

16114, 16116 (DEA 1991); Arthur Sklar, R.Ph., d/b/a King Pharmacy, 54 FR 34623 (DEA 1989).

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 DEA Certificate of Registration BM2751736, issued to Medicap Pharmacy, be, and hereby is, revoked, and any pending applications for renewal of such registration be denied. This order is effective January 4, 2001.

Dated: November 21, 2000.

Julio F. Mercado,

Deputy Administrator.

[FR Doc. 00-30930 Filed 12-4-00; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated August 8, 2000, and published in the **Federal Register** on August 23, 2000, (65 FR 51331), Radian International LLC, 14050 Summit Drive #121, P.O. Box 201088, Austin, Texas 78720-1088, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Gamma hydroxybutyric acid (2010).	I
Thebaine (9333)	II

The firm plans to manufacture small quantities of the listed controlled substances to make deuterated and non-deuterated drug reference standards which will be distributed to analytical and forensic laboratories for drug testing programs.

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 Radian International LLC to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Radian International LLC on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, 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: November 20, 2000.

John H. King,

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

[FR Doc. 00-30934 Filed 12-4-00; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 99-7]

In the Matter of Mary Thomson, M.D.; Continuation of Registration With Restrictions

The Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause dated October 30, 1998, to Mary Thomson, M.D. (Respondent), seeking to revoke the Respondent's DEA Certificate of Registration, BT3320203, pursuant to 21 U.S.C. 824(a)(2) and (4); and deny any pending application for renewal of such registration pursuant to 21 U.S.C. 823(f) because her registration would be inconsistent with the public interest as defined by 21 U.S.C. 823(f). Specifically, the Order to Show Cause alleged that Respondent (1) became opiate dependent on Demerol, a Schedule II Controlled Substance, and received in-patient treatment for chemical dependency; (2) tested positive for opiates and benzodiazepines in October of 1995 and had her hospital privileges suspended; (3) obtained controlled substances by fraud or misrepresentation by issuing prescriptions for controlled substances in names of persons for whom such controlled substances were not intended and administered the controlled substances to herself for no legitimate medical purpose and not in the usual course of her professional practice; (4) pled guilty to one felony count of obtaining controlled substances by fraud and received three years of probation, community service, and a fine; and (5) admitted to using controlled substances without a legitimate medical purpose and diverting controlled substances to

her own use. Respondent requested to hearing in a letter filed November 30, 1998. The requested hearing was held in Dallas, Texas, on April 6-8, 1999. 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 January 4, 2000, Judge Randall issued her Opinion and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, recommending that Respondent's registration be continued, subject to three restrictions. The Government thereafter filed Exceptions to Judge Randall's Opinion and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision; and Respondent filed Responses to the Government's Exceptions, The record was transmitted to the Deputy Administrator for final decision February 16, 2000.

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 Rulings, 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 fact or matter of law. The Deputy Administrator finds the following facts especially relevant to his decision.

Respondent was a practicing pharmacist from 1980 until 1987. Respondent has practiced medicine since 1994, when she completed her medical education. During the course of her medical education, Respondent earned several performance awards, including "Resident Physician of the Month," "Resident of the Year," and "Outstanding Third Year Resident." Respondent was employed by St. Mary's Hospital from 1994 until she resigned by letter received May 6, 1996. Respondent is currently employed as the sole full time physician for Special Health Resources of East Texas (SHRET). SHRET is a non-profit public organization funded at least in part by government grants. Respondent works in three clinics serving a large part of East Texas and also provides treatment for HIV patients at the Well Spring Recovery Center, a center for patients with HIV and substance abuse problems. Most of the patients who avail themselves of SHRET's services

are the needy and indigent, and who are also mostly suffering from HIV and related complications. Respondent also administers Phase III clinical trials of experimental AIDS drugs, and follows the treatment of participating patients. Respondent's co-workers at SHRET variously describe her patient care as "excellent" and "exceptional." Respondent also provides HIV/AIDS awareness and treatment training to local healthcare professionals, including other physicians.

Before, during, and after the events at issue, Respondent suffered from a number of serious medical disorders, including Lyme Disease and Bipolar Disorder, Type II. The Bipolar Disorder was diagnosed in June of 1996, subsequent to the events forming the basis for the Show Cause Order. Prior to this diagnosis, Respondent's Bipolar Disorder symptoms had been incorrectly diagnosed as depression, and were being treated as such. Judge Randall credited Respondent's treating psychiatrist's testimony that this misdiagnosis of Respondent's Bipolar Disorder contributed to her susceptibility to drug use. Since her diagnosis, Respondent's Bipolar Disorder has been treated with lithium, and her levels are monitored by a psychiatrist on a monthly basis.

On June 28, 1995, Respondent was escorted from St. Mary's Health Care clinic, her place of employment, because nurses there noticed Respondent behaving strangely, that her speech was slurred, and that she was unsteady on her feet. Following Respondent's departure, hospital staff found in Respondent's desk drawer two used syringes and four vials labeled "Demerol 50 mg", one partially empty. Each vial listed the same patient's name, hereinafter referred to as J.T. Rather Than resign, or submit to close monitoring by St. Mary's Hospital, Respondent entered an in-patient recovery center for one week, and thereafter attended recovery groups three to five times a week.

On October 13, 1995, nurses working with Respondent again noticed strange behavior by Respondent, who seemed confused while examining patients, and again exhibited slurred speech. Respondent agreed to provide a urine sample to test for controlled substances. The test was positive for opiates and benzodiazepines. At the time, however, Respondent had just had minor surgery, and the evidence shows that the positive results of this test were from validly prescribed drugs related to this surgery.

On November 15, 1995, Respondent entered into an impaired physician

agreement with St. Mary's Hospital. The agreement provided that Respondent would submit to weekly drug testing, would attend Alcoholics Anonymous meetings three times a week, and that Respondent would not prescribe any medication for herself.

On March 20, 1996, Respondent tested positive for amphetamines, and subsequently resigned from St. Mary's, rather than face a peer review committee. Respondent's supervisor subsequently testified that this drug test was a false positive, that could be explained by Respondent's use of a decongestant, an antihistamine, or by prescription antidepressant drugs.

On February 11, 1997, Respondent was indicted in the United States District Court for the Northern District of Texas, Lubbock Division (Court), for 12 counts of knowingly and intentionally obtaining and acquiring injectable meperidine, also known as Demerol, a Schedule II narcotic controlled substance, by misrepresentation, fraud, forgery, deception, or subterfuge, in violation of 21 U.S.C. 843(a)(3), and one count of knowingly and intentionally obtaining and acquiring oxycodone, a Schedule II narcotic controlled substance, by misrepresentation, fraud, forgery, deception, or subterfuge, in violation of 21 U.S.C. 843(a)(3). On June 9, 1997, Respondent pled guilty to count eight of the indictment and was sentenced to three years probation. Pursuant to the plea agreement, Respondent was required to participate in a program for the treatment of narcotic dependency, including drug testing; refrain from employment as a physician or pharmacist for the duration of probation except with the written consent of the Court; participate in mental health services as directed by the probation officer; provide 50 hours of community service; and pay a fine.

On August 9, 1997, the Texas Board of Medical Examiners (Board) revoked Respondent's license to practice medicine in Texas; however, the Board probated the revocation, placing Respondent on probation for ten years, subject to the terms and conditions set forth in an Agreed Order with Respondent. The Deputy Administrator finds the following conditions set by the Board especially relevant: (1) Respondent shall obtain written consent from the United States District Court during the probationary period for employment as a physician in the State of Texas; (2) Respondent may only practice in an institutional setting as approved by the Board; (3) Respondent shall not consume alcohol, dangerous drugs, or controlled substances unless

prescribed by another physician for a legitimate and therapeutic purpose; (4) Respondent shall submit to random drug and alcohol testing at the request of the authorized representative of the Board and at the request of any of the physicians required and authorized to evaluate or treat Respondent pursuant to the terms of the Order; (5) Respondent shall submit to a Board approved psychiatrist for monthly counseling and evaluation of her lithium level; (6) Respondent shall participate in an ongoing substance abuse program approved by the Board at least three times a week, and shall provide written reports to the Board documenting the number and locations of the meetings attended; (7) Respondent shall participate in physician health and rehabilitation society meetings and make written reports documenting the Respondent's attendance and participation; (8) Respondent shall complete at least 50 hours per year of continuing AMA approved medical education; (9) Respondent must keep a log book available for inspection at all times of all prescriptions of controlled substances or dangerous drugs with potential for abuse; (10) Respondent's medical practice must be monitored by at least one or more physicians approved by the Board and practicing in Texas; (11) Respondent must not treat or otherwise serve as physician for her immediate family; (12) Respondent shall not unilaterally withdraw from any evaluation, treatment, or medical care required by the Order, upon penalty of the suspension of her medical license; (13) Respondent shall provide written reports regarding any aspect of Respondent's mental or physical condition and compliance with the terms of the Order upon the request of the Board or Board Staff; (14) Respondent may not possess alcohol, controlled substances, or dangerous drugs with potential for abuse, except as authorized by the Order; and (15) Respondent must cooperate with all requests by the Board and Board Staff to monitor her compliance with this Agreed Order.

On October 20, 1997, the Court issued an order consenting to Respondent's "accepting employment as a physician with SHRET, and practicing medicine with that organization in accordance with the Agreed Order, dated August 9, 1997, issued by the Texas State Board of Medical Examiners." Respondent has been employed by SHRET since July or August of 1997 as a consultant, and since November of 1997 as a physician. She has not maintained nor dispensed

controlled substances since her employment with SHRET.

Pursuant to 21 U.S.C. 824(a), the Deputy Administrator may revoke a DEA Certificate of Registration as a practitioner if the registrant has been convicted of a felony *inter alia* under any law of the United States, relating to controlled substances; or if the continuance of such a registration would be inconsistent with the public interest. Pursuant to 21 U.S.C. 823(f) and 824(a)(4) and subdelegations of authority thereunder, (28 CFR 0.100(b) and 0.104 (1998)), the Deputy Administrator may deny pending applications for renewal or modification of this registration as a practitioner if the issuance of such application 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; and (5) Such other conduct which may threaten the public health and safety. These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See Henry J. Schwarz, Jr., MD., 54 FR 16,422 (1989).

It is undisputed that Respondent in this case has been convicted of a felony within the meaning of 21 U.S.C. 824(a)(2). Her June 9, 1997, plea of guilty to count eight of the indictment for violating 21 U.S.C. 843(a)(3) resulted in a sentence of three years probation with standard and additional conditions. Respondent's DEA Certificate of Registration may be revoked upon this basis alone. See George Forest Landman, D.O., 52 FR 1,258 (1987); Fairbanks T. Chua, M.D., 51 FR 41,676 (1986). The statute is discretionary, however, and the relevant language states "A registration pursuant to section 823 of this title * * * may be suspended or revoked by the Attorney General upon a finding that the registrant—* * * (2) has been convicted of a felony under this subchapter * * * " (Emphasis added). In this case, the Deputy Administrator finds that the

public interest is best served by continuing Respondent's registration, as set forth below.

Regarding factor one of the public interest analysis pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator finds that it is undisputed that Respondent's license to practice medicine in the State of Texas was revoked, and the revocation probated for ten years subject to the Agreed Order dated August 9, 1997. The Texas Board placed no restrictions on Respondent's authority to prescribe, administer, or dispense controlled substances, except that she keep a log of such prescriptions available for inspection at all times, and that she only possess such substances as permitted by the Agreed Order. Thus, Respondent is authorized to practice medicine and handle controlled substances in the State of Texas, pursuant to the Agreed Order. While 21 U.S.C. 824(a)(3) requires a registrant to have a valid State license or registration, this is not the only requirement for DEA registration, and therefore is not determinative.

Regarding factor two, Respondent has been employed as both a pharmacist and a physician during her career. While Judge Randall found that Respondent demonstrated a knowledge and understanding of applicable State and federal laws and regulations concerning the handling of controlled substances, the Government accurately points out in its Exceptions that Judge Randall failed to take note of her finding that Respondent failed to understand that DEA regulation required Respondent to notify DEA of Respondent's new registered address, even though Respondent neither dispensed nor maintained controlled substances at that place of business. It is undisputed that Respondent failed to formally notify DEA of the change of her registered address after she began employment with SHRET. This oversight, however, while cause for some concern, is also not dispositive.

Regarding factor three, it is undisputed that Respondent pled guilty to one count of knowingly and intentionally obtaining and acquiring injectable Demerol, a Schedule II narcotic substance, by misrepresentation, fraud, forgery, deception, and subterfuge. This conviction resulted from Respondent's actions on June 26, 1995, when she wrote a prescription for Demerol for J.T., and administered the Demerol to herself while at work. Judge Randall credited the testimony of Respondent and her treating psychiatrist in finding that Respondent's drug use was caused by her various medical and emotional

diagnoses, and especially her previously undiagnosed Bipolar Disorder. The Deputy Administrator finds the record contains no evidence that Respondent's illegal actions harmed anyone other than herself. In addition, there appears to be no evidence in the record that Respondent's patients failed to receive needed medications. On the other hand, there is significant evidence in the record that Respondent is successfully recovering from her drug abuse, and she has effective professional and personal support networks in place to ensure against further relapse. It is undisputed that Respondent has not improperly used controlled substances since at least May of 1996.

Regarding factor four, Respondent admitted to diverting controlled substances on at least two or three occasions, between February 15, 1995, and June 26, 1995. This is in addition to the specific instance forming the basis of her conviction. Respondent alleges that she cannot remember exactly how many times she diverted controlled substances to her own use, nor from whose prescriptions the controlled substances were diverted. The Deputy Administrator shares Judge Randall's concern with regard to respondent's diversion history. While the record is not clear regarding the number of occasions the Respondent diverted, nor the quantity of controlled substances she diverted, the Deputy Administrator finds that there is sufficient evidence in the record to believe that Respondent's estimates regarding her diversion history substantially minimize the extent of her illegal activity. Judge Randall twice noted in her Recommended Rulings that Respondent's attitude at the hearing showed an attempt to minimize her illegal actions. Not only did Respondent studiously avoid admitting that she diverted the very Demerol upon which her criminal conviction was based, she further alleged that she could not remember any specific instances of diversion whatsoever. In addition, Judge Randall credited the Government's showing that Respondent's claims of an ongoing patient-physician relationship with J.T. were false, and that the Respondent was using J.T.'s name merely to obtain Demerol and to conceal her own illicit use. Judge Randall found, and the Deputy Administrator concurs, that absent the evidence of Respondent's strong efforts to rehabilitate herself, her continual minimizations of her criminal actions and significant breaches of professional judgment would weigh heavily against her retention of a DEA Certificate of

Registration. It is undisputed, however, that Respondent is in compliance with the terms of her Federal probation, and also with the terms of the Agreed Order.

Finally, with regard to the fifth factor, there is no question that Respondent abused controlled substances while performing her duties as a physician. Also troubling is Respondent's false physician-patient relationship with J.T., which Respondent continued to refuse to acknowledge as a subterfuge to supply Respondent's own drug addition. Fortunately for Respondent's patients, and for Respondent herself, there is no evidence that Respondent's illicit drug abuse harmed any others than herself, and further, there is no evidence that Respondent's patients failed to receive needed medications. Without the strong and extensive controls set in place by the Agreed Order, and without the strong evidence of Respondent's sincere efforts to rehabilitate herself, her retention of a DEA Certificate of Registration would not be in accord with the public interest.

The Deputy Administrator agrees with Judge Randall that the Government has met its *prima facie* burden in its case to revoke Respondent's DEA Certificate of Registration and to deny her pending application for renewal. As Judge Randall notes in her Recommended Rulings, however, the governing statute is discretionary. 21 U.S.C. 823(f) states in relevant part that "[t]he Attorney General *may* deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest." (Emphasis added). The Deputy Administrator previously has concluded that, in exercising his discretion in determining the appropriate remedy in any given case, he should consider all the facts and circumstances of the case. See Martha Hernandez, M.D., 62 FR 61,145 (1997). The Deputy Administrator concurs with Judge Randall that the Respondent has presented sufficient evidence to alter the ultimate determination of her case.

Specifically, the Deputy Administrator finds that the Texas Board's Agreed Order with the Respondent provides the public and Respondent herself with effective protection against future criminal diversion of controlled substances. The evidence shows that Respondent is in compliance with all terms of the Agreed Order. In addition, Respondent currently maintains a lifestyle that will help to prevent a relapse of the substance abuse problems she experienced in 1995. Currently, the Respondent attends a substance

recovery group, maintains a relationship with a therapist, receives lithium to control the effects of her Bipolar Disorder, submits to regular drug testing, and has developed strong familial and religious associations.

Another significant factor influencing the Deputy Administrator's decision in this case is that Respondent's current professional position at SHRET is devoted to serving the public interest. The Deputy Administrator finds that the public interest is best served in this case by continuing Respondent's registration, with appropriate restrictions, as set forth below. Through SHRET, Respondent provides critical services to a medically under-served community. Respondent also is committed to performing training and continuing education to other health professionals, including physicians, regarding AIDS and HIV issues, over a large geographic area. At least some of this training is performed during her personal time, and not during her regular work hours. Respondent additionally has been approved by the FDA to administer Phase III clinical trials of experimental AIDS drugs, and thereafter to monitor the results. As of the date Respondent's testimony in the present hearing, she had administered six trials in the previous 18 month period. Respondent and her co-workers all credibly testified that her work at SHRET gives Respondent great professional satisfaction. Additionally, Respondent's quality of work at SHRET was credibly characterized by co-workers as "excellent" and "exceptional." Respondent is also the medical director at Well Spring, a recovery center designed to assist individuals who are suffering from HIV and who are also substance abusers. The 60 to 90 day program is designed to teach participants alternative methods of pain and stress management, including massage, Acudetox, and neuro-feedback. Well Spring Recovery Center is the only program of its type in Texas, and one of only three in the United States (the other two are located on the East and West Coasts).

The Deputy Administrator agrees with Judge Randall's finding that Respondent effectively has addressed the personal and professional problems that contributed to her drug abuse. While it is troubling that Respondent attempted to tailor her testimony to limit and minimize her illicit activity, the record indicates that Respondent did take affirmative responsibility for her misconduct. The strong and extensive controls set by the Texas Board's Agreed Order, combined with Respondent's actions clearly showing a great personal

desire to rehabilitate herself personally and professionally, provide a sufficient level of protection for both Respondent and the public that Respondent should be allowed to maintain her DEA Registration, with restrictions.

Therefore, 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 is to forward on a quarterly basis her prescription log to the DEA regional office for the entire three year period of this registration;
2. Respondent is to promptly forward whatever evidence of drug screen results available to her to the DEA regional office for the entire three year period of this registration;
3. Respondent is to promptly forward to the DEA regional office any changes the Texas Board of Medical Examiners may make to the terms of her probation;
4. Respondent shall not prescribe, dispense, administer, or otherwise handle any narcotic controlled substance as defined under the Controlled Substances Act; this restriction shall also extend to the Controlled Substances Buprenorphine, Butorphanol, and Pentazocine; and
5. Consistent with the Court's October 20, 1997 order, Respondent's Registration is contingent upon continuing her employment with SHRET for the entire three year period of the Registration. If for any reason Respondent terminates her employment with SHRET, Respondent shall promptly notify the DEA regional office in writing, setting forth the facts and circumstances leading to said termination of employment.

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 DEA Certificate of Registration BT3320203, submitted by Mary Thomson, M.D. be, and hereby is, continued, and any pending applications for renewal be granted, for Schedules II, III, IV, and V non-narcotics, excepting Butorphanol and Pentazocine, and subject to the above-described restrictions. This order is effective upon the issuance of the DEA Certificate of Registration, but no later than January 4, 2001.

Dated: November 21, 2000.

Julio F. Mercado,

Deputy Administrator.

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