997, a search warrant for Respondent's office, residence and car was executed. In Respondent's car, the investigators found prescription receipts and numerous empty prescription bottles in the names of Donald Gram and Carol Jordan. In the master bedroom of Respondent's residence, the investigators found empty prescription bottles and physician samples.

During the search an investigator with the Medical Board of California (Medical Board) interviewed a physician assistant whom Respondent supervised. The physician assistant admitted to calling in about four prescriptions for Vicodin for Respondent during the previous year using another physician's name.

Respondent cooperated with the investigators during the search, and admitted that he was addicted to Vicodin. Respondent told the Medical Board investigator that he was originally prescribed Vicodin for two or three months for a back problem. At some point he stopped taking the drug for approximately six months but resumed taking it sometime in 1995. Respondent told the Medical Board investigator that initially he took two or three tablets per day, but that as of the date of the search he was taking eight to twelve tablets per day. Respondent also admitted to taking Ionamin, Ambien, Doral, Brontex, and Xanax, all controlled substances. Further, Respondent admitted that he had issued prescriptions in the fictitious names Donald Gram and Carol Jordan; that he asked the physician assistant to call in prescriptions for him; and that he knew that when the physician assistant called in those prescriptions the

physician assistant indicated that they were authorized by another physician.

Following the execution of the search warrant, Respondent was arrested and charged with obtaining a controlled substance by fraud, prescribing for a non-patient, and possession of a controlled substance.

After Respondent's arrest, the Medical Board investigator continued her investigation of Respondent and discovered several additional prescriptions written prior to Respondent's arrest in the name of Donald Gram or Carol Jordan for a total of 720 dosage units of Vicodin or its generic equivalent. In addition the investigator found four prescriptions, each for 50 dosage units of Vicodin ES, that were called into a local pharmacy between July 23, 1996 and October 30, 1997. Three of these prescriptions were called in by the physician assistant and one was called in by a nurse practitioner at the clinic where Respondent was employed. All of these prescriptions indicated that they were authorized by a physician other than Respondent. The Medical Board investigator interviewed the physicians who allegedly authorized these prescriptions and they indicated that they had not authorized the prescriptions and were unaware that their names had been used.

On December 1, 1997, Respondent was arraigned in the Sacramento Superior/Municipal Court on three felony counts of obtaining and attempting to obtain hydrocodone by fraud. On March 9, 1998, Respondent pled nolo contendere to one count and the court ordered that he be diverted from further proceedings for an 18-month period. On March 18, 1998, the Sacramento County Probation Department ordered Respondent to obtain counseling from the Mexican-American Alcohol Program. Respondent testified that he successfully completed this program. On April 12, 1999, the court entered an order terminating Respondent's diversion, and ultimately dismissed the criminal proceedings.

On December 23, 1997, an interim suspension of Respondent's license to practice medicine was issued. Thereafter, on January 9, 1998, the Medical Board filed an Accusation against Respondent alleging that Respondent had written prescriptions for Vicodin for fictitious persons, asked a physician assistant to call in prescriptions for Vicodin purportedly on the authorization of another physician, admitted abusing Vicodin and other controlled substances, and tested positive for hydrocodone on November 24, 1997.

Effective March 19, 1998, Respondent and the Medical Board entered into an Agreement in Lieu of Discipline wherein Respondent agreed to enter and complete the Medical Board's Diversion Program and the Medical Board agreed to withdraw the Accusation upon Respondent's successful completion of that program. Respondent's authority to handle controlled substances was not limited.

On April 9, 1998, the Medical Board issued a Modification of Interim Suspension Order, permitting Respondent to return to the practice of medicine on condition that he be monitored by the Diversion Program, meet with the Diversion Evaluation Committee, and sign a Diversion Agreement after that meeting. In May 1998, Respondent formally entered the Medical Board's Diversion Program and on June 24, 1998, the Medical Board terminated the interim suspension of Respondent's medical license.

At the hearing in this matter, Respondent testified that he injured his back in 1991, and that after his physician stopped issuing him prescriptions for Vicodin, he took samples of the drug from his office. He also admitted that although Vicodin was his drug of choice, he also took samples of other drugs to avoid the symptoms of withdrawal. According to Respondent, his drug abuse intensified in 1995 during the breakup of his marriage. He became concerned that he was taking too many samples from his office, so he began issuing prescriptions using the fictitious names of Donald Gram and Carol Jordan. Respondent testified that he was relieved when he was arrested.

According to Respondent, upon his arrest he contacted that Medical Board's Diversion Program and began attending diversion group meetings. However, Respondent was concerned that it could take several months to be formally admitted to the Diversion Program, so on December 4, 1997, he voluntarily entered a hospital in Oregon that offered a treatment program for addicted physicians. Respondent was an inpatient at the hospital until March 13, 1998.

While Respondent was in treatment, the medical director of the clinic where he was employed sent Respondent a letter advising him that the clinic intended to terminate his employment, but because he was participating in a professional assistance program, the clinic would indefinitely suspend his termination if he entered into a Last Chance Agreement with the clinic. Respondent agreed to the terms of this Last Chance Agreement which requires Respondent, among other things, to (1)

Submit to a minimum of two random urine tests each month; (2) notify the medical director in writing of any prescriptions he has filled at any pharmacy; (3) abstain from consuming any controlled or mood-altering substances; (4) provide a certificate from both the court-ordered and Medical Board diversion programs stating that he has begun and, when applicable, completed a treatment program; and (5) participate in the diversion programs' recommended aftercare program. Respondent also agreed that he would not order or accept any controlled substance samples and that the agreement would be in effect for four years from February 26, 1998. There was testimony at the hearing that Respondent has complied with this Last Chance Agreement.

The Associate Medical Director for Quality Management at the clinic where Respondent is employed testified that the Credentialing Committee reviewed approximately 50 randomly selected records of patients that Respondent treated in the three months prior to his arrest, between 50 and 100 controlled substance prescriptions issued by Respondent between 1996 and 1999, and 50 patient records for the three months after Respondent returned to work following his suspension. This review did not disclose any problems with Respondent's practice of medicine. Further, none of the staff who worked with Respondent perceived that he engaged in any impaired behavior or inappropriate prescribing of medications.

As of the date of the hearing, Respondent was still participating in the Medical Board's Diversion Program. He regularly attends diversion meetings and undergoes random urine tests three to four times a month, which have all been negative. The staff of the Diversion Program believes that Respondent can safely practice medicine.

The Administrator of the Medical Board's Diversion Program testified that in order to successfully complete the program a physician must have a minimum of three years of continuous sobriety or abstinence, and must have implemented lifestyle changes that are sufficient to maintain the physician's abstinence and recovery. The Administrator testified that because Respondent has not been abstinent for three years he cannot be considered to have successfully completed the Diversion Program, but if he maintains the lifestyle changes he has made and continues to be abstinent, he will complete the program.

Respondent is also monitored by the Wellness Committee of the hospital

where he sees patients. In addition, Respondent's physician manager and workplace monitor testified that he randomly reviews patient records after Respondent sees a patient and he has found no problem with the quality of care provided by Respondent. Several supervisors and/or colleagues testified that Respondent practices competently, he has never appeared to be under the influence of any substance, and his rehabilitation is progressing well.

Respondent testified that he has not abused drugs since November 24, 1997. Respondent further testified that although he is not proud of his addiction, he is proud that he was honest with investigators, he sought help, he admitted his shortcomings, and he has a support group that monitors his recovery and ability to practice on a daily basis.

According to Respondent, he needs a DEA registration in order to effectively treat his patients and in order to maintain his employment since the Last Chance Agreement with his current employer requires him to have an unrestricted ability to practice medicine.

Pursuant to 21 U.S.C. 824(a)(2), the Deputy Administrator may revoke a DEA Certificate of Registration upon a finding that the registrant has been convicted of a felony relating to controlled substances under state or Federal law. It is undisputed that on March 9, 1998, Respondent pled nolo contendere in state court to one felony count of obtaining hydrocodone by fraud. The court granted a deferred entry of judgment and the criminal proceedings were dismissed after Respondent completed criminal diversion program.

Respondent contends that he was not convicted of a felony offense since no judgment was entered against him and the criminal proceedings were dismissed. The Deputy Administrator agrees with Judge Bittner that Respondent has been convicted of a controlled substance related felony offense for purposes of these proceedings.

DEA has consistently held that a plea of nolo contendere constitutes a "conviction" within the meaning of 21 U.S.C. 824(a)(2). See Clinton D. Nutt, D.O., 55 FR 30,992 (1990); Eric A. Baum, M.D., 53 FR 47,272 (1988). Further, DEA has held that there is still a "conviction" within the meaning of the Controlled Substances Act even if the proceedings are later dismissed. The Deputy Administrator agrees with Judge Bittner that any other interpretation would mean that "the conviction could only be considered between its date and

the date of its subsequent dismissal * * * [which would be] inconsistent with holdings in other show cause cases that the passage of time since misconduct affects only the weight to be given the evidence" citing Mark Binette, M.D., 64 FR 42,977, 42,980 (1999); Thomas H. McCarthy, D.O., 54 FR 20,938 (1989), aff'd No. 89-3496 (6th Cir. Apr. 5, 1990).

Therefore, since Respondent has been convicted of a felony relating to controlled substances, the Deputy Administrator finds that grounds exist to revoke Respondent's DEA Certificate of Registration pursuant to 21 U.S.C. 824(a)(2).

Also, pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered 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 and safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See Henry J. Schwarz, Jr., M.D., 54 FR 16,422 (1989).

Regarding factor one, it is undisputed that Respondent's license to practice medicine was suspended in December 1997. Subsequently the Medical Board filed an Accusation against Respondent and in March 1998, Respondent and the Medical Board entered into an Agreement in Lieu of Discipline wherein Respondent agreed to complete the Medical Board's Diversion Program. On April 9, 1998, the suspension order was modified to allow Respondent to return to the practice of medicine, but he was required to remain in the Diversion Program. No restrictions have been placed on Respondent's ability to handle controlled substances by the Medical Board. Therefore, Respondent

is authorized to practice medicine and handle controlled substances in California subject to his continued participation in the Medical Board's Diversion Program. But, as Judge Bittner stated, "inasmuch as State licensure is a necessary but not sufficient condition for a DEA registration, * * * this factor is not determinative."

As to factors two and four, Respondent's experience in handling controlled substances and his compliance with applicable laws, Respondent has admitted that he issued controlled substance prescriptions in fictitious names, took office samples of controlled substances, and used his authority over subordinates to obtain controlled substances. Clearly these actions violated 21 U.S.C. 843(a)(3) as well as California law. However, the Deputy Administrator finds that Respondent's behavior was motivated by his addiction to controlled substances for which he has since received extensive rehabilitative treatment.

As previously discussed, factor three is relevant since the Deputy Administrator finds that Respondent was convicted of a felony offense relating to controlled substances.

Regarding factor five, there is no question that Respondent abused controlled substances for several years prior to November 1997 when he was arrested. Particularly troubling to the Deputy Administrator is that Respondent abused these substances while performing his duties as a physician.

In light of Respondent's abuse of controlled substances, the methods he employed to obtain the drugs, and his felony conviction, the Deputy Administrator agrees with Judge Bittner that the Government has made a *prima facie* case that Respondent's continued registration would be inconsistent with the public interest. Judge Bittner concluded however that while "Respondent's misconduct was obviously egregious[,] his testimony and that of his witnesses was credible "that Respondent now understands the gravity of his actions and is remorseful, that he had been conscientious in pursuing his recovery, and that he has a support network, including appropriate monitoring at his workplace, to assist him in those efforts."

Therefore, Judge Bittner recommended that Respondent be permitted to retain his DEA registration subject to the following restrictions:

1. For three years after issuance of a final order in this proceeding, Respondent shall not be employed as a

physician with any entity that does not impose the same conditions on him that MedClinic imposed in the February 26, 1998, Last Chance Agreement.

2. Each calendar quarter, Respondent shall provide to the Special Agent in Charge of the local DEA office (or that agent's designee) a list of all controlled substance prescriptions he has issued, including the patient's name and contact information, the name of the substance, the dosage form, strength, and quantity prescribed of the substance, and the number of refills authorized, if any.

The Deputy Administrator agrees with Judge Bittner that revocation of Respondent's DEA registration is not warranted. Respondent has accepted responsibility for his actions. He underwent extended inpatient treatment for his addiction, completed the court-ordered treatment program, and is still participating in the Medical Board's Diversion Program. His practice of medicine, as well as his continued recovery, is monitored by the Medical Board's Diversion Program, his employer through the Last Chance Agreement, and the hospital's Wellness Committee. However, the Deputy Administrator is troubled by the relatively short period of time that Respondent has been drug-free. Therefore, the Deputy Administrator concludes that additional restrictions should be imposed on Respondent's DEA Certificate of Registration in order to protect the public health and safety.

The Deputy Administrator concludes that Respondent's DEA Certificate of Registration should be continued subject to the following restrictions for three years from the effective date of this final order:

1. Respondent shall continue to participate in the Medical Board of California's Diversion Program regardless of whether the Medical Board authorizes the termination of his participation at an earlier date.

2. Respondent shall not practice medicine as a solo practitioner and he shall not be employed as a physician with any entity that does not impose the same conditions on him that MedClinic imposed in the February 26, 1998 Last Chance Agreement.

3. Upon request, Respondent shall submit copies of the results of his random urine screens to DEA.

4. Respondent shall not prescribe any controlled substances for himself or any immediate family member.

5. Each calendar quarter, Respondent shall provide to the Special Agent in Charge of the local DEA office, or his designee, a log of all controlled substances that he prescribes, dispenses

or administers, including the patient's name and contact information, the name of the substance, the dosage form, strength and quantity prescribed, administered or dispensed, and the number of refills authorized on prescriptions, if any.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BR1670012, previously issued to Edson W. Redard, M.D., be and it hereby is continued, subject to the above described restrictions. This order is effective June 12, 2000.

Dated: May 4, 2000.

Donnie R. Marshall,
Deputy Administrator.

[FR Doc. 00-11890 Filed 5-11-00; 8:45 am]

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DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Assessment of Institutional Culture

AGENCY: National Institute of Corrections, Department of Justice.

ACTION: Solicitation for a cooperative agreement.

SUMMARY: The Department of Justice (DOJ), National Institute of Corrections (NIC) announces the availability of funds in FY-2000 for a cooperative agreement to develop and document a methodology and process to assess institutional culture within prison settings.

Background

Beginning in 1996 the Prisons Division initiated a special emphasis on addressing staff sexual misconduct. NIC's approach to assisting agencies has included on-site technical assistance, training programs and dissemination of information. Throughout the extensive work with institutions in addressing staff sexual misconduct, consistent themes from correctional staff and the offender population underscore the importance of the institutional environment. Additional work at NIC in the area of mission change of institutions and the identification of the challenges of keeping an effective workforce also provide background for NIC's interest in institutional culture. Staff and inmate relations, consistent and fair supervisors, well trained staff, and strong institutional and agency