Factor Five—Other Conduct Which May Threaten Public Health and Safety

Even were I to adopt the ALJ's findings and credit Respondent's testimony that he was unaware of the misuse of his registration until an April 2008 phone call from a South Carolina pharmacy, *see* ALJ at 37, the record supports a further finding that he engaged in other conduct which threatened public health and safety. While Respondent claimed that he reported the incident to the Tennessee Medical Board sometime in 2009 and well after the fact,[27] he did not notify DEA of the incident until the June 2009 interview.[28] Tr. 371–72. However, the record contains evidence establishing that numerous additional prescriptions were issued under his registration through Secure Telemed following the April 2008 phone call, many of which were filled. *See* GX 17, at 1 (spreadsheet listing multiple prescriptions filled by South Carolina residents); GX 8, at 5 (Pt. S.P.H.); GX 12, at 3–4 (Pt. E.F.); GX 14, at 1–2 (Pt. H.B.); GX 15, at 15 (Pt. K.P.); GX 6, at 9 (entry for patient for E.F. showing additional hydrocodone prescription filled on 8/4/08).

Thus, even crediting his testimony, Respondent was aware that his registration was being used for criminal purposes, and yet did nothing to prevent this. *See* 21 U.S.C. 822(a) (requiring registration to lawfully dispense a controlled substance) and § 841(a)(1) (''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute[] or dispense . . . a controlled substance[.]''); *see also id.* § 843(a)(2) (''It shall be unlawful for any person knowingly or intentionally . . . to use in the course of the . . . distribution[] or dispensing of a controlled substance, . . . a registration number which is . . . issued to another person.''). His failure to inform the Agency of the unlawful use of his registration [29] led to additional acts of diversion of controlled substances and constitutes ''other conduct which . . . threaten[s] the public health and safety.'' 21 U.S.C. 823(f)(5).

I thus conclude that this factor also supports a finding that Respondent has committed acts which render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, the Government has made out a *prima facie* case that a registrant has committed acts which render his registration ''inconsistent with the public interest,'' he must '''present[] sufficient mitigating evidence to assure the Administrator that [he] can be [en]trusted with the responsibility carried by such a registration.''' *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe-Jonesborough,* 73 FR at 387. As the Sixth Circuit has recognized, this Agency also ''properly considers'' a registrant's admission of fault and his candor during the investigation and hearing to be ''important factors'' in the public interest determination. *See Hoxie,* 419 F.3d at 483.

More recently, the Tenth Circuit upheld the Agency's rule, explaining that:

> When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his behavior in the future. And that consideration is vital to whether [his] continued registration is in the public interest. Without Dr. MacKay's testimony, the . . . Administrator had no evidence that Dr. MacKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

MacKay, 664 F.3d at 820.

Here, the ALJ found that the Respondent ''fully accepted responsibility'' for his misconduct. ALJ at 43. Yet this conclusion was premised on the ALJ's finding that Respondent did not write any of the out-of-state prescriptions, a finding which I reject. As explained above, the record as a whole contains substantial evidence that Respondent, notwithstanding his testimony to the contrary, issued numerous controlled substance prescriptions to out-of-state patients, with whom he did not establish a legitimate doctor-patient relationship, and that he acted outside of the usual course of professional practice because he engaged in the unauthorized practice of medicine. Because Respondent failed to accept responsibility for this aspect of his misconduct, which was the most egregious of the various types of misconduct he engaged in, and continues to deny doing so, I conclude that he has not rebutted the Government's *prima facie* case. Accordingly, I will order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BD8297461, issued to Kevin Dennis, M.D., be, and it hereby is, revoked. I further order that any pending application of Kevin Dennis, M.D., to renew or modify his registration, be, and it hereby is denied. This Order is effective September 25, 2013.

Dated: August 17, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–20677 Filed 8–23–13; 8:45 am]

BILLING CODE 4410–09–P

[27] Respondent initially testified that he did not file the report with the State until June 2009 (the same month that he was interviewed by DEA Investigators). Tr. 372. Respondent then stated that he could not recall the exact month although it was sometime in 2009. *Id.* Respondent did not, however, maintain a copy of the report. *Id.*

[28] Contrary to the ALJ's understanding, *see* ALJ at 43–44, Respondent's claim that he reported the misuse of his DEA registration to the State authorities (approximately one year after the incident) neither mitigates his misconduct nor manifests that he accepts responsibility. State authorities did not issue his DEA registration and obviously have no authority to cancel a registration issued by an Agency of the federal government. Moreover, the lengthy delay in his reporting of the incident is consistent with the conduct of someone who has something to hide.

[29] Had Respondent reported the misuse of his registration, the Agency could have—with his agreement—cancelled his number and posted this information in the database which the Agency makes available to other registrants for verifying the validity of another person's registration. However, short of issuing an Immediate Suspension Order, the Agency could not have indicated in the database that he did not have a valid registration.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Catalent CTS., LLC.

Pursuant to Title 21, of the Code of Federal Regulations 1301.34(a), this is notice that on March 27, 2013, Catalent CTS., LLC., 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Poppy Straw Concentrate (9670)	II

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for a clinical trial study. In addition, the company plans to import an ointment for the treatment of wounds which contain trace amounts of the controlled substances normally found in poppy straw concentrate for packaging and labeling to be used in clinical trials.

Comments and requests for any hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417(2007).

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 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 Morrissette Drive, Springfield, VA 22152; and must be filed no later than September 25, 2013.

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 schedule 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: August 15, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–20717 Filed 8–23–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Chattem Chemicals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on June 21, 2013, Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Methamphetamine (1105)	II
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II
Tapentadol (9780)	II

The company plans to import the listed controlled substances to manufacture bulk controlled substances for sale to its customers. The company plans to import an intermediate form of Tapentadol (9780); and then to bulk manufacture Tapentadol for distribution to its customers.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417(2007).

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act [21 U.S.C. 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 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than September 25, 2013.

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 schedule 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: August 15, 2013.

Joseph T. Rannazzisi,

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

[FR Doc. 2013–20720 Filed 8–23–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Organix, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 2, 2013, Organix, Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Psilocybin (7437)	I
Psilocyn (7438)	I

The company plans to synthesize small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

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 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 25, 2013.