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.


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 an 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,” “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 yet 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 for Summary Disposition, inter alia, “because ‘holding revocation proceedings in abeyance 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 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 
disparity 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 
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 
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 this case does not support the 
issuance of stay of proceedings involving the 
suspension or revocation of DEA registrations. See, 
e.g., Judson H. Somervaille, 82 FR 21408, 21409 n.3 
(2017). 

 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 
issuing 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). 

Pursuant to 21 U.S.C. 824(a)(3), the 
Attorney General is authorized to 
suspend or revoke a registration issued 

3 Under the Administrative Procedure Act (APA), an 
agency’s “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 
give a hearing on the matter” under the APA 5 U.S.C. 
556(e); 802 CFR 1316.59(e). To 
Allow Respondent the 

Discussion 

Pursuant to 21 U.S.C. 824(a)(3), the 
Attorney General is authorized to 
suspend or revoke a registration issued 

3 See www.idfpr.com/Forms/DISCLPML/2018 
01en.pdf.

Id. 

8201(40) & 8201(51). 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 this case does not support the 
issuance of stay of proceedings involving the 
suspension or revocation of DEA registrations. See, 
e.g., Judson H. Somervaille, 82 FR 21408, 21409 n.3 
(2017).
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


Robert W. Patterson,
Acting Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

Company FR docket Published
Sharp (Bethlehem), LLC 83 FR 539 January 4, 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.

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.


Susan A. Gibson,
Deputy Assistant Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

Company FR docket Published
Nanosyn, Inc 82 FR 56993 December 1, 2017.
Cambrex High Point, Inc 82 FR 61795 December 29, 2017.
AMPAC Fine Chemicals LLC 82 FR 61795 December 29, 2017.

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.

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

4 For the same reasons which led the IDFPR to conclude that the public interest necessitates that this Order be effective immediately, 21 CFR 1316.67.