

Dated: March 3, 2004.

William J. Walker,

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

[FR Doc. 04-5474 Filed 3-10-04; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Marvin L. Gibbs, Jr., M.D.; Revocation of Registration

On July 28, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Marvin L. Gibbs, Jr., M.D. (Dr. Gibbs) of Tempe, Arizona, notifying him of an opportunity to show cause as to why DEA should not revoke his Certificate of Registration No. AG7790644 under 21 U.S.C. 824(a)(4) and deny any pending applications for renewal or modification of his practitioner registration. As a basis for revocation, the Order to Show Cause alleged Dr. Gibbs' continued registration was inconsistent with the public interest. The Order alleged that from October 2000 through December 2001, Dr. Gibbs was affiliated with companies selling controlled substances and other drugs over the internet. During that period he issued thousands of controlled substance prescriptions, including refills, which were not issued in the normal course of professional practice, in violation of 21 CFR 1306.04 and 21 U.S.C. 841(a).

The Order alleged that without conducting physical examinations, Dr. Gibbs issued prescriptions to individuals requesting controlled substance prescriptions over internet web sites with which he had no prior doctor-patient relationship. Dr. Gibbs would review questionnaires completed on-line by the customer and then have a brief, pre-scheduled telephone conversation with the requestor. He did not consult with the customer's primary physician and failed to maintain any patient records of his own. The bulk of the controlled substance prescriptions issued by Dr. Gibbs in this manner were alleged to have been for hydrocodone 7.5 mg., a Schedule III controlled substance. It was further alleged Dr. Gibbs filed a prescription for Vicodin in the above manner which was requested by a DEA investigator using a fictitious name and medical complaint.

The order notified Dr. Gibbs that (1) he could file a written request for a hearing, (2) file a written waiver of

hearing, together with a statement regarding his position on the matters of fact and law involved, or (3) if he failed to file a request for a hearing within 30 days, that his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Gibbs' registered location at 2078 E. Southern Avenue, Suite D101, Tempe, Arizona 85282-7521. According to the return receipt, the Order to Show Cause was accepted on Dr. Gibbs' behalf on or around August 8, 2003. On September 4, 2003, Dr. Gibbs filed a response with Administrative Law Judge Gail A. Randall which was ambiguous as to which option he was electing. After Judge Randall afforded him an opportunity to file a clear election, by his letter dated October 9, 2003, Dr. Gibbs selected option two, waiving his right to a hearing and asking that his October 1, 2003, written submission be considered.

On October 30, 2003, consistent with that election, Judge Randall terminated the case and returned the file to the Government's counsel for further administrative processing. On November 26, 2003, the Chief Counsel forwarded the file to the Acting Deputy Administrator for final agency action in accordance with 21 CFR 1301.43(e) and 1301.46.

Other than as set forth above, DEA has not received a request for a hearing from Dr. Gibbs or anyone representing him in this matter. Therefore, the Acting Deputy Administrator, finding that Dr. Gibbs has waived his hearing right and requested that the agency make its decision based on the investigative file and his written submission, now enters her final order without a hearing pursuant to 21 CFR 1301.43(c) and (e) and 1301.46.

The Acting Deputy Administrator finds that Dr. Gibbs is registered with DEA as a practitioner under Certificate AG7790644 for Schedule II through V controlled substances, with a registered location of Alliance Healthcare Services, 2078 E. Southern Avenue, Tempe, Arizona. He was previously registered with DEA under Certificate BG729030, which was retired on September 30, 1991. He is currently licensed with the Arizona Medical Board of Medical Examiners (Board) under License Number 13736, which was issued on November 26, 1982, and expires on December 21, 2004. He is currently engaged in a solo medical practice and his only specialty is obstetrics and gynecology.

In February 2001, Dr. Gibbs was identified as an integral participant in Myprivatedoc, an Internet business

which had contracted with him to prescribe narcotics and other controlled substances to requesters after reviewing on-line questionnaires filled out by the customers and a brief telephone call. The prescriptions were then filled by Genrich Pharmacy of Phoenix, Arizona and sent to the customer's address by mail or delivery service.

A joint investigation conducted by DEA and the Board showed that in May or June 2000, Dr. Gibbs had been approached by two men about prescribing medicine over the Internet. They were owners of an auto parts business in Mesa, Arizona. At the time, Dr. Gibbs had recently lost his privileges at Mesa Lutheran Hospital, the facility where ninety percent of his patient volume was generated. Another physician, who recommended that Dr. Gibbs become involved in the Internet prescribing business, knew he needed help in generating income at the time.

Dr. Gibbs agreed to participate in Myprivatedoc's scheme and would be paid \$20 for each consultation. Visitors to the Web site would initially fill out a questionnaire regarding their medical history and complaint. Dr. Gibbs then reviewed the forms over the Internet and received a schedule of when customers would be calling him for a consultation. Initially he evaluated 10 to 15 individuals per day, spending approximately five to ten minutes with each customer. By December 2000, his consultations had increased to approximately 30 per day.

Dr. Gibbs made no effort to validate information provided to him via the Internet and while Myprivatedoc requested that customers verify their identities with picture identifications, Dr. Gibbs made no independent verification of the caller's identity. Dr. Gibbs, who had not taken any courses or continuing medical education in chronic pain management or identification of drug seeking behavior, did not perform physical examinations on customers, request or obtain medical records from their treating physicians or maintain any medical records on the individuals he prescribed to over the Internet. The majority of prescriptions prescribed were for thirty day supplies of controlled substance medications, with a maximum of two refills. Dr. Gibbs stated he did not believe he was establishing a doctor-patient relationship with the individuals requesting prescriptions.

Around February 2001, after receiving approximately \$52,000 in consultation fees, Dr. Gibbs terminated his relationship with Myprivatedoc. In April 2001, he associated with Medsworldwide, another internet

company located in Tampa, Florida. Using essentially the same evaluation process as with Myprivatedoc, Dr. Gibbs prescribed controlled substances to customers requesting them over Medsworldwide's web site. He was now paid \$70.00 per consult and received approximately \$36,000 before his relationship with that company was severed.

In August 2001, Dr. Gibbs started his own web site titled Expressmedcare.com. He associated with a Florida pharmacy which issued medications prescribed by Dr. Gibbs and began charging \$100.00 to \$125.00 per consult. Up until December 21, 2001, when DEA confiscated his computers and Dr. Gibbs stopped internet prescribing, he had consulted with approximately 900 customers through Expressmedcare's web site. As with Myprivatedoc and Medsworldwide, Dr. Gibbs prescribed controlled substances to Expressmedcare requestors after reviewing their questionnaires and a brief telephone conversation, but without physical examinations or entries in medical records.

Genrich Pharmacy records showed that from October 25, 2000, to August 28, 2001, Dr. Gibbs prescribed 8,040 controlled substance prescriptions, including refills, to approximately 2620 internet clients. This amounted to approximately 639,430 dosage units of controlled substances, including 560,650 dosage units of hydrocodone, 55,250 dosage units of benzodiazepines, 6,960 dosage units of controlled substances with the ingredient codeine and 16,570 dosage units of various other controlled substances. Additionally, Dr. Gibbs prescribed 56,460 dosage units of carisoprodol (Soma), which is not a controlled substance, but is frequently abused together with hydrocodone products.

In July 2001, a DEA investigator entered a fictitious name on the Medsworldwide web site seeking Vicodin ES, count 60, after purportedly suffering a back injury from an automobile accident. He was directed to phone Dr. Gibbs at a specific time on July 31, 2001. After minimal questioning as to when the accident occurred, if the caller was on any medications and what medication he wanted, Dr. Gibbs prescribed 60 Vicodin tablets with two refills. He did not question the agent about allergic reactions, his overall physical condition or any prior surgeries.

On September 15, 2001, at approximately 8 p.m., the 30 year-old son of the Aikin County, South Carolina, coroner was killed in a single car accident when he ran off the road

and suffered fatal head injuries. He had talked to his mother about an hour before the accident, when he told her he was on his way home. The coroner's preliminary investigation indicated the victim most likely fell asleep or became unconscious at the wheel after taking alprazolam (Xanax), which was obtained through an Internet pharmacy. A prescription bottle for Xanax, issued by Genrich Pharmacy in Phoenix, Arizona, was found in the victim's car and documents reflected he received the medication through a prescription authorized by Dr. Gibbs.

On October 2, 2001, the Aikin County Coroner's Office contacted Dr. Gibbs by phone in his Arizona office. He advised investigators that the victim was not a patient of his because he was an OB/GYN physician. DEA investigators reviewing Dr. Gibbs' Physician Profile from Genrich Pharmacy then found he had prescribed the victim 1 mg alprazolam (Xanax), 30 count, on March 3, 2001. Two 30 count refills were authorized by Dr. Gibbs and filled by Genrich Pharmacy on April 19, 2001 and June 5, 2001. Based on the circumstances of the accident and Dr. Gibbs having prescribing Xanax, the Coroner's Office believed it was very likely Dr. Gibbs contributed to the accident and the victim's subsequent death.

A review of seized computer files indicated that Dr. Gibbs also prescribed controlled substances to four health care professionals who were also obtaining controlled substances from other physicians associated with different internet websites.

Updated pharmacy records, including those obtained from United Prescription Services in Tampa, Florida, indicated that from October 2000 until December 2001, Dr. Gibbs was responsible for issuing a total estimated 14,500 controlled substance prescriptions and approximately 1200 carisoprodol prescriptions, including refills, over the internet. He prescribed in excess of 1,018,000 dosage units of controlled substances and 90,000 dosage units of carisoprodol during that period. It is estimated that over a fourteen month period Dr. Gibbs received in excess of \$180,000 for prescribing controlled substances through the Myprivatedoc, Medsworldwide and Expressmedcare websites.

Based on the DEA and Arizona Medical Board's investigation, the Board initiated case No. MD-01-0861 against Dr. Gibbs. On May 14, 2003, after a formal interview with Dr. Gibbs in which he was represented by counsel, the Board issued its Findings of Fact, Conclusions of Law and Order. The

Board found the standard of care for the management of prescribing medications requires there be a doctor-patient relationship, established on a face-to-face basis, before prescribing and that Dr. Gibbs' conduct was unreasonable, given that standard of care. The Board found Dr. Gibbs' conduct posed the potential harm of patients becoming addicted to the medications and harm to the community through the diversion of those medications.

The Board concluded Dr. Gibbs' actions constituted unprofessional conduct as defined in A.R.S. § 32-1401 by failing or refusing to maintain adequate records on a patient, engaging in conduct or practice that is or might be harmful or dangerous to the health of the patient or the public and by prescribing prescription medication without a physical examination to persons whom he did not have a previously established a doctor-patient relationship.

The Board issued Dr. Gibbs a Decree of Censure, ordered him to pay a civil penalty of \$10,000 within one year and placed him on ten years probation, which included the following provisions: He was to prescribe Schedule II and III controlled substances only for individuals who were established patients of his obstetrics and gynecology practice; attend CME classes; pay for costs associated with monitoring his probation; and submit quarterly declarations under penalty of perjury that he has complied with all conditions of probation.

In his written submission to the Order to Show Cause, Dr. Gibbs does not contest the allegations in the Order to Show Cause and concedes having prescribed controlled substances over the internet without taking patient's histories, conducting physical examinations or documenting information in medical records.

In defense, Dr. Gibbs notes he has been in practice for 23 years and never inappropriately prescribed controlled substances in his obstetrics and gynecology practice. He states he was unaware of any prohibitions against internet prescribing and became involved with "2 local businessmen" after they were referred to him by an anesthesiologist who Dr. Gibbs had known for 21 years. He states the "2 businessman [SIC] told me they had retained legal counsel, and not knowing there were statutes governing the practice of medicine I did not do my own inquiries." Based on reading a text titled "Practical Management of Pain," Dr. Gibbs states he took a "naive approach" to internet consulting and

did not consider the possibility of diversion or abuse in treating chronic pain patients. He states he believed people suffering chronic pain feared losing their jobs if they took time off from work to see physicians and that the internet process afforded them an opportunity to alleviate their pain and suffering.

Based on taking a medical ethics course ordered by the Board and a Physician Prescribing Course on his own volition, Dr. Gibbs states he now knows why it was wrong "to address these issues over the internet." He stresses the state board did not revoke his medical license after conducting a 2½ hour interview and having him undergo a comprehensive proficiency evaluation in obstetrics and gynecology, general medicine, clinical pharmacology and medical ethics.

After taking a medical ethics course ordered by the Board, Dr. Gibbs states he now knows why prescribing over the internet is the "wrong way to meet the needs of chronic pain sufferers" and that "Prior to taking the course, I was unaware of scams in which doctors in medical clinics and pharmacies (pharmacists) set up elaborate schemes to make large profits from selling and reselling the same prescription needs." Dr. Gibbs also states he did not consider the possibility that people would use the internet for the purpose of diversion and abuse of these medications and he "can assure DEA that I am acutely aware, and understand why laws exist governing the practice of medicine."

He also cites the assessment of Dr. Russell McIntyre, Th.D, director of a three day Professional Renewal Through Ethics course ordered by the Board, in which Dr. McIntyre concludes Dr. Gibbs now has unqualified capacity for "ethical thinking and insight" "should be thought of as remediated." Dr. Gibbs further notes his voluntary completion of a three day Physician Prescribing Course at the University of California, San Diego School of Medicine in October 2003.

He finally stresses the Arizona Medical Board's reputation and credibility for protecting the public and assessing the worthiness of physicians in maintaining their state medical licenses after professional misconduct and that he cannot prescribe Schedule II and II controlled substances outside his obstetrics and gynecology practice under the terms of his ten year probation. Dr. Gibbs states that in his speciality, were DEA to revoke his certificate, it would not be possible for him to care for either surgical or non-surgical patients and that if he were allowed to retain his certificate, he

would do nothing to jeopardize his medical license or warrant future revocation of his certificate.

The Acting Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications for such certificate if she determines the respondent's registration would be inconsistent with the public interest, as determined pursuant to 21 U.S.C. 823(a)(4) and 823(f). Section 823(f) requires consideration of the following factors:

(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.

As a threshold matter, it should be noted that the factors specified in section 823(f) are to be considered in the disjunctive: The Acting Deputy Administrator may properly rely on any one or a combination of the factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or denied. Henry J. Schwarz, Jr., M.D., 54 FR 16422 (1989)

With regard to the first public interest factor, the Arizona Medical Board has not made a specific recommendation regarding this action. It has allowed Dr. Gibbs to retain his medical license and prescribe Schedule II and III controlled substances to established patients in the regular course of his obstetrics and gynecology practice. However, the Board also concluded he engaged in unprofessional conduct, issued him a Decree of Censure, ordered him to pay a civil penalty of \$10,000 and placed him on ten years probation. Since state licensure is a necessary but insufficient condition for DEA registration, the Acting Deputy Administrator concludes that this factor is not determinative. See Barry H. Brooks, M.D., 66 FR 18305, 18308 (2001); Martha Hernandez, M.D., 62 FR 61145, 61147-48. Further, while it is relevant that the state currently allows Dr. Gibbs to prescribe Schedule II and III controlled substances to established patients, the Acting Deputy Administrator does not find that dispositive of whether his continued registration is in the public interest. See Roger Pharmacy, 61 FR 65079, 65080 (1996).

With regard to the second public interest factor, respondent's experience in dispensing controlled substances, the Acting Deputy Administrator finds Dr. Gibbs is an experienced obstetrician/gynecologist who has prescribed controlled substances for many years and there is no evidence that he violated state or federal regulations until October 2000. However, at that time, when financially pressed as a result of losing accreditation at the hospital where the bulk of his patient volume was being generated, he was quite willing to engage in internet prescribing with an organization run by two men who owned a local auto parts business. Dr. Gibbs, who had no experience or continuing medical education in chronic pain management or identification of drug seeking behavior, entered into this activity without even minimal research or inquiry into relevant professional standards, the state statutes governing unprofessional conduct, or any apparent thought to the threats of diversion and harm to individuals receiving controlled substance prescriptions under these circumstances.

Given the numerous red flags the business proposal should have generated and the Arizona statute (A.R.S. § 32-1401(26)(e)), which includes as "unprofessional conduct" the prescribing of medications without physical examination to an individual who does not have a previously established doctor-patient relationship, it is readily apparent that if Dr. Gibbs was, in fact, unaware of the constraints against this activity, it was because he simply turned a blind eye to the dangers and the standards of the normal course of professional practice. In that regard, his lengthy experience as a physician in prescribing controlled substances makes his voluntary participation in this scheme even more egregious.

In a little over a year, Dr. Gibbs prescribed over a million dosage units of controlled substance medications to thousands of internet requestors without a physical examination, adequate medical history, sufficient verification of identity or any documentation in patient medical records. Considering the foregoing, the Acting Deputy Administrator finds that factor two weighs against Dr. Gibbs' continued registration.

With regard to the third public interest factor, Dr. Gibbs has not been convicted of any Federal or State laws relating to the manufacture, distribution or dispensing of controlled substances, which weighs in favor of continued registration.

As to the fourth factor, compliance with State and Federal law and regulations, Dr. Gibbs violated Arizona law by (1) failing to conduct physical examinations before prescribing controlled substances, (2) failing to maintain adequate records on these patients and (3) engaging in conduct that is or might be harmful or dangerous to the health of the patient or the public. See A.R.S. § 32-1401(26)(e), (q) and (ss). Dr. Gibbs also violated Federal regulations by prescribing controlled substances outside the usual scope of his professional practice. See 21 CFR 1306.04(a). Accordingly, the Acting Deputy Administrator finds that factor four weighs against continued registration.

With regard to the fifth public interest factor, such other conduct which may threaten the public health and safety, the Acting Deputy Administrator finds the conduct of Dr. Gibbs discussed under factors two and four, is also applicable under factor five. The large amounts of controlled substance medications prescribed by Dr. Gibbs to individuals without physical examination or adequate consideration of the possibilities for diversion, abuse or adverse effects upon the recipients, all lead to the inevitable conclusion that his activities presented significant risk to public health and safety.

The Acting Deputy Administrator has considered the matters addressed in Dr. Gibbs' written submission but, in determining the weight to be attached to the matters of fact asserted therein, has done so in light of the absence of cross-examination. See 21 CFR 1301.43(d). While his efforts to educate himself regarding ethical and professional responsibilities and the dangers of internet prescribing are laudable, they are mitigated by the fact they were initiated only after Dr. Gibbs became aware of DEA and Board investigations into his conduct and taken in anticipation of or pursuant to state disciplinary proceedings.

The Acting Deputy Administrator is troubled by Dr. Gibbs' apparent continuing assertion that his underlying intent in engaging in internet prescribing was to care for patients who suffered from chronic pain and were unable financially to consult with a physician. This smacks of self-serving and rationalization. To the contrary, the record clearly infers that his prime motivation, from the beginning to the end, was financial gain. At a time when he had just lost accreditation at the hospital where ninety percent of his patient volume was being generated, he readily agreed to associate with two then-strangers who owned an auto parts

business. After that relationship terminated, Dr. Gibbs affiliated himself with a second Internet Web site company, which increased his consultation fee from the \$20 he had been receiving from Myprivatedoc, to \$70 per consult with Medsworldwide. Even this increase was not sufficient, as Dr. Gibbs then formed his own Web site where, until his computers were seized by DEA, he charged \$100 to \$125 per consult. In sum, given the investigative record, Dr. Gibbs' assertion that his underlying motivation was to serve the public good and relieve pain and suffering, rings hollow.

After considering the totality of the investigative record and Dr. Gibbs' written submission, the Acting Deputy Administrator concludes his continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4).

Accordingly, the Acting 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 AG7790644, issued to Marvin L. Gibbs, Jr., M.D., be, and it hereby is, revoked. The Acting Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effective April 12, 2004.

Dated: February 20, 2004.

Michele M. Leonhart,

Acting Deputy Administrator.

[FR Doc. 04-5484 Filed 3-10-04; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Stephen J. Graham, M.D. Revocation of Registration

On August 11, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Stephen J. Graham, M.D. (Dr. Graham) of Ketchum, Idaho, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration BG0868971 under 21 U.S.C. 824(a) and deny any pending application for renewal or modification of that registration. As a basis for revocation, the Order to show Cause alleged that Dr. Graham is not currently authorized to practice medicine or handle controlled substances in Idaho, his state of registration and practice.

The Order to Show Cause further alleged that Dr. Graham's continued registration was inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). This was based on Dr. Graham's employment by Prescibus, an internet company selling controlled substances and other drugs over the Internet. During the period Dr. Graham worked for Prescibus he issued at least four or five thousand prescriptions over the internet, the majority of which were for controlled substances and not issued in the usual course of professional medical practice. He was alleged to have issued controlled substance prescriptions to individuals with whom he did not have a prior doctor-patient relationship, failed to conduct physical examinations of those customers and did not create or maintain records on them. The only information usually reviewed prior to issuing prescriptions was a questionnaire completed by the customer. Dr. Graham would then have a brief telephone conversation with the customer and did not consult with the customer's primary care physician. Undercover investigators were alleged to have obtained controlled substances prescriptions from Dr. Graham under these circumstances on three occasions. The order notified Dr. Graham 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. Graham at his address of record at 180 First Street West, No. 21, Ketchum, Idaho 83340 and to P.O. Box 83340, Ketchum, Idaho 83340-5860. According to the return receipts, the order was accepted on Dr. Graham's behalf on or around August 21 and August 22, 2003. DEA has not received a request for hearing or any other reply from Dr. Graham or anyone purporting to represent him in this matter.

Therefore, the Acting Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Dr. Graham is deemed to have waived his hearing right. See Samuel S. Jackson, D.D.S., 67 FR 65145 (2002); David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file, the Acting Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Deputy Administrator finds that Dr. Graham possesses DEA Certificate of Registration BG0868971. The Acting Deputy Administrator further finds that on or about May 27, 2003, the Idaho Board of Medicine