

position on the matters of fact and law that are involved in this proceeding. Accordingly, after considering material from the investigative file and Dr. Burkich's Written Statement, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(c) and (e) and 1301.46.

The Deputy Administrator finds Dr. Burkich currently possesses DEA Certificate of Registration BB4812043, which expires on July 31, 2005. The Deputy Administrator further finds that on March 17, 2004, Tennessee Board of Medical Examiners (Tennessee Board) issued a Final Order revoking Dr. Burkich's license to practice medicine in Tennessee. The Tennessee Board's action was based upon its findings of fact that Dr. Burkich had been convicted in the United States District Court for the Eastern District of Tennessee of one felony count of mail fraud (18 U.S.C. 1341) and that the Georgia Composite State Board of Medical Examiners (Georgia Board) had revoked Dr. Burkich's license to practice medicine in Georgia, as a result of that conviction.

In his Written Statement, Dr. Burkich concedes he pled guilty to the criminal charge. However, he alleges he had a viable defense of entrapment and only pled guilty after being misadvised by his retained defense counsel who, Dr. Burkich asserts, was ineffective and had a conflict of interest. Attached to his Written Statement is a Motion for a Certificate of Appealability, which Dr. Burkich filed in the United States Court of Appeals for the Sixth Circuit (Case No. 04-6027). In that Motion, Dr. Burkich asserts in detail the factual and legal basis for the claims in his Written Statement.

The Deputy Administrator has determined that on November 23, 2004, the court of Appeals issued an Order denying Dr. Burkich's Motion for a Certificate of Appealability. He subsequently filed a Petition for an En Banc Rehearing which has not yet been acted upon by the Court. Accordingly, the federal conviction which was the underlying basis for Dr. Burkich's license revocation remains a valid judgment.

More significantly for purposes of this proceeding, Dr. Burkich does not contend in either his Written Statement or the accompanying Motion, that the Tennessee Board's Final Order has been stayed, modified or terminated or that either of his state medical licenses have been reinstated. Further, there is no evidence in the investigative file indicating the Tennessee Board's Final Order is no longer in effect.

Therefore, the Deputy Administrator finds Dr. Burkich is not currently

authorized to practice medicine in the States of Tennessee and Georgia. As a result, it is reasonable to infer he is also without authorization to handle controlled substances in either 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 11661 (2004); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988).

Here, it is clear Dr. Burkich's Tennessee medical license has been revoked and he is not currently licensed to handle controlled substances in that state, where he is registered with DEA. Therefore, he is not entitled to a DEA registration in Tennessee.

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 DEA Certificate of Registration BB4812043, issued to Robert A. Burkich, 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 June 17, 2005.

Dated: May 9, 2005.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Salvatore DeFrank, D.P.M. Revocation of Registration

On October 28, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Salvatore DeFrank, D.P.M. (Dr. DeFrank) of Dallas, Texas. Dr. DeFrank was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, BD8259346, as a practitioner, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that his continued registration would be inconsistent with the public interest. Dr.

DeFrank was further notified that his DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension of Registration alleged in sum, that Dr. DeFrank was illegally prescribing controlled substances over the Internet without personal contacts, examinations or bona fide physician/patient relationships with the customers ordering the medications. These prescriptions were not issued "in the usual course of professional treatment" and violated 21 CFR 1306.04 and 21 U.S.C. 841(a).

According to the investigative file, the order to Show Cause and Immediate Suspension of Registration was personally accepted on Dr. DeFrank's behalf by his attorney in Carrolltown, Texas, on November 4, 2004. More than thirty days have passed since service of the Order to show Cause and Immediate Suspension of Registration and DEA has not received a request for hearing or any other reply from Dr. DeFrank or anyone purporting to represent him in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to Dr. DeFrank's attorney, and (2) no request for hearing having been received, concludes that Dr. DeFrank is deemed to have waived his hearing right. See David W. Linder, 67 FR 12579 (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.

While some consumers use Internet pharmacies for convenience, privacy and cost savings, others, including minor children, use the anonymity of the Internet to procure controlled substances illegally. The role of a legitimate online pharmacist is to dispense prescription medications and to counsel patients about the proper use of these medications, not to write or originate prescriptions. Internet profiteers are online suppliers of prescription drugs, be they owners, operators, pharmacists, or doctors, who illegally and unethically market controlled substances via the Internet for quick profit. Operation PHARMNET, which this Order to show Cause and Immediate Suspension of Registration is a part of, is a nationwide action by the DEA to disrupt and dismantle this illegal and dangerous cyberspace threat to the public health and safety.

The Controlled Substances Act (CSA) establishes a "closed system" of distribution regulating the movement of controlled medications from their importation or manufacture, through delivery to the ultimate user patient, pursuant to a lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a).

Prescriptions issued not in the "usual course of professional treatment" are not "prescriptions" for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's controlled substances provisions.

In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court held that, "Implicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician.'" *Id.*, at 141. In *Moore* the court implicitly approved a jury instruction that acting "as a physician" is acting "in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.*, at 138-139; see, *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986).

Responsible professional organizations have issued guidance in this area. The American Medical Association's guidance for physicians on the appropriate use of the Internet in prescribing medication (H-120.949 Guidance for Physicians on Internet Prescribing) states:

"Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:

- i. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
- ii. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
- iii. As appropriate, follow up with the patient to assess the therapeutic outcome;
- iv. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and

v. Include the electronic prescription information as part of the patient medical record."

In April 2000, the Federation of State Medical Boards adopted Model Guidelines for the Appropriate Use of the Internet in Medical Practice, which state, in pertinent part, that:

"Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care."

The CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's "corresponding responsibility" regarding the proper dispensing of controlled substances is explicitly described in 21 CFR 1306.04(a). It provides:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

In an April 21, 2001, policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR 21 181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, inter alia, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship requires that the patient have a medical complaint, a medical history taken, a physical examination performed and some logical connection between the medical complaint, the medical history, the physical examination and the drug prescribed. The policy statement specifically explains that the completion of "a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship * * *"*Id.*, at 21 182-21183.

Rogue Internet pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory and incomplete online questionnaire or perfunctory telephone "consult" with a doctor, who usually has a contractual

arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. The Food and Drug Administration (FDA) considers the questionnaire, in lieu of face-to-face interaction, to be a practice that undermines safeguards of direct medical supervision and amounts to substandard medical care. See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (<http://fda.gov/oc/buyonline/default.htm>).

The National Association of Boards of Pharmacy considers Internet pharmacies to be suspect if:

"they dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional."

See National Association of Boards of Pharmacy, VIIPS Program, Most Frequently Asked questions (<http://www.nabp.net/viips/consumer/faq.asp>).

Rogue Internet pharmacies often use persons with limited or no knowledge of medications and standard pharmacy practices to fill prescriptions, do not advertise the availability of pharmacists for medication consultation, and focus on select medications, usually lifestyle, obesity and pain medications. Rogue Internet pharmacies generally do not protect the integrity of original faxed prescriptions by requiring that they be received directly from the prescriber (not the patient) and do not verify the authenticity of suspect prescriptions.

When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice. The FDA has stated:

"We know that adverse events are under-reported and we know from history that tolerating the sale of unproven, fraudulent, or adulterated drugs results in harm to the public health. It is reasonable to expect that the illegal sales of drugs over the Internet and the number of resulting injuries will increase as sales on the Internet grow. Without clear and effective law enforcement, violators will have no reason to stop their illegal practices.

Unless we begin to act now, unlawful conduct and the resulting harm to consumers most likely will increase.”

See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (<http://fda.gov/oc/buyonline/default.htm>).

The Deputy Administrator finds that Dr. DeFrank is currently registered with DEA as a practitioner under DEA Registration, BD8259346 with a registered address in Dallas, Texas. He is licensed as a podiatrist in the State of Texas.

Prior to October 2003, Dr. “J.D.” had been issuing large amounts of controlled substances from his clinic, the Mid-Florida Medical Clinic (MFMC), located in Haines City, Florida. These prescriptions, issued pursuant to an unlawful Internet scheme as described above, were dispensed directly from MFMC and from National Scripts, Inc. (NSI), a pharmacy located in Earth City, Missouri, which was filling thousands of Internet prescriptions authorized by various physicians, in addition to Dr. J.D.

On October 16, 2003, as a result of a DEA investigation into these activities, Dr. J.D. was served with an Order to Show Cause and Immediate Suspension of his DEA practitioner’s registration. Shortly thereafter, Dr. DeFrank met with Dr. J.D. and others associated with MFMC and NSI, to discuss who would take over Dr. J.D.’s role, now that he could no longer issue prescriptions because of the suspension order. Dr. DeFrank agreed to take over Dr. J.D.’s prescribing responsibilities.

On October 21, 2003, after a diversion investigator from DEA’s Orlando District Office discovered Dr. DeFrank was issuing controlled substance prescriptions from MFMC’s Florida location, he contacted Dr. DeFrank to advise him he was not authorized to issue Internet prescriptions in Florida, as he was not licensed to practice in that state. Dr. DeFrank responded that his prescribing was lawful, because it was done over the Internet. The investigator then advised Dr. DeFrank that they knew that Dr. DeFrank’s Florida-licensed physician assistants were authorizing Internet controlled substance prescriptions in Dr. DeFrank’s name, which was a violation of Florida law. The investigator further advised Dr. DeFrank that issuing prescriptions for controlled substances without a face-to-face examination was illegal and that this practice was the basis for the immediate suspension of Dr. J.D.’s registration, which was ultimately surrendered in lieu of further proceedings.

On November 20, 2003, an investigator from DEA’s Dallas Field Division contacted Dr. DeFrank’s Texas attorney to advise him that DEA prohibited issuance of controlled substance prescriptions without a face-to-face examination and that such prescribing practices also violated Texas law.

On December 4, 2003, DEA served a Federal search warrant on the NSI pharmacy in Earth City, Missouri. Over 3,000 controlled substance dispensing records were recovered showing Dr. DeFrank had prescribed controlled substances over the Internet, mostly hydrocodone, a Schedule III controlled substance. These records showed Dr. DeFrank continued Internet prescribing even after he and his attorney were specifically warned of its illegal nature and put on notice that DEA was investigating this activity.

On February 24, 2004, Dr. DeFrank’s Texas attorney was again contracted by DEA investigators. They advised counsel that his client was continuing to unlawfully prescribe controlled substances through the Internet and unsuccessfully sought surrender of Dr. DeFrank’s registration.

On April 9, 2004, a DEA undercover investigator went online to order a controlled substance prescription through the Web site <http://www.mypainmeds.com>. He falsely filled out an Internet questionnaire indicating he was overweight and suffering from back pain and insomnia. After providing an undercover phone number where he could be contacted, at a designated time the investigator was called by an unknown male and asked a few questions. While refusing to order one controlled medication because of its high asking price, the investigator agreed to purchase 60 dosage units of 10 mg. hydrocodone, at a price which included a \$38.00 doctor’s “consultation” fee. The hydrocodone was then shipped via Federal Express to an undercover address in Florida and Dr. DeFrank was listed on the vial’s label as the prescribing physician.

While Dr. DeFrank was issuing controlled substance prescriptions over the Internet, he was licensed in the State of Texas as a podiatrist. Because Texas law permits a podiatrist to issue controlled substances *only* for the treatment of foot ailments, Dr. DeFrank’s Internet prescribing for complaints that were unrelated to foot ailments was prohibited by state law.

Further, as of December 1999, Texas has imposed the following requirements, (1) A physician must verify the identity of the person requesting medication. (2) The

physician must establish a diagnosis with accepted medical practices such as patient history, mental status exam, physical exam and appropriate diagnostic and laboratory testing. (3) The physician must discuss with the patient the diagnosis and evidence of the medical complaint and the risks and benefits of treatment options. (4) The physician must insure the availability of appropriate follow-up care. The Internet prescriptions issued by Dr. DeFrank did not comply with these state requirements.

On September 15, 2004, Dr. DeFrank was interviewed by two detectives from the Sheriff’s Department of Ventura County, California. Dr. DeFrank admitted he was then-currently managing a web site call center which employed one physician and a physician’s assistant to issue controlled substance prescriptions over the Internet. The California investigation also discovered that between July 16 and 28, 2004, Dr. DeFrank personally issued 32 controlled substance prescriptions for Internet customers.

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 application 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, 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 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 16422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to a determination of whether Dr. DeFrank’s continued registration

remains consistent with the public interest.

With regard to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that Dr. DeFrank has been the subject of a state disciplinary proceeding, nor is there evidence demonstrating that his state podiatry license or state controlled substance authority are currently restricted in any form. Nevertheless, state licensure is a necessary, but not sufficient condition for registration, and therefore, this factor is not dispositive. *See e.g.*, Wesley G. Harline, M.D., 65 FR 5665–5672 (2000); James C. Lajevic, D.M.D., 64 FR 55962 (1999).

With regard to factors two and four, the Deputy Administrator finds the primary conduct at issue in this proceeding (*i.e.*, the unlawful prescribing and dispensing of controlled substance prescriptions for use by Internet customers) relates to Dr. DeFrank's experience in prescribing controlled substances, as well as his compliance with applicable state, federal, or local laws relating to controlled substances.

A DEA registration authorizes a physician to prescribe or dispense controlled substances only within the usual course of his or her professional practice. For a prescription to have been issued within the course of a practitioner's professional practice, it must have been written for a legitimate medical purpose within the context of a valid physician-patient relationship. *See* Mark Wade, M.D., 69 FR 7018 (2004). Legally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription. *See* Floyd A. Santner, M.D., 55 FR 37581 (1990).

The Deputy Administrator concludes from a review of the record that Dr. DeFrank did not establish valid physician-patient relationships with the Internet customers to whom he prescribed controlled substances. DEA has previously found that prescriptions issued through Internet websites under these circumstances are not considered as having been issued in the usual course of medical practice, in violation of 21 CFR 1306.04 and has revoked DEA registrations of several physicians for participating in Internet prescribing schemes similar to or identical to that of Dr. DeFrank. *See*, Marvin L. Gibbs, Jr., M.D., 69 FR 11658 (2004); Mark Wade, M.D., *supra*, 69 FR 7018; Ernesto A. Cantu, M.D., 69 FR 7014–7015 (2004); Rick Joe Nelson, M.D., 66 FR 30752 (2001).

Similarly, DEA has issued orders to show abuse and subsequently revoked DEA registrations of pharmacies which have failed to fulfill their corresponding responsibilities in Internet prescribing operations similar to, or identical to that of Dr. DeFrank. *See*, EZRX, L.L.C. (EZRX), 69 FR 63178 (2004); Prescriptiononline.com, 69 FR 5583 (2004).

In the instant case, Dr. DeFrank and other practitioner associated with this Internet scheme, authorized prescriptions for controlled substances without the benefit of face-to-face physician-patient contact, physical exam or medical tests. Beyond occasional phone calls to customers or their family members, there is no information in the investigation file demonstrating that Dr. DeFrank and other issuing physicians even took time to corroborate responses to the questionnaire submitted by the customers. Here, it is clear that the issuance of controlled substance prescriptions to persons whom Dr. DeFrank had not established a valid physician-patient relationship is a radical departure from the normal course of professional practice and he knowingly participated in this scheme.

With regard to factor three, Dr. DeFrank's conviction record under federal or state laws relating to the dispensing of controlled substances, the record does not reflect that he has yet been convicted of a crime related to controlled substances.

Regarding factor five, such other conduct which may threaten the public health or safety, the Deputy Administrator finds this factor particularly relevant. Dr. DeFrank continued prescribing to Internet customers, not only after issuance of policy statements designed to assist licensed practitioner and pharmacies in the proper prescribing and dispensing of dangerous controlled drugs, but after multiple warnings were personally delivered to Dr. DeFrank and his attorney and he was put on notice of the reason for his MFMC predecessor's immediate suspension. That he continued this activity after being made aware of its illegal nature and that it was the focus of an investigation, speaks volumes regarding Dr. DeFrank's willingness to abandon his responsibilities as a practitioner and registrant.

The Deputy Administrator has previously expressed her deep concern about the increased risk of diversion which accompanies Internet controlled substance transactions. Given the nascent practice of cyber-distribution of controlled drugs to faceless individuals,

where interaction between individuals is limited to information on a computer screen or credit card, it is virtually impossible to insure that these highly addictive, and sometimes dangerous products will reach the intended recipient, and if so, whether the person purchasing these products has an actual need for them. The ramifications of obtaining dangerous and highly addictive drugs with the ease of logging on to a computer and the use of a credit card are disturbing and immense, particularly when one considers the growing problem of the abuse of prescription drugs in the United States. *See*, EZRX, *supra*, 69 FR at 63181; Mark Wade, M.D., *supra*, 69 FR 7018.

The Deputy Administrator has also previously found that in a 2001 report, the National Clearinghouse for Alcohol and Drug Information estimated that 4 million Americans ages 12 and older had acknowledged misusing prescription drugs. That accounts for 2% to 4% of the population—a rate of abuse that has quadrupled since 1980. Prescription drug abuse—typically of painkillers, sedatives and mood-altering drugs—accounts for one-third of all illicit drug use in the United States. *See*, EZRX, *supra*, 69 FR at 63181–63182; Mark Wade, M.D., *supra*, 69 FR 7018.

The Deputy Administrator finds that with respect to Internet transactions involving controlled substances, the horrific untold stories of drug abuse, addiction and treatment are the unintended, but foreseeable consequence of providing highly addictive drugs to the public without oversight. The closed system of distribution, brought about by the enactment of the Controlled Substances Act, is completely compromised when individuals can easily acquire controlled substances without regard to age or health status. Such lack of oversight describes Dr. DeFrank's practice of issuing prescriptions for controlled substances to indistinct Internet customers which were then filled by pharmacies participating in the scheme. Such conduct contributes to the abuse of controlled substances by Dr. DeFrank's customers and is relevant under factor five, further supporting revocation of his DEA Certificate of Registration.

Blindly motivated by financial gain, Dr. DeFrank demonstrated a cavalier disregard for controlled substance laws and regulations and a disturbing indifference to the health and safety of individuals purchasing dangerous drugs through the Internet. Such lack of character and flaunting of the responsibilities inherent with a DEA registration show, in no uncertain terms,

that Dr. DeFrank's continued registration would be inconsistent with the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration DB8259346, issued to Salvatore DeFrank, D.P.M., 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 June 17, 2005.

Dated: May 9, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04-30]

Lance L. Gooberman, M.D.; Denial of Registration

On March 15, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Lance L. Gooberman, M.D. (Dr. Gooberman), notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AG9773703, as a practitioner, pursuant to 21 U.S.C. 824(a)(3) and (a)(4) and deny any pending applications for renewal or modification of that registration pursuant to 21 U.S.C. 823(f).

The Order to Show Cause alleged that Dr. Gooberman's license to practice medicine in New Jersey, where he was registered, had been suspended by the State of New Jersey, Board of Medical Examiners (New Jersey Board) and he was not authorized to handle controlled substances in that state.

On April 13, 2004, Dr. Gooberman, acting pro se, requested a hearing and on April 20, 2004, Administrative Law Judge Gail A. Randall (Judge Randall) issued an Order for Prehearing Statements. On July 7, 2004, in response to a Government motion for Consolidation, Judge Randall ordered Dr. Gooberman's case consolidated with the pending case of David W. Bradway, M.D. (Docket No. 04-27). Dr. Bradway had been in practice with Dr. Gooberman and they had been disciplined by the New Jersey Board in

a joint proceeding, for the same professional misconduct.

After authorized delays, on September 8, 2004, counsel for the Government filed a Motion for Summary Disposition. It alleged that on July 14, 2004, the Commonwealth of Pennsylvania, Department of State, State Board of Medicine (Pennsylvania Board) issued an Adjudication and Order suspending Dr. Gooberman's Pennsylvania medical license. That action was predicated on the New Jersey Board's Final Order of March 10, 2003, which suspended Dr. Gooberman's New Jersey medical license for a period of two years from the Order's effective date of June 19, 2003. The Government attached a copy of both the Pennsylvania and New Jersey Orders and argued that, since Dr. Gooberman's licenses to practice medicine in New Jersey and Pennsylvania were both suspended, he was not authorized to handle controlled substances in the jurisdiction of his registration and ineligible for a modification of location to Pennsylvania.

Judge Randall issued an order allow Dr. Gooberman to respond to the Government's motion. Having noticed that Dr. Gooberman's DEA Certificate of Registration had expired prior to initiation of the show cause proceedings, she also directed the Government to address the impact of its apparent expiration.

The Government replied that Dr. Gooberman submitted a renewal application one week before his registration's expiration. On the application, Dr. Gooberman noted he had left New Jersey and requested a change in registered location to an address in Pennsylvania. Judge Randall agreed with the Government that Dr. Gooberman's New Jersey registration was terminated by operation of law and that his request for an address modification must be treated as an application for registration in Pennsylvania. See 21 CFR 1301.51 and 1301.52.

The Government argued Dr. Gooberman's application was thus still pending before the administrative law judge and, based on lack of state authority to handle controlled substances in Pennsylvania, the Government moved for summary disposition. When Dr. Gooberman was given an opportunity to respond, he acknowledged his New Jersey and Pennsylvania licenses were suspended and that he did not "have a basis on which to hold a DEA Certificate of registration at this time." Thus, he did not oppose the Government's motion.

On October 14, 2004, Judge Randall issued her Order, Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Randall granted the Government's Motion for Summary Disposition, finding Dr. Gooberman's New Jersey DEA registration had terminated by operation of law and he lacked authorization to handle controlled substances in Pennsylvania, the jurisdiction where he was seeking registration.

In granting the Government's motion, Judge Randall recommended that Dr. Gooberman's application to renew and modify his registration be denied. No exceptions to the Opinion and Recommended Decision were filed and on November 23, 2004, Judge Randall forwarded her Opinion and Recommended Decision to the Deputy Administrator for final order pursuant to 21 CFR 1316.65(c).

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 Dr. Gooberman currently possesses DEA Certificate of Registration AG9773703, as a practitioner in schedules II through V, with a registered location in Merchantville, New Jersey. On September 30, 2003, that registration was due to expire. However, a week earlier, Dr. Gooberman submitted a renewal application, requesting a change to a Pennsylvania location. Because Dr. Gooberman had abandoned his New Jersey registered location, Certificate of Registration AG9773703 was terminated under 21 CFR 1301.52.

The Deputy Administrator finds Dr. Gooberman's license to practice medicine in New Jersey was suspended by the New Jersey Board's Final Order of March 10, 2003, and his Pennsylvania license was suspended by the Pennsylvania Board's Adjudication and Order of July 14, 2004. There is no evidence before the Deputy Administrator that either the New Jersey or Pennsylvania Orders have been lifted, stayed or modified. Therefore, the Deputy Administrator finds Dr. Gooberman is currently not licensed to practice medicine in either New Jersey or Pennsylvania. As a result, it is reasonable to infer he is also without authorization to handle controlled substances in either state.