Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Stephen K. Jones, M.D.; Denial of Registration

On November 10, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Stephen K. Jones, M.D. (Dr. Jones) who was notified of an opportunity to show cause as to why DEA should not deny his application for DEA Certificate Registration as a practitioner to handle controlled substances, pursuant to 21 U.S.C. 823 and 824.

The Order to Show Cause alleged in relevant part, that Dr. Jones was not licensed to practice medicine or handle controlled substances in Utah, the state in which he was applying for registration and intended to practice. Secondarily, the Order alleged Dr. Jones had previously been disciplined in Iowa, where he currently lives and practices, for personal drug abuse, signing a fraudulent prescription and diverting controlled substances. The Order to Show Cause also notified Dr. Jones that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Jones Residence at 3525 Mayfield Road, Iowa City, Iowa and to his proposed registered location in Salt Lake City, Utah. According to certified mail receipt records, the Order to Show Cause sent to his residence was received by Dr. Jones on December 10, 2004. DEA has not received a request for hearing or any other reply from Dr. Jones 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 to the applicant's home and address of record, and (2) no request for hearing having been received, concludes that Dr. Jones is deemed to have waived his wearing right. See David W. Linder, 67 FR 12,579 (2002). After considering material from the investigate 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 on July 2, 2004, Dr. Jones applied for DEA registration to handle Schedule II through IV controlled substances. His proposed registered address was at the LDS Hospital, 8th Avenue & C Street, Salt Lake City, Utah 84143. The application indicated Dr. Jones was previously disciplined by the Iowa Board of Medical Examiners which, in April 2004, had suspended his Iowa license to practice medicine for 30 days and placed it in a probationary status upon his completion of a two month residential treatment program for opioid dependency.

According to information in the investigative file, on July 27, 2004, a Diversion Investigator conducting an inquiry into Dr. Jones application was advised by the Utah Department of Commerce, Division of Occupational and Professional Licensing, that he did not hold a Utah Physician and Surgeon License or state Controlled Substance License. Further, there is no evidence before the Deputy Administrator showing that Dr. Jones has since been granted a license to practice medicine or handle controlled substance 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 Rory Patrick Doyle, M.D., 69 FR 11,655 (2004); Dominick A. Ricci, M.D., 58 FR 51,104 (1993); Bobby Watts, M.D., 53 FR 11,919 (1988).

Here, it is clear Dr. Jones is not licensed to practice medicine in Utah, his state of applied-for-registration and practice, and he is not authorized to handle controlled substances in that jurisdiction. Therefore, is not entitled to a DEA registration in that state. As a result of the finding that Dr. Jones lacks state authorization to handle controlled substances in his state of applied-for-registration, the Deputy Administrator concludes it is unnecessary to address further whether his application should be denied based upon the public interest grounds asserted in the Order to Show Cause. See Samuel Silas Jackson, D.D.S., 67 FR 67,145 (2002); Nathaniel-Aikens-Afful, M.D., 62 FR 16,871 (1997); Sam F. Moore, D.V.M., 58 FR 14,428 (1993).

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 DEA Certificate of Registration submitted by Stephen K. Jones, M.D., be, and it hereby is, denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–9246 Filed 5–9–05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 04–56]

Michael J. Millette, M.D.; Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Michael J. Millette, M.D. (Dr. Millette) of Crystal Lake, Illinois and Elizabethtown, Kentucky. Dr. Millette was notified of an opportunity to show cause as to why DEA should not revoke his DEA Certificates of Registration, BM2349012 and BM8086236, as a practitioner, and deny any pending applications for renewal or modification of such registrations 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. Millette was further notified that his DEA registrations were 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 alleged in sum, that Dr. Millette was engaged in illegally prescribing controlled substances as part of a scheme in which controlled substances were dispensed by pharmacies, based on Internet prescriptions issued by Dr. Millette and associated physicians, based solely on their review of Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued ''in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.

According to the investigative file, the Order to Show Cause and Immediate Suspension of Registration was personally served upon Dr. Millette by DEA Diversion Investigators on May 19, 2004. Through counsel, Dr. Millette filed a timely request for a hearing and the matter was docketed before Administrative Law Judge Mary Ellen Bittner. On June 22, 2004, Judge Bittner issued an Order for Prehearing Statements directing Dr. Millette to file a prehearing statement no later than August 4, 2004.

On August 18, 2004, as a result of Dr. Millette's failure to file a prehearing statement, Judge Bittner issued an Order Terminating Proceeding. In that Order, Judge Bittner concluded that by his inactivity, Dr. Millette had waived his right to a hearing and she ordered the proceeding terminated so it could be presented to the Deputy Administrator for issuance of a final order. On February 17, 2005, the investigative file was forwarded by the DEA Office of Chief Counsel to the Deputy Administrator for final agency action.

Accordingly, the Deputy Administrator finds that Dr. Millette is deemed to have waived his right to a hearing and after considering material from the investigative file in this matter, 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 filing 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 pharmacists 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 21,182–83.

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 prescription 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

FAQ's (*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/vipps/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 not 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 Dr. Millette is currently registered with DEA as a practitioner under DEA Registrations BM2349012 and BM8086236 for Schedule II through V Controlled Substances. Their respective registered addresses are in Crystal Lake, Illinois and Elizabethtown, Kentucky and they expire on January 31, 2005 and January 31, 2006.

While Dr. Millette had a medical office, his main occupation was issuing controlled substance prescriptions to patients (hereinafter ''customers'') through the Internet company E.V.A. Global, Inc., and others doing business under a number of names. Customers accessing Web sites owned by these companies would complete cursory questionnaires and indicate what drugs were wanted and a method of payment. The questionnaires would be electronically forwarded to Dr. Millette and, based solely on the answers, he would issue prescriptions for controlled substance. These prescriptions would then be dispensed by participating pharmacies and sent to customers by such means as FedEx and the U.S. Postal Service.

On six different occasions between March 2003 and April 2004, DEA investigators acting in an undercover capacity went online to order controlled substances from five Internet company Web sites: Clickhererx.com, Activeliferx.com, Dietdrugs.com, IntegraRX.com and RX-MAX.com In each instance, investigators filled out online questionnaires and ordered drugs such as Bontril and Phentermine which are, respectively, Schedule III and IV controlled substances. These controlled substances were then shipped to the addresses provided and were received by investigators. Each of the labels on the bottles identified Dr. Millette as the prescribing physician. Other than initially filling out e-mail questionnaires, the investigators had no communications with Dr. Millette or the pharmacies before the prescriptions were issued or dispensed.

On March 9, 2004 Dr. Millette was interviewed by DEA Diversion Investigators. He admitted prescribing controlled substances over the Internet for several companies since October or November 2002 and estimated that on an average day, he issued a ''couple hundred'' prescriptions without any personal contact with the customers. Dr. Millette admitted being compensated based on the number of questionnaires he reviewed and records seized from E.V.A. Global, Inc. covering an eight month period during 2004, indicated Dr. Millette was paid over $175,000.00 for assisting in this scheme.

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 16,422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to the determination of whether Dr. Millette's continued registration remains consistent with the public interest.

With regards 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. Millette has yet been the subject of a state disciplinary proceeding, nor is there evidence demonstrating that his state medical licenses or state controlled substance authorities 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.,* Mario Avello, M.D., 70 FR 11,695 (2005); Wesley G. Harline, M.D., 65 FR 5,665–01 (2000); James C. LaJevic, D.M.D., 64 FR 55,962 (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. Millette'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* Mario Avello, M.D., *supra,* 70 FR 11,695; Mark Wade, M.D., 69 FR 7,018 (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 37,581 (1990).

The Deputy Administrator concludes from a review of the record that Dr. Millette 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 Web sites 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. Millette. *See,* Mario Avello, M.D., *supra,* 70 FR 11,695; Marvin L. Gibbs, Jr., M.D., 69 FR 11,658 (2004); Mark Wade, M.D., *supra,* 69 FR 7,018; Ernesto A. Cantu, M.D., 69 FR 7,014–02 (2004); Rick Joe Nelson, M.D., 66 FR 30,752 (2001).

Similarly, DEA has issued orders to show cause 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. Millette. *See,* EZRX, L.L.C. (EZRX), 69 FR 63,178 (2004); Prescriptiononline.com, 69 FR 5,583 (2004).

In the instant case, Dr. Millette and other practitioners 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 a couple of rare direct e-mail contacts with customers, there is no information in the investigative file demonstrating that Dr. Millette and other issuing physicians even took time to corroborate responses to the questionnaires submitted by the customers. Here, it is clear the issuance of controlled substance prescriptions to persons whom Dr. Millette 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. Millette'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.

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,* Mario Avello, M.D., *supra,* 70 FR 11,695; EZRX, *supra,* 60 FR at 63,181; Mark Wade, M.D., *supra,* 69 FR 7,018.

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,* Mario Avello, M.D., *supra,* 70 FR 11,695; EZRX, *supra,* 69 FR at 63,181–82; Mark Wade, M.D., *supra,* 69 FR 7,018.

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. Millette'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. Millette's customers and is relevant under factor five, further supporting revocation of his DEA Certificates of Registration.

Dr. Millette also continued prescribing to Internet customers after issuance of policy statements designed to assist licensed practitioners and pharmacists in the proper prescribing and dispensing of dangerous controlled drugs. Apparently motivated purely by financial gain, Dr. Millette has 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. Millette'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 Certificates of Registration BM2349012 and BM8086236, issued to Michael J. Millette, M.D., be, and hereby are, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registrations be, and they hereby are, denied. This order is effective June 9, 2005.

Dated: May 2, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Thomas J. Mulhearn, III, M.D.; Revocation of Registration

On August 20, 2004, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Thomas J. Mulhearn, III, M.D. (Dr. Mulhearn) of Monroe,