

Mix, Inc., 832 F.2d 601, 607 (DC Cir. 1987) (“an agency may ordinarily dispense with a hearing when no genuine dispute exists”).² At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the State of Kentucky. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that the Respondent is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide sufficient grounds to allow the Respondent to continue to hold his COR. I therefore conclude that further delay in ruling on the Government’s motion for summary disposition is not warranted. See *Gregory F. Saric, M.D.*, 76 Fed. Reg. 16821 (2011) (stay denied in the face of Respondent’s petition based on pending state administrative action wherein he was seeking reinstatement of state privileges).

Accordingly, I hereby
GRANT the Government’s Motion for Summary Disposition;
DENY the Government’s Motion for Stay of Proceedings as moot; and further RECOMMEND that the Respondent’s DEA registration be REVOKED forthwith and any pending applications for renewal be DENIED.

July 2, 2012.
John J. Mulrooney II,
Chief Administrative Law Judge.
[FR Doc. 2012-27522 Filed 11-9-12; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. 12-56]

Fernando Valle, M.D.; Decision and Order

On August 10, 2012, Chief Administrative Law Judge John J. Mulrooney, Jr., issued the attached Recommended Decision. Neither party filed exceptions to the Recommended Decision.

²Even assuming *arguendo* the possibility that the Respondent’s state controlled substances privileges could be reinstated, summary disposition would still be warranted because “revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement.” *Rodriguez*, 70 Fed. Reg. at 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.*, 65 Fed. Reg. 5661, 5662 (2000).

Having reviewed the entire record, I have decided to adopt the ALJ’s findings of fact, conclusions of law, and recommended order. Accordingly, I will order that Respondent’s DEA Certificates of Registration be revoked and that any pending applications to renew or modify his registrations be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration Numbers FV1935595, FV2000711, and FV2000735, issued to Fernando Valle, M.D., be, and they hereby are, revoked. I further order that any pending applications of Fernando Valle, M.D., to renew or modify his registrations, be, and they hereby are, denied. This Order is effective immediately.¹

Dated: October 26, 2012.

Michele M. Leonhart,
Administrator.

Michelle Gillice, Esq., for the
Government.

Dale Sisco, Esq., for the Respondent.

Order Granting the Government’s Motion for Summary Disposition and Recommended Decision

Chief Administrative Law Judge John J. Mulrooney, II. On June 25, 2012, the Administrator of the Drug Enforcement Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) immediately suspending and proposing to revoke the DEA Certificate of Registration (COR), Number FV1935595, of the Respondent pursuant to 21 U.S.C. 824(a), and to deny any pending applications for registration, renewal or modification pursuant to 21 U.S.C. 823(f) and 824(a) because the Respondent’s continued registration would “be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).” As grounds for these proposed actions, the OSC/ISO alleges that the Respondent “prescribed * * * controlled substances to * * * undercover law enforcement officers not for a legitimate medical purpose in the usual course of professional practice in violation of applicable Federal, State and local law.” OSC/ISO, at 1. The OSC/ISO was served on the Respondent on June 27, 2012. Gov’t Not. of Service. On July 26, 2012, the Respondent,

¹Based on the findings of the Florida Department of Health’s Order of Emergency Suspension of License, I conclude that the public interest requires this Order be effective immediately. 21 CFR 1316.67.

through counsel, filed a timely request for hearing.

On July 27, 2012, the Government filed a Motion for Summary Disposition and Motion to Stay Proceedings (“MSD”), in which it represented that “[o]n June 26, 2012, the State of Florida [the state in which Respondent holds his COR] Department of Health executed an emergency order suspending Respondent’s medical license M41752, effective immediately.”¹ MSD, at 1. Based on the foregoing, the Government sought the following relief: (1) Summary disposition; (2) a recommendation that the “Respondent’s DEA registration be revoked and any pending application for renewal or modification of such registration be denied;” (3) the transmission of the instant matter to the Administrator for Final Agency Action; and (4) a stay of these administrative proceedings pending the results of the Government’s motion for summary disposition. MSD, at 3.

By a July 27, 2012, Order, this tribunal granted the Government’s motion to stay, and directed the Respondent to file a response to the Government’s motion for summary disposition on or before August 6, 2012. Order Regarding Government’s Motion for Summary Disposition, at 2.

On August 3, 2012, the Respondent filed his response to the MSD. Respondent’s Response to Government’s Motion for Summary Disposition (“Response”). In the Response, the Respondent contends that revocation based on the Emergency Order “will effectively result in a denial of Due Process to Respondent without notice or opportunity for hearing and based only on the minimal standards of probable cause.” Response, at 2–3. The Respondent further submits that:

Summary Disposition is inappropriate prior to resolution of the numerous questions of material fact, as well as procedural issues, associated with the emergency suspension of his Florida Medical License and immediate suspension of his DEA registrations. With regard to his DEA registrations, these include, but are not limited to, whether the immediate suspension of the Respondent’s registration was based on a valid inspection and investigation; whether the continued registration of the Respondent constitutes an imminent danger to the public health and safety; and whether other grounds exist for the Government to limit the suspension of the Respondent’s registration.

Response, at 3.

On August 6, 2012, the Government filed a Reply to Respondent’s Response

¹The order of suspension (“Emergency Order”) is attached to the MSD as “Exhibit A.” The emergency suspension appears to be based on the same allegations set forth in the OSC/ISO.

to Motion for Summary Disposition and Motion to Stay Proceedings ("Reply"). In its reply, the Government contends that the "Respondent does not dispute that his medical license is suspended and that he lacks authority to handle controlled substances in the State of Florida, the jurisdiction where he is licensed to practice medicine. Absent authority by the State of Florida, Respondent simply is not authorized to possess a DEA registration in that state." Reply, at 1.

In its MSD and its Reply, the Government correctly contends that state authority is a necessary condition precedent for the acquisition or maintenance of a DEA registration, and the suspension of the Respondent's state practitioner's license precludes the continued maintenance of his DEA COR, thus requiring revocation. MSD at 1–2; Reply at 1–2. The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in "the jurisdiction in which he practices." See 21 U.S.C. § 802(21) ("[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice"); see also *id.* § 823(f) ("The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). DEA has long held that possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *Serenity Café*, 77 FR 35027, 35028 (2012); *David W. Wang*, 72 FR 54297, 54298 (2007); *Sheran Arden Yeates*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, M.D., 58 FR 51104 (1993); *Bobby Watts*, M.D., 53 FR 11919 (1988). Notwithstanding the foregoing, the Respondent contends that the Emergency Order may not form the basis of revocation insofar as the order was issued prior to a hearing. Response, at 3.

Because "possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration," this Agency has consistently held that "the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority]." *Roy Chi Lung*, 74 FR 20346, 20347 (2009); see also *Scott Sandarg*, D.M.D., 74 FR 17528, 174529 (2009); *John B. Freitas*, D.O., 74 FR 17524, 17525 (2009); *Roger A.*

Rodriguez, M.D., 70 FR 33206, 33207 (2005); *Stephen J. Graham*, M.D., 69 FR 11661 (2004); *Abraham A. Chaplan*, M.D., 57 FR 55280 (1992); see also *Harrell E. Robinson*, 74 FR 61370, 61375 (2009). Notably, "revocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action at which he may ultimately prevail." *Kamal Tiwari*, M.D., 76 FR 71604, 71606 (2011) (emphasis added); see also *Bourne Pharmacy, Inc.*, 72 FR 18273, 18274 (2007); *Anne Lazar Thorn*, 62 FR 12847 (1997).

The Respondent's assertions that the State of Florida and DEA acted in temporally close fashion has no bearing on the correct resolution of the issue raised by the Government's MSD. Neither does it matter that the Respondent intends to contest the emergency order at a state administrative hearing. *Tiwari*, M.D., 76 FR at 71606. It is uncontested that the Respondent does not presently enjoy the privileges of handling controlled substances in the State of Florida, the state where his COR is registered. In *Anne Lazar Thorn*, M.D., 62 FR 12847 (1997), the Agency affirmed the Administrative Law Judge's summary disposition recommended decision and specifically rejected the view that a COR could coexist in the face of an absence of state authority to handle controlled substances. In that case, the Agency held that:

the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances in the state. In the instant case, it is undisputed that Respondent is not currently authorized to handle controlled substances in the [state where his COR has its listed address]. Therefore * * * Respondent is not currently entitled to a DEA [COR].

Id. at 12848 (emphasis supplied). Similarly, in *Calvin Ramsey*, M.D., 76 FR 20034, 20036 (2011), the Agency stated its position with such unambiguous precision that little room is realistically left for debate on the matter:

DEA has repeatedly held that the CSA requires the revocation of a registration issued to a practitioner whose state license has been suspended or revoked. *David W. Wang*, 72 [FR] 54297, 54298 (2007); *Sheran Arden Yeates*, 71 [FR] 39130, 39131 (2006); *Dominick A. Ricci*, 58 [FR] 51104, 51105 (1993); *Bobby Watts*, 53 [FR] 11919, 11920 (1988). This is so even where a state board has suspended (as opposed to revoked) a practitioner's authority with the possibility

that the authority may be restored at some point in the future.

[*Roger A. Rodriguez*, 70 FR 33206, 33207 (2005)].

Although the Respondent avers his intention to vigorously contest the grounds for Florida's emergency order,² that intention does not affect the correct resolution of the present question. The Agency has held that even without evaluating the specific bases for state administrative action against a medical license, a "[s]tate's action in suspending [a registrant's] medical license is by itself, an independent ground to revoke [a] registration." *James L. Hooper*, M.D., 76 FR 71371, 71372 (2011).

The seminal issue presented by the MSD, whether a hearing is appropriate under the uncontested circumstances present here, must be answered in the negative. Congress does not intend for administrative agencies to perform meaningless tasks. *See Philip E. Kirk*, M.D., 48 FR 32887 (1983), aff'd sub nom. *Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); see also *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994); *NLRB v. Int'l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL-CIO*, 549 F.2d 634 (9th Cir. 1977); *United States v. Consol. Mines & Smelting Co.*, 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. *See Jesus R. Juarez*, M.D., 62 FR 14945 (1997); *Dominick A. Ricci*, M.D., 58 FR 51104 (1993).

At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the State of Florida. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that the Respondent is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide DEA with the authority to allow the Respondent to continue to hold his COR. I therefore conclude that further delay in ruling on the Government's motion for summary disposition is not warranted.³ *See Veg-*

² Response at 3.

³ Even assuming *arguendo* the possibility that the Respondent's state controlled substances privileges could be reinstated, summary disposition would still be warranted because "revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement," *Rodriguez*, 70 FR at 33207 (citations omitted), and even where there is a judicial

Mix, Inc., 832 F.2d 601, 607 (D.C. Cir. 1987) (“an agency may ordinarily dispense with a hearing when no genuine dispute exists”); see also *Gregory F. Saric, M.D.*, 76 FR 16821 (2011) (stay denied in the face of Respondent’s petition based on pending state administrative action wherein he was seeking reinstatement of state privileges).

Accordingly, I hereby grant the Government’s Motion for Summary Disposition; and recommend that the Respondent’s DEA registration be revoked forthwith and any pending applications for renewal be denied.

Dated: August 10, 2012.

/s/ JOHN J. MULROONEY, II,
Chief Administrative Law Judge.

[FR Doc. 2012-27554 Filed 11-9-12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Watson Pharma, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on August 28, 2012, Watson Pharma, Inc., 2455 Wardlow Road, Corona, California 92880-2882, made application to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II

The company plans to import the listed controlled substances for analytical testing and clinical trials.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 U.S.C.

challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.*, 65 FR 5661, 5662 (2000).

952(a)(2)(B) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than December 13, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 5, 2012.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration, SA INTL GMBH C/O., Sigma Aldrich Co., LLC.

By Notice dated August 17, 2012, and published in the **Federal Register** on August 20, 2012, 77 FR 50162, SA INTL GMBH C/O., Sigma Aldrich Co., LLC., 3500 Dekalb Street, St. Louis, Missouri 63118, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
Aminorex (1585)	I
Gamma Hydroxybutyric Acid (2010). .	I

Drug	Schedule
Methaqualone (2565)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marijuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391). .	I
4-Bromo-2,5-dimethoxyphenethylamine (7392). .	I
4-Methyl-2,5-dimethoxyamphetamine (7395). .	I
2,5-Dimethoxyamphetamine (7396). .	I
3,4-Methylenedioxymethamphetamine (7400). .	I
N-Hydroxy-3,4-methylenedioxymethamphetamine (7402). .	I
3,4-Methylenediox-N-ethylamphetamine (7404). .	I
3,4-Methylenedioxymethamphetamine (7405). .	I
4-Methoxyamphetamine (7411)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470). .	I
N-Benzylpiperazine (7493)	I
Heroin (9200)	I
Normorphine (9313)	I
Etonitazene (9624)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Egonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaiane (9333)	II
Opium, powdered (9639)	II
Levo-alphacetylmethadol (9648) ..	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis.

No comments or objections have been received. DEA has considered the