Controlled substance	Drug code	Schedule
Phenmetrazine	1631	II.
Methylphenidate	1724	II.
Amobarbital	2125	II.
Pentobarbital	2270	II.
Secobarbital	2315	II.
Glutethimide	2550	II.
Nabilone	7379	II.
1-Phenylcyclohexylamine	7460	II.
Phencyclidine	7471	II.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II.
Phenylacetone	8501	II.
1-Piperidinocyclohexanecarbonitrile	8603	II.
Alphaprodine	9010	II.
Anileridine	9020	II.
Cocaine	9041	II.
Codeine	9050	II.
Etorphine HCl	9059	II.
Dihydrocodeine	9120	II.
Oxycodone	9143	II.
Hydromorphone	9150	II.
Diphenoxylate	9170	II.
Ecgonine	9180	II.
Ethylmorphine	9190	II.
Hydrocodone	9193	II.
Levomethorphan	9210	II.
Levorphanol	9220	II.
Isomethadone	9226	II.
Meperidine	9230	II.
Meperidine intermediate-B	9233	II.
Metazocine	9240	II.
Methadone	9250	II.
Methadone intermediate	9254	II.
Metopon	9260	II.
Dextropropoxyphene, bulk (non-dosage forms)	9273	II.
Morphine	9300	II.
Thebaine	9333	II.
Dihydroetorphine	9334	II.
Levo-alphacetylmethadol	9648	II.
Oxymorphone	9652	II.
Noroxymorphone	9668	II.
Phenazocine	9715	II.
Piminodine	9730	II.
Racemethorphan	9732	II.
Racemorphan	9733	II.
Alfentanil	9737	II.
Remifentanil	9739	II.
Sufentanil	9740	II.
Carfentanil	9743	II.
Tapentadol	9780	II.
Bezitramide	9800	II.
Fentanyl	9801	II.

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 4, 2018.

Susan A. Gibson,

Deputy Assistant Administrator.

[FR Doc. 2018–07442 Filed 4–10–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–46]

Witold Marek Zajewski, M.D.; Decision and Order

On July 27, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Witold Marek Zajewski, M.D. (Respondent), of Mount Prospect, Illinois. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration No. BZ5641419 on the ground that he has ''no state authority to handle controlled substances.'' Order to Show Cause, at 1 (citing 21 U.S.C. 824(a)(3)). For the same reason, the Order also proposed the denial of any of Respondent's ''applications for renewal or modification of such registration and any applications for any other DEA registrations. *Id.*

With respect to the Agency's jurisdiction, the Show Cause Order

alleged that Respondent is the holder of Certificate of Registration No. BZ5641419, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 609 N. Main Street, Suite 102, Mount Prospect, Illinois. *Id.* The Order also alleged that this registration does not expire until May 31, 2018. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on June 29, 2017, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (IDFPR), ''issued an Order suspending [his] Illinois Physician and Surgeon License No. 036.096849 and suspending [his] Illinois Controlled Substance License No. 336.063325,'' and he is therefore ''without authority to practice medicine or handle controlled substances in the State of Illinois, the [S]tate in which [he is] registered with the DEA.'' *Id.* at 1–2. Based on his ''lack of authority to [dispense] controlled substances in . . . Illinois,'' the Order asserted that ''DEA must revoke'' his registration. *Id.* at 2 (citing 21 U.S.C. 824(a)(3)); 21 CFR 1301.37(b)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of his right to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

On August 21, 2017, Respondent, through counsel, filed a letter requesting a hearing on the allegations. Letter from Respondent's Counsel to Hearing Clerk (dated Aug. 18, 2017) (hereinafter, Hearing Request). In this letter, Respondent ''objects to the statement that his licenses have been suspended'' because the IDFPR ''entered only a temporary order of suspension of his license'' until ''an informal hearing'' scheduled in December 2017.'' *Id.* at 1. Respondent also requested to ''continue this matter to in or after January 2018.'' *Id.* at 1 (emphasis omitted).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On August 25, 2017, the ALJ ordered the Government to ''file evidence to support the allegation that the Respondent lacks state authority to handle controlled substances,'' ''respond to the Respondent's request for continuance,'' and file ''any motion for summary disposition'' no later than September 6, 2017. Order Directing the Filing of Government Evidence of Lack of State Authority and Briefing Schedule, at 1. The ALJ also directed Respondent to file his response to any summary disposition motion no later than September 15, 2017. *Id.* at 2.

On September 1, 2017, the Government filed its Motion for Summary Disposition. In its Request, the Government argued that it is undisputed that Respondent lacks authority to handle controlled substances in Illinois because the IDFPR suspended Respondent's medical license and his controlled substance license. Government's Motion for Summary Disposition (hereinafter Government's Motion or Govt. Mot.) at 2. The Government also noted that, in his Hearing Request, Respondent did not dispute that the IDFPR had suspended these licenses. *Id.* at 3 n.1. The Government further argued that, ''[a]bsent authority by the State of Illinois to dispense controlled substances, Respondent is not authorized to possess a DEA registration in that state.'' *Id.* at 3. Lastly, the Government argued that under Agency precedent, revocation is warranted even where a State has temporarily suspended a practitioner's state authority and has yet to provide the practitioner with a hearing where he may prevail. Govt. Mot., at 3–4 (citations omitted). As support for its summary disposition request, the Government attached, *inter alia,* a copy of the IDFPR's June 29, 2017 Order directing that (1) Respondent's medical and controlled substance licenses ''be **SUSPENDED,** pending proceedings before an Administrative Law Judge at'' IDFPR and (2) Respondent to ''immediately surrender all indicia of licensure(s) to'' IDFPR. Government Exhibit (GX) 2 to Govt. Mot., at 1.

In his responsive pleading, Respondent did not dispute that the IDFPR ''temporarily suspended'' his medical and controlled substance licenses. Respondent's Sept. 15, 2017 Motion for Extension of Time to Respond to Government's Motion for Summary Disposition (hereinafter, Resp. Reply), at 1. Instead, he argued that the suspensions were ''pending proceedings'' before a state administrative law judge and that he ''believe[s] this matter may be resolved'' at an ''informal hearing'' in December 2017. *Id.* Respondent also argued that the ALJ should grant him an extension of time to respond to the Government's Motion in ''the interest of administrative/judicial economy'' until then. *Id.* at 1–2 (quoting *Robert Clark Maiocco, M.D.,* 82 FR 19383, 19384 (2017)).

The ALJ denied ''Respondent's request for an extension of time—in essence to stay these proceedings,'' noting that ''revocation of a practitioner's registration is warranted whenever his (or its) state authority to dispense controlled substances has been suspended or revoked.'' Order Denying the Respondent's Request for an Extension of Time, Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (R.D.), at 2 (internal quotations and citations omitted), 3. While he was ''not unmindful of the Respondent's argument that granting an extension of time has been used in the past'' in *Maiocco,* the ALJ nevertheless ''disagree[d]'' that the same ''interest of administrative/judicial economy'' that was present in *Maiocco* was present in this case. *Id.* at 2–3, 3 n.3. Specifically, the ALJ in *Maiocco* granted that respondent's three-week extension of time request because the Colorado Board of Medicine was scheduled to consider Respondent's proposed ''Stipulation and Final Agency Order'' ''two weeks after the Respondent submitted his Motion for Extension of Time to the ALJ.'' *Id.* at 3 n.3 (citing *Maiocco,* 82 FR at 19384). Here, the ALJ reasoned, Respondent lacked the same ''interest of administrative/judicial economy'' because ''Respondent has submitted no[ ] proposed stipulation, Respondent only 'anticipates' an informal hearing to take place.'' *Id.* (citing Resp. Reply at 1). Finally, the ALJ concluded that the DEA has previously held ''that a stay in administrative enforcement proceedings is 'unlikely to ever be justified' due to ancillary proceedings involving the Respondent.'' *Id.* at 3 (quoting *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44104 n.97 (2012)).[1]

[1] I agree with this statement of the Agency's precedents. However, the ALJ also cited *Odette L. Campbell,* 80 FR 41062 (2015), as contrary authority. *See id.* The ALJ characterized Campbell as ''holding revocation proceedings in abeyance at the post-hearing adjudication level for a lengthy period pending the resolution of both criminal fraud charges and concurrent state administrative proceedings against the respondent,'' *id.* Notably, Campbell involved an application for registration, not a revocation of an existing registration, at the time the proceeding was held in abeyance. This is significant, as an applicant, like Campbell, does not have the current authority to handle controlled substances during any stay of the proceedings, while a registrant does.

Moreover, one week before the evidentiary hearing, the respondent was indicted on 30 counts

Continued

The ALJ then found that there was no dispute over the fact that ''Respondent currently lacks state authority to handle controlled substances in Illinois due to [the IDFPR's] Order dated July 29, 2017, which suspended his state licenses to practice medicine and distribute controlled substances.'' *Id.* at 5. Reasoning that ''[b]ecause the Respondent lacks state authority at the present time . . . he is not entitled to maintain his DEA registration,'' the ALJ granted the Government's motion and recommended that his registration be revoked and that any pending renewal applications be denied. *Id.* at 5–6.

Neither party filed exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action. Having reviewed the record, I adopt the ALJ's finding that by virtue of the IDFPR's Order, Respondent is currently without authority to handle controlled substances in Illinois, the State in which he holds his registration with the Agency, and is thus not entitled to maintain his registration. I further adopt the ALJ's recommendation that I revoke his registration and deny any pending renewal application. I make the following factual findings.

Findings of Fact

Respondent is the holder of DEA Certificate of Registration No. BZ5641419, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner. GX 1. Although not alleged in the Show Cause Order, I also find that Respondent is the holder of DATA-Waiver Identification Number XZ5641419, *see id.,* which authorizes Respondent to dispense or prescribe schedule III–V narcotic controlled substances which ''have been approved by the Food and Drug Administration . . . specifically for use in maintenance or detoxification treatment'' for up to 100 patients. 21 CFR 1301.28(a) & (b)(1)(iii). Respondent's registered address is 609 N. Main Street, Suite 102, Mount Prospect, Illinois. GX 1. Respondent's registration and DATA-Waiver authority do not expire until May 31, 2018. *Id.*

On June 29, 2017, the IDFPR issued an Order suspending Respondent's Illinois Physician and Surgeon License No. 036.096849 and his Illinois Controlled Substance License No. 336.063325 ''pending proceedings before an Administrative Law Judge at the'' IDFPR. GX 2, at 2. The Order also directed Respondent to ''immediately surrender all indicia of licensure(s) to the'' IDFPR. *Id.*

In January 2018, the IDFPR announced another enforcement action regarding Respondent's state licenses, stating that his ''physician and surgeon license [is] restored to indefinite probation for a minimum of three years and [his] controlled substance license, 336063325, [is] indefinitely suspended, 12 months minimum, effective retroactive to June 29, 2017 for inappropriately prescribing controlled substances to patients of his practice.'' [2] I take official notice of the IDFPR's January 2018 enforcement action [3] and find that Respondent currently does not possess a controlled substance license in the State of Illinois, and thus does not possess authority to dispense controlled substances in the State in which he is registered with the DEA. *See* 77 Ill. Adm. Code § 3100.370(a) (''A prescription for a controlled substance may be issued only by an individual practitioner who: (1) Holds an active professional license in Illinois as an individual practitioner; and (2) Holds an active controlled substances license under the Act or is exempted from licensure pursuant to Section 3100.80'').

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA, ''upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' Also, DEA has long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *see also Frederick Marsh Blanton,* 43 FR 27616 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'').

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[ ] a . . . physician . . . or other person 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.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f).

Thus, ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration ''is currently authorized to handle controlled substances in the [S]tate'' in which the practitioner is registered. *Hooper,* 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)). Here, there is no dispute over the material fact that Respondent is no longer currently authorized to dispense controlled substances in Illinois, the State in which he is registered. *See* 77 Ill. Adm. Code § 3100.370(a). Accordingly, he is not entitled to maintain his registration.

I will therefore adopt the ALJ's recommendation that I revoke Respondent's registration and deny any pending applications to renew his registration. R.D. at 6. I will also deny any pending application to modify his registration, or any pending application for any other registration in Illinois, as requested in the Show Cause Order. Order to Show Cause, at 1. Finally, because Respondent's DATA-Waiver

of Health Care Fraud, as well as five counts of altering records during a federal investigation. 80 FR at 41063. Had the respondent been convicted of Health Care Fraud, she would have been subject to mandatory exclusion from federal healthcare programs under 42 U.S.C. 1320a–7(a) and her application would have been subject to denial on that basis as well. *Id.* at 41064 (citing 21 U.S.C. 824(a)(5)). Furthermore, even after the respondent successfully completed pre-trial diversion and the charges were dismissed, the state medical board brought a proceeding against her license, and had the board suspended or revoked her medical license, denial of her application would have been required under the CSA. *Id.* (citing 21 U.S.C. 802(21) & 823(f)). Given the pending proceedings, *Campbell* was the rare case where withholding the issuance of a final decision was warranted. For these reasons, and those set forth in other final orders, I hold that *Campbell* does not support the issuance of stay of proceedings involving the suspension or revocation of DEA registrations. *See, e.g., Judson H. Somerville,* 82 FR 21408, 21409 n.3 (2017).

[2] *See www.idfpr.com/Forms/DISCPLN/2018_01enf.pdf.*

[3] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

authority is contingent on Respondent being a practitioner with a valid DEA registration, *see* 21 U.S.C. 823(g)(2)(A); 21 CFR 1301.28(a), I will revoke his DATA-Waiver authority as well.

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 No. BZ5641419 and DATA-Waiver Identification Number XZ5641419, issued to Witold Marek Zajewski, M.D., be, and they hereby are, revoked. I further order that any pending application of Witold Marek Zajewski to renew or modify the above registration, or any pending application of Witold Marek Zajewski for any other registration in the State of Illinois, be, and it hereby is, denied. This Order is effective immediately.[4]

Dated: April 4, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–07454 Filed 4–10–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of various classes of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION:

The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
Sharp (Bethlehem), LLC	83 FR 539	January 4, 2018.
Catalent Pharma Solutions, LLC	83 FR 2215	January 16, 2018.
Janssen Pharmaceuticals, Inc	83 FR 2214	January 16, 2018.
Mylan Pharmaceuticals, Inc	83 FR 5809	February 9, 2018.
Meridian Medical Technologies, Inc	83 FR 5810	February 9, 2018.
Noramco, Inc	83 FR 5810	February 9, 2018.
Johnson Matthey, Inc	83 FR 5811	February 9, 2018.
Mylan Technologies, Inc	83 FR 5811	February 9, 2018.
Mylan Pharmaceuticals, Inc	83 FR 8107	February 23, 2018.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or II controlled substances to the above listed companies.

Dated: April 4, 2018.

Susan A. Gibson,

Deputy Assistant Administrator.

[FR Doc. 2018–07444 Filed 4–10–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION:

The companies listed below applied to be registered as bulk manufacturers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted for these notices.

Company	FR docket	Published
Nanosyn, Inc	82 FR 56993	December 1, 2017.
Janssen Pharmaceutical, Inc	82 FR 58027	December 8, 2017.
Cambrex High Point, Inc	82 FR 61795	December 29, 2017.
AMPAC Fine Chemicals LLC	82 FR 61795	December 29, 2017.
Organix, Inc	83 FR 150	January 2, 2018.
Johnson Matthey Inc	83 FR 2215	January 16, 2018.
Chemtos, LLC	83 FR 2671	January 18, 2018.
Alcami Wisconsin Corporation	83 FR 2675	January 18, 2018.

[4] For the same reasons which led the IDFPR to revoke Respondent's controlled substance license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.