DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 99–11]

Robert M. Golden, M.D.; Grant of Restricted Registration

On January 22, 1999, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Robert M. Golden, M.D. (Respondent) of Alpharetta, GA, notifying him of an opportunity to show cause as to why DEA should not deny his application for registration as a practitioner under 21 U.S.C. 823(f), for reason that this registration would be inconsistent with the public interest.

By letter dated February 2, 1999, Respondent requested a hearing, and following prehearing procedures, a hearing was held in Atlanta, GA on June 9, 1999, before Administrative Law Judge Mary Ellen Bittner. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted proposed finding of fact, conclusions of law and argument. On November 23, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings, of Fact, Conclusions of Law and Decision (Opinion), recommending that Respondent's application for a DEA Certificate of Registration be granted in Schedules IV and V subject to several conditions. Neither party filed exceptions to Judge Bittner's Opinion and on December 23, 1999, she transmitted the record of these proceedings to the Office of the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon finding of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, with slight modifications to the recommended decision as noted below. 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 Deputy Administrator finds that Respondent previously possessed DEA Certificate of Registration AG6243125. On May 25, 1994, an Order to Show Cause was issued proposing to revoke that Certificate of Registration and alleging that Respondent's continued registration would be inconsistent with the public interest. Following a hearing before Administrative Law Judge Paul A. Tenney, the then-Deputy Administrator revoked Respondent's DEA registration effective June 17, 1996. See Robert M. Golden, M.D., 61 FR 24808 (May 16, 1996).

In that prior proceeding, the then-Deputy Administrator found that in April 1987, Respondent entered into a Consent Order with the Georgia State Board of Medical Examiners (Board) based upon allegations of recordkeeping violations, the prescribing or dispensing of controlled substances while not acting in the usual course of professional practice, and the prescribing or ordering of controlled substances for an illegitimate medical purpose, Respondent's medical license was placed on probation for four years, and he was prohibited from prescribing, administering or dispensing Schedule II and III controlled substances, except in an institutional setting; required, for at least one year, to personally maintain a log of all Schedule IV controlled substances that he prescribed, administered or dispensed in his office; and required to attend at least 100 hours of continuing medical education focusing on drug abuse and/or pharmacology. The Consent Order specified that it was ''not an admission of wrongdoing for any purpose other than resolving the matters pending before the Board.''

In addition in the prior proceeding, the then-Deputy Administrator found that in 1992 a confidential informant received prescriptions for Xanax, a Schedule IV controlled substance, from Respondent who issued the prescriptions using names other than that of the informant. Also, on two occasions in 1992, Respondent issued prescriptions for Xanax to an undercover police officer for no legitimate medical purpose. Further, Respondent increased the dosage strength of the controlled substances prescribed based upon the patient's demands rather than on his own medical judgment.

In his final order revoking Respondent's previous DEA Certificate of Registration, the then-Deputy Administrator found that Respondent's conduct ''demonstrate[s] a cavalier behavior regarding controlled substances''; and that ''Respondent did not acknowledge any possibility of questionable conduct in his prescribing practices.'' The then-Deputy Administrator found that he ''was provided no basis to conclude that Respondent would lawfully handle controlled substances in the future.''

On April 4, 1996, Respondent entered into another Consent Order with the Board wherein the Board contended that following the termination of Respondent's earlier probation in 1991, he ''prescribed and otherwise distributed controlled and/or dangerous substances without adequate medical justification.'' Respondent's license was placed on probation for a least four years and he was required to relinquish his right to prescribe, administer, dispense, order or possess Schedule I, II, IIN, III and IIIN controlled substances, as well as specifically named drugs to include the Schedule IV controlled substances Xanax and Stadol, and their generic equivalents. In addition pursuant to this Consent Order, Respondent is required to utilize triplicate prescriptions for all controlled substances prescribed by him; to maintain a contemporaneous log of his handling of controlled substances; and to successfully complete a specific continuing medical education course regarding the appropriate prescribing of controlled substances, as well as other continuing medical education.

On June 15, 1997, Respondent submitted an application for a new DEA Certificate of Registration. On January 9, 1998, DEA issued an Order to Show Cause proposing to deny this application and alleging that Respondent's registration would be inconsistent with the public interest. Respondent did not reply to the Order to Show Cause, and consequently the then-Acting Deputy Administrator deemed that Respondent had waived his right to a hearing. On July 10, 1998, the then-Acting Deputy Administrator issued a final order denying Respondent's application for registration effective August 17, 1998. See 63 FR 38669 (July 17, 1998).

In his final order denying Respondent's application, the then-Acting Deputy Administrator found that the circumstances had not changed sufficiently from the revocation of Respondent's previous DEA registration to warrant granting Respondent's application.

On October 12, 1998, Respondent submitted an application for a new DEA registration in Schedules II through V. Subsequently, Respondent's application was amended to seek registration in Schedules IV and V only. That application is the subject of these proceedings.

The Deputy Administrator concludes that the then-Deputy Administrator's findings in the 1996 final order revoking Respondent's previous DEA Certificate of Registration are res judicata since they were made following an evidentiary hearing. See Stanley Alan Azen, M.D., 61 FR 57893 (1996).

However, since the then-Acting Deputy Administrator's findings in the 1998 final order denying Respondent's previous application for registration were based on the investigative file and following an evidentiary hearing, res judicata does not apply and therefore, Respondent is not precluded from litigating the matters at issue in the 1998 proceeding.

Accordingly, the Deputy Administrator concludes that the critical consideration in this proceeding is whether the circumstances, which existed at the time of the 1996 revocation of Respondent's previous DEA Certificate of Registration, have changed sufficiently to support a conclusion that Respondent's registration with DEA would be in the public interest.

As discussed previously, Respondent is subject to a Consent Order with the Board until at least April 4, 2000. A DEA investigator testified at the hearing in this matter that Respondent has been in compliance with the terms of this Consent Order.

Respondent testified that he has been practicing medicine for approximately 20 years, and for most of that time he practiced general or family medicine. In or about 1995, he realized that he was not suited for that type of medical practice and changed his specialization to cosmetic surgery. Specifically, Respondent specializes in tumescent liposuction where the cosmetic surgeon uses local rather than general anesthesia during the procedure.

Respondent testified that in his current practice he needs to use Schedule IV and V controlled substances to effectively treat his patients. According to Respondent and his medical assistant, some patients have a heightened sense of anxiety that is not relieved by non-controlled sedatives. Respondent testified that if needed, he prefers to use Valium to help patients with anxiety pre-operatively, intra-operatively, and post-operatively. According to Respondent and literature in evidence, patients who undergo tumescent liposuction surgery experience minimal post-operative pain, and therefore do not need narcotic pain relievers. In those situations where a patient has needed some type of pain relief, Respondent has prescribed a non-controlled, non-sterodial, anti-inflammatory analgesic.

Respondent introduced evidence of his completion of a course in the proper handling of controlled substances. He testified that in the future, he is ''going to practice very defensive medicine.'' According to Respondent, ''[t]the old Dr. Robert Golden is dead and buried as far as I'm concerned.''

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration, if he determines that the 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 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 denied. See Henry J. Schwarz, Jr., M.D., 54 FR 16422 (1989).

Regarding factor one, it is undisputed that until at least April 4, 2000, Respondent is subject to the terms of a Consent Order entered into with the Board. Pursuant to this Consent Order, Respondent is limited to handling Schedule IV and V controlled substances only and is further precluded from handling the Schedule IV controlled substances Xanax and Stadol, and their generic equivalents.

As to factors two and four, the then-Deputy Administrator found in the 1996 final order revoking Respondent's previous DEA Certificate of Registration that prior to 1993 Respondent prescribed controlled substances knowing that a person other than the one named on the prescription was the intended recipient of the controlled substances in violation of 21 CFR 1306.05, and that Respondent increased the strength of the medication prescribed based on the patient's request rather than using his professional medical judgment. The then-Deputy Administrator concluded that these prescriptions were not issued for a legitimate medical purpose in violation of 21 CFR 1306.04.

The Deputy Administrator finds that there was no evidence presented in this proceeding to warrant a finding that Respondent has improperly handled controlled substances since 1993. The Consent Order with the Board dated April 4, 1996, alleges that Respondent prescribed and otherwise distributed controlled and/or dangerous substances without adequate medical justification. However, the Consent Order also indicates that Respondent denies these allegations and no evidence of the underlying facts of these allegations was introduced by the Government at this hearing.

As to factor three, there is no evidence that Respondent has ever been convicted under State or Federal laws relating to controlled substances. Further, the record contains no evidence of other conduct that may threaten the public health and safety that would be considered under factor five.

Judge Bittner noted that Respondent's last application for registration was denied because he had not presented sufficient evidence to indicate that his registration with DEA would be in the public interest. However, she concluded that Respondent has now presented such evidence. Judge Bittner noted that ''Respondent has completed a six day seminar in the appropriate prescribing of controlled substances, he is in compliance with the Board's 1996 Consent Order, and he has changed his practice to a specialty in which the use of controlled substances is limited to very specific purposes and for specific periods of time.''

Judge Bittner found Respondent's testimony to be credible and concluded that Respondent ''now understands and accepts the responsibility inherent in a DEA registration.'' Therefore, she recommended that Respondent be issued a DEA registration limited to Schedule IV and V, with the exception of Xanax and Stadol, subject to the following conditions:

1. Respondent shall maintain accurate records showing all purchases, administering, and dispensing (including prescribing) of all controlled substances; and

2. Respondent shall submit copies of all such records to the Special Agent in Charge of the DEA's Atlanta office, or his designee, quarterly, for two years from the effective date of his registration.

The Deputy Administrator finds that the Government has established a prima facie case for denial of Respondent's application for registration. However, like Judge Bittner, the Deputy Administrator concludes that it would not be in public interest to deny Respondent's application, but rather to register him on a very limited a basis to give him the opportunity to demonstrate

that he can responsibly handle controlled substances.

Therefore, the Deputy Administrator concludes that Respondent should be issued a DEA Certificate of Registration in Schedules IV and V subject to the following restrictions for three years from the date of issuance of the DEA Certificate of Registration:

(1) While Respondent will be registered in Schedule IV, he shall not prescribe, dispense, administer, order or otherwise handle Xanax, Stadol, or their generic equivalents.

(2) Respondent shall send copies of records documenting all of his purchases of controlled substances to the Special Agent in Charge of the DEA Atlanta office, or his designee, on a quarterly basis.

(3) Respondent shall submit, on a quarterly basis, a log of all of the controlled substances he has prescribed, administered, or dispensed during the previous quarter, to the Special Agent in charge of the DEA Atlanta office, or his designee. The log shall include: the patient's name; the date that the controlled substance was prescribed, administered or dispensed; and the name, dosage and quantity of the controlled substance prescribed, administered or dispensed. If no controlled substances are prescribed, administered or dispensed during a given quarter, Respondent shall indicate that fact in writing in lieu of submission of the log.

(4) Respondent shall consent to random, unannounced inspections by DEA without requiring an Administrative Inspection Warrant.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for registration submitted Robert M. Golden, M.D., be, and it hereby is, granted in Schedules IV and V, subject to the above described restrictions. This order is effective upon the issuance of the DEA Certificate of Registration, but no later than March 6, 2000.

Dated: January 18, 2000.

Donnie R. Marshall,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96–10]

Wesley G. Harline, M.D.; Continuation of Registration With Restrictions

On October 27, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Wesley Harline, M.D. (Respondent) of Ogden, Utah, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AH1650248 and deny any pending applications for renewal of such registration as a practitioner 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.

By letter dated December 14, 1995, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Salt Lake City, Utah on April 1 through 3 and May 6 through 8, 1997, and by telephone in Salt Lake City and Arlington, Virginia, on August 18 through 21, 1997, before Administrative Law Judge Mary Ellen Bittner. At the hearing both parties called witnesses to testify and introduced documentary evidence. After the hearing both parties submitted proposed findings of fact, conclusions of law and argument.

In his brief, Respondent's counsel included findings based upon evidence that was not introduced at the hearing. On January 5, 1998, the Government filed a Motion to Strike Post Record Evidence from Respondent's Proposed Findings of Fact, Conclusions of Law and Argument. On January 21, 1998, Respondent filed his Opposition to Government's Motion to Strike Post Record Evidence, and in the alternative, Motion to Reopen the Record.

On April 2, 1999, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (Opinion), granting the Government's motion to strike the additional evidence, denying Respondent's motion to reopen the record, and recommending that Respondent's DEA Certificate of Registration be revoked and any pending applications be denied. On June 14, 1999, Respondent filed exceptions to Judge Bittner's Opinion and on August 2, 1999, the Government filed its response to Respondent's exceptions. Thereafter, on August 10, 1999, Judge Bittner transmitted the record of these proceedings to the Deputy Administrator.

While this matter was pending with the Deputy Administrator, Respondent submitted a letter dated November 4, 1999, responding to the Government's response to his exceptions and formally moving that the record be reopened to allow additional evidence to be considered. As will be discussed more fully below, the Deputy Administrator denies Respondent's motion to reopen the record and has not considered Respondent's letter dated November 4, 1999, in rendering his decision in this matter.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. This final order replaces and supersedes the final order issued on December 9, 1999, and published at 64 FR 72678 (December 28, 1999). The Deputy Administrator adopts, except as specifically noted below, the findings of fact set forth in Judge Bittner's Opinion, but does not adopt Judge Bittner's recommended conclusions of law and decision.

The Deputy Administrator finds that Respondent graduated from medical school in 1945. In or about 1953, Respondent joined a general surgery practice in Ogden, Utah. He has been a licensed physician in Utah since 1953 and has held state and Federal authorizations to handle controlled substances since approximately the time he obtained his medical license. According to Respondent, sometime in the 1980s, he virtually terminated his general surgery practice to concentrate on cosmetic surgery. Respondent testified that he considered weight control to be a part of cosmetic surgery, and as of 1997, he saw 15 to 20 weight control patients every weekday and a few weight control patients on Saturdays.

Primarily at issue in this proceeding is whether Respondent properly prescribed controlled substances to his weight control patients. Therefore, provisions of Utah law relating to this issue were placed into evidence. As of 1987 [1], the Utah Administrative Code (Administrative Code) authorized the Utah Division of Occupational and Professional Licensing (DOPL) to revoke a State license to handle controlled substances if the holder ''[p]rescribes or administers any controlled substance for weight control for more than 30 days in any 12 twelve-month period.'' Utah Admin. Code R153–38–8 (1987–1988).

[1] The Government did not provide any evidence of the statutory provisions relating to weight control in existence prior to 1987.