

what happened is simply a case of crying crocodile tears. Because Respondent has not accepted responsibility for his misconduct and that misconduct manifests an egregious disregard for his responsibilities as a DEA registrant, I hold that Respondent has not rebutted the Government's *prima facie* showing that his continued registration is "inconsistent with the public interest." 21 U.S.C. 824(a)(4). Accordingly, Respondent's registration will be revoked and any pending application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as by 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BB3698632, issued to Scott C. Bickman, M.D., be, and it hereby is, revoked. I further order that any application for renewal or modification of such registration be, and it hereby is, denied. This Order is effective April 29, 2011.

Dated: March 22, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-7393 Filed 3-29-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Roger A. Pellmann, M.D.; Revocation of Registration

On January 29, 2010, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration (Order) to Roger A. Pellmann, M.D. (Respondent), of Germantown, Wisconsin. The Order proposed the revocation of Respondent's registration, AP1892822, on the ground that his "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f) and (g)(2)(E)(i)." Order, at 1.

The Order alleged that Respondent "possessed and dispensed controlled substances at 3129 S. Ridge Crest, New Berlin, Wisconsin," an unregistered location, in violation of 21 U.S.C. 841(a)(1). Order, at 1. The Order further alleged that beginning "in approximately June 2009," Respondent "prescribed controlled substances to an employee for other than legitimate medical purposes," in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04. *Id.* at 2. The Order also alleged that at Respondent's "request," a local pharmacy dispensed controlled

substances which were "returned" to Respondent for his "personal use," in violation of 21 U.S.C. 843(a)(3). *Id.*

Next, the Order alleged that an "accountability audit performed at [Respondent's] office in November 2009" found "an unexplained shortage of approximately 10,470 fentanyl citrate 0.05 mg/ml (2 ml ampule) during the first audit and an unexplained shortage of approximately 9,556 fentanyl citrate 0.05 mg/ml (2 ml ampule) during the second audit." *Id.* The Order also alleged that "accountability audits for morphine sulfate indicated a shortage of approximately 780 units of morphine sulfate injection 15 mg/ml (20 ml vial); 1825 units of morphine sulfate injection 10 mg/ml (1 ml vial); 550 units of morphine sulfate injection 8 mg/ml (1 ml vial); and 200 units of morphine sulfate injection 5 mg/ml (1 ml vial)." *Id.* Finally, the Order alleged that "[n]o initial inventory was taken upon the establishment of the registered location, nor was a biennial inventory taken of the controlled substances on the premises of the registered location every two years" and that "records were not properly maintained for the dispensed controlled substances." *Id.* (citing 21 CFR 1304.11, 1304.11(b) & (c), and 1304.22(c)). Based on the above, I concluded that Respondent's continued registration during these proceedings "constitutes an imminent danger to the public health and safety" and immediately suspended his registration. *Id.* (citing 21 U.S.C. 824(d)).

On February 24, 2010, Respondent timely filed a request for a hearing on the allegations. The matter was placed on the docket of the DEA Administrative Law Judges (ALJ) and was set for hearing on June 22, 2010. Order Terminating Proceeding, at 1. However, on June 7, 2010, counsel for Respondent notified the ALJ that following Respondent's criminal conviction after trial "on facts related to the allegations set forth" in the Order, he "no longer wished to pursue a hearing." *Id.* The same day, Respondent's Counsel also wrote a letter to the ALJ stating that he was "waiving his opportunity to participate in the hearing" and submitting his statement of facts and his position. Letter from Adam C. Essling (June 7, 2010), at 1 (citing 21 CFR 1301.43(c)).

Mr. Essling's letter additionally stated that Respondent "maintains that his registration is not inconsistent with [the] public interest under 21 U.S.C. 823(f)." *Id.* More specifically, the letter related that Respondent "maintains that [J.E.] has been a patient of his since 2005" and that "[a]ll of the controlled substances provided to [J.E.] were for a

legitimate purpose." *Id.* However, the letter conceded that Respondent "did not maintain a proper inventory or records for the controlled substances dispensed within the scope of his practice." *Id.*

By order of June 8, 2010, the ALJ terminated the proceeding. Order Terminating Proceeding, at 2. Thereafter, the Investigative Record was forwarded to me for Final Agency Action.

Based on relevant evidence contained in the Investigative Record, I conclude that Respondent has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4). I will therefore, order that Respondent's registration be revoked and that any pending applications to renew or modify his registration be denied. I make the following findings of fact.

Findings

Respondent is a physician licensed by the State of Wisconsin who practices radiology. Respondent also holds DEA Certificate of Registration, AP1892822; the registration, which does not expire until March 31, 2011, authorizes him to dispense controlled substances as a practitioner at the registered location of CMI—Center for Medical Imaging, W178 N9912 Rivercrest Drive, Suite 102, Germantown, Wisconsin ("CMI," or "Germantown clinic"). Certificate of Registration Status (March 11, 2010). However, on January 29, pursuant to my authority under 21 U.S.C. 824(d), I ordered that Respondent's registration be immediately suspended; Respondent was served with the Order on February 2, 2010.

On September 4, 2009, a confidential source (CI) informed a DEA Diversion Investigator (DI) that Respondent had "been providing [J.E.] with large quantities of liquid Fentanyl and morphine sulfate, both of which are Schedule II controlled substances,"¹ for

¹ See 21 CFR 1308.12(b)(1)(ix) & (c)(9). According to the FDA-approved package insert for fentanyl citrate injection, a dosage of 0.1 mg in 2 ml. solution is "approximately equivalent in analgesic activity to 10 mg of morphine"; fentanyl is thus approximately 100 times more powerful than morphine. Its approved uses are primarily for analgesic action "during anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period" as needed, and also as "a narcotic analgesic supplement in general or regional anesthesia." Other uses include "administration with a neuroleptic such as droperidol injection as an anesthetic premedication, for the induction of anesthesia, and as an adjunct in the maintenance of general and regional anesthesia," and "as [an] anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures."

no legitimate medical purpose and that [J.E.] is addicted to these drugs.” Affidavit of G. Connor, at 2–3. The CI further stated that J.E. and Respondent had been involved in a sexual relationship for the past two years, and that J.E. worked at Respondent’s Germantown clinic, but “since approximately June 2009,” had “been doing most of her work at home because she [was] too addicted to narcotic drugs to go to the office.” *Id.* at 3.

According to the CI, approximately two years earlier, the CI was at J.E.’s residence when J.E. complained of a migraine headache; J.E. called Respondent and asked him to bring something for her headache. *Id.* Respondent later arrived “with an IV bag * * * an IV bag holder, several vials and syringes.” *Id.* at 3. At that point, the CI left the premises. *Id.*

The CI further stated that several months earlier the company underwriting Respondent’s employees’ health insurance had informed Respondent that the plan might not “be renewed because of the high number of prescriptions [Respondent] was writing for Schedule II controlled substances for one of the employees at the clinic.” *Id.* at 4. The CI further stated that clinic employees filled their prescriptions at Walgreen’s pharmacies. *Id.*

A DI obtained records of all the prescriptions written by Respondent and filled at “Walgreens pharmacies located in southeastern Wisconsin during the two-year period from September 1, 2007 through August 31, 2009.” *Id.* at 6. The records showed that Walgreen’s had filled 409 prescriptions issued by Respondent for narcotic controlled substances in this period, of which “138 (approximately 35%) had been” issued for J.E. *Id.*

The prescriptions for J.E. included six for morphine sulfate, ten for oxycodone, and two for fentanyl patches (or its generic equivalent), all of which are Schedule II controlled substances. *Id.*; see 21 CFR 1308.12(b)(1)(xiii). The prescriptions filled for J.E. also included approximately 109 prescriptions for hydrocodone and seven prescriptions for Hydromet, a hydrocodone-based cough syrup, both of which are Schedule III controlled substances. Affidavit of G. Connors, at 6; see 21 CFR 1308.13(e)(1).

The package insert furthers that the drug “SHOULD BE ADMINISTERED ONLY BY PERSONS SPECIFICALLY TRAINED IN THE USE OF INTRAVENOUS ANESTHETICS AND MANAGEMENT OF THE RESPIRATORY EFFECTS OF POTENT OPIOIDS. AN OPIOID ANTAGONIST, RESCUCITATIVE AND INTUBATION EQUIPMENT, AND OXYGEN SHOULD BE READILY AVAILABLE.”

J.E.’s prescriptions also fell into a pattern, with the number of dosage units of oxycodone or hydrocodone increasing from 90 to 170 dosage units per month in 2007 to as much as 380 dosage units by January 2009; in addition, during 2008 and 2009, Respondent added morphine sulfate and fentanyl patches to J.E.’s prescriptions. Affidavit of G. Connors, at 7. However, in July 2009, Respondent’s prescriptions for J.E. “decreased dramatically”; a Special Agent (SA) attributed this to Respondent’s insurance company having told him that it might cancel his clinic’s employee-health insurance. *Id.*

A DI obtained data from ARCOS, DEA’s Automated Reports and Consolidated Order Systems database. The data showed that while in 2008, Respondent had not obtained any schedule II or III controlled substance, in June 2009; he ordered and received 1,000 dosage units of fentanyl and 250 dosage units of morphine sulfate. *Id.* at 8. Also, in July 2009, Respondent ordered and received 1,280 dosage units of fentanyl and 280 dosage units of morphine sulfate; in August 2009, he ordered and received 1,660 dosage units of fentanyl and 280 dosage units of morphine sulfate; and in September 2009, he ordered and received 3,100 dosage units of fentanyl and 280 dosage units of morphine sulfate. *Id.* As the SA noted, “[t]his substantial increase in [Respondent’s] ordering of controlled substances generally coincided with the substantial reduction in the number of prescriptions for controlled substances, which were written by [Respondent], and filled by [J.E.] at Walgreens pharmacies.” *Id.*

On November 3, 2009, a DI, with assistance from the Waukesha Metro Drug Enforcement Unit, conducted a search of the garbage at J.E.’s residence. *Id.*; Declaration of K. Federico, at 1. The officers found 421 empty 2-ml. ampules labeled “Fentanyl Citrate 100mcg./1ml.,” thirteen (13) empty 1-ml ampules labeled “Morphine Sulfate 8mg./1ml.,” one (1) empty 20-ml. bottle labeled “Morphine Sulfate 15mg./1ml.,” and numerous syringes and used alcohol pads. Affidavit of G. Connors, at 8; Declaration of K. Federico, at 1.

On November 10, 2009, DEA SAs obtained warrants to search both Respondent’s Germantown clinic and J.E.’s residence. Affidavit of E. Roy, at 2. On November 12, 2009, during the execution of the search warrant at the Germantown clinic, the SAs interviewed Respondent. *Id.* at 3. Respondent stated that J.E. was one of two registered nurses employed by his practice and that she was also the vice president of CMI. *Id.* Respondent further

stated that he had been treating J.E. since approximately March 2009 for pain “resulting from a fractured tooth.” *Id.* Respondent maintained that the tooth subsequently became infected and that he then started treating J.E. with liquid fentanyl. *Id.*

Respondent further stated that he initially injected J.E. with three to five 2-ml. ampules of fentanyl three times per day, but by the time of the interview, he was injecting her with approximately fifty ampules per day. *Id.* He also stated that he had prescribed Vicodin for J.E.’s lower back pain and that J.E. was intermittently taking hydrocodone along with the fentanyl for her pain. *Id.*

Respondent stated that J.E. had not been billed for any of the fentanyl which he had provided to her. *Id.* at 4. He further admitted that he did not have a medical file or chart documenting his treatment of J.E. and a search of the clinic failed to yield a medical record for J.E. *Id.* at 4, 6.

Respondent also stated that he had had several conversations with J.E. in which he told her that she needed a longer-acting narcotic than fentanyl. *Id.* at 4. However, J.E. did not want to change medications. *Id.* Nevertheless, Respondent tried J.E. on morphine sulfate, which left her with a “drug hangover” the next morning. *Id.* Respondent also admitted that J.E. had developed a tolerance to fentanyl and was addicted to it. *Id.* Respondent further admitted that he did not think his dispensing of fentanyl and morphine sulfate to J.E. was “in the usual course of practice,” and that “the situation going on between himself and [J.E.] [was] not in the usual course of practice.” *Id.* He also admitted that he never conducted an inventory of the controlled substances kept at his clinic. Declaration of S. Osborne, at 4.

Respondent further admitted that he self-administered morphine sulfate for a neck injury and that sometimes J.E. assisted him with the injections. Affidavit of E. Roy, at 8; Declaration of K. Federico, at 1. Based on this information, DEA contacted his attorney regarding “his possession and personal use of morphine.” Affidavit of E. Roy, at 8. On November 19, 2009, the attorney turned over to DEA a box intended to hold ten smaller boxes, each of which holds twenty-five 1-ml. ampules of morphine. *Id.* at 8–9. However, the box contained only nine of the smaller boxes of morphine ampules. *Id.* at 9.

DEA audited the records of the Germantown clinic and found significant discrepancies in the amount of fentanyl received and used by Respondent. In the period from

February 26, 2009, when records indicated Respondent had ninety-four ampules of fentanyl in stock, through November 12, 2009, he received 11,490 such ampules.² *Id.* at 5. At the time of the search, he had seven ampules on hand, plus DEA found another 600 ampules in his car, which Respondent claimed he was taking to his home because of a theft at the clinic. *Id.* No dispensing logs for September or October 2009 were found, and the remaining dispensing logs accounted for the disposition of only 507 ampules, less than ten percent of what had been received in this period. *Id.*

The Germantown clinic had a record of all patients who had received fentanyl as part of a medical procedure for the period June 1, 2009 through November 12, 2009. *Id.* at 6. While during this period Respondent purchased 10,590 ampules of fentanyl, the clinic records showed that only 427 ampules were used during medical procedures at the clinic. *Id.* These ampules, combined with the 600 found in the car, likewise account for less than ten percent of the fentanyl Respondent received. *Id.*

The Investigators also performed an audit of Respondent's handling of morphine sulfate for the period February 26, 2009 through November 12, 2009. The audit showed that Respondent could not account for 3,155 vials of the drug, which was "the majority of the morphine sulfate he received" in that period.³ Declaration of S. Osborne, at 2. According to several clinic employees, morphine "was not used in CMI[s] procedures." *Id.* Moreover, the search of the clinic revealed that Respondent "failed to take an initial inventory [and] maintained no biennial inventory" for any of the controlled substances Respondent had obtained; nor did it have proper records documenting the disposition of the morphine that Respondent obtained. *Id.* at 3.

² Pharmacy records from Ye Olde Pharmacy, where Respondent filled his "general use" prescriptions for controlled substances for "office use," indicate that between February 1, 2009 and July 14, 2009, Respondent obtained 4,100 ampules of fentanyl. See Declaration of S. Osborne, at 2–3. ARCOS data from June through September 2009 indicate that he obtained a further 7,040 ampules from distributors for a total of 11,140 ampules. It is not clear what accounts for the difference between the 11,490 figure and the total of 11,140.

³ Dispensing records from Ye Olde Pharmacy indicate that Respondent received 2,025 dosage units of morphine sulfate between February 2009 and July 14, 2009. ARCOS data for the months of July 2009 through September 2009 indicate that in this period, Respondent obtained a further 1,010 vials of morphine sulfate, making for a total of 3,035 vials. Respondent, however, could account for only 100 vials.

On November 12, 2009, DEA Investigators also conducted a consensual search of Respondent's residence. Declaration of K. Federico, at 1. While Respondent's residence is not a registered location, the Investigators found "large amounts of empty and full fentanyl citrate ampules, morphine sulfate vials, drug packaging, and intravenous drug use paraphernalia." *Id.*

On November 19, 2009, DEA received information from a second confidential source (CI2) that on November 16, 2009, Respondent had received a box of morphine; according to CI2, morphine was not used in the clinic's procedures. Affidavit of E. Roy, at 8. CI2 later observed Respondent placing one of the containers of morphine in his pocket. *Id.*

On November 23, 2009, pursuant to an immunity agreement with the U.S. Attorney's Office, J.E. was interviewed by DEA investigators. *Id.* at 6. J.E. stated that Respondent gave her Vicodin for back pain in 2007. *Id.* He also prescribed oxycodone, morphine sulfate, and fentanyl patches on several occasions for pain management. *Id.*

J.E. stated that around the summer of 2009, Respondent provided J.E. with fentanyl for a dental problem. *Id.* Respondent began administering the fentanyl to J.E. via an intravenous (IV) line on a regular basis. *Id.* J.E. stated that she consumed two to three vials per week this way. *Id.* She also indicated that morphine made her sleepy and that sometimes Respondent would give her morphine to help her sleep. *Id.* at 7.

As J.E.'s dental problem worsened, her use of fentanyl increased. *Id.* Rather than receive the drug via IV administration, she began injecting herself with a solution of fentanyl and saline. *Id.* By November 12, 2009 (when the search warrant was executed at her residence), J.E. was self-administering approximately forty to fifty vials of fentanyl per day. *Id.* She was also receiving morphine from Respondent to help with her sleep several times each week. *Id.* While typically Respondent brought the drugs to her residence, on a few occasions another clinic employee brought them. *Id.*

In addition, at times J.E. would go to Respondent's house to use fentanyl or morphine that Respondent kept there. *Id.* J.E. stated that she never paid for medication or treatment provided by Respondent. *Id.* She further stated that every few weeks she and Respondent would have conversations about her growing tolerance to fentanyl. *Id.*

On November 11, 2009, J.E. checked herself into a treatment center, where she stayed until November 18, 2009. *Id.* at 8. She further told Investigators that

she was receiving treatment from a physician for her fentanyl addiction and was taking Suboxone as part of that treatment. *Id.*

On January 11, 2010, DEA received further information from CI2. CI2 told the Investigators that in the last week, Respondent had noted on CMI's dispensing log that he had dispensed 250 ampules of fentanyl to J.E. *Id.* at 9. CI2 also stated that he had noticed that fifty ampules of fentanyl were missing and were not accounted for in the dispensing log. *Id.* He also reported discovering three plastic zip-lock bags in the Germantown clinic's trash containing empty fentanyl ampules, syringes, dirty cotton pads, and other items; CI2 provided the bags to DEA. *Id.* According to CI2, CMI disposes of needles in a "sharps" bio-hazard container," and not via the trash. *Id.*

DEA Investigators examined the three plastic bags. They found thirty-eight empty fentanyl ampules, four empty plastic trays (each capable of holding ten (10) fentanyl ampules), syringes, needles, alcohol swabs, gauze dirtied with blood, "Y" adapters for an IV line, and packaging for needles. *Id.* at 10.

On January 12, 2010, CI2 further reported that Respondent had added notes to CMI's fentanyl dispensing log. *Id.* The note indicated that Respondent had used two ampules of fentanyl on January 8, 2010. *Id.*

On January 13, 2010, a criminal complaint was filed against Respondent, and on February 2, 2010, a grand jury indicted him on ten counts of intentionally and knowingly possessing with intent to distribute and unlawfully distributing fentanyl without a legitimate medical purpose on various dates in October and November 2009, in violation of 21 U.S.C. 841(a)(1), as well as six counts of obtaining morphine sulfate by misrepresentation, fraud, and deception in violation of 21 U.S.C. 843(a)(3). Declaration of S. Osborne, at 6; Indictment, *United States v. Pellmann*, No. 10–CR–014 (E.D. Wis., filed Feb. 2, 2010).

Respondent was arrested after the filing of the criminal complaint. Following his release from custody, he travelled with J.E. to a Brookfield, Wisconsin hotel where he administered approximately two ampules of fentanyl to her during their stay. Declaration of S. Osborne, at 5. Thereafter, on the weekend of January 15–17, 2010, the two traveled to a Kohler, Wisconsin hotel, where Respondent administered midazolam, a schedule IV controlled substance,⁴ to J.E. several times so that she could "detox" from the Fentanyl. *Id.*

⁴ See 21 CFR 1308.14(c)(35).

Respondent told J.E. not to mention the hotel visits to anyone. *Id.*

The Investigative Record contains copies of prescriptions which Respondent issued for morphine sulfate and for fentanyl citrate “for office use.” The morphine sulfate prescriptions are dated April 23; May 6, 13, 14, 23, and 28; June 6, 16, 23, and 30; and July 6 and 14, 2009. The fentanyl citrate prescriptions date back to August 2007 and extend through July 2009. Typically those prescriptions were for between 50 and 100 vials. However, the prescriptions of May 23 and June 8, 2009 were for 200 vials each.

Respondent went to trial; on June 4, 2010, a federal jury found him guilty of all sixteen counts alleged in the indictment. *U.S. v. Pellmann*, Verdict (June 4, 2010). After the return of the verdicts, the District Court allowed Respondent to remain free on bond on several conditions, including that he “have ‘no contact whatsoever’” with J.E. and that he “not . . . ‘administer even to himself or anyone else any drugs whatsoever.’” Aff. of E. Roy in Supp. of Mot. to Revoke Order of Release, *U.S. v. Pellmann*, at 1 (filed July 30, 2010).

However, on July 29, 2010, an Assistant U.S. Attorney received a phone call from another confidential source who reported that a nurse at CMI had confronted Respondent after observing him near the narcotics box and that the nurse thereafter found missing five vials of midazolam. *Id.* Respondent told the nurse he was taking the midazolam to his other clinic in New Berlin. *Id.* This CS further stated that Respondent was continuing to treat J.E., that she was coming to the clinic, and also that Respondent was treating her at his house. *Id.*

Shortly thereafter, a DI interviewed a CMI employee, who stated that the employee who performs CT scans at the clinic was called in on a Saturday by Respondent to do a CT scan of J.E. Aff. of E. Roy in Supp. of Mot. to Revoke Order of Release, at 2. The employee also stated that Respondent talked regularly about his contacts with J.E. and stated that he was treating her for her pain and that the two had been staying together. *Id.*

On July 29, 2010, the DI and other Investigators went to CMI. *Id.* at 2. Clinic employees stated that on July 23, 2010, the clinic had received ten boxes of midazolam, with each box containing ten vials for a total of 100 vials. *Id.* CMI’s records showed that five vials had been administered to patients and that ten of the vials had been taken to Respondent’s New Berlin office, supposedly at the request of a physician (Dr. Z.) who sublets space at that office

and who is registered with DEA at both the Germantown clinic and the New Berlin office. *Id.* The DI counted the vials; the count matched the records at eighty-five vials. *Id.*

Respondent was present during the July 29 visit. *Id.* Dr. Z. was not present, and, according to clinic staff, had not been there at all that day. *Id.* According to a clinic employee, Respondent had done at least one patient procedure prior to the Investigators’ arrival during which he administered midazolam to the patient. *Id.* After noticing that the computerized office records did not reflect that Respondent had done so, the DI confronted Respondent. *Id.* at 2–3. Respondent admitted that he had, in fact, administered the midazolam, but claimed to have done so under Dr. Z.’s supervision. *Id.* at 3.

That evening, the DI and other investigators went to the New Berlin office and met with Dr. Z. *Id.* at 3. Dr. Z. stated that the New Berlin office did not have any midazolam, that he had never requested Respondent to bring the drug to that office, and that he does not typically use midazolam there. *Id.* Moreover, he stated that he had not authorized Respondent to administer controlled substances during procedures. *Id.*

The following morning, the CMI employee called the DIs and reported that after the DIs left the clinic, she had inspected the supposedly sealed boxes of midazolam. *Id.* She reported that the boxes appeared to have been tampered with and that some of the vials appeared to have been refilled and their tops reglued. *Id.* Investigators then contacted Dr. Z. and gained his consent to seize all of the controlled substances at the Germantown clinic which had been procured using his DEA registration. *Id.* As the Investigators traveled to the clinic, the employee called again and stated that Respondent had just left the clinic with a bag containing drug vials. *Id.* Upon the Investigators’ arrival, the employee told them that Respondent’s sister had come to the clinic that morning and delivered ten vials of midazolam. *Id.* Respondent’s sister claimed to have obtained the vials from the New Berlin office. *Id.*

Clinic employees opened the controlled substances cabinet, and the Investigators counted the drugs. *Id.* at 4. The Investigators observed signs of tampering on five boxes of midazolam. They also found only fifty-five vials of the drug and concluded that forty vials were missing. *Id.*

Thereafter, Respondent entered the clinic carrying a plastic shopping bag which contained thirty-six empty vials of midazolam. *Id.* Respondent claimed

that he had gotten the vials out of the trash and that Dr. Z. had “told him to ‘bring back the trash.’”⁵ *Id.* The bag also contained Respondent’s personal medication, a seven-day pill container, and some pharmacy pamphlets. *Id.*

Based on Respondent’s having violated the conditions of release, on July 30, 2010, a United States District Judge issued an arrest warrant for Respondent. *U.S. v. Pellmann*, Arrest Warrant (July 30, 2010). Respondent was then arrested.

As noted above, on June 7, 2010, Respondent’s Counsel submitted Respondent’s Statement of Facts and Position. Therein, Respondent maintained that “all of the controlled substances he administered or dispensed to J.E. were for treatment of her pain related to Trigeminal Neuralgia” and that treating J.E. “required house calls given the nature of the pain and the time of her pain attacks.” He further asserted that he discussed with J.E. “her condition on a daily basis and he monitored her condition through daily interactions,” and that “[h]e used several different pain medications, anti-inflammatory medication, and antibiotics in association with her pain caused by her Trigeminal Neuralgia and dental problems.” He then asserted that all of the controlled substances he provided to J.E. “were for a legitimate medical purpose.” However, Respondent admitted that “he did not maintain a proper inventory or records for the controlled substances dispensed within the scope of his practice.”

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a “registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration * * * inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). With respect to a practitioner’s registration, the CSA directs that the following factors be considered in determining the public interest:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing * * * controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to

⁵ To make clear, I do not find either statement credible.

the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conducts which may threaten the public health and safety. 21 U.S.C. 823(f).⁶

"[T]hese factors are * * * considered in the disjunctive." *Robert A. Leslie*, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application. *Id.* Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173–74 (DC Cir. 2005).

Having reviewed the Investigative Record, I conclude that the evidence relevant to factors two, four, and five establishes that Respondent has committed acts which render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4). Accordingly, Respondent's registration will be revoked and any pending application will be denied.

Factor One: The Recommendation of the Appropriate State Licensing Authority

The record contains no evidence that the Wisconsin Medical Examining Board has made any recommendation to DEA regarding Respondent's registration. Therefore, I find that this factor neither weighs in favor of, or against, a finding that Respondent's continued registration is inconsistent with the public interest.

Factors Two and Four: Registrant's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not effective unless it is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 CFR 1306.04(a). This regulation further provides that an "order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of * * * 21 U.S.C. 829 * * * and

* * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.* See also 21 U.S.C. 802(10) (Defining the term "dispense" as meaning "to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance.")

As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)).

Under Agency precedent, "[i]t is fundamental that a practitioner must establish and maintain a bona-fide doctor-patient relationship in order to be acting 'in the usual course of * * * professional practice' and to issue a prescription for a 'legitimate medical purpose.'" *Paul H. Volkman*, 73 FR 30630, 30642 (2008), *aff'd sub nom. Volkman v. DEA*, 567 F.3d 215 (6th Cir. 2009) (citing *United States v. Moore*, 423 U.S. 122, 142–43 (1975) ("noting that the evidence established that physician 'exceeded the bounds of 'professional practice,' when 'he gave inadequate physical examinations or none at all,' 'ignored the results of the tests he did make,' and 'took no precautions against * * * misuse and diversion.'")).

Wisconsin law likewise states that "[a] practitioner may dispense or deliver a controlled substance to or for an individual * * * only for medical treatment * * * in the ordinary course of that practitioner's profession." Wis. Stat. Ann. § 961.38. Wisconsin law also provides that "[a]dministering, dispensing, prescribing, supplying, or obtaining controlled substances * * * otherwise than in the course of legitimate professional practice, or as otherwise prohibited by law" is "unprofessional conduct" by a physician. Wis. Admin. Code [Med.] § 10.02(2)(p).

Respondent's experience in dispensing controlled substances and record of compliance with applicable laws is characterized by his numerous and brazen violations of multiple laws related to controlled substances. As found above, Respondent admitted that he administered and/or distributed to J.E. large quantities of fentanyl, a schedule II controlled substance; he also

prescribed to J.E. other schedule II drugs such as oxycodone and morphine, as well as large quantities of Vicodin, a schedule III controlled substance containing hydrocodone. Moreover, Respondent frequently personally brought the drugs to J.E.'s residence.

While in his Statement of Facts and Position, Respondent now asserts that he had a legitimate medical purpose in dispensing the controlled substances to J.E.; Respondent previously admitted in his November 10, 2009 interview that he did not have a medical chart documenting his treatment and medical purpose for administering and distributing controlled substances to her. Respondent's failure to maintain a medical chart on J.E. provides substantial evidence that he did not establish a legitimate doctor-patient relationship with her, a fact which is confirmed by his admission during the interview that his distribution of fentanyl and morphine to J.E. was not in the usual course of professional practice and that the situation between himself and J.E., with whom he likely had a sexual relationship, was not within the usual course of professional practice.⁷

During their respective November 2009 interviews, both Respondent and J.E. asserted that he provided the fentanyl to her to treat pain caused by a tooth which fractured in March 2009 and subsequently became infected. Notably, neither Respondent nor J.E. claimed that at any time after he determined the cause of her pain did he refer her to a dentist, who could have properly diagnosed her problem and treated it. Instead, he supplied her with an ever-increasing amount of fentanyl, a highly potent and abused narcotic.⁸ Such a gross departure from accepted standards of medical practice manifests that Respondent lacked a legitimate

⁷ Respondent admitted this in his interview during the execution of the search warrant at the Germantown clinic. While his counsel's letter of June 7, 2010 now maintains that J.E. had been his patient since 2005 and had been diagnosed as having Trigeminal Neuralgia, Respondent made no such contention in the November 2009 interview and there is no medical record for J.E. documenting this. The absence of any patient file for J.E. confirms Respondent's admission in the interview that he did not distribute drugs to her in the course of professional practice.

⁸ Even assuming that Respondent, a radiologist, has been trained in the proper use of the drug and the management of its respiratory effects, given that the injections took place at J.E.'s residence, it seems implausible that any of items which the package inserts warns should be readily available to counter fentanyl's respiratory depression effects such as an opioid agonist, resuscitative and intubation equipment, and oxygen were available. Finally, given the potency of this drug and the serious adverse reactions which it can cause, it does not seem that this is the type of drug that patients should be self-administering.

⁶ Section 304(a)(2) further provides that a registration may be revoked "upon a finding that the registrant * * * has been convicted of a felony under this subchapter [the CSA] * * * or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance." 21 U.S.C. 824(a)(2).

medical purpose and acted outside of the usual course of professional practice when he dispensed fentanyl to J.E. 21 CFR 1306.04(a).

Finally, having been found guilty by a jury of all ten counts of unlawfully distributing fentanyl without a legitimate medical purpose in violation of 21 U.S.C. 841(a)(1), Respondent is collaterally estopped from re-litigating the issue of whether he had a legitimate medical purpose when he distributed fentanyl to J.E. *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008) (citing *New Hampshire v. Maine*, 532 U.S. 742, 748–49 (2001)). I therefore reject Respondent's contention that he had a legitimate medical purpose for providing fentanyl to J.E.

While Respondent admitted in the November 2009 interview that he knew J.E. was addicted to fentanyl, he continued to provide fentanyl to her even after she began receiving treatment for her addiction. Indeed, he continued to administer controlled substances to J.E. even after he had been criminally charged and arrested. More specifically, in January 2010, he administered fentanyl to her at a Brookfield, Wisconsin hotel room; several days later, the two checked in to a Kohler, Wisconsin hotel room where he gave J.E. midazolam to detox her from the fentanyl. The evidence therefore shows that Respondent repeatedly violated the CSA by unlawfully distributing controlled substances to J.E. See 21 U.S.C. 841(a)(1) (“[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally * * * to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance”); see *Michael F. Myers*, 72 FR 36484, 36486 (2007) (revoking physician's registration where physician, *inter alia*, continued to prescribe OxyContin to a “patient” notwithstanding the “patient's” informing physician that he was addicted to the drug).

Respondent further violated Federal law when he obtained controlled substances by fraud. See 21 U.S.C. 843(a)(3) (“It shall be unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge [.]”). As found above, Respondent wrote numerous prescriptions for fentanyl and morphine sulfate to obtain these drugs from local pharmacies; while Respondent noted on the prescriptions that the controlled substances were “for office use,” the evidence shows that only a miniscule portion of the fentanyl (427 ampules out

of more than 4,100 ampules obtained in this manner) was used for medical procedures at the clinic and that the vast majority of the fentanyl was being provided to J.E.

As for the morphine, the evidence showed that Respondent obtained more than 2,000 dosage units from a local pharmacy. However, Respondent's clinic did not use this drug in any procedures. Rather, Respondent both self-administered the morphine and distributed it to J.E. It is thus clear that by representing that the fentanyl and morphine were “for office use,” Respondent obtained the drugs by fraud and deception.⁹ 21 U.S.C. 843(a)(3). See *Randall Relyea*, 73 FR 40378, 40380 (2008) (revoking physician's registration based on violations of section 843(a)(3) and physician's personal abuse of controlled substances thus obtained); *Alan H. Olefsky*, 72 FR 42127, 42128 (2007) (denying application based on physician's violations of section 843(a)(3) and personal abuse of controlled substances thus obtained). Relatedly, DEA regulations prohibit the use of a prescription by “an individual practitioner to obtain controlled substances for supplying the * * * practitioner for the purpose of general dispensing to patients.” 21 CFR 1306.04(b).

Wisconsin law prohibits a practitioner from “tak[ing] without a prescription a controlled substance * * * for the practitioner's own use.” Wis. Stat. Ann. § 961.38(5). Because Respondent did not obtain the morphine pursuant to a prescription from a physician, he violated Wisconsin law when he used the morphine. He likewise violated the CSA, which renders it “unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice.” 21 U.S.C. 844(a).

⁹ Under Federal law, to obtain schedule II controlled substances, a DEA Form 222 must be completed and sent to the distributor. See 21 U.S.C. 828(c)(2). This applies even where a practitioner obtains a schedule II controlled substance from a pharmacy. 21 CFR 1307.11(a)(1)(iii). It is unclear whether Respondent ever submitted DEA Form 222s to the pharmacies he obtained schedule II drugs from. However, the Government has the burden of proof on the issue.

As for the morphine and fentanyl he obtained from distributors, Federal law makes it “unlawful for any person to obtain by means of order forms * * * controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice.” 21 U.S.C. 828(e) (emphasis added). Thus, Respondent's obtaining of fentanyl and morphine from various distributors was also illegal.

Respondent further violated both the CSA and DEA regulations by failing to maintain proper records. As found above, during the search of the clinic, there were neither initial inventories nor biennial inventories, dispensing logs were missing for several months, and the dispensing logs that were available were clearly not being properly maintained as demonstrated by the audits which could not account for more than 10,000 dosage units of fentanyl and more than 3,000 dosage units of morphine. See 21 U.S.C. 827(a); 21 CFR 1304.03(a), 1304.11, and 1304.22(c). Respondent also admitted that he had failed to maintain the lawfully required records. Even were there no other evidence of Respondent's unlawful conduct, his failure to comply with his recordkeeping obligations is so egregious that it alone would support the revocation of his registration.

As the foregoing demonstrates, Respondent's experience in dispensing controlled substances and his record of compliance with applicable laws related to the distribution and dispensing of controlled substance are characterized by his repeated and flagrant disregard for Federal and State laws. This evidence clearly supports the conclusion that Respondent has committed acts which render his registration inconsistent with the public interest.¹⁰

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

On January 29, 2010, Respondent's registration was immediately suspended because his misconduct created an imminent danger to public health and safety. As a consequence of the Order, which was served on him on February 2, Respondent was prohibited from possessing controlled substances (other than those he obtained through a legal prescription) and dispensing them.

¹⁰ As found above, on June 4, 2010, a jury found Respondent guilty of ten counts of violating 21 U.S.C. 841(a)(1) and six counts of violating 21 U.S.C. 843(a)(3), both of which are felony offenses. The record does not, however, include a copy of the judgment of conviction entered by the District Court.

Factor three authorizes the Agency to consider a registrant's conviction record under Federal or State laws related to the distribution or dispensing of controlled substances. See 21 U.S.C. 823(f)(3); see also 21 U.S.C. 824(a)(2) (authorizing revocation where registrant “has been convicted of felony under this subchapter”). However, in light of the substantial misconduct proved on this record, it is unnecessary to determine whether the term “conviction” as used in factor 3 and section 304(a)(2) means a judgment of conviction or simply a finding of guilty which precedes the entry of a final judgment of conviction. See *Deal v. United States*, 508 U.S. 129, 131 (1993). I therefore make no findings on this factor.

Notwithstanding the Order (as well as that of the District Court following the jury verdicts which allowed him to remain free on bond on the condition that he not administer any drugs either to himself or others), in July 2010, Respondent proceeded to possess midazolam, a schedule IV controlled substance, and he admitted to administering the drug to a patient. While Respondent claimed that he had administered the midazolam under the supervision of another physician, the latter physician stated that he had not authorized Respondent to administer any controlled substances.

The next day, Investigators received a report from a clinic employee that boxes containing midazolam had been tampered with. Later that day, Investigators went to the clinic and determined that forty vials of midazolam were missing; thereafter, Respondent entered the clinic and had in his possession thirty-six vials which had contained the drug.¹¹ This evidence supports the conclusion that Respondent possessed these additional amounts of midazolam in violation of the Immediate Suspension Order.

Respondent's violation of the Order (as well as the conditions imposed by the District Court) is egregious and demonstrates that he has no respect for the laws governing the distribution and dispensing of controlled substances and the authority of this Agency and the Courts. This factor buttresses the conclusion that Respondent has committed acts which render his registration inconsistent with the public interest and that his registration should be revoked. For the same reason which led me to order the immediate suspension of his registration, I conclude that this Order should be effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, AP1892822, issued to Roger A. Pellmann, M.D., be, and it hereby is, revoked. I further order that any application of Roger A. Pellmann, M.D., to renew or modify his registration be, and it hereby is, denied. This order is effective immediately.

Dated: March 22, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-7411 Filed 3-29-11; 8:45 am]

BILLING CODE 4410-09-P

¹¹ To make clear, Respondent did not have a prescription for midazolam.

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the "Report on Current Employment Statistics." A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before May 31, 2011.

ADDRESSES: Send comments to Carol Rowan, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue, NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202-691-5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Carol Rowan, BLS Clearance Officer, 202-691-7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Current Employment Statistics (CES) program provides current monthly statistics on employment, hours, and earnings, by industry and geography. CES estimates are among the most visible and widely-used Principal Federal Economic Indicators (PFEIs). CES data are also among the timeliest of the PFEIs, with their release each month by BLS in the *Employment Situation*, typically on the first Friday of each month. The statistics are fundamental inputs in economic decision processes

at all levels of government, private enterprise, and organized labor.

The CES monthly estimates of employment, hours, and earnings are based on a sample of U.S. nonagricultural establishments. Information is derived from approximately 290,600 reports (from a sample of 140,000 employers with State Unemployment Insurance (UI) accounts comprised of 440,000 individual worksites), as of January 2011. Each month, firms report their employment, payroll, and hours on forms identified as the BLS-790. The sample is collected under a probability based design. Puerto Rico and the Virgin Islands collect an additional 5,600 reports using a quota sample.

A list of all form types currently used appears in the table below. Respondents receive variations of the basic collection forms, depending on their industry.

The CES program is a voluntary program under Federal statute. Reporting to the State agencies is voluntary in all but four States (Oregon, Washington, North Carolina, South Carolina), Puerto Rico, and the Virgin Islands. To our knowledge, the States that do have mandatory reporting rarely exercise their authority. The collection form's confidentiality statement cites the Confidential Information Protection and Statistical Efficiency Act of 2002 and mentions the State mandatory reporting authority.

II. Current Action

Office of Management and Budget clearance is being sought for the Report on Current Employment Statistics.

Automated data collection methods are now used for most of the CES sample. Approximately 131,200 reports are received through Electronic Data Interchange as of January 2011. Web data collection accounts for 58,900 reports. Computer Assisted Telephone Interviewing is used to collect 62,000. Fax is also a significant collection mode, as 15,300 reports are collected via this method. Touchtone Data Entry is used for 10,900 reports. In comparison, only 5,700 reports are collected by mail.

The balance of the sample is collected through other automated methods including submission of tapes, diskettes, and email.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including