

Addo-Yobo was convicted in the United States District Court for the Southern District of New York on one count of mail fraud in violation of 18 U.S.C. 1341 and one count of conspiracy to commit Medicaid and mail fraud in violation of 18 U.S.C. 371.

By letter dated June 27, 1994, the United States Department of Health and Human Services notified Dr. Addo-Yobo that he was being excluded, pursuant to 42 U.S.C. 1320a-7(a), from participation in Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs for a period of five years.

The Acting Deputy Administrator concludes that in light of the revocation of Dr. Addo-Yobo's state medical license, he is not currently authorized to handle controlled substances in the State of New York. The 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 his business, 21 U.S.C. 802(21), 823(f), and 824(a)(3). This prerequisite has been consistently upheld. See Dominick A. Ricci, M.D., 58 Fed. Reg. 51,104 (1993); James H. Nickens, M.D., 57 Fed. Reg. 59,847 (1992); Roy E. Hardman, M.D., 57 Fed. Reg. 49,195 (1992). Here, it is clear that Dr. Addo-Yobo is not currently authorized to handle controlled substances in the State of New York. Therefore, Dr. Addo-Yobo is not currently entitled to a DEA registration. Because Dr. Addo-Yobo is not entitled to a DEA registration due to his lack of state authorization to handle controlled substances, the Acting Deputy Administrator concludes that it is unnecessary to address whether Dr. Addo-Yobo's DEA registration should be revoked based upon his exclusion from participating in Medicare/Medicaid programs.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, AA2601981, previously issued to Charles Addo-Yobo, 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 March 10, 1997.

Dated: January 31, 1997.
James S. Milford,
Acting Deputy Administrator.
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[Docket No. 95-16]

Mark J. Berger, D.P.M.; Continuation of Registration With Restrictions

On December 23, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mark J. Berger, D.P.M. (Respondent) of Riverwoods, Illinois, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, BB2461604, and deny any pending applications for renewal of such registration as a practitioner under 21 U.S.C. 823(f), for reason that his continued registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4).

By letter dated January 17, 1995, the Respondent, acting *pro se*, filed a timely request for a hearing, and following prehearing procedures, a hearing was held in Chicago, Illinois on April 12, 1995, before Administrative Law Judge Mary Ellen Bittner. At the hearing, the Government called witnesses and introduced documentary evidence and Respondent testified in his own behalf. After the hearing, the Government submitted proposed findings of fact, conclusions of law and argument, and Respondent submitted a post hearing brief. On April 11, 1996, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's DEA registration not be revoked, but be restricted in that Respondent shall not prescribe, administer or otherwise dispense any controlled substances for any member of his family or himself, and shall handle controlled substances only in treating podiatric patients and not for any purpose outside the usual practice of podiatry. Neither party filed exceptions to Judge Bittner's Opinion and Recommended Ruling, and on May 14, 1996, the record of these proceedings was transmitted to the Deputy Administrator.

The Acting Deputy Administrator has considered the record in its entirety, and pursuant to 21 C.F.R. 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Acting Deputy Administrator adopts, in its entirety, the Opinion and

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Acting Deputy Administrator finds that Respondent is a podiatrist initially licensed to practice in the State of Illinois in the early 1980's. However, as of at least March 1984, Respondent had never been licensed to handle controlled substances in the State of Illinois.

In March 1984, the Illinois Department of Registration and Education (now known as the Department of Professional Regulation and hereinafter referred to as DPR) received information from DEA that Respondent had recently ordered 500 Quaalude tablets (the brand name for methaqualone) after methaqualone had been rescheduled in Illinois from Schedule II to Schedule I. As a result of this information, a DPR investigator and a local police officer went to Respondent's office on March 8, 1984, intending to conduct an administrative search and take possession of the Quaalude tablets. Respondent acknowledged ordering the Quaalude, but stated that he kept the tablets at his home due to recent break-ins or attempted break-ins. Respondent was told that his possession of Quaalude was illegal and he agreed to relinquish the drugs after seeing his last patient of the day. Subsequently, Respondent admitted that he had self-administered 1,000 to 1,500 Quaalude tablets over a period of approximately a year and a half to relieve pain caused by an injury.

Respondent then consented to a search of his office, which revealed an empty bottle labeled 100 Quaalude, an open bottle of Empirin with codeine (a Schedule III controlled substance) with 79 tablets missing, and an open bottle of diazepam (a Schedule IV controlled substance) with 22 tablets missing. Respondent advised the officers that he had no records for the dispensation of these controlled substance.

After being taken into investigative custody, Respondent consented to the search of his home. This search revealed two empty 100-tablet bottles and one empty 500-tablet bottle of Quaalude, two full 100-tablet bottles of Quaalude, seven Empirin with codeine tablets, plant material suspected to be cannabis, and drug paraphernalia.

A review of DEA order forms revealed that during the period November 11, 1982 through January 23, 1984, Respondent ordered the following controlled substances: 2,500 dosage

units of Quaalude, 100 dosage units of Empirin with codeine #3, 100 dosage units of Valium 5 mg., 100 dosage units of Valium 10 mg., 500 Dexedrine 5 mg., and 100 dosage units of Tenuate Dospan 75 mg. Respondent did not maintain any records regarding these drugs in violation of both state and Federal laws.

Respondent was subsequently charged in the Circuit Court of Cook County, Illinois with one count of possession of cannabis with intent to deliver, one count of possession of methaqualone with intent to deliver, and one count of unlawful dispensing of methaqualone. Following a bench trial, Respondent was convicted on June 18, 1984, of possession of a controlled substance and sentenced to three years' probation.

Respondent testified during the hearing before Judge Bittner that in 1981 he had ruptured and then re-ruptured his Achilles tendon, and that he took methaqualone to enable him to sleep. He further testified that he never sold methaqualone or prescribed, administered or dispensed it to anyone else and that he realizes in retrospect that he should not have taken it.

On March 23, 1984, DPR filed a complaint against Respondent alleging that Respondent obtained and self-administered controlled substances when not properly registered to handle controlled substances in the State of Illinois. On May 11, 1984, Respondent and DPR entered into a Stipulation and Recommendation for Settlement pursuant to which Respondent agreed that his license to practice podiatry would be indefinitely suspended; he would not petition for restoration of his license for at least nine months from the effective date of the Podiatry Examining Committee's (Committee) order approving the settlement; he would obtain counseling and rehabilitation; and he would not apply for an Illinois controlled substance license for at least two years after the effective date of the order. On June 20, 1984, the Committee approved the Stipulation and Recommendation for Settlement, and on July 11, 1984, the Director of DPR issued an order adopting the terms of the settlement. Subsequently, on September 19, 1984, Respondent surrendered his previous DEA Certificate of Registration.

Following the reinstatement of his state podiatry license and the issuance of his license to handle controlled substances in the State of Illinois, Respondent executed a new application dated February 27, 1990, for DEA registration as a practitioner in Schedules II through V. On that application, Respondent answered "yes" to the question which asked:

Have you ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a DEA registration revoked, suspended or denied, or ever had a State professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation?

Applicants who respond affirmatively to this question are required to explain their answers on the back of the application form. Respondent's explanation referred to his lack of a separate state license to handle controlled substance, and his arrest for ordering controlled substances without the proper licensure. Respondent claimed in his explanation that he "did not knowingly violate the state licensing requirement, since I did not know about it." Respondent's explanation however, did not mention his conviction for possession of methaqualone, the state's suspension of his license to practice podiatry, or the surrender of his previous DEA Certificate of Registration.

Following receipt of Respondent's application, the DEA Chicago office issued a Notice of Hearing advising Respondent that there would be an informal hearing regarding his application. This informal hearing resulted in a memorandum of understanding being executed on August 30, 1990, by Respondent and representatives of the United States Attorney's Office and DEA. The memorandum of understanding stated that the Notice of Hearing had alleged that (1) Respondent had been the defendant in an information charging him with three felony violations of the Illinois Controlled Substances Act: possession of more than 30 grams of methaqualone with intent to deliver, possession of cannabis with intent to deliver, and unlawful dispensing of methaqualone; and (2) Respondent had been found guilty of possession of a controlled substance and sentenced to three years' probation. The memorandum of understanding further stated that Respondent had been "fully advised of the prohibited acts which have occurred" and had agreed to comply with the provisions of the Controlled Substances Act (CSA) and its implementing regulations and, more specifically, that he agreed that (1) he would "prescribe and dispense controlled substances in strict accordance with the [CSA] and the regulations issued thereunder"; (2) "any prescriptions written for controlled substances by the Respondent will be for medical purposes and will be issued within the usual course of professional practice for which the Respondent is registered with the [DEA] and

professionally licensed by the State"; (3) "Respondent's handling of controlled substances * * * shall be limited to controlled drugs in Schedules III through V and that the Respondent not be allowed to handle any controlled substance found in Schedule II for a period of not less than one (1) year * * *"; and (4) when renewing his DEA registration Respondent would "answer fully and truthfully any question regarding if the Respondent has ever been convicted of a crime in connection with controlled substances under State or Federal law, or ever surrendered or had a DEA registration revoked, suspended or denied, or ever had a State professional license or controlled substance registration revoke[d], denied, restricted or placed on probation."

Other than the memorandum of understanding, there is no other evidence in the record as to what was discussed during the course of the informal hearing. Shortly after execution of the memorandum of understanding, Respondent was issued DEA Certificate of Registration BB2461604, however there is nothing in the record to indicate what schedules of controlled substances were listed on the Certificate of Registration.

On June 28, 1993, Respondent executed a renewal application for DEA registration BB2461604 in Schedules II through V. On this application, Respondent had answered "yes" to the same question that he had answered affirmatively on his 1990 application for registration. Respondent testified that he had photocopied his 1990 explanation and pasted it onto the back of the 1993 application, stating,

I was giving what I thought was more new information and I wasn't omitting anything purposely. I thought conviction, surrender of license, etc., was known to the DEA and there was no reason to give a long, detailed explanation of that. I believe this was common knowledge.

Certainly, I didn't falsify anything. I did omit things, but not in a purposeful way. I would've gladly listed the things that I thought the DEA would've wanted me [sic] on the application, had I known that this is what they wanted. I didn't know that.

Respondent also testified that "[t]he things that have happened, 11 years ago, I can't change that. And I'm not trying to exonerate my involvement in that." However, Respondent further testified that, "[f]or the past 11 years, I've been totally in accordance with the law. And for the past five years, since receiving my DEA license, I've been totally in accordance with the law."

During the course of his testimony, Respondent stated that he had never falsified any state application. On cross-

examination, Respondent conceded that he had been convicted of attempted petty theft, a misdemeanor, 1970, yet he answered "no" on a 1982 DPR application to the question, "Have you ever been convicted of a criminal offense in Illinois or in another state or in federal court, other than a minor traffic violation?" Respondent explained that he answered in the negative because he thought the question referred to felony convictions only. As to the conviction, Respondent testified that he was 18 years old, and that "I shouldn't have been [convicted], it wasn't even me," but upon his attorney's advice, he pled to a misdemeanor.

Respondent contends in his brief that he was prejudiced because the Government failed to provide him notice in advance of the hearing that the 1982 DPR application would be at issue in these proceedings. At the hearing, the Government offered into evidence the 1982 application and a police report of the incident that led to his 1970 conviction. Judge Bittner properly rejected the admission of these documents into evidence since they were not supplied to Respondent in advance of the hearing as required by the Administrative Law Judge's prehearing ruling on March 29, 1995, and therefore did not consider the application as affirmative evidence against Respondent. Judge Bittner did however, allow Respondent to be cross-examined about the contents of the documents. The Acting Deputy Administrator concurs with Judge Bittner's conclusion that, "a major issue in this proceeding was Respondent's alleged misstatements on his application for DEA registration, and in these circumstances * * * examination as to his truthfulness in other applications was a proper subject of cross-examination, and that the Government was entitled to use the prior application and police report for impeachment purposes."

The Government in its posthearing filing argues that Respondent materially falsified two applications for registration and that such falsification provides an independent statutory basis for revocation of Respondent's DEA Certificate of Registration pursuant to 21 U.S.C. 824(a)(1). However, the Government did not assert that 21 U.S.C. 824(a)(1) was a basis for the proposed revocation in either the Order to Show Cause or in any of its prehearing filings, and the issue in this proceeding, agreed upon by the parties, makes no reference to 824(a)(1) as a basis for revocation. Therefore, the Acting Deputy Administrator does not consider whether Respondent's

registration should be revoked pursuant to 21 U.S.C. 824(a)(1).

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending applications, if he determines that he continued registration would be inconsistent with the public interest. Section 823(f) requires that he following factors be considered:

(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 and safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See *Henry J. Schwartz, Jr., M.D.*, Docket No. 88-42, 54 FR 16,422 (1989).

Regarding factor one, it is undisputed that Respondent's license to practice podiatry was suspended in 1984. However, it is also undisputed that such license was restored sometime prior to his 1990 application for DEA registration and that he was issued a state controlled substance registration. From the evidence in the record, it appears that Respondent has practiced without incident since being issued his state licenses. Therefore, the Acting Deputy Administrator concurs with Judge Bittner's conclusion that this factor weighs in favor of Respondent's continued registration.

As to factor two, Respondent's experience in dispensing controlled substances, it is uncontested that sometime in 1982 until his arrest in March 1984, Respondent ordered and self-administered controlled substances while not properly registered to handle controlled substances in the State of Illinois. The Acting Deputy Administrator concludes that the fact that Respondent dispensed controlled substances without proper state licensure is properly considered under factor four regarding Respondent's compliance with applicable state law. The Acting Deputy Administrator concurs with Judge Bittner's conclusion

that under this factor, the question is whether Respondent's actions would have been medically appropriate had he been properly registered with the State.

Respondent claims that he had a legitimate medical reason for using the drugs he ordered. The Acting Deputy Administrator concludes that Respondent's use of methaqualone after January 1, 1984, when it was rescheduled into Schedule I in the State of Illinois, was clearly improper. However, the Acting Deputy Administrator agrees with Judge Bittner that the record is insufficient to warrant a finding that Respondent's self-administration of controlled substances prior to January 1, 1984 was for no legitimate medical purpose. There is nothing in the record concerning whether the substances are not appropriate to treat the conditions for which Respondent used them, whether Respondent's treatment of such conditions was outside the scope of his practice of podiatry, or whether the self-administration of controlled substances was impermissible in the State of Illinois.

Also relevant to this factor is the Respondent's uncontroverted testimony that he never prescribed, administered, or otherwise dispensed controlled substances to anyone else, and that he has properly handled controlled substances since his DEA registration was restored in 1990.

The Acting Deputy Administrator concurs with Judge Bittner's conclusion regarding factor three. While Respondent was charged with possession of controlled substances with intent to deliver and with unlawful distribution of a controlled substance, he was ultimately convicted of possession of methaqualone. Thus, Respondent has no conviction record relating to the manufacture, distribution or dispensing of controlled substances.

Regarding factor four, it is undisputed that during the events in question in the early 1980's, Respondent failed to maintain records regarding his handling of controlled substances in violation of both Federal and state law. See 21 U.S.C. §§ 827 and 842(a)(5) and I.R.S. Chap. 56½ § 1306. In addition, Respondent violated state law from 1982 to March 1984, by handling controlled substances when not properly registered by the State of Illinois and by possessing methaqualone after January 1, 1984, when it was placed into Schedule I in Illinois.

As to factor five, on his 1990 application for registration, Respondent did not give a complete explanation for his affirmative response to the questions about whether he had ever been

convicted of a controlled substance related crime, had ever surrendered a DEA registration or had one revoked, suspended, denied, or had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation. Thereafter, Respondent was issued a Notice of Hearing which alleged that Respondent had been charged with three felony violations of state law and that he had been found guilty of one count of possession of a controlled substance. As Judge Bittner correctly notes, "[a]s far as this record shows, the Notice of Hearing did not make any reference to Respondent's explanation on his application of his answer to the liability question."

Respondent then participated in an informal hearing with DEA personnel and a representative from the United States Attorney's Office. Again as Judge Bittner correctly notes, "there is no evidence about the discussion at that meeting and, more specifically, about whether any of the government personnel advised Respondent that his statements on his [1990] application for DEA registration were inadequate."

Respondent ultimately entered into a memorandum of understanding in August 1990 wherein he agreed to "answer fully and truthfully" the questions on renewal applications. However, there is nothing in the memorandum of understanding that documents that Respondent was told that his previous explanation on the 1990 application was inadequate, nor was there any testimony at the hearing as to whether the parties discussed the meaning of this provision of the memorandum of understanding.

Respondent was then issued a DEA registration. Given the lack of evidence in the record that Respondent was advised that his answer in 1990 was inadequate, it is reasonable to accept Respondent's explanation for giving the same answer on his 1993 renewal application. Respondent testified, "I figured if this was good enough the first time, it's good enough the second time." Therefore, the Acting Deputy Administrator concludes that while Respondent may have technically violated the memorandum of understanding by failing to provide full and truthful answers on future applications, such a violation is understandable given that he was apparently not told his earlier explanation was inadequate.

The Acting Deputy Administrator concurs with Judge Bittner's conclusion that the Government has not established by a preponderance of the credible evidence that Respondent's continued

registration would be inconsistent with the public interest. While Respondent handled controlled substances from 1982 to March 1984 without proper state authorization and failed to maintain the required records, these events occurred over 12 years ago, and there is no evidence in the record that Respondent has improperly handled controlled substances since being issued a DEA registration in 1990. In addition, there is no evidence in the record that Respondent was ever advised that the explanation on his 1990 application was not sufficient, and therefore his use of the same explanation on his 1993 application is understandable.

Judge Bittner recommended that Respondent's registration not be revoked, but that it be subject to the following restrictions:

(1) Respondent shall not prescribe, administer or otherwise dispense any controlled substances for any member of his family or himself.

(2) Respondent shall handle controlled substances only in treating podiatric patients, and not for any purpose outside the usual practice of podiatry.

Under the circumstances of this case, the Acting Deputy Administrator finds Judge Bittner's recommended restrictions to be reasonable. Therefore, the Acting Deputy Administrator concludes that Respondent's DEA registration should be continued in Schedules II through V subject to Judge Bittner's recommended restrictions. It should be noted that it is unclear from the record, which schedules Respondent is currently registered to handle. He applied for Schedule II through V in 1990, however, the memorandum of understanding executed in August 1990 states, "[t]hat Respondent's handling of controlled substances pursuant to his Federal controlled substances registration upon issuance of such registration by the DEA, shall be limited to controlled drugs in Schedules III through V and that Respondent not be allowed to handle any controlled substance found in Schedule II for a period of not less than one (1) year from the date of the execution of the agreement." His 1993 renewal application, which is the subject of this proceeding, indicates that Respondent wishes his registration to be renewed in Schedules II through V. Regardless of Respondent's current authorization, the Acting Deputy Administrator concludes that in light of all of the evidence, Respondent should be registered in Schedules II through V subject to the above-referenced restrictions.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement

Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BB2461604, issued to Mark J. Beger, D.P.M., be continued, and any pending applications be granted in Schedules II through V, subject to the above restrictions. This order is effective March 10, 1997.

Dated: January 30, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97-3082 Filed 2-6-97; 8:45 am]

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Manufacturer of Controlled Substances; Notice of Registration

By Notice dated July 25, 1996, and published in the Federal Register on July 31, 1996, (61 FR 39986), Guilford Pharmaceuticals, Inc., Attn: Ross S. Laderman, 6611 Tributary Street, Baltimore, Maryland 21224, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of cocaine (9041), a basic class of controlled substance listed in Schedule II.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. § 823(a) and determined that the registration of Guilford Pharmaceuticals, Inc. to manufacture cocaine is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. § 823 and 28 CFR §§ 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: January 9, 1997.

Gene R. Haislip,

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

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[Docket No. 95-20]

Joseph S. Hayes, M.D.; Grant of Restricted Registration

On January 25, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Joseph S. Hayes, M.D. (Respondent) of Bristol, Tennessee, notifying him of an opportunity to show