

where he was applying for registration. Judge Bittner recommended that Respondent's application for a DEA Certificate of Registration be denied.

No exceptions were filed by either party to Judge Bittner's Opinion and Recommended Decision and on March 22, 2005, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommended Decision of the Administrative Law Judge.

The Deputy Administrator finds that Respondent previously held DEA Certificate of Registration BR4105032, which he surrendered on June 19, 2003, while a Federal Search Warrant was being executed upon his medical office. Three weeks later, Respondent filed the application for DEA registration which is the subject of these proceedings.

The Deputy Administrator further finds that, effective December 20, 2004, Respondent's license to practice medicine in Illinois and his Illinois Controlled Substances Registration were temporarily suspended, pending further proceedings, after the Illinois Board found "the public interest, safety, and welfare imperatively require emergency action to prevent the continued practice of the Respondent, in that Respondent's actions constitute an immediate danger to the public." The Illinois Board's action was based primarily on the facts alleged in DEA's Order to Show Cause, coupled with Respondent's violation of an Agreement of Care, Counseling and Treatment, which he had entered into with state authorities.

The Deputy Administrator therefore finds Respondent is currently not licensed to practice medicine in Illinois and lacks authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See* Stephen J. Graham, M.D., 69 FR 11,661 (2004); Dominick A. Ricci, M.D., 58 FR 51,104 (1993); Bobby Watts, M.D., 53 FR 11,919 (1988). Denial or revocation is also appropriate when a state license has been suspended, but with the possibility of future

reinstatement. *See* Paramabalothe Edwin, M.D., 69 FR 58,540 (2004); Alton E. Ingram, Jr., M.D., 69 FR 22,562 (2004); Anne Lazar Thorn, M.D., 62 FR 847 (1997).

Here, it is clear Respondent is not currently licensed to handle controlled substances in Illinois, the jurisdiction in which he has applied for a DEA registration. Therefore, he is not entitled to registration in that state.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for a DEA Certificate of Registration submitted by Roger A. Rodriguez, M.D., be, and it hereby is, denied. This order is effective July 7, 2005.

Dated: May 25, 2005.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Robert A. Smith, M.D., Revocation of Registration

This order serves as a correction of the final order previously issued in this matter and published on May 10, 2005. On September 29, 2004, the Deputy Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause/Immediate Suspension of Registration to Robert A. Smith, M.D. (Dr. Smith) who was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AS6932669 under 21 U.S.C. 824(a)(4) and deny any pending applications for renewal or modification of that registration under 21 U.S.C. 823(f). Dr. Smith was further notified that his registration was being immediately suspended under 21 U.S.C. 824(d) as an imminent danger to the public health and safety.

The Order to Show Cause alleged in relevant part, that Dr. Smith diverted controlled substances for a substantial time by knowingly issuing fraudulent prescriptions to individuals, without a bona fide doctor-patient relationship or legitimate medical purpose. The Order to Show Cause also notified Dr. Smith that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

On October 20, 2004, a DEA investigator personally served the Order to Show Cause/Immediate Suspension

of Registration on Dr. Smith's attorney at Respondent's medical office in Philadelphia, Pennsylvania. Since that date, DEA has not received a request for a hearing or any other reply from Dr. Smith or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since personal delivery of the Order to Show Cause/Immediate Suspension of Registration to the registrant and (2) no request for hearing having been received, concludes that Dr. Smith is deemed to have waived his hearing right. *See* David W. Linder, 67 FR 12,579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Smith is registered with DEA as a practitioner under Certificate of Registration AS6932669 with a registered location at 1420 Locust Street, Suite 200, Philadelphia, Pennsylvania. In May 2003, DEA began investigating Dr. Smith as a result of complaints from area pharmacies that were encountering large numbers of young, seemingly healthy individuals, filling prescriptions issued by Dr. Smith for OxyContin and Percocet, both schedule II controlled substances. These individuals paid cash for their prescriptions and appeared to be traveling long distances to have them prescribed and filled.

On June 27, 2003, Independence Blue Cross (IBC) insurance investigators interviewed IBC beneficiary "H.B." regarding prescriptions for OxyContin, Percocet and Methadone which had been issued by Dr. Smith under her name and insurance data. H.B. had never seen or heard of Dr. Smith and had no medical conditions warranting the prescriptions. It was also established that H.B.'s son's father, "M.P.," was a heroin addict and that M.P.'s sister, "L.P.," who also had a history of narcotic's abuse, worked for Dr. Smith as his office assistant.

On July 9, 2003, NBC investigators interviewed "C.P.," who was L.P.'s sister. IBC's records reflected that on May 10, 2003, Dr. Smith issued prescriptions for Percocet and Alprazolam (Xanax), a schedule IV controlled substance, using C.P.'s name and policy, which were then paid for by insurance company. Investigators determined C.P. had never met or been examined by Dr. Smith, that she did not receive the prescriptions written in her name and had no medical conditions warranting them.

On November 6, 2003, DEA Diversion Investigators responded to the Lombard Apothecary in Philadelphia to interview "D.N.," who had attempted to fill a prescription for OxyContin issued by Dr. Smith using D.N.'s mother's name and insurance. D.N. admitted that her mother had no knowledge of the prescription and was not a patient of Dr. Smith. D.N. had asked Dr. Smith to issue her fraudulent prescriptions, as she had no medical insurance of her own. He also had written her a prescription for OxyContin, using her brother's name and insurance data. D.N. then used the OxyContin to feed her personal narcotics addiction.

On November 26, 2003, "J. S." was interviewed by local law enforcement authorities, with DEA Diversion Investigators present. She admitted receiving seven to ten prescriptions for OxyContin from Dr. Smith, per visit, on a weekly basis. These prescriptions would be written in J.S.'s name, as well as her father's and fiancée's names. She paid \$65.00 per visit and an additional \$100.00, each time, to ensure Dr. Smith would continue providing her fraudulent prescriptions. Additionally, Dr. Smith would ask J.S. for sexual favors during her office visits. While she personally declined to fulfill his requests, as a substitute, she paid another woman \$100.00 to perform a sexual act upon Dr. Smith. J.S. also reported that Dr. Smith's office assistant, L.P., had provided her blank prescriptions in return for \$40.00 and OxyContin pills.

Dr. Smith also wrote prescriptions for "A.D.," who had heard of Respondent's "street" reputation for providing controlled substance prescriptions. A.D. was first seen by Dr. Smith in February 2003 and the only examination involved measuring A.D.'s blood pressure. In March and April 2003, Dr. Smith issued prescriptions for OxyContin and Percocet, using both A.D.'s and his wife's names. In February 2004, Dr. Smith also wrote ten prescriptions for A.D. using A.D.'s name, his wife's name and a friend's name.

On February 22, 2004, "S.K." was found, apparently unresponsive, by her mother-in-law, who called 911. S.K. died of a drug overdose and a few weeks later S.K.'s mother-in-law contacted DEA Diversion Investigators and advised that S.K. had been addicted to narcotics and Dr. Smith was the source of her prescriptions. The Philadelphia Medical Examiner's Office provided DEA investigators 31 prescription bottles recovered from S.K.'s residence. All of their labels indicated they were prescribed by Dr. Smith and the

majority was for schedule II and IV controlled substances.

On May 20, 2004, a Confidential Source (CS) was provided \$400.00 to purchase fraudulent prescriptions written by Dr. Smith. The CS used that money to obtain twelve separate prescriptions from an individual who, in turn, had received them from Dr. Smith.

On May 27, 2004, Diversion Investigators interviewed "J.G." who, for six or eight months, had been seeing Dr. Smith on a weekly basis. J.G. would give Dr. Smith a list of fictitious names and types of controlled substances he desired and Dr. Smith would issue three prescriptions under each name, usually for Percocet, OxyContin and Xanax. Dr. Smith issued between nine and fifteen fraudulent prescriptions for controlled substances per visit and received \$100.00 for each set of three prescriptions. J.G. then sold the prescriptions to a third party who, in turn, sold the drugs on the street. Dr. Smith was aware of and knowingly participated in this scheme.

On June 1, 17 and 19, 2004, a CS visited Dr. Smith's medical office. On each occasion, he obtained fraudulent prescriptions for Xanax, OxyContin and Percocet, paying Dr. Smith \$500.00 for fifteen prescriptions, written under five different fraudulent identities.

On June 29, 2004, Diversion Investigators were contacted by Family Meds, a mail order pharmacy in Connecticut. On June 22, 2004, the pharmacy received five prescriptions for controlled substances written by Dr. Smith for "M.B." Family Meds had contacted Dr. Smith, who verified issuing the prescriptions. However, the pharmacy ultimately refused to fill them and verified that on June 6, 2004, M.B. had filled identical prescriptions issued by Dr. Smith at another pharmacy.

A review of reports from the Pennsylvania Attorney General's Office, Bureau of Narcotics Investigation and Drug Control showed that from January 14, 2002, to April 30, 2004, Dr. Smith issued over 6,500 prescriptions for schedule II narcotic controlled substances. These prescriptions constituted a significant portion of the total schedule II prescriptions filled in the Philadelphia and New Jersey area.

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 for renewal of such registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be

considered in determining the public interest:

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

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

(3) The applicant's conviction record under Federal or state laws relating to the manufacture, distribution, and 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 considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See *Henry J. Schwartz, Jr., M.D.*, 54 FR 16,422 (1989).

As to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that the State of Pennsylvania has yet taken adverse action against Dr. Smith's medical license. However, "inasmuch as State licensure is a necessary but not sufficient condition for a DEA registration* * * this factor is not dispositive." See *Edson W. Redard, M.D.*, 65 FR 30,616, 30,619 (2000).

With regard to factors two and four, Respondent's experience in handling controlled substances and his compliance with applicable controlled substance laws, the investigative file contains overwhelming evidence that Dr. Smith unlawfully prescribed and diverted controlled substances over an extensive period of time. He knowingly prescribed controlled substances to individuals without bona fide doctor-patient relationships and issued fraudulent prescriptions destined to feed the recipient's personal addiction or to be sold on the street. He did so in a calculated manner, for financial gain, violating multiple state and federal laws and abysmally failing to meet the rudimentary responsibilities of a physician and registrant. Thus, factors two and four weigh in favor of a finding that continued registration would be inconsistent with the public interest.

Factor three, the applicant's conviction record under Federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances, is not relevant for consideration, as there is no evidence Dr. Smith has yet been convicted of any

crime related to controlled substances. However, it is noted the investigation has been provided to Federal authorities for possible initiation of criminal charges.

With respect to factor five, other conduct that may threaten the public health and safety, Respondent's actions discussed above are also relevant under this factor. The Deputy Administrator is particularly troubled by Dr. Smith's efforts to enrich himself at the expense of the public health and safety. Not only has a large quantity of controlled substances been diverted over an extensive period of time as a result of his illegal activities, at least one patient has died of a drug overdose after taken medications prescribed by Dr. Smith.

The exact degree of suffering and costs, both social and economic, stemming from Dr. Smith's activities will never be known. Suffice it to say, his unprofessional and criminal conduct has resulted in the diversion of large quantities of controlled substances in the Philadelphia area for a lengthy period of time, with correspondingly severe consequences for public health and safety.

In sum, Dr. Smith's cavalier disregard for the law and abandonment of his responsibilities as a physician and registrant cannot be tolerated. They weigh, irresistibly, in favor of a finding that continued registration would not be in the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 28 CFR 0.100(b), and 0.104, hereby orders that DEA Certificate of Registration AS6932669, issued to Robert A. Smith, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective July 7, 2005.

Dated: May 25, 2005.

Michele M. Leonhart,
Deputy Administrator.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 030-33656]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for PPD, Inc.'s (formerly PPD Development and PPD Pharmaco) Facility in Richmond, VA

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: John Nicholson, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, telephone (610) 337-5236, fax (610) 337-5269; or by e-mail: jjn@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) is issuing a license amendment to PPD, Inc. for Materials License No. 45-25314-01, to authorize release of its facility in Richmond, Virginia for unrestricted use. NRC has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this notice.

II. EA Summary

The purpose of the action is to authorize the release of the licensee's Richmond, Virginia facility for unrestricted use. PPD, Inc. was authorized by NRC from November 23, 1994, to use radioactive materials for research and development purposes at the site. On November 18, 1997, PPD, Inc. requested that NRC release the facility for unrestricted use. PPD, Inc. has conducted surveys of the facility and provided information to the NRC to demonstrate that the site meets the license termination criteria in subpart E of 10 CFR part 20 for unrestricted use.

The NRC staff has prepared an EA in support of the license amendment. The facility was remediated and surveyed prior to the licensee requesting the license amendment. The NRC staff has reviewed the information and final status survey submitted by PPD, Inc. Based on its review, the staff has determined that there are no additional remediation activities necessary to complete the proposed action.

Therefore, the staff considered the impact of the residual radioactivity at the facility and concluded that since the residual radioactivity meets the requirements in subpart E of 10 CFR part 20, a Finding of No Significant Impact is appropriate.

III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of the license amendment to release the facility for unrestricted use. The NRC staff has evaluated PPD, Inc.'s request and the results of the surveys and has concluded that the completed action complies with the criteria in subpart E of 10 CFR part 20. The staff has found that the radiological environmental impacts from the action are bounded by the impacts evaluated by NUREG-1496, Volumes 1-3, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities" (ML042310492, ML042320379, and ML042330385). The staff also found that the non-radiological impacts are not significant. On the basis of the EA, the NRC has concluded that the environmental impacts from the action are expected to be insignificant and has determined not to prepare an environmental impact statement for the action.

IV. Further Information

Documents related to this action, including the application for the license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are: The Environmental Assessment [ML051510116], NRC Inspection Report No. 45-25314-01/98-01 [ML050450536] and Final Radiological Survey Report for 2246C Dabney Circle dated October 1997 prepared by RSO, Inc., for PPD Pharmaco [ML050450524]. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at (800) 397-4209 or (301) 415-4737, or by e-mail to pdr@nrc.gov.

Documents related to operations conducted under this license not specifically referenced in this notice may not be electronically available and/or may not be publicly available.