

interest. As noted by my predecessors, from 1990 to 1992, City Drug could not account for over 80,000 dosage units of controlled substances and dispensed more than 25,000 dosage units of controlled substances without a physician's authorization. The Acting Deputy Administrator remains concerned that City Drug has yet to present any persuasive evidence of meaningful procedural changes since 1992 that would ensure that it will not again fail to account for controlled substances or dispense controlled substances without authorization.

The Acting Deputy Administrator however notes that Joseph Grimes has apparently directed his efforts toward educating himself on the proper handling of controlled substances, as evidenced by the information provided with his most recent DEA registration application. Such evidence may be given favorable consideration in conjunction with a future application for registration. However, without credible evidence of any procedural changes having taken place at City Drug, and the lack of acknowledgement or explanation for previous shortages of large quantities of controlled substances, the Acting Deputy Administrator remains unconvinced that the granting of the pending application of City Drug is consistent with the public interest.

The Acting Deputy Administrator acknowledges that many of the violations recited above took place more than 10 years ago. However, in light of City Drug's failure to request a hearing in this matter, and the absence of evidence to rebut the above allegations, the Acting Deputy Administrator is left with the conclusion that the applicant has not corrected the deficiencies which led to the revocation of its previous Certificate of Registration and the denial of a previous application for registration. City Drug, although given the opportunity to request a hearing or to submit a written statement, has failed to do either. Thus, the facts recited above stand uncontroverted. *See, Ruggero Angiolicchio, M.D.*, 58 FR 14426 (March 17, 1993). In view of the foregoing, the Acting Deputy Administrator reiterates that City Drug cannot be entrusted to handle controlled substances, and the granting of its application would not be in the public interest.

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 the application for DEA Certificate of Registration executed

by City Drug Company be, and it hereby is, denied. This order is effective February 9, 2004.

Dated: December 18, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 02-11]

Marlou D. Davis, M.D.; Revocation of Registration

On October 12, 2001, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Marlou D. Davis, M.D. (Respondent). The show cause order proposed the revocation of DEA Certificate of Registration AD7084217 pursuant to 21 U.S.C. 824(a), and denial of any pending applications for renewal or modification of such registration for reason that such registration was deemed inconsistent with the public interest pursuant to 21 U.S.C. 823(f). The Order to Show Cause alleged in substantive part, the following:

1. On November 25, 2000, the Respondent notified the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") that he was moving his office/practice from his registered location in Bridgeton, Missouri to a new location in St. John, Missouri.

2. On December 7, 2000, BNDD notified the Respondent by certified mail that his Missouri controlled substance registration was valid only for his registered location in Bridgeton, Missouri. The letter referenced 19 CSR 30-1.030(1)(J), which states, in part, that "the registration of any person shall terminate if and when that person changes his/her address as shown on the certificate of registration." The Respondent was also notified in the letter that he did not currently have a registration and therefore did not have authority to order, stock, dispense, prescribe or administer controlled substances in the State of Missouri. Ref. 19 CSR 30-1.030(1)(E) 1 ("Any person who is required to be registered and who is not so registered shall not engage in any activity for which registration is required, until the application is granted and a certificate of registration is issued by the Board of Health").

3. Effective December 20, 2000, the Respondent's Missouri State Controlled Substances Registration was terminated. Therefore, the Respondent lacked

authority under Missouri state law to prescribe, dispense and/or administer controlled substances. Consequently, the Respondent was not authorized to possess a Federal controlled substances registration.

4. In addition, on October 18, 2000, the Respondent was arrested by the St. Louis Division Tactical Diversion Squad and charged at the state felony level with 14 counts of attempt to deliver a controlled substance and three (3) counts of delivery of a controlled substance. One of the conditions of the Respondent's release on bond by a St. Louis County Circuit Judge was that the Respondent would be prohibited from writing controlled substance prescriptions until his criminal case was concluded.

5. On April 27, 2001, DEA became aware that the Respondent wrote two (2) prescriptions for controlled substances for patient B.F. The first prescription, dated April 23, 2001, was for Triazolam, .25 mg #30, a Schedule IV controlled substance, and Fioricet, #100, a non-controlled substance. The second prescription, dated May 29, 2001, was for Triazolam, .25 mg, #30.

By letter dated November 12, 2002, the Respondent, acting *pro se*, timely requested a hearing. The matter was subsequently assigned to Administrative Law Judge Gail A. Randall (Judge Randall) and on January 11, 2002, Judge Randall issued to the Government and the Respondent an Order for Prehearing Statements.

In lieu of filing a prehearing statement, the Government filed Government's Request for Stay of Proceedings and Motion for Summary Judgment. The Government argued that the Respondent was without authorization to handle controlled substances in Missouri, and as a result, further proceedings in the matter were not required. Attached to the Government's motion was a copy of a letter dated December 7, 2000, from the Administrator of the Missouri Department of Narcotics and Dangerous Drugs ("BNDD") to the Respondent. The letter notified the Respondent that as a result of his changing the location of his medical practice, and because his controlled substance registration was valid only for his registered practice location, the Respondent's Missouri controlled substance registration was terminated. While the BNDD letter informed the Respondent that he lacked state authority to handle controlled substances in Missouri, the Respondent was nevertheless provided an opportunity to apply for a new Missouri state certificate of registration at his new business address.

The Government also attached to its motion a declaration dated January 25, 2002, from the Assistant Bureau Chief of the Missouri Department of Health and Senior Services' Bureau of Narcotics and Dangerous Drugs. The declaration corroborated information regarding the termination of the Respondent's state controlled substance authority, and further asserted that he had not submitted an application for a new state controlled substance registration.

In his reply to the Government's motion, the Respondent acknowledged that he had closed his Bridgeton office on December 1, 2000, and was informed by a BNDD representative that his state controlled substance license terminated upon closure of that office. The Respondent further acknowledged that as of July 1, 2001, his DEA and BNDD licenses ceased to exist, and that a hearing was not necessary in this matter. The Respondent subsequently argued that his DEA registration remained valid pending a resolution of these proceedings.

On March 13, 2002, Judge Randall issued an "Order of Clarification" requesting that the parties explain: (1) The status of the Respondent's current medical practice, (2) his authorization to handle controlled substances at this St. John, Missouri address, and (3) whether or not the Respondent had a viable DEA Certificate of Registration to revoke. In its March 19, 2002 response, the Government proffered that DEA had not modified the Respondent's place of business; the Respondent had abandoned his DEA registered location and established a new practice in St. John, Missouri; was without state authority to handle controlled substances in the state; and that the Respondent had a viable DEA registration to revoke. The Government again requested that its Motion for Summary Disposition be granted.

In his April 11, 2002, response to the Order for Clarification, the Respondent argued that following his review of federal statutes, he discovered that the grounds for revocation provided for under 21 U.S.C. 824(a) were not applicable in this matter. Specifically, the Respondent argued that his state license had never been suspended or revoked by competent state authority, but rather, had been "administratively dissolved" as a result of relocating his medical practice.

By Memorandum of Order dated April 22, 2002, Judge Randall denied the Government's Motion for Summary Disposition. In denying the Government's motion, Judge Randall found that pursuant to the plain language of 21 U.S.C. 824(a)(3),

revocation of the Respondent's Certificate of Registration was not authorized. In addition, Judge Randall found that in this case, DEA had an avenue for terminating, as opposed to revoking, the Respondent's DEA registration. She further outlined the distinction between the termination and revocation of a DEA registration, and found that a revocation results in a "stigma" with more significant consequence upon the Respondent than a mere termination. Judge Randall concluded that since the State of Missouri had not taken or attempted to take any adverse action against the Respondent's state registration, the statutory provisions authorizing revocation of a DEA registration had not been met.

On May 6, 2002, the Government filed a Motion for Reconsideration, Or in the Alternative, Request for Authorization to File Interlocutory Appeal, and Motion for Stay of Proceedings. In its motion, the Government renewed its Motion for Summary Disposition. On July 3, 2002, the Administrative Law Judge issued a Memorandum and Order, again denying the Government's Motion for Summary Disposition and Granting the Government's Motion for Authorization to File Interlocutory Appeal. Accordingly, on July 24, 2002, the Government filed an interlocutory appeal with the then-Deputy Administrator of the Drug Enforcement Administration.

By Order dated November 14, 2002, the then-Deputy Administrator found that pursuant to 21 U.S.C. 823(a)(3), and where as in the instant matter a practitioner's state controlled substance authority has terminated by operation of law and not adverse state action, revocation of a DEA registration is warranted. The Order further remanded the matter to the Administrative Law Judge for disposition consistent with the then-Deputy Administrator's ruling.

On November 21, 2002, Judge Randall issued Opinion, Order and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision) in which she granted the Government's motion for summary disposition and found that the Respondent lacked authorization to handle controlled substances in the State of Missouri. In granting the Government's motion, Judge Randall also recommended that the Respondent's DEA registration be revoked and any pending applications for renewal be denied. Neither party filed exceptions to her Opinion and Recommended Decision, and on January 21, 2003, Judge Randall transmitted the

record of these proceedings to the Office of the Deputy Administrator.

The Acting Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. The Acting Deputy Administrator adopts, in full, both the November 14, 2002 Order of the then-Deputy Administrator with respect to the Government's interlocutory appeal, as well as the Opinion and Recommended Decision of the Administrative Law Judge.

As noted above, in her March 13, 2002, "Order for Clarification" Judge Randall requested the parties to apprise of whether or not the Respondent had a viable DEA Certificate of Registration to revoke. The Acting Deputy Administrator's review of the record reveals that the Respondent's DEA Certificate of Registration was due to expire on June 30, 2003. There is no evidence in the record that a renewal application has been submitted on behalf of the Respondent. DEA has previously held that "[i]f a registrant has not submitted a timely renewal application prior to the expiration date, then the registration number expires and there is nothing to revoke." *Ronald J. Riegel, D.V.M.*, 63 FR 67132 (1998). However, because the record in these proceedings was transmitted to the Office of Deputy Administrator prior to the expiration date of the Respondent's DEA Certificate of Registration, the Acting Deputy Administrator will address this matter on its merits, specifically, the status of the Respondent's DEA Certificate of Registration.

In his Order of November 14, 2002 (Interlocutory Order), the then-Deputy Administrator found that the following matters were not in dispute: (1) The Respondent held DEA Certificate of Registration AD7084217, as a practitioner; (2) he relocated his medical practice from his registered location in Bridgeton, Missouri to an office location in St. John, Missouri; (3) pursuant to Missouri law (19 CSR 30-1.030(1)(j)) the controlled substance registration of any person terminates if and when that person changes his/her address as shown on the certificate of registration; (4) the Respondent had not obtained state authorization to handle controlled substances at his St. John location; (5) the Respondent's Missouri controlled substance registration had not been suspended or revoked by any authority in that state nor has such action been recommended; (6) according to the Missouri Department of Health, the Respondent was without authorization

to handle controlled substances in Missouri, the state in which he held a DEA registration.

While there was no dispute that the Respondent lacked state authorization to handle controlled substances, the then-Deputy Administrator found that the primary issues for resolution of the interlocutory appeal were (1) whether DEA has statutory authority under the Controlled Substances Act to revoke a Certificate of Registration when the lack of state authority arose by operation of law and not adverse action; (2) whether 21 U.S.C. 824(a)(3) authorizes revocation of a registration regardless of the manner in which the practitioner's state authority was terminated; and (3) whether DEA should avail itself the avenue of terminating as opposed to revoking the Respondent's Certificate of Registration.

21 U.S.C. 824(a), provides in pertinent that:

(a) A registration pursuant to section 823(f) of this title to manufacture, distribute, or dispense controlled substances or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority.

21 CFR 1301.52(a) provides in pertinent part:

“* * * the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice.”

21 CFR 1301.12(a) states:

“A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, or dispensed by a person.”

In support of its Motion for Summary Disposition, and as a basis for filing the interlocutory appeal, the Government recited well-settled DEA authority that the agency cannot register a practitioner to handle controlled substances who is without authority to handle controlled substances in the state in which he practices. With respect to the termination of the Respondent's state controlled substance authority, the Government argued that pursuant to DEA precedent, the method by which a

state terminates such authority is unimportant, and that DEA has no discretion in this regard other than to revoke a DEA registration: *Javen Shah*, 59 FR 4103 (1993); *Cornelius Beukenkamp*, 58 FR 28415 (1993); *Samuel Brint*, 51 FR 45067 (1986); and *Trinidad Bascara*, 51 FR 37090 (1986). The then-Deputy Administrator also incorporated in his Interlocutory Order additional DEA cases cited by the Government: *George P. Gotsis, M.D.*, 49 FR 33,750 (1984); *Henry Weitz, M.D.*, 46 FR 34,858 (1981); and *Sam Misasi, D.O.*, 50 FR 11,469 (1985).

With respect to the *Shah*, Judge Randall in her July 3, 2002 Memorandum and Order noted that the Deputy Administrator in that matter did not rely solely upon the provisions of 21 U.S.C. 824(a)(3) as the basis for the revocation decision; rather, the Deputy Administrator relied upon the public interest provisions of 21 U.S.C. 823(f) and 824(a)(4). Judge Randall further noted that the State of Illinois took an adverse action against the registrant prior to DEA's final order in the matter.

Similarly, with respect to the *Brint*, and *Bascara*, Judge Randall found that the relevant medical boards had taken adverse actions against the two Respondents prior to DEA revocation actions. The then-Deputy Administrator concurred with Judge Randall's finding that each of the above cited cases were distinguishable from matters raised in the interlocutory appeal, and these matters did not address one of the predominant issues of that appeal, namely, whether or not DEA may revoke a registration in a situation where removal of state authority occurred by operation of law and not by adverse state action.

The Government cited three additional DEA final orders where the agency held that revocation of a Certificate of Registration was appropriate even where the practitioner's state registration merely expired of its own terms and the registrant had not reapplied for state registration: *Mark L. Beck, D.D.S.*, 64 FR 40,899 (1999); *William D. Levitt, D.O.*, 64 FR 49,822 (1999); and *Charles H. Ryan, M.D.*, 58 FR 14,430 (1993). Judge Randall observed however, that “[r]egrettably these * * * Final Orders defy the plain language of the statutory provisions, for in neither of these * * * cases does the Final Order recount adverse action either taken or initiated by the state licensing authority.” In comparing the findings of *Beck*, *Levitt* and *Ryan* to the instant matter, Judge Randall concluded that the Government failed to meet the requirement of 21 U.S.C. 824(a)(3) because the record

contained no evidence that the State of Missouri had acted to suspend, revoke, or deny the Respondent's authority to handle controlled substances, nor had the State recommended such action be taken.

Nevertheless, the then-Deputy Administrator expressed a reluctance to “accord such a narrow interpretation to section 824(a)(3),” and instead concluded that it was “clear from the precedent cited by the Government that DEA has broadly construed section 824(a)(3), and extended its provisions beyond situations involving adverse actions taken or initiated by state licensing authorities. Such interpretation is consistent with the doctrine [outlined in] *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842–43, 81 L. Ed. 2D 694, 104 S. Ct. 2778 (1984), where it was held that administrative agencies are given broad discretion to construe their own regulations and authorizing statutes.” See, e.g. *Culbertson v. United States Department of Agriculture*, 69 F. 3d 465 (10th Cir. 1995); *Valley Comp. of Utah, Inc. v. Babbitt*, 24 F3d 1263, 1267 (10th Cir. 1994).

The then-Deputy Administrator noted that the above principle governing broad administrative discretion in statutory interpretation is supported by a number of policies, including, but not limited to the following: (1) Agencies tend to be familiar with, and sophisticated about, the statutes they administer, in other words, agencies understand the relationships among various provisions, and the practical implications of adopting one interpretation as opposed to another. (2) As unforeseen problems develop in the administration of a complex regulatory scheme, the agency needs flexibility if it is to make the program function effectively. *Gellhorn & Levin, Administrative Law and Process, 4th Edition* at p. 81–2 (1997).

The then-Deputy Administrator further noted that pursuant to the holding in *Levitt*, state authorization was clearly intended to be a prerequisite to DEA registration, and Congress could not have intended for DEA to maintain a registration if a registrant is no longer authorized by the state in which he practices to handle controlled substances. In the instant proceeding, the then-Deputy Administrator found that DEA precedent allowed for a liberal construction of section 824(a)(3), and also found it reasonable for DEA to interpret that section as allowing for the revocation of a DEA Certificate of Registration where, as here, the respondent's authorization under Missouri law had terminated.

As noted above, Judge Randall also based, in part, the denial of the Government's January 28, 2002, Motion for Summary Disposition upon the proposition that DEA "had an avenue for terminating, as opposed to revoking, the Respondent's authority for handling controlled substances." Judge Randall also noted that the distinction between the termination and revocation of a DEA registration had significance, since revocation has a more severe consequence upon the Respondent, and thus, a "stigma" with consequences attached to the act of revoking a registration. However, the then-Deputy Administrator rejected the Administrative Law Judge's finding, and instead concluded that any "stigma" attendant to the revocation of a DEA registration was speculative, and if any exists, such stigma is secondary to public interest considerations in ensuring full and truthful responses on DEA registration applications. The then-Deputy Administrator also found that the termination provision under 21 CFR 1301.52 was inapplicable since the only relevant issue in the instant matter was whether the Respondent was currently authorized to handle controlled substances. *Levitt* at 49822.

Consistent with the Interlocutory order of the then-Deputy Administrator, Judge Randall recommended the revocation of the Respondent's DEA Certificate of Registration, and denial of any pending applications for renewal of such registration based on the Respondent's lack of authority to handle controlled substances in Missouri. There is no evidence before the Acting Deputy Administrator that the Respondent's Missouri state controlled substance privileges have been reinstated.

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 *Karen Joe Smiles, M.D.*, 68 FR 48944 (2003), *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Here, it is clear that the Respondent is not currently authorized to handle controlled substances in the State of Missouri, where he is registered with DEA. Therefore, he is not entitled to maintain that registration. Because the Respondent is not entitled to a DEA registration in Missouri due to his lack of state authorization to handle controlled substances, the Acting

Deputy Administrator concludes that it is unnecessary to address whether the Respondent's registration should be revoked based upon the other grounds asserted in the Order to Show Cause. See *Fereida Walker-Graham, M.D.*, 68 FR 24761 (2003); *Nathaniel-Aikens-Affud, M.D.*, 62 FR 16871 (1997); *Sam F. Moore, D.V.M.*, 58 FR 14428 (1993).

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, AD7084217, issued to Marlou D. Davis, 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 February 9, 2004.

Dated: December 18, 2003.

Michele M. Leonhart,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John F. Hildebrand, M.D.; Revocation of Registration

On May 5, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to John F. Hildebrand, M.D. (Dr. Hildebrand) of Elk Grove, California, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AH5626099 under 21 U.S.C. 824(a) and deny any pending applications for renewal or modification of that registration. As a basis for revocation, the Order to Show Cause alleged that Dr. Hildebrand is not currently authorized to practice medicine or handle controlled substances in California, his state of registration and practice. The order also notified Dr. Hildebrand 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. Hildebrand at his registered location at 9410 Elk Grove-Florin Road, Elk Grove, California. According to the return receipt, on or around June 6, 2003, the Order was accepted on Dr. Hildebrand's behalf. By his letter of June 30, 2003, Dr. Hildebrand advised the Hearing Clerk in

DEA's Office of Administrative Law Judges that he wished to waive his right to a hearing in this matter. In that letter Dr. Hildebrand also asked that DEA delay revoking his certificate of registration until an appeal of the state board's revocation of his medical license was adjudicated. However, Dr. Hildebrand proffered no legal basis for delaying action on this matter and the Acting Deputy Administrator finds he affirmatively waived his hearing right. Accordingly, 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. Hildebrand possesses DEA Certificate of Registration AH5626099, which expired on October 31, 2003. The Acting Deputy Administrator further finds that the Medical Board of California (the Board) filed an accusation against Dr. Hildebrand alleging, *inter alia*, that he engaged in sexual abuse/misconduct with a patient and gross negligence, in violation of California Business and Professions Code, sections 726 and 2234(b).

During June 2001, an eight day hearing was held before an Administrative Law Judge from the Office of Administrative Hearings, State of California. The Administrative Law Judge issued a Proposed Decision sustaining the relevant accusations and recommending that Dr. Hildebrand's California Physician and Surgeon's license be revoked. On July 30, 2001, the Board approved the Administrative Law Judge's Proposed Decision and issued its Decision, effective August 29, 2001, revoking Dr. Hildebrand's license to practice medicine in the State of California for an indefinite period. On August 24, 2001, Dr. Hildebrand obtained an *ex parte* temporary stay of the Board's action from the Hon. Ronald B. Robie of the Sacramento County Superior Court so that the court could review the submitted documents. On September 20, 2001, the court lifted the stay and the Board's Revocation Order took effect.

The investigative file contains no evidence that the Board's Decision has been further stayed, that an appeal has been adjudicated adversely to the Board or that Dr. Hildebrand's medical license has been reinstated. Therefore, the Acting Deputy Administrator finds that Dr. Hildebrand is not currently authorized to practice medicine in the State of California. As a result, it is reasonable to infer that he is also without authorization to handle controlled substances in that state.