By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–11843 Filed 5–27–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Two Amendments to Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'')

Consistent with Section 122(d) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9622(d), and 28 CFR 50.7, notice is hereby given that on May 20, 2008, the United States lodged two amendments to the Consent Decree approved by the Court on February 23, 2001 in *United States of America* v. *Abex Aerospace Division, et al,* Civil No. 00-cv-012471 TJH(JWJx) (USDC C.D. Cal.). The original Consent Decree resolved the liability of certain defendants for the ''Phase 1a Area'' of the Site under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA''), 42 U.S.C. 9606 and 9607, as amended, and Section 7003 of the Resource Conservation and Recovery Act, 42 U.S.C. 6973, as alleged in the Complaint filed in this matter.

The First Amendment primarily amends the Statement of Work under the original Consent Decree to add certain response activities necessary to address indoor air contamination observed at an indoor roller skating rink located adjacent to the Omega Chemical Corporation Superfund Site, listed on the National Priorities List on January 19, 1999, 64 FR 2950 (''Site''). The Second Amendment adds additional Settling Work Defendants, and Settling Cash Defendants to those covered by the original Consent Decree, as amended. The Second Amendment also incorporates additional volume and related payments of certain original Settling Cash Defendants, and corrects certain omissions and typographical errors in the caption. The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree Amendments. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–06529.

The Consent Decree Amendments may be examined at U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105 (contact Stephen Berninger, Esq. (415) 972–3909). During the public comment period, the Consent Decree Amendments may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please refer to *United States of America* v. *Abex Aerospace Division, et al,* Civil No. 00-cv-012471 TJH(JWJx) (USDC C.D. Cal.) (DOJ Ref. No. 90–11–3–06529), and enclose a check in the amount of $57.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–11846 Filed 5–27–08; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[No. 06–45]

Paul H. Volkman; Denial of Application

On February 10, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Paul H. Volkman, M.D. (Respondent), of Chillicothe, Ohio. The Order immediately suspended Respondent's DEA Certificate of Registration, AV6952837, as a practitioner, on the grounds that his continued registration during the pendency of the proceeding ''would constitute an imminent danger to public health and safety because of the substantial likelihood that [he] will continue to divert controlled substances to persons who will abuse these products.'' *Id.* at 12.

More specifically, the Show Cause Order alleged that in twelve instances, Respondent had prescribed multiple controlled substances to persons who, within days, died of overdoses of the drugs. *Id.* at 9–11. The Show Cause Order further alleged that Respondent had issued prescriptions to these persons for multiple controlled substances including opiates in schedule II (oxycodone) and/or schedule III (hydrocodone); schedule IV benzodiazepines such as diazepam and valium; and carisoprodol, a non-controlled drug which is nonetheless highly abused. *Id.; see also id.* at 3. Relatedly, the Order alleged that in July 2005, the assistant coroner for the county in which Respondent was practicing, had notified DEA ''that his staff [had] observed an increase in emergency room overdoses and believed that several recent drug-related deaths involving young [and] otherwise healthy individuals could be attributed to the consumption of large amounts of oxycodone, hydrocodone and alprazolam,'' which Respondent had dispensed. *Id.* at 8.

The Show Cause Order also alleged that DEA had received information from various distributors that Respondent was ordering excessive quantities of controlled substances. *Id.* Relatedly, the Show Cause Order alleged that during 2004, Respondent was the largest practitioner-purchaser of oxycodone in the country having purchased 438,000 dosage units, when the average amount of this drug purchased by other physicians ''was only 4,792 dosage units.'' *Id.* at 2.

The Show Cause Order further alleged that DEA investigators interviewed several of Respondent's patients who informed them that Respondent had prescribed controlled substances without performing physical examinations, that the clinic charged between $160 and $200 for an office visit, and that the clinic required that the patients pay cash and would not accept third-party payments from insurers, Medicare, Medicaid or worker's compensation. *Id.* at 4.

The Show Cause Order also alleged that on various dates, confidential sources had visited the clinic, and that Respondent had issued these persons prescriptions for controlled substances without performing physical examinations and other medical tests. *Id.* at 5. The Show Cause Order specifically alleged that on two occasions, the confidential sources had told the clinic's employees that their pain levels were ''one or two'' and ''zero'' on a scale of one-to-ten (with the latter being the most severe); that upon Respondent's asking them how they felt, the sources had told him ''fair'' and ''pretty good''; and that Respondent,

without performing a physical exam on either person, immediately issued to each of them, prescriptions for 180 tablets of hydrocodone/acetaminophen 10/650 mg., 90 tablets of diazepam 10 mg., and 60 tablets of carisoprodol. *Id.* at 5–6. Both sources then allegedly filled the prescriptions at Respondent's clinic for an additional charge. *Id.* at 6.

The Show Cause Order further alleged that in May 2005, DEA investigators received information from another confidential source who acknowledged his/her involvement in diverting controlled substances. *Id.* The source allegedly identified Respondent as a physician who would write prescriptions for Oxycontin and other controlled substances without performing a physical examination; the source allegedly stated that he and a friend had obtained from Respondent prescriptions for drugs which they then sold on the street. *Id.*

Next, the Show Cause Order alleged that in July 2005, DEA investigators conducted an accountability audit of the controlled substances which were ordered under Respondent's registration by the clinic where he worked. *Id.* at 7. The investigators allegedly found that Respondent did not maintain dispensing records in violation of Federal regulations. *Id.* Moreover, Respondent allegedly ''could not account for more than 850,000 dosage units of controlled substances that were ordered and dispensed under [his] DEA registration.'' *Id.* The Order specifically alleged that Respondent was short nearly 89,000 dosage units of alprazolam 2 mg., nearly 48,000 dosage units of diazepam 10 mg., 77,000 dosage units of hydrocodone/apap [1] (10/500 mg.), and more than 126,000 dosage units of hydrocodone/apap 10/650. *Id.* With respect to drugs containing oxycodone, the Order alleged, *inter alia,* that Respondent was short more than 49,000 dosage units of oxycodone 5 mg., 48,506 dosage units of oxycodone/apap (5/325 mg.), 165,500 dosage units of Roxicodone 15 mg., and 130,000 dosage units of Roxicodone 30 mg. *Id.* at 7–8.

Respondent requested a hearing on the allegations, and the matter was assigned to Administrative Law Judge (ALJ) Gail Randall. Following various extensions which both parties sought, as well as pre-hearing procedures,[2] a hearing was held in Columbus, Ohio on December 5–8, 2006, and January 9–10, 2007. At the hearing, both parties submitted documentary evidence and presented the testimony of witnesses.

Following the hearing, the Government submitted a brief containing its proposed findings, conclusions of law, and recommendations. Respondent chose not to submit a post-hearing brief and instead filed a petition for review with the Sixth Circuit.

On June 20, 2007, the ALJ issued her recommended decision (hereinafter cited as ALJ). In her decision, the ALJ found that ''[t]he record contains abundant evidence to demonstrate that the Respondent did not issue prescriptions 'in the usual course of his professional practice,''' and that he ''failed to limit his prescribing of controlled substances to cases where such medication would be provided for a legitimate medical purpose.'' ALJ at 39–40 (citation omitted). More specifically, the ALJ concluded that ''without adequate physical examinations and development of medical histories, the Respondent failed to adequately diagnose the patients,'' and yet ''prescribed controlled substances even when interacting with a patient for the first time.'' *Id.* at 40.

The ALJ further noted that ''Respondent prescribed the same combinations of controlled substances to a majority of his patients, again without adequate examinations or ongoing diagnoses,'' and that ''[t]his combination of drugs was common in the drug-abuse community'' and was known as ''a cocktail or the trifecta.'' *Id.* (int. quotation and citations omitted). Finally, the ALJ noted that ''Respondent treated at least sixteen patients between June of 2003 and February of 2006 who died of drug-related causes,'' and that ''Respondent's lack of adequate monitoring of these patients directly contributed to [their] deaths.'' *Id.* at 41.

The ALJ further noted that Respondent was dispensing controlled substances ''obtained through the use of [his] DEA registration,'' *id.,* and yet failed to maintain the required inventory and dispensing records and ''to adequately supervise the individuals to whom he had delegated such dispensing responsibilities.'' *Id.* at 43. Moreover, Respondent ''was unable to account for over one million tablets of controlled substances.'' *Id.* at 42. Finally, the ALJ noted that Respondent had failed to accept responsibility for his conduct. *Id.* at 44.

The ALJ thus concluded that the Government had established a prima facie case that Respondent's continued registration would be inconsistent with the public interest. *Id.* at 45. Because Respondent had failed to ''justify his past conduct'' and ''to provide adequate assurances that his future handling of controlled substances would meet the standards required of a DEA registrant,'' the ALJ recommended that I revoke his registration and deny his pending applications to renew and modify his registration. *Id.*

Respondent filed exceptions to the ALJ's decision raising numerous issues, and the Government filed a response. More specifically, Respondent contends that the Government failed to provide adequate notice and thus violated his rights under the Due Process Clause because it expanded its presentation beyond the allegations of the Show Cause Order, Exceptions at 4–10; that the proceeding violated his First Amendment rights because the ALJ failed to exclude an e-mail which the Government introduced into evidence in which Respondent portrayed the Agency, the ALJ, and the prosecuting attorney in a ''not flattering'' manner, *id.* at 10–11; that the Agency was unlawfully regulating the practice of medicine, *id.* at 11–12; that the ALJ failed to consider his evidence; and that records which he subpoenaed were not turned over to him.[3]

Having considered the record as a whole, I reject each of Respondent's exceptions. While I do not adopt all of the ALJ's factual findings, I adopt the ALJ's conclusions of law that Respondent repeatedly dispensed controlled substances outside of the usual course of professional practice and without a legitimate medical purpose. I also adopt her conclusions with respect to Respondent's failure to maintain proper records and properly supervise clinic employees, as well as his inability to account for large quantities of controlled substances. Finally, I adopt the ALJ's conclusion that the Government has established its prima *facie case* that Respondent's registration is inconsistent with the public interest and that Respondent has not demonstrated that he can be entrusted with a registration.

As explained below, Respondent did not file a timely renewal application in accordance with agency rules, and therefore, there is no existing registration to revoke or modify. Respondent did, however, apply for a registration; that application will be denied. I make the following findings.

[1] Apap is the abbreviation for acetaminophen.

[2] While Respondent requested an expedited hearing, on March 17, 2006, his first counsel withdrew. ALJ at 2. While on May 2, 2006, a new counsel entered an appearance on Respondent's behalf, on October 10, 2006, a third counsel entered a notice of appearance. *Id.*

[3] To the extent that Respondent's exceptions are based on the ALJ's weighing of the evidence or alleged failure to consider certain evidence, the ALJ's decision is only a recommendation. *See* 21 CFR 1316.65(a). As ultimate factfinder, I have carefully considered the entire record including the ALJ's report and Respondent's exceptions.

Findings

Respondent formerly held DEA Certificate of Registration, AV6952837, which authorized him to dispense controlled substances in schedules II through V, and which expired on May 31, 2006. GX 1. Between April 16, 2003, and November 18, 2003, Respondent's registered location was Tri-State Health Care (hereinafter, Tri-State), 1200 Gay Street, Portsmouth, Ohio. GX 2. Between November 19, 2003, and September 11, 2005, Respondent's registered location was 1219 Findlay St., Portsmouth, *id.,* which apparently was Tri-State's new location. GX 11, at 2 (inspection report of Ohio State Board of Pharmacy). Subsequently, Respondent left Tri-State, and on September 12, 2005, Respondent changed his registered location to 1310 Center St., Portsmouth. GX 2. On May 12, 2006, at which time his registration was suspended and which was less than forty-five days before the expiration of his registration, Respondent applied for a renewal of his registration and requested an address change to his home in Chicago, Illinois. *Id., see also* RX P at 1.

Respondent holds both an M.D. and Ph.D. from the University of Chicago and has practiced as an emergency room physician, as well as in family practice and pediatrics. *Id.* at 3. Respondent testified that in the course of his practice, he had two medical malpractice cases which his insurers settled without his consent and his admitting liability, and ''two cases [that] resulted in judgments against'' him. Tr. 1400. According to Respondent, by 2003, the awards and settlements totaled ''over a million-and-a-half dollars,'' and as a result, he was ''unable to obtain malpractice insurance.'' *Id.* As a consequence, Respondent ''could no longer work in emergency medicine, and * * * couldn't work for another clinic * * * because virtually every clinic that required hospital coverage of nighttime patients requires the doctor to have insurance.'' *Id.*

Respondent therefore needed to find a job which did not require malpractice insurance. *Id.* Searching on the internet, Respondent found a job posting for Tri-State Health Care in Portsmouth, Ohio. *Id.* at 1400–01. During discussions with Tri-State's owner, Ms. Denise Huffman, Respondent was told that he did not need malpractice insurance to work for her clinic. *Id.* at 1401. Respondent accepted the position, and in June 2003, he obtained board certification in pain management. *Id.* at 1402.

In April 2003, Respondent began working at Ms. Huffman's clinic under an ''informal handshake'' agreement which paid him $5000 a week to start; his pay was later raised to $5500. *Id.* at 1404. Ms. Huffman was not a licensed physician and was ''not any type of a health care professional'' even though she was running ''a pain clinic.'' *Id.* Respondent ''did not think'' to ask to see Ms. Huffman's licenses or verify her credentials. *Id.* at 1404. Respondent further maintained that he ''didn't know that I should have done'' that, and that he did not find out that he should have made these inquiries until being advised of this (''two years later'') by one of his attorneys. *Id.* In light of Respondent's thirty years of experience in the medical profession and his educational background, I find implausible Respondent's testimony regarding his failure to verify whether Ms. Huffman was properly licensed.

Ms. Huffman's daughter Alice was Tri-State's office manager. ALJ at 3–4 (stipulated findings). According to the report of Agent Kevin Kinneer of the Ohio State Board of Pharmacy, Alice Huffman was a ''former employee and patient of Dr. [David] Proctor,'' GX 12, at 4, a convicted drug dealer. Tr. 1014–15. Mr. Chad Ball, who was Alice Huffman's boyfriend (and subsequently became her husband), worked as a security guard at the clinic. Tr. 521, 530. Other employees included Chris Helton (who also worked as security guard) and Denise Huffman's nieces, Ms. Tara Bentley and Ms. Elizabeth Madden. *Id.* at 530. Respondent was the only licensed physician and DEA registrant at the clinic. *Id.* at 530–31.[4]

During an interview with a DEA diversion investigator (DI), Ms. Denise Huffman stated that Tri-State ''was a full cash business'' and did no ''third-party billing.'' *Id.* at 543. The DI further testified that Ms. Huffman stated that ''it would not be cost effective to have somebody file a medical insurance claim.'' *Id.* at 544.[5] Tri-State charged $200 for an office visit. *Id.* at 854–56.

Beginning in the summer of 2003, numerous pharmacies refused to fill Respondent's prescriptions. Tr. 1428–29. Accordingly, Respondent and Denise Huffman decided that they ''should institute a dispensary on-site'' so that they could provide pain medicines for their patients. *Id.* Respondent agreed that his registration could be used to order controlled substances, *id.* at 1550, and Tri-State proceeded to order large quantities of both oxycodone, a schedule II controlled substance, and combination hydrocodone/apap, a schedule III controlled substance. GX 10. For example, between August 18, 2003, and December 30, 2003, Tri-State ordered nearly 136,000 dosage units of oxycodone under Respondent's DEA registration. *Id.* at 140. During 2004, Tri-State ordered more than 457,000 dosage units of oxycodone under his registration. *Id.* at 143. Finally, between January 1, 2005, and September 2, 2005 (shortly before he left Tri-State), the clinic ordered more than 414,000 dosage units of oxycodone under his registration. *Id.* at 145. Respondent was the largest practitioner-purchaser of oxycodone in the nation during both 2004 and the first nine months of 2005. *Id.* at 5 & 28.

Moreover, Respondent's purchases of oxycodone dwarfed that of other Ohio-based practitioners. For example, during the last six months of 2003, Respondent purchased more than twenty-eight times the amount of oxycodone purchased by the second largest Ohio-based practitioner (4,800 dosage units); by contrast, the fourth through thirteenth largest purchasers bought only between 300 to 100 dosage units. *Id.* at 51.

In 2004, Respondent purchased nearly 110 times the amount of oxycodone purchased by the second largest Ohio-based practitioner (4,160 dosage units); by contrast, the third through tenth largest practitioners purchased between 3,228 and 400 dosage units. *Id.* at 29. Finally, in a little more than the first eight months of 2005, Respondent purchased approximately thirty-eight times the amount of oxycodone purchased by the second largest Ohio-based practitioner-purchaser; by contrast, the sixth through tenth largest practitioner-purchasers bought between 600 and 240 dosage units. *Id.* at 7.

With respect to hydrocodone, between July 24, 2003, and the end of that year, Respondent purchased 222,600 dosage units. *Id.* at 148. In 2004, Respondent purchased 263,500 dosage units, and in a little more than the first eight months of 2005, he purchased 168,500 dosage units of the drug. *Id.* at 150–52. Between 2003 and

[4] To clarify, the clinic did not hold a DEA registration.

[5] The record does, however, contain a document entitled ''UTILIZATION REVIEW—NOTICE OF DENIAL'' issued by Liberty Mutual Managed Care, Inc., which is addressed to Respondent at Tri-State's Findlay St. address. GX 65. This document stated that Liberty Mutual had performed a utilization review for the Kentucky Worker's Compensation program of a ''proposed treatment/service request'' for a patient named ''Paul Huffman,'' and determined that it did not meet ''nationally accepted practice protocols.'' *Id.* More specifically, the document noted that ''[t]he request for oxycodone 425 pills per month (fourteen/day) and Valium 125 pills per month (four/day) is not medically necessary or appropriate. The current narcotic situation is not beneficial in that the claimant is taking narcotics around the clock.'' *Id.*

2005, Respondent ranked between the eleventh to twenty-third largest purchaser nationwide of combination hydrocodone drugs, and was the largest Ohio-based practitioner-purchaser of combination hydrocodone drugs by a wide margin.[6] *Id.* at 72–73, 95–96, 118–20.

A DEA DI subsequently obtained a report of the prescriptions written by Respondent that were filled by Kentucky pharmacies during 2004 from the State of Kentucky's KASPER system.[7] Upon review of the data, the DI found that Respondent had prescribed three or more drugs per visit to 419 of his patients and that Respondent had issued three or more prescriptions per visit 1974 times. GX 71. The DI further found that 54 percent of Respondent's prescribing involved ''three or more prescriptions per visit,'' and that in 1065 separate instances, Respondent had prescribed four drugs including oxycodone, hydrocodone, a benzodiazepine, and carisoprodol. *Id.* at 2. The DI also found that during 2004, Kentucky pharmacies dispensed 647,440 dosage units of oxycodone and 537,691 dosage units of hydrocodone pursuant to Respondent's prescriptions. *Id.*

The Investigations of Respondent

As found above, in April 2003, Respondent commenced his employment at Tri-State. On April 17, 2003, one day after Respondent obtained his DEA registration at Tri-State's 1200 Gay Street location, Agent Kevin Kinneer of the Ohio State Board of Pharmacy received two reports from Portsmouth pharmacists regarding Respondent's prescribing practices. GX 12, at 1–2.

The first pharmacist reported that Respondent was ''writing large quantities of narcotics and benzodiazepines,'' and that his patients were presenting ''prescriptions for 180 to 300 tablets of Lorcet 10/650 mgs.,'' *id.*, a schedule III controlled substance containing hydrocodone and acetaminophen. ALJ at 5. The pharmacist further reported that some patients had ''two types of narcotic prescriptions,'' that the prescriptions were for a quantity beyond the ''manufacturer's suggested [daily] supply of Tylenol [acetaminophen] intake,'' and that ''[t]hese patients also had prescriptions [for] Xanax 2 mg. and a Soma [carisoprodol] prescription.'' *Id.* The pharmacist further reported that ''many of the patients are prior problem patients'' of a physician (Dr. Proctor),[8] who had been convicted of drug trafficking and is currently incarcerated. *Id.* at 1–2; Tr. 1015. According to the pharmacist, these persons ''had prior drug abuse problems'' including arrests on drug charges. GX 12, at 1–2. The pharmacist also told Agent Kinneer that ''he would not fill any of'' Respondent's prescriptions. *Id.* at 2.

The second pharmacist told Agent Kinneer that he had ''refused to fill prescriptions for high quantities of narcotics and Xanax 2mgs and Soma [that were] prescribed by'' Respondent. *Id.* The pharmacist further notified Agent Kinneer that Respondent was prescribing ''duplicate therapy of narcotics'' and large amounts of acetaminophen. *Id.*

Approximately two months later, another Portsmouth-area pharmacist informed Agent Kinneer of ''trouble with [Respondent's] patients.'' *Id.* More specifically, the pharmacist reported that on or about June 11, 2003, five persons came in a van to his pharmacy and that one of them ''smelled of beer and dope.'' *Id.* These persons all presented ''the same type of prescriptions'' and the pharmacist refused to fill them. *Id.*; Tr. 255–56.

One week later on June 18, 2003, Respondent telephoned Agent Kinneer and complained that local pharmacists were refusing to fill his prescriptions. Tr. 256. Respondent demanded that the Board order the pharmacists to fill his prescriptions. *Id.*; GX 12, at 3. Agent Kinneer told Respondent that he was not going to do so because the pharmacists had the right to exercise their own professional judgment in practicing pharmacy. GX 12, at 3; Tr. 256.

Throughout the summer of 2003, Agent Kinneer received further complaints from pharmacists about Respondent's prescribing practices. GX 12, at 3. These included that many of the patients were from Kentucky, West Virginia and Tennessee; that Respondent was writing prescriptions for multiple narcotics, Xanax 2 mg. and carisoprodol ''for the same patient [in] high quantities''; that the prescriptions were for drugs with ''a high abuse potential''; that ''[f]amily members within the same address [were] receiving the same type of controlled substance''; that ''many of the patients'' were known ''to be drug abusers''; and that some of the patients had ''large amounts of cash on their person.'' *Id.* Agent Kinneer also received information that Respondent had called pharmacists and demanded that they fill his prescriptions. *Id.* Moreover, between July and September 2003, pharmacists in Columbus and Cincinnati notified Agent Kinneer that persons were presenting prescriptions issued by Respondent. *Id.* at 5.

On July 22, 2003, Agent Kinneer (and another state agent) visited Tri-State to conduct an inspection pursuant to Respondent's obtaining of a clinic license, which under Ohio law, was required ''to obtain controlled substances to dispense out of [the] clinic.'' Tr. 244; *see also* GX 12, at 3. During the inspection, Alice Huffman told the agents that a bodyguard patrolled the parking area and monitored the waiting room.[9] GX 12, at 3–4. The agents observed the security arrangements, explained recordkeeping requirements, provided Respondent and Ms. Huffman with copies of the applicable federal and state laws and regulations, and gave Respondent the license. *Id.* at 4.

On December 30, 2003, Agent Kinneer and another agent went to Tri-State's new address at 1219 Findlay St. to conduct an inspection for a new license. *Id.* at 5. Agent Kinneer found numerous violations including incomplete dispensing logs for several controlled substances. GX 11, at 2. More specifically, the dispensing log for hydrocodone/apap 10/650 had not been completed since August 15, 2003. *Id.* Respondent had, however, ordered thousands of dosage units of this drug after August 15th. *See* GX 10, at 147–48. As for the other controlled substances the clinic was dispensing, Agent Kinneer found that the last entries for

[6] In the first nine months of 2005, Respondent purchased 11 times the amount of hydrocodone purchased by the second largest Ohio-based practitioner; in 2004, he purchased 11.7 times the amount purchased by the second largest Ohio-based practitioner; in the last six months of 2003, he purchased approximately 16.5 times the amount purchased by the second largest Ohio-based practitioner. *Id.* at 73–74, 96–97, 120–21.

[7] KASPER is the ''Kentucky All Scheduled Prescriptions Electronic Reporting'' program. GX 71. Under KASPER, pharmacies are required to periodically report to the State all scheduled-drug prescriptions that they dispense. Physicians are also able to access the database to determine whether their patients are obtaining controlled substances from other practitioners. GX 26, Tr. 1030.

These figures do not, however, include prescriptions issued by Respondent which were filled at pharmacies in Ohio and other States; nor do they include the prescriptions dispensed at Tri-State.

[8] The pharmacist also stated that these individuals were patients of another problem physician, Dr. Williams. GX 12, at 2. The testimony indicates that another area physician, Dr. Fortune Williams, was convicted of drug trafficking, but his conviction was overturned on appeal. Tr. 1016. It is unclear whether the pharmacist's reference to Dr. Williams was to this individual.

[9] It is unclear whether there were multiple bodyguards on the premises. During an inspection conducted on December 30, 2003, Agent Kinneer noted that there were two bodyguards at the clinic.

both Xanax 1 mg., and diazepam 10 mg., had been made on August 15, 2003.[10] GX 11, at 2. He also found that while the log for hydrocodone/apap 10/325 mg. had been started on August 11, 2003, the last entry was dated the following day. *Id.*

Agent Kinneer further found that numerous DEA 222 forms, which are required to order schedule II controlled substances, were not properly completed. *Id.* He observed that Alice Huffman, who was not a registered pharmacist, was dispensing drugs without obtaining Respondent's final approval. *Id.* at 3–5. He also found ''four vials of unmarked pills with unknown medications [in] the dispensing area.'' *Id.* at 6.

In his report, Agency Kinneer further stated that he ''found this clinic not to be your normal Doctor's Office.'' *Id.* In support of his conclusion, Agent Kinneer noted that there was a Glock handgun in the dispensing area, that there were two night sticks and a four-foot long club with leather straps, and that these were ''things that [he] normally would not see in a physician's office or a dispensing area.'' Tr. 259–60; GX 12, at 7. Agent Kinneer also noted that Respondent was treating both Denise and Alice Huffman, that he had prescribed narcotics for them, and that both appeared to be ''over medicated.'' GX 12, at 6. In his testimony, Agent Kinneer also related that he had received reports that ''there would be 20 to 30 cars lined up outside of [Respondent's] practice,'' and that people would be lined up waiting to enter the clinic. Tr. 260–61; *see also* Tr. 455–56 (testimony of Detective John Koch, Scioto County Sheriff's Office that he observed a ''large group of people outside the office,'' and that he had ''never seen that outside of a doctor's office, where groups of people would hang out'').

Agent Kinneer thus concluded that Respondent was running a ''prescription mill.'' *Id.* at 260. Nonetheless, on February 4, 2004, following receipt of a letter from Respondent which stated that Tri-State was ''now currently in compliance with all issues'' found at the inspection and that ''[a]ll log books are current and up to date and are being kept current,'' GX 11,[11] Agent Kinneer delivered a new license to Tri-State and obtained Respondent's dispensing records. GX 12, at 6. The same day, Agent Kinneer contacted three distributors (Cardinal, McKesson, and Moore Medical) to obtain copies of Respondent's purchases from them. GX 12, at 6–7.

The purchase records showed, *inter alia,* that between October 13, 2003, and January 12, 2004, Respondent had purchased 277,500 tablets of Roxicodone 30 mg., a schedule II controlled substance. GX 12, at 7. Moreover, between August 18, 2003, and January 6, 2004, Respondent purchased 65,700 tablets of oxycodone hcl 5 mg., and 59,000 tables of oxycodone/apap (5/325 mg.). *Id.*

The records also showed that between July 24, 2003, and October 21, 2003, Respondent purchased more than 57,000 dosage units of combination hydrocodone/apap drugs in 10/325 mg., 10/500 mg., and 10/650 mg. strengths.[12] *Id.* Furthermore, between various dates, he had purchased more than 32,600 dosage units of benzodiazepines including alprazolam in 1 mg. and .5 mg. strengths, and both diazepam and lorazepam in 10 mg. strength.[13] *Id.* at 7.

In late June 2003, a Diversion Investigator (DI) with DEA's Columbus, Ohio office received a phone call from a pharmacist in Kenova, Ohio. Tr. 472, 508, GX 6. The pharmacist inquired as to whether Respondent had an active DEA registration; he also told the DI that he was ''receiving numerous prescriptions for OxyContin and Percocet,'' as well as Lorcet, Xanax and Soma (carisoprodol), which Respondent had written. Tr. 472–73, 508. The pharmacist also stated that between June 1, 2003, and July 15, 2003, Respondent's ''prescriptions had tripled'' and that the prescriptions were for ''very large'' quantities. *Id.* at 473. The pharmacist further told the DI that the persons who were presenting prescriptions from Respondent ''were lining up outside'' of his pharmacy to get them filled. *Id.* at 507–08.

The DI further testified that she had received phone calls from numerous other pharmacies regarding Respondent's prescribing practices including pharmacies that were located in Northern Kentucky and Columbus, Ohio. *Id.* 476. The pharmacists reported that Respondent was prescribing ''very high quantities'' of OxyContin, Percocet, Lortab, Xanax, and Somas, and that the patients were paying cash for their drugs.[14]

The DI also received a phone call from a DI in Forth Worth, Texas, regarding a report from McKesson, a distributor, that Respondent had ordered large quantities of combination hydrocodone/apap. Tr. 482. More specifically, McKesson had reported that on August 7, 2003, Respondent ordered thirty 100-count bottles of combination hydrocodone/apap, and on August 15, 2003, he ordered forty 100-count bottles of the drug. *Id.* Moreover, on August 22, 2003, Respondent ordered twenty 100-count bottles of combination hydrocodone/apap, as well as twenty 100-count bottles of alprazolam. *Id.*; see also GX 15, at 3–5. Thereafter, the DI obtained copies of invoices documenting Respondent's purchases of controlled substances from McKesson and other distributors. GX 14–16.

In November 2003, the Columbus-based DI was contacted by another Portsmouth-based physician who informed her that ''there were numerous patients that were coming from [Respondent's] office'' who were seeking detoxification treatment. Tr. 483. The physician related that Respondent had put the patients on excessive amounts of opiates such as OxyContin, Percocet, and hydrocodone. *Id.* The physician also told the DI that Respondent was telling the patients to go to particular pharmacies to get their prescriptions filled.[15] *Id.* at 484.

[10] Both logs were started on July 30, 2003. GX 11, at 2.

[11] While the letter is dated January 19, 2003, it references the December 30, 2003 inspection report. *See* GX 11. I thus find that the letter was actually sent on January 19, 2004. As discussed below, during a search warrant which was executed on June 7, 2005, Tri-State did not have any logbooks for 2004. *See* Tr. 612.

[12] Respondent was also purchasing large quantities of combination hydrocodone/apap drugs from PD–RX Pharmaceuticals, Inc., during this period *See* GX 10, at 147–48.

[13] According to the testimony of a detective with the narcotics unit of the Scioto County Sheriff's Office, the illegal trafficking of prescriptions drugs is ''[t]he number one [drug] problem'' in the County. Tr. 444. The Detective further testified that oxycodone, which is the ''most abused'' drugs sells ''for between 30 and 40 dollars per pill'' of thirty milligram strength, that Xanax sells for ''between $5 and $12'' per pill depending upon its strength, and that combination hydrocodone drugs sell for ''between $7 to $15'' per pill. Id. at 450.

[14] The DI also received information from an FBI task force officer. Tr. 475. The officer told the DI that an informant had obtained a prescription from Respondent without the latter having performed an evaluation on him, and that Denise Huffman had filled the prescription for ''approximately $200.'' *Id.* The DI did not, however, testify as to what drug was involved. *See id.*

[15] The DI also testified that she had been informed that one of Respondent's ''patients'' had contacted DEA regarding her visit with Respondent. *Id.* The patient related that she had taken a friend with her to the clinic and had been ''scolded'' for doing so by Denise Huffman, the clinic owner, because ''she didn't like anybody coming with patients,'' *id.* at 486, and ''law enforcement was watching the building.'' *Id.* at 488. The patient further stated that Respondent had prescribed Soma and an analgesic even though he ''only saw her for a couple of minutes'' and had little interest in reviewing her x-ray. *Id.* at 485. Because of what was going on at the clinic, the patient decided to see another physician. *Id.* at 486. Respondent's office repeatedly refused to send her records to her new physician and the patient had to retain an attorney to obtain them. *Id.* at 486–87.

Thereafter, DEA investigators obtained records from various pharmacies pertaining to Respondent's prescriptions. *Id.* 489; see also GX 18–20, 22–25. A DI also obtained from the State of Kentucky the previously mentioned KASPER report. *See* GX 26. Moreover, in April-May 2005, the Agency also obtained records pertaining to Respondent's purchases from four distributors (PD–RX Pharmaceuticals, Cardinal, McKesson, and Moore Medical). *See* GX 29.

On June 7, 2005, DEA investigators executed a search warrant at the Tri-State facility and seized the controlled substances that were on the premises, patient records, invoices, DEA Form 222s, and financial records.[16] Tr. 541, 696–97. One of the DIs interviewed Denise Huffman, Tri-State's owner. Denise Huffman told the DI that based on what Respondent ''told her to order,'' she would order the controlled substances from the distributors. *Id.* at 543. Ms. Huffman also stated that the clinic did not do third-party billing and was a ''full cash business.'' *Id.* Ms. Huffman further related that her daughter Alice and Respondent ''were in complete control of the dispensing center.'' *Id.* at 545.

The DI also interviewed Alice Huffman, who confirmed that Tri-State ''was a cash only business'' with ''no third-party billing.'' *Id.* at 544. Alice Huffman admitted that she filled ''all the prescriptions and was supposed to keep the records,'' including the dispensing records, but did not. *Id.* Alice Huffman further stated that ''she wasn't sure'' if there were any inventories and ''didn't know if they'' would be accurate if there were any. *Id.* at 545. When asked by the DI whether she was aware of whether any of Tri-State's patients had overdosed, Huffman gave the names of two persons ''that she believed had overdosed on prescriptions that were written from the clinic.''[17] *Id.*

The same day, DEA investigators attempted to interview Respondent at his residence, but he declined. *Id.* at 691. Later that day, Respondent arrived at the clinic and he eventually agreed to an interview. *Id.* at 692. Regarding the interview, the DI testified that Respondent ''declined to talk'' when asked about the deaths of Tri-State's patients. *Id.* at 694. Respondent further maintained that he was an independent contractor and serving as a ''loc[um] ten[ens]'' practitioner[18] who had found his position on the internet. *Id.* at 695. Respondent could not, however, ''recall what company * * * he was a loc[um] ten[ens] for,'' *id.,* and, of course, had been working at Tri-State for more than two years at that point.

Moving on to other subjects, Respondent stated that the clinic did not have a physical therapist on its staff and he was not sure whether the clinic even had a nurse. *Id.* at 695. Respondent also told the DI that he ''rarely recommend[ed] people to other physicians'' and that ''for the most part,'' he did not associate with other area physicians. *Id.* at 695–96.

On the same day that the warrant was executed, DEA investigators attempted to conduct an accountability audit. *Id.* at 546. The investigators inventoried all of the controlled substances that were being seized. *Id.* at 613–14. Consistent with Alice Huffman's testimony, the DIs did not find either any initial or biannual inventories as required by Federal regulations. *Id.* at 615. Nor were there any dispensing logs for the year 2004. *Id.* at 612.

Using records subsequently obtained from various distributors, the DI was able to determine the amounts of the various controlled substances Respondent purchased during the audit period and concluded that there were substantial shortages of the drugs. *Id.* at 615. These records also showed that Respondent had ordered large quantities of alprazolam (2 mg.) and diazepam (10 mg.), hydromorphone (4 mg.), and both oxycodone and combination hydrocodone in various strengths. GX 30.

I find it unnecessary to make findings regarding the actual amounts of the shortages.[19] Instead, I find that Respondent authorized the ordering of large quantities of numerous controlled substances, and that the disposition of these drugs cannot be adequately accounted for because Respondent failed to maintain accurate records.

On September 9, 2005, Respondent's relationship with Tri-State ended. *Id.* at 1433–34. Respondent initially saw patients at his apartment in Portsmouth. *Id.* at 1434–35. Regarding his activities at this location, a DEA Investigator testified that he had interviewed the friend (DC) of one of Respondent's deceased patients (M.R.). Tr. 761. DC told the investigator that he and M.R. ''knew that [Respondent] was writing prescriptions without any type of medical examination.'' *Id.* Accordingly, they decided to see Respondent (at his Center St., Portsmouth) address to obtain drugs that they could sell on the street. *Id.*

DC related that upon his arrival at Respondent's office, he encountered a former girlfriend who was now working for Respondent. *Id.* at 762. After filling out various forms, the ex-girlfriend asked DC what he was taking. *Id.* DC asked her: ''what is he writing?'' *Id.* She then wrote out ''prescriptions for oxycodone, a hydrocodone product, and Xanax.'' *Id.*

DC further related that Respondent did not physically examine him. Respondent signed the prescriptions and engaged in small talk with DC before Respondent left the exam room. *Id.* at 763–64.

On October 4, 2005, the Portsmouth Police Department executed a warrant at Respondent's apartment and seized various items including patient files.[20] *Id.* at 1436–37. The Chief of Police also issued a condemnation notice, which in Respondent's words, ordered him ''to immediately vacate the premises.'' *Id.* at 1437.

Approximately a week later, Respondent relocated to Chillicothe, Ohio. *Id.* at 1437–38. On February 6, 2006, DEA investigators obtained a warrant to search Respondent's Chillicothe office. GX 78. On February 10, 2006, the warrant was executed and additional patient files were seized. GX 73.

A DI subsequently reviewed the 1258 patient files that were seized during both the June 2005 search of Tri-State and the February 2006 search of Respondent's Chillicothe office. *Id.* Most significantly, the DI determined

[16] ''To accommodate'' Respondent, the investigators made copies of the medical records and provided them to the clinic before ''the summer ended.'' Tr. 697.

[17] The circumstances surrounding the overdose of one of these persons (K.R.) is discussed below.

[18] As commonly understood, the term ''locum tenens'' means ''one filling an office for a time or temporarily taking the place of another.'' *Webster's Collegiate Dictionary* 684 (10th ed. 1998).

[19] Because Tri-State had no inventories, the DI used the starting figure of ''0'' for each drug. Under the heading for the closing inventory, the audit chart stated ''as of 12–31–04.'' GX 30. The DI testified, however, that the actual inventory was taken on June 7, 2005. Tr. 613. The record does not establish how the DI arrived at the inventory figures for December 31, 2004.

There was also testimony that during the search, Denise Huffman stated that the dispensing logs ''were probably at her house.'' Tr. 669. Eventually, Ms. Huffman produced logbooks for 2005; Ms. Huffman admitted, however, that there were no records for 2004. *Id.* at 670. The DI further testified that the logbooks were provided only after the Government provided copies of the patient files subsequent to the search. *Id.* at 674–75. The logbooks ''were brand new,'' and appeared to have been newly created based on the copies of the medical records. *Id.*

[20] Respondent testified that the seizure occurred because the police ''were bigger than I was, and they decided that they were going to come in and do that.'' Tr. 1436. He also maintained that the ''search warrant * * * contained a lot of frankly irrelevant materials.'' *Id.* Respondent did not, however, produce any evidence that a court had quashed the warrant.

that 900 of the patient files lacked documentation that Respondent had performed a physical examination on the patient. *Id.*

During the course of the investigation, DEA investigators received information from various sources including family members, friends, emergency room physicians, and various coroners indicating that sixteen persons had died of drug overdoses shortly after seeing Respondent. Tr. 617–20; *see also* GXs 32–60. For example, the widow of J.R. testified that her husband had obtained prescriptions from Respondent for Oxycontin, oxycodone, hydrocodone, valium, and Soma, and was receiving as many as 622 pills per month. Tr. 40, 42–43. At one point J.R. attempted to commit suicide and was hospitalized; J.R., however, was released. *Id.* at 81–82. On November 18, 2003, J.R. visited Respondent. Id. at 53; GX 61.

On the morning of November 20, 2003, J.R. was found dead in the bathroom. Tr. 52. According to the Deputy Coroner's report, there were four pill bottles on the bathroom sink: two bottles were labeled as containing oxycodone (Rx'd on 10/3/03 and 10/20/03) although both were found empty; one contained 12 tablets of diazepam out of the original 90 count which was prescribed on 11/18/03; and one bottle contained three methadone tablets. See GX 60, at 4. Respondent was listed as the prescriber on the two oxycodone and the diazepam bottles. *Id.* No prescriber was listed on the bottle which contained methadone. Id.

The coroner found that the immediate cause of J.R.'s death was an ''overdose'' due to multiple drug intoxication. GX 60, at 1. *See* also GX 59. According to J.R.'s widow, her husband was addicted to drugs. Tr. 33, 45. She also testified that her husband was selling some of his drugs to pay for his visits with Respondent. *Id.* at 64. According to her testimony, her husband had told her that Respondent ''was trying to give him [S]omas also and to take them, and that [Respondent] said if he didn't take them to sell them.'' *Id.* at 42.

J.R.'s step-daughter corroborated this testimony. More specifically, she testified that her step-father had ''said that I could get more if I wanted. [Respondent] offered me [S]omas, and I told him that I was allergic to them, and he [Respondent] said sell them, trade them, whatever you need to do.'' [21] *Id.* at 104.

During the June 2005 search of Tri-State, DEA investigators ''could not find [J.R.'s] medical chart.'' *Id.* at 706; see also id. at 709. The investigators did, however, find a ''sign-in sheet'' which indicated that J.R. had visited Respondent on November 18, 2003, two days before his death. *Id.*; see also GX 61.

DEA did, however, obtain the medical charts of six ''patients'' who died while under Respondent's care and provided these to L. Douglas Kennedy, M.D., for his review. GX 74. Dr. Kennedy holds medical licenses in Kentucky, Ohio, and Florida, and board certifications in anesthesiology and pain medicine. GX 63, at 9. He has been a fellow in pain medicine at the Cleveland Clinic Foundation, served as an assistant professor of anesthesiology and director of the chronic pain management program at the University of Kentucky Medical Center, and has approximately fifteen years experience as the medical director of a pain management practice. GX 63, at 1–2. Dr. Kennedy has also lectured on pain management at numerous symposia and conferences. *Id.* at 3–7. Dr. Kennedy was qualified as an expert witness in the standard of care in pain management and the prescribing of controlled substances for the treatment of chronic pain. Tr. at 1021–22.

Dr. Kennedy specifically reviewed records including Respondent's patient files for six individuals (M.C., S.H., S.J., C.J., D.P, and K.R.). GX 74, at 1–5; *see also* Tr. 1084–89. He also ''reviewed past or concurrent medical records present on [Respondent's] 'patient' charts from other physicians [and]/or medical facilities,'' police reports, as well as death certificates, autopsy, coroner's, and post-mortem toxicology reports. GX 74, at 1. In his report, Dr. Kennedy further stated that he had reviewed, and was ''generally familiar with, regulations including Ohio Administrative Code, Chapter 4731–21 on Intractable Pain,'' the Federation of State Medical Board's Model Policy for the Use of Controlled Substances for the Treatment of Pain, and ''other applicable standards and guidelines with respect to pain management and the prescription of controlled substances for same.'' *Id.* at 2.[22]

Dr. Kennedy specifically noted that the drugs Respondent prescribed ''were present in the Toxicology Testing post-mortem and were the primary (in some cases the only) cause of death.'' [23] *Id.* at

[21] While Soma (carisoprodol) is a prescription drug, it is not a controlled substance. It is, however, a highly abused drug which metabolizes into meprobamate, a schedule IV depressant. *See* 21 CFR 1308.14(c); ALJ Ex. 11, at 4; Tr. 934 (testimony of Dr. Wheeler). Respondent's statements to J.R. to sell or trade the drug are nonetheless relevant to show his knowledge and intent.

[22] While much of the cross-examination of Dr. Kennedy focused on his reliance on the Kentucky guidelines, in both his report and testimony, Dr. Kennedy made clear that he had also reviewed the Ohio Administrative Code. *See* Tr. 1198–1203. When Dr. Kennedy offered to explain why Respondent also violated the Ohio regulations, Respondent's counsel declined to pursue this line of questioning. *Id.* at 1202–03.

[23] With respect to patient M.C., the record establishes that she saw Respondent on January 8, 2004, and died on January 10, 2004, at the age of 32. GX 84, at 6–7; GX 44. During the January 8 visit, Respondent issued her three prescriptions: one for 300 tablets of Norco (hydrocodone/apap 10/325); one for 60 tablets of oxycodone 30 mg.; and one for 120 tablets of Xanax 2 mg. GX 84, at 6–7. The coroner concluded that M.C. died from ''intoxication'' caused ''by the combined effects of oxycodone and hydrocodone.'' GX 42 & 44.

With respect to patient S.H., the record establishes that he saw Respondent on April 19, 2005, and died the next morning at the age of 33. GX 84, at 12–14; GX 38, at 3. During the April 19 visit, Respondent issued him prescriptions for 360 tablets of oxycodone (15 mg.) with an instruction to take 12 per day; 120 tablets of Valium (10 mg.); 30 tablets of Xanax (2 mg.), and another drug Carafate, which is not controlled. GX 84, at 12–13. Respondent also issued an RX for an MRI during this visit. The coroner concluded that S.H. overdosed and died of the ''acute combined effects of oxycodone, diazepam, and alprazolam.'' GX 38, at 1.

With respect to S.J., the record establishes that she saw Respondent on both September 16 and September 29, 2005. On September 16, Respondent prescribed to her 270 tablets of oxycodone 30 mg.; 270 tablets of Percocet 5/325 (oxycodone/apap); 60 tables of Xanax (2 mg.), and 120 tablets of Soma (350) even though her pain was indicated as being ''2/10.'' GX 84, at 21–24. On September 26, 2005, Respondent prescribed to S.J. an additional 135 tablets of both Percocet 5/325 and oxycodone 30. *Id.* at 25–26. The form documenting the 9/26/05 visit does not contain any indication of a medical complaint and the entry for ''Pain: Location, Description, Duration'' is blank. *Id.* at 26. S.J. died September 30, 2005; the coroner concluded that the cause of death was ''[m]ultiple drug intoxication, with acute bronchopneumonia contributing.'' GX 55, at 2. The coroner further noted that S.J., who was 30 years old, had ingested oxycodone, alprazolam, cocaine and diphenhydramine. *Id.* at 2–3.

With respect to K.R., the record establishes that on March 8, 2004, Respondent gave her two separate prescriptions for 90 tablets of oxycodone 30 mg., a prescription for 180 tablets of Lorcet 10/650 (hydrocodone/apap), and a prescription for 120 Xanax (2 mg.). GX 84, at 10. The progress note for the visit suggests that Respondent also gave her a prescription for Soma 350. *Id.* at 11. K.R, who was 39 years old, died the following day of a drug overdose. GX 51, at 2. The toxicology report indicates that oxycodone, benzodiazepines, and carisoprodol /meprobamate were present. *Id.* at 3.

Dr. Kennedy specifically noted that Respondent had ''essentially doubled'' K.R.'s medication ''the day before she died,'' and that he saw ''no indication for her being on the medicines in the first place, let alone [Respondent's] doubling them.'' Tr. 1090.

With respect to C.J., the record establishes that on October 16, 2003, Respondent gave him prescriptions for 120 tablets of oxycodone 30 mg., 180 tablets of Percocet 10/650 (oxycodone/apap); 180 Xanax 2 mg., and 90 Soma 350 mg. GX 84, at 3–5. The progress note indicated that C.J.'s pain level was 5–6/10, and his spasms were 0/10. *Id.* at 5. C.J. died five days later; the coroner determined that the cause of his death was ''acute opioid (oxycodone) toxicity.''

With respect to D.P., the record establishes that on August 11, 2004, Respondent issued to him prescriptions for 300 tablets of oxycodone 30 mg.,

4. He further found that Respondent ''practiced 'polypharmacy[,]' prescribing multiple controlled substances at the same time.'' *Id.* at 5. Relatedly, Dr. Kennedy observed that Respondent ''averaged 3.8 controlled substance prescriptions for each 'patient' visit,'' and that ''[t]his increased the likelihood of sedation, respiratory depression and death.'' *Id.* He also noted that ''[d]eath occurred on average * * * [three] days after the last visit with [Respondent] [with] some [occurring] the next day.'' *Id.*

Dr. Kennedy further described Respondent's practices as ''prescrib[ing] drug 'cocktails' * * * often including an opioid[] (often 2–3 types), a benzodiazepine, and Soma.'' *Id.* at 3. According to Dr. Kennedy, Respondent's prescribing practices ''greatly increased the chance for drug abuse, diversion, [and]/or addiction.'' *Id.*

Moreover, based upon his review of the ''patient charts'' (which is more fully set forth in GX 82), Dr. Kennedy found that Respondent ''did not establish a doctor-patient relationship on initial visits, and did not establish or maintain such a relationship on followup visits.'' GX 74, at 3. Relatedly, Dr. Kennedy noted that ''[t]here was inadequate or no history [and] physical examination,'' that ''[t]here was seldom any diagnostic testing or past medical record present,'' and that ''[w]here there was, [Respondent] did not rely upon it for medical decision making.'' *Id.* at 4.

Dr. Kennedy also observed ''[t]here existed no plan to diagnose or treat the person's problem(s),'' and that ''[t]he 'plan of care' was essentially the same for every person: drugs (predominately controlled substances), for which no medical necessity was established.'' *Id.* Moreover, once Respondent began his '' 'plan of care' * * * [he] continued [it] with no reassessment as to effect, success, or ill effects.'' *Id.* Relatedly, Dr. Kennedy found that Respondent ''did not regularly and consistently address pain complaints with other methods, for example, nonprescription drugs, non-controlled substance prescription drugs, physical therapy or behavioral medicine consultation, before resorting to controlled substance prescriptions.'' *Id.* at 3.

Dr. Kennedy also concluded that Respondent ''ignored and failed to obtain necessary testing and consultations (with Behavioral Medicine, Psychiatry, or Addiction Medicine) that would have identified and then allowed treatment for abuse and addiction as well as identifying those persons who may have been diverting the drugs.'' *Id.* at 5. More specifically, Dr. Kennedy found that Respondent ''rarely tested, checked for, or heeded signs of addiction (he rarely performed in office urinary drug screens). When he did perform in office urinary drug screens, the tests were inadequate.'' [24] *Id.* at 3. As Dr. Kennedy explained, if a test does not pick up a drug that a physician has prescribed, it raises the possibility that the ''person could have been selling those drugs.'' Tr. 1091. Dr. Kennedy further noted that Respondent ''prescribed and continued to prescribe controlled substances to persons who exhibited behavior consistent with possible drug abuse, addiction [and]/or diversion.'' *Id.* at 3.

Dr. Kennedy thus concluded that Respondent ''did not establish'' a bona-fide doctor patient relationship or ''any relationship adequate for prescribing controlled substances on the [patient's] initial visit'' or ''on subsequent visits.'' *Id.* at 4. Most significantly, he concluded that Respondent ''knowingly and intentionally distribute[d] prescriptions for oxycodone and other controlled substances not for a legitimate medical purpose and beyond the bounds of medical practice.'' *Id.* Finally, Dr. Kennedy concluded that Respondent's ''distribution of multiple and regular controlled substances resulted in the death'' of ''all [six]'' patients whose records he examined, and that ''each one of these [six] deaths was preventable.'' *Id.* at 4–5.[25]

360 tablets of hydrocodone/apap (10/325), 120 tablets of alprazolam 2 mg., and 180 tablets of carisoprodol 350 mg. GX 26, at 385. D.P. filled the first two prescriptions the same day, and filled the latter two the next day. *Id.* According to the chart, D.P. reported that his pain level was ''O–1/10,'' and his spasms were ''0/10.'' GX 84, at 17. There is a notation ''See Cleve. Clinic Report,'' but the note does not say what the referral was for. *Id.* There is also a notation that Rx Express Pharmacy had been called and D.P. had not filled either the Soma or Xanax prescriptions, *Id.*; he did, however, fill them the next day. *Id.*

While the record does not contain D.P.'s death certificate, the testimony establishes that he died on August 12, 2004. Tr. 736. Moreover, the toxicology report confirmed the presence of oxycodone in D.P.'s blood. GX 34, at 2. According to the spreadsheet compiled by Dr. Kennedy, there is a handwritten note on a preliminary toxicology sheet which states that D.P.'s death was caused by ''acute oxycodone toxicity.'' GX 82.

[24] According to Dr. Kennedy's spreadsheet, Respondent did not perform a single urinary drug screen on M.C., even though she made five visits to him over a four month period. GX 82. Notably, M.C.'s toxicology report was positive for cannabinoids. *Id.* Dr. Kennedy thus concluded that M.C.'s use of marijuana ''most likely would have been picked up by [Respondent] if he had checked, triggering an addiction medicine [and]/or law enforcement evaluation.'' *Id.* According to Dr. Wayne Wheeler, who also testified as an expert witness for the Government, M.C.'s emergency room records indicate that on August 5, 2003, she had been in a car accident; a drug test done at the hospital indicated that she was positive for marijuana and ''the police report indicated she had taken Soma and Percocet and lost control of her vehicle.'' Tr. 946.

Dr. Kennedy noted that S.J. ''had been dismissed in 2003 for falsifying symptoms and cancer records.'' GX 82. Respondent did not, however, perform a drug screen on S.J. *Id.* Dr. Wheeler noted that S.J. had made ''multiple visits to the emergency room'' for conditions (falls, headaches, dental pain) that are the ''hallmarks of * * * pill-seeking behavior'' because it is ''very hard to find objective evidence'' that the patient is not telling the truth. Tr. 948.

Dr. Kennedy also noted that Respondent did not perform a single drug screen on D.P., even though he had visited Respondent seventeen times over the course of sixteen months and had received a total of 74 controlled-substance prescriptions from him. GX 82.

Respondent performed only a single drug screen on S.H., even though he was a patient for more than two years and saw Respondent thirteen times. *Id.* He also noted that S.H. had previously been treated at Tri-State (albeit at a different location) and that records of an earlier visit indicated an abnormal drug screen in that S.H. indicated that he was currently taken Lortab 10/500 and the screen was negative. *Id.* Moreover, S.H. had previously been hospitalized for mental illness; these records indicated that S.H. had stated that ''he has smoked pot [and], taken Cocaine.'' *Id.* Moreover, S.H. had a Xanax bottle which had been filled ten days earlier but was then empty. S.H. had also stated that he was out of medications and that prior to his admission, he was taking Xanax, Oxycontin, and oxycodone. *Id.* The note also stated that S.H. had a history of ''significant alcohol abuse'' and ''[s]uicidal ideation with family member stating that the patient does have the potential for self-destructive behavior.'' *Id.* Moreover, the patient had tested positive for benzodiazepines and cocaine but negative for opiates. *Id.* As Dr. Kennedy noted in the spreadsheet, ''[t]here are numerous 'red flags' for significant mental illness * * * with medication non-compliance, drug abuse & addiction (polysubstance abuse), and general non-compliance with treatment recommendations.'' *Id.*

Respondent performed a single drug screen on C.J., who was his patient for more than six months and saw him seven times. *Id.* During the screen, only cocaine and THC were checked for. *Id.*

Finally, with respect to K.R., who was a patient for nearly eleven months and made 14 office visits during this period, Dr. Kennedy noted in his spreadsheet that Respondent had obtained two in-office drug screens. GX 82. On cross-examination, it appeared that both screens were ordered by a different physician, who was practicing in Tri-State's South Shore, KY office, and not Respondent. *Id.*; *see also* Tr. 1182–83, 1186. The first of these occurred on December 1, 2003, nearly eight months after K.R.'s first visit; the second drug screen was obtained on January 23, 2004. GX 82. Dr. Kennedy noted that the first screen did not test for oxycodone and that the second test did not check for specific opiates or benzodiazepines. *Id.* Dr. Wheeler noted that while Respondent had referred K.R. to a yoga class, she went only one time and decided not to go back. Tr. 949. According to Dr. Wheeler, allowing the patient to quit after one class does not give that treatment ''modality a reasonable chance to produce any positive results.'' *Id.*

[25] The Government also called to testify Dr. Wayne Wheeler, who is licensed in Ohio and other states, and holds board certifications in both emergency and occupational medicine, as well as quality assurance and utilization review. Tr. 907–08. Dr. Wheeler also has extensive experience in emergency medicine and has served as a deputy coroner of Scioto County, Ohio, since 1990. GX 69, at 2. Dr. Wheeler is a member of the Ohio Medical

Continued

On cross-examination, Dr. Kennedy acknowledged that K.R's medical records indicated that Respondent had performed a physical exam on her on April 17, 2003, which was the date of K.R.'s first visit to him.[26] Tr. 1174–78. However, during his lengthy cross-examination of Dr. Kennedy, Respondent's counsel did not establish that Respondent had ever performed a followup physical examination or that he properly monitored K.R.

Moreover, Dr. Kennedy noted that during K.R.'s first visit with Respondent, the latter proceeded to prescribe what Dr. Kennedy termed the ''cocktail'' or ''trifecta'' of Soma, Xanax, and Lorcet 10, which is ''one of the highest doses of hydrocodone.'' *Id.* at 1178.[27] While Respondent testified as to the general rationale for his prescribing practices,[28] *id.* at 1416–18, he did not testify regarding his prescribing to the six deceased patients and presented no expert testimony refuting Dr. Kennedy's opinion that there was no legitimate medical purpose for prescribing these drugs in combination. GX 64, at 2; GX 74, at 5 (noting that prescribing this combination of drugs ''increased the likelihood of sedation, respiratory depression and death''); Tr. 1047 (noting that the ''cocktail * * * is very popular amongst those individuals who go to doctors' offices to take drugs to abuse them, [and] not [use them] for legitimate medical purposes''); *see also id.* at 1036–37; 1189. Moreover, Respondent did nothing to impeach Dr. Kennedy's findings with respect to the remaining five deceased patients (M.C., S.H., S.J., C.J. and D.P.).

In his defense, Respondent testified that when he ''started seeing these patients, they were all new to me, and so I had to evaluate all of them pretty much from scratch.'' *Id.* at 1407. Respondent maintained that he ''did a physical exam on all of them, and evaluated their complaints, evaluated the medical records that were in the charts, as far as prior treatments, prior x-rays, prior MRIs, prior lab tests, prior consultations with other physicians.'' [29] *Id.* Relatedly, he asserted that ''[v]irtually all the patients that I found had previous consultations with neurosurgeons or neurologists,'' and ''[m]ost of them had surgery one or more times,'' and ''extensive injections given by neurosurgeons, which they reported to me had done very little to treat their pain.'' *Id.* at 1409.

Respondent further testified that ''[m]ost of'' his patients ''had run the gamut of treatment from specialists, and were still in severe chronic pain,'' and ''fit the diagnosis and the category of chronic intractable pain patients'' who ''would need medicine on a continuing basis for the rest of their lives [as] there was no other treatment available to them which would in any way alleviate their pain.'' *Id.* He also maintained that ''I at all times attempted to verify that all the patients were in fact genuine patients who had a legitimate need and requirement for pain medication.'' *Id.* at 1407. He also testified that if he did see a patient who would be helped by surgery, he would refer them to the Cleveland Clinic. *Id.* at 1410.[30]

Respondent further testified that ''each and every one of'' his patients ''signed narcotic contracts'' which set forth that his patients were ''to take their medicine'' as he prescribed it and how the patients were to secure the drugs. *Id.* 1420. Relatedly, Respondent testified that he directed that the Tri-State staff call in his patients for random pill counts and that his patients were subject to ''random drug screens.'' *Id.* at 1421. He further asserted that he sent his patient to two hospitals ''for more extensive blood and urine tests,'' *id.* at 1424, and that he dismissed those patients who were non-compliant and referred them to addiction treatment programs. *Id.* at 1444.

Respondent further testified that ''at all times,'' he documented his diagnosis, *id.* at 1471, and that he ''always wrote my justification and my thinking as to why I put patients on certain medicines, and I believe that would be apparent in any reading of my charts.'' *Id.* at 1472. Moreover, he maintained that he would document the patients' ''response to the medication,'' and any ''adverse [drug] effect'' and changes in medication. *Id.* at 1473. He also contended that ''[a]t all times [he] would look for signs of diversion'' such as abnormal drug tests and physical signs of ''intravenous drug abuse or perhaps intranasal drug abuse.'' *Id.* at 1474.

Regarding the six deceased patients whose files Dr. Kennedy reviewed, Respondent's testimony was limited to

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Malpractice Commission, a board member of the Ohio Patient Safety Institute, and Chairman of the Ethics Committee at the Southern Ohio Medical Center of Portsmouth. *Id.* Dr. Wheeler was accepted as an expert in occupational medicine. Tr. 915.

Dr. Wheeler testified that prescription drug abuse is ''a particular problem in Scioto County.'' *Id.* at 917. Dr. Wheeler explained that in treating a chronic pain patient, a physician must determine the patient's complaint, the history of the problem including ''what therapies have been tried'' and ''who has been taking care of the problem,'' and how the condition has ''developed.'' *Id.* at 922. Dr. Wheeler also testified that the treating physician ''need[s] to get a past medical history, which included other injuries, other illnesses,'' including ''psychiatric histories'' and ''social backgrounds.'' *Id.* Next, the physician should do ''a top-to-bottom physical exam.'' *Id.* Finally, if other practitioners have been ''caring for [the] patient, it become * * * fairly important that you get their records and find out what they have done and what their impressions have been.'' *Id.* at 923. Dr. Wheeler explained that patients sometimes ''don't really understand what has been told them about their condition or they cover up material or just intentionally leave it out.'' *Id.*

Dr. Wheeler further testified that in evaluating a patient, it is ''essential'' to determine if there is ''a history of overdosing on drugs'' or of psychiatric problems. *Id.* at 927. He also explained that he would have his patients sign releases so that he could obtain the patients' records from the other physicians who had previously treated them, as well as emergency room and hospital records. *Id.* at 928. According to Dr. Wheeler, obtaining emergency room records is ''not a terribly laborious or complicated process.'' *Id.* at 951. On cross-examination, Dr. Wheeler further explained that while it was not his experience that a hospital would fail to provide the records to a physician, a patient is entitled to her medical record. *Id.* at 988.

While Dr. Wheeler acknowledged that ''pain is very subjective,'' he added that some patients exaggerate their pain level. *Id.* Moreover, he would not prescribe a narcotic unless he ''truly believed'' the patient was ''experiencing pain somewhere in the 5 to 6 level.'' *Id.* Dr. Wheeler particularly noted that drug abusers ''have long track records of pain-medicine seeking behavior'' with multiple visits to emergency rooms. *Id.* at 929.

[26] Dr. Kennedy noted that Respondent's diagnosis of ''left sciatica'' was ''odd, because the left straight leg raise had a greater range of motion than did the right.'' *Id.* at 1177.

[27] Respondent's counsel also cross-examined Dr. Kennedy about two referrals that K.R. was given, one for a neurosurgeon, the other for a neurologist. Tr. at 1183–84; 1186–87. Neither document was admitted into the record, and the testimony suggests that both referrals were issued by a doctor who was working at a Tri-State Clinic in South Shore, Kentucky, and not Respondent. *Id.* Moreover, Respondent's counsel did not establish that K.R. ever went to either specialist, and Respondent did not testify that he had reviewed a report from either specialist.

[28] In his testimony, Respondent described at length the role of opiates in the treatment of pain; he testified that he used both oxycodone and hydrocodone because ''it was perfectly appropriate, as well as usually necessary, to treat chronic severe intractable pain with two opiates, usually a stronger or long acting one [oxycodone], as well as a shorter acting one,'' hydrocodone, which he used ''for [his] breakthrough medicine.'' 1418. As support for his testimony, Respondent cited various guidelines, Ohio's regulations, and a document of frequently asked questions published by this Agency and two other entities. Tr. 1412–15. He also justified his prescribing of carisoprodol on the grounds that ''I learned that almost [all] of my patients complained of severe muscle spasms * * * usually radiating down one or both legs.'' *Id.* at 1415. Finally, he justified his prescribing of either Valium (diazepam) or Xanax (alprazolam) on the ground that ''virtually all of these patients needed medicine to help them sleep.'' 1417–18. He also justified his prescribing of benzodiazepines as medically necessary to relieve muscle spasms. *Id.*

[29] Respondent maintained that he ''would always'' do a physical exam during his first visit with a patient. *Id.* at 1469. He further testified that he would not necessarily do a new physical exam at a subsequent visit because in ''many instances,'' there was ''no new factor to evaluate.'' *Id.*

[30] He also testified that he arranged for a yoga instructor to come to Portsmouth, and that the instructor did so ''two days a week'' for about ''the better part of a year,'' when Ms. ''Huffman decided that she did not want to subsidize the * * * instructor any longer.'' Tr. 1411–12.

a discussion of their autopsies and toxicology results, with in some instances, Respondent disputing the findings that the patients had taken drugs in amounts that could be definitively shown to be the cause of their deaths. *See* 1475–86.; *id.* at 1481 (testifying that ''post mortem values of opiates are irrelevant to any determination of cause of death,'' because the values only show ''the patient having ingested those compounds, but could not speak to whether they were involved in the cause of death.''); *id.* at 1482–83 (testifying regarding toxic levels of meprobamate).

However, with respect to several patients, the coroners found that these individuals had ingested not only opiates, but opiates in combination with benzodiazepines (S.H.), opiates in combination with a benzodiazepine and illicit drugs (S.J.), or opiates in combination with benzodiazepines and carisoprodol (K.R.). Moreover, even with respect to those patients who were found to have ingested only opiates, I reject Respondent's testimony either because there were other findings consistent with the Coroner's finding (M.C., GX 42; noting presence of extreme pulmonary edema, which according to Dr. Wheeler, ''typically occurs when someone has overdosed on a narcotic drug [or] narcotic drugs,'' Tr. 945), or because I presume that the officials performing the autopsies are competent and reviewed other information (including the clinical history, EMS run sheet, and emergency room report) that is relevant in determining the cause of death. Tr. 1196–97.

The ALJ did not make a credibility finding pertaining to this portion of Respondent's testimony. She did, however, find that she ''doubt[ed] Respondent's credibility'' with respect to his testimony regarding his treatment practices such as whether he took medical histories and performed physical exams, had his patients sign narcotic contracts, called patients in for pill counts, and performed drug screens. ALJ at 34–35. As the ALJ explained, ''[n]either Dr. Wheeler nor Dr. Kennedy testified about finding such safeguards in the patient charts they reviewed for this proceeding.'' *Id.* at 35.

I adopt the ALJ's credibility finding. While I acknowledge that there is evidence that Respondent performed a physical exam during K.R's initial visit, he did not introduce any evidence to corroborate that he performed a physical exam on any of the five other patients whose records were reviewed by Dr. Kennedy. Notably, Respondent was provided with the patients files for these six patients and testified that he always documented his findings. Tr. 1471. Moreover, there was other evidence suggesting that Respondent frequently failed to perform physical exams including testimony regarding an interview with DC, Tr. 762–64, and a DI's analysis that in 900 of the 1258 patient files she reviewed, there was no documentation that Respondent had performed a physical exam. GX 73.

Furthermore, Dr. Kennedy's review of the six patient files establishes that Respondent rarely performed drug screens on those patients. *See* n.22. For example, Respondent did not perform a single drug screen on D.P., even though he issued 74 controlled-substances prescriptions to him during some seventeen visits over a sixteen-month period. GX 82. He performed but a single drug screen on S.H., even though he saw S.H. thirteen times over a period of two years. *Id.* This evidence, which is unrebutted by any documentary evidence, gives ample reason to reject Respondent's testimony.[31]

Moreover, none of Respondent's other evidence (including the various exhibits he submitted on pain management and the testimony of his witnesses) rebuts Dr. Kennedy's ultimate findings that Respondent did not establish and maintain valid doctor-patient relationships with the six deceased patients and that his prescribing lacked a legitimate medical purpose and was outside of the usual course of professional practice. Only one of Respondent's three witnesses (I.A.) testified that she knew one of the deceased patients (D.P.), and she did not even know that D.P. had died of a drug overdose. Tr. 1286–87. Ms. I.A., who worked at Tri-State, and apparently did so only ''a few hours now and then,'' *id.* at 1284, testified that she ''opened the doors,'' ''basically answered the phones,'' ''pulled charts, and once in a while . . . would write a few patients up if somebody was gone'' based on what the patient told her. *Id.* at 1287–88. Ms. I.A. had no personal knowledge of Respondent's treatment of any of the six patients whose files were reviewed by Dr. Kennedy.[32]

S.S. (who was I.A.'s sister) also testified. S.S. did not work at Tri-State and started working for Respondent only after his falling out with the Huffmans; her employment was thus limited to the time he worked out of his Portsmouth apartment and in Chillicothe. *Id.* at 1328–29. S.S. testified that she ''would set up the charts'' and obtain information from both the patients and the hospitals to corroborate their stories. *Id.* at 1331. S.S. further testified that Respondent ''usually required his patients to have at least a year of therapy.'' *Id.* at 1332. S.S. further maintained that ''we obtained histories. We did physicals. We did the drug exams'' and monitored the patients' ''drug levels.'' *Id.* S.S. did not, however, have any knowledge regarding Respondent's treatment of patients (other than her sister) at Tri-State and offered no testimony regarding his treatment of the six deceased patients.

Respondent's remaining witness (E.S.M.) likewise worked for him for only two months at his Chillicothe office. *Id.* at 1363. While E.S.M. testified that Respondent made ''a lot of referrals,'' and that ''[h]e was very strict with'' monitoring patient compliance, *id.* at 1368, she did not work under him during the period in which he treated the six patients whose files were reviewed by Dr. Kennedy. Furthermore, at the time she was employed by him, Respondent clearly had reason to know that he was the subject of criminal investigations because various law enforcement authorities had twice searched his offices. Under these circumstances, even if true, evidence that Respondent was making referrals, was closely monitoring his patients and attempting to corroborate their stories,

[31] In his exceptions, Respondent notes that he attempted to subpoena records from a hospital that would have showed that he ''routinely and consistently ordered urine drug screens on his patients.'' Exceptions at 13. Respondent states: ''[o]f course, such records were simply 'not available,' '' implying that there is a conspiracy to deny him access to records that would vindicate him. According to Respondent: ''[t]he non-production of the forgoing documents, records, and evidence fits synergistically with the course of conduct of the hearing before the ALJ and stands as a poignant indictment of the legality of the process utilized by the agency.'' *Id.* at 14.

The letter from King's Daughters Medical Center merely stated that the hospital was ''unable to retrieve the information * * * from our system without patient specific information.'' RX T. My review of the subpoena indicates that it sought ''records of all urine drug screens ordered by [Respondent] from April 2003, through February 2006.'' RX O, at 5. Respondent offered no evidence that the records could, in fact, be retrieved based solely on his name, and there is no evidence that he subsequently provided patient names to the hospital.

[32] While Ms. I.A. testified that Respondent had sent her to several specialists, Tr. 1268, this testimony is not probative of Respondent's treatment of the six deceased patients whose files were reviewed by Dr. Kennedy. It should also be noted that I.A. was related to Denise Huffman, *id.* at 1288–89, and had testified before a grand jury on matters related to her employment at Tri-State. *Id.* Ms. I.A. also testified that Respondent ordered that blood be drawn on any patient he prescribed to, *id.* at 1318, yet there was no evidence of blood tests being performed on any of the six patients with the possible exception of a test done on S.H. at King's Daughters Hospital on March 2, 2005 (although it is unclear whether the test was a urine screen or blood test). GX 82. Based on the weight of the evidence, I reject this testimony.

and performing physical exams, is not probative of Respondent's practices while he was employed at Tri-State.

Finally, as for his exhibits, most of them are only marginally relevant to the issues in this case. While one of Respondent's Exhibits (an FAQ supported by DEA, the Last Acts Partnership, and the Univ. of Wisconsin) indicates that it may be appropriate ''on a case by case basis'' to prescribe more than one opiate including a short-acting one to address ''breakthrough pain,'' RX I, at 25; nothing in this document refutes the testimony of the Government's experts regarding the medical propriety of Respondent's prescribing of the trifecta and quadfecta cocktails.

Moreover, this document notes the importance of ''tak[ing] a detailed history and perform[ing] an appropriate physical examination,'' ''[s]creen[ing] for addictive behaviors of other family members,'' and ''[i]dentify[ing] concurrent psychiatric illness.'' *Id.* at 31. The document further notes that the physician should ''[c]onsider multiple approaches to the treatment of chronic pain'' including ''[n]onpharmacological and nonopioid analgesic approaches.'' *Id.* The document also explains that the physician should ''[r]ecognize that opioid therapy is as much a 'therapeutic trial' as any other treatment[,]'' and that ''[i]f the benefits are not clear, or the risks of adverse effects are not easily managed, the therapy can be modified or stopped.'' *Id.*

Relatedly, the document suggests that the physician ''[s]tructure the treatment in a manner that maintains the safety of the patient, and increases both the patient's ability to maintain control and the clinician's ability to identify medication misuse.'' *Id.* at 37. Among the measures which the document recommends that a physician employ are: ''the prescribing of small quantities,'' ''the use of a single drug (typically a long-acting opioid''), ''pill counts,'' and ''regular screening of urine toxicology (to provide evidence of therapeutic adherence and non-use of other drugs).'' *Id.* As found above, the credible evidence establishes that Respondent rarely followed these recommendations.

Most significantly, as found above, there is abundant evidence that Respondent did not regularly perform physical exams, rarely conducted drug screenings, rarely used methods other than prescribing controlled substances to treat the six deceased patients, and continued to prescribe controlled substances to persons whose behavior was consistent with either diversion or self-abuse. Moreover, as found above, Respondent's testimony that he complied with these standards is not credible. Contrary to Respondent's contention, this document does not support Respondent.

Discussion

Respondent's Exceptions

Two of Respondent's remaining exceptions raise constitutional claims which are not intertwined with the merits. Accordingly, they will be discussed before addressing the application of the public interest standard.[33]

The first of these is Respondent's contention that the Government was allowed to introduce over his objection an e-mail in which ''Respondent expresse[d] some opinions about the DEA, the ALJ, and the prosecuting DEA attorney,'' which ''are not flattering.'' Exceptions at 10. Respondent notes that he ''objected based upon relevance, prejudice, and intentional inflammation of the factfinder,'' that the evidence was not relevant ''to the factual issues in dispute,'' and the admission of the evidence punished him ''for merely expressing his Constitutionally protected opinions.'' *Id.*

Respondent is correct that the e-mail was not relevant to any issue in the case. The e-mail does not contain any evidence that is probative of either the allegations that he failed to maintain proper records and could not account for large quantities of controlled substances, or the allegations that his prescribing of controlled substances to various patients violated Federal law. GX 83. The Government's contention at the hearing that the e-mail was relevant because Respondent made ''disparaging remarks'' about the proceeding, DEA counsel and the ALJ, and that this ''raise[s] questions about judgment, and [is] therefore relevant to the public interest consideration,'' Tr. 1506, finds no support in the decisions of this Agency.

While a registrant's judgment may be relevant in determining the public interest, what makes it relevant is the nexus between the registrant's judgment and the performance of his obligations under the CSA and DEA regulations. As one example, entrusting one's registration to someone without doing a background check and failing to adequately supervise that person reflects poor judgment that is relevant in the public interest determination. *See, e.g., Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). In contrast to his conduct, the opinions expressed by Respondent in his e-mail do not establish whether he committed any violations in the past or whether he is likely to do so in the future. The e-mail should not have been admitted into evidence and Respondent should not have been questioned about it.

That being said, the Administrative Procedure Act recognizes a rule of prejudicial error. *See* 5 U.S.C. 706. The ALJ did not rely on the e-mail in her recommended decision. Most significantly, having concluded that it is irrelevant, as ultimate factfinder, I have not considered it. Respondent's exception is therefore rejected.

Respondent's second constitutionally based exception is that the Agency violated his right to Due Process because it failed to provide him with ''fair notice'' of its ''theory of the case'' because the Government was repeatedly allowed to introduce ''evidence which grossly exceeded the scope of the February 2006 show cause order.'' Exceptions at 5 (citation omitted). While acknowledging that each of the unnamed patients listed in the Show Cause Order (most of whom were alleged to have died shortly after obtaining prescriptions from Respondent, see Show Cause Order at 9–11), were identified by the Government in its March 2006 pre-hearing statement, Respondent contends that the Government was allowed to introduce evidence ''about more than *twenty-five* specific patients,'' and that this ''effectively expanded'' the scope of the hearing ''without proper notice or any realistic chance to defend.'' Exceptions at 6. Respondent also notes that the Government was allowed to ask him ''about many more patients by reading names from a spreadsheet.'' *Id.*

Respondent did not, however, identify who the twenty-five patients were by citation of either the transcript or exhibits. *See* 21 CFR 1316.66(a) (''[t]he party shall include a statement of supporting reasons for such exceptions together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits)''). Respondent has therefore failed to properly preserve this exception.[34]

Respondent also argues that he was denied a meaningful opportunity to

[33] Respondent's exception that DEA is engaged in the unlawful regulation of the practice of medicine will be discussed in the public interest analysis.

[34] It appears that the twenty-five patients included those patients who were listed on the KASPER report as having obtained controlled substances from Respondent (*see* GX 26, Exceptions at 8 n.6); the Government merely asked Respondent whether he recalled each of these patients. Tr. 1521–29. Respondent has made no showing that the Government failed to timely provide this document to him. In any event, I do not rely on this portion of his testimony.

respond to the Government's case because it used ''patient charts to prepare its own expert witnesses,'' but denied him ''timely access to these charts.'' Exceptions at 7. Respondent contends that ''it was essential to a meaningful hearing that [he] receive copies of the very same charts the [G]overnment used in order to procure expert opinion testimony from their own witnesses.'' *Id.* Respondent further argues that he ''asked for the charts,'' but the Government would not provide them because it had decided not to enter them into the record. *Id.*

Respondent acknowledges, however, that the Government provided him with nine patient charts, including five of the charts which were reviewed by Dr. Kennedy. Exceptions at 8 n.6. Moreover, the record establishes that Respondent received all six of the patient files which Dr. Kennedy reviewed in creating his report on Respondent's prescribing to the six deceased patients. Tr. 1126–27. While Respondent contends that he did not have enough time to review the charts and consult an expert witness because the Government turned over the charts only four days before the hearing convened, Exceptions at 8 n.6, Respondent ignores that the hearing was adjourned for approximately one month and that the ALJ allowed him to defer his cross-examination of Dr. Kennedy until the hearing reconvened. Tr. 1094–95.

Respondent thus had a meaningful opportunity to prepare for his cross-examination of Dr. Kennedy, as well as to retain an expert witness to review the patient files which Dr. Kennedy reviewed. Accordingly, there is no merit to his contention that the proceeding violated his rights under the Due Process Clause.[35]

The Public Interest Analysis

Respondent's Registration Status

At the outset, the scope of this proceeding must be determined. As found above, Respondent's registration expired on May 31, 2006, and he did not submit a renewal application (and his request for a modification) until May 12, 2006. While one of the Government's exhibits states that because Respondent filed a renewal application, his registration has ''remained in effect on a day-to-day basis pending the resolution of administrative proceedings,'' the document cited no authority for this statement which is contrary to Agency regulations. GX 2.

Under the Administrative Procedure Act, ''[w]hen [a] licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.'' 5 U.S.C. 558(c). When, however, a Show Cause Order has been issued to a registrant, DEA's regulation provides that:

> [i]n the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at *least 45 days before the date on which the existing registration is due to expire,* and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, if the Administrator finds that such extension is not inconsistent with public health and safety.

21 CFR 1301.36(i) (emphasis added).

Notwithstanding that he had previously been served with a Show Cause Order, Respondent did not file his renewal application until nineteen days before his registration expired. Accordingly, Respondent did not make a timely renewal application in accordance with agency rules; his registration has not remained in effect pending the resolution of this proceeding. *See* 5 U.S.C. 558(c). Moreover, in light of the allegations of the Show Cause Order (and the facts found above), the extension of his registration pending this Final Order would be manifestly ''inconsistent with public health and safety.'' 21 CFR 1301.36(i). I therefore conclude that Respondent's registration has expired.[36]

Respondent did, however, submit a renewal application and a request for modification, which under Agency regulation, is ''handled in the same manner as an application for registration.'' 21 CFR 1301.51. Accordingly, Respondent does have an application pending before the Agency.

The Public Interest Factors

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the CSA requires the consideration of the following factors:

> (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 the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

''These factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 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 * * * an application for registration [should be] denied.'' *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 considered all of the factors, I conclude that factors two, four, and five amply demonstrate that issuing a registration to Respondent ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In this matter, there is abundant evidence that Respondent repeatedly violated Federal law by prescribing controlled substances without a legitimate medical purpose and outside of the course of professional practice. Moreover, the evidence also establishes that Respondent authorized Tri-State personnel to use his registration to order huge quantities of

[35] While it is true that DEA's regulations and the Administrative Procedure Act require that an Order to Show Cause contain ''a summary of the matters of fact and law asserted,'' 21 CFR 1301.37(c), an agency is not required ''to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront.'' *Boston Carrier, Inc.,* v. *ICC,* 746 F.2d 1555, 1560 (*DC* Cir. 1984). As the ALJ explained at the hearing, the Show Cause Order only sets forth the parameters of the proceedings. *See Medicine Shoppe-Jonesborough,* 73 FR 364, 368 (2008). The actual conduct of the proceeding is controlled by the pre-hearing statements.

Respondent also raises an exception based on the ALJ's denial of his request for a subpoena requiring Dr. Kennedy to produce ''[c]opies of all opinion reports evaluating medical care by physicians written for the DEA from December 2001 through December 2006.'' RX O, at 1. The ALJ denied Respondent's ''request absent any further justification.'' *Id.* at 2. Respondent did not, however, provide any further justification. Accordingly, this exception is without merit. *See* 5 U.S.C. 555(d); 21 U.S.C. 875 & 876.

At Respondent's request, the ALJ issued a subpoena which directed DEA to provide patient release forms it had obtained from Dr. Joseph Delzotto. *Id.* at 1–3. Upon receipt of the subpoena, DEA searched its case files and found no such documents. *Id.* at 10. Respondent has made no showing that this was not the case.

[36] No footnote.

controlled substances and that he failed to ensure the accountability of these drugs by maintaining lawfully required records. Accordingly, Respondent's application will be denied.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Laws

Respondent's Prescribing Practices

One of the principal issues in this case is whether the prescriptions Respondent issued complied with Federal law. While Respondent maintains that his prescribing practices were compliant with the State of Ohio's regulations of the practice of medicine, the evidence conclusively establishes that Respondent used his prescribing authority to act as a drug pusher.

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 related to controlled substances.'' *Id.*

In *Gonzalez* v. *Oregon*, the Supreme Court explained that ''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.'' 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 & 143 (1975)).

It 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.'' *See Moore*, 423 U.S. at 142–43 (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''). Moreover, as I have explained, ''the CSA looks to state law in determining whether a physician has established [and is maintaining] a valid doctor-patient relationship.'' *United Prescription Services, Inc.*, 72 FR 50397, 50407 (2007) (citing DEA, *Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181, 21182–83 (2001)). *See also Kamir Garces-Mejias*, 72 FR 54931, 54935 (2007) (citing numerous state practice standards violated by physician).

Respondent argues that under *Gonzales*, DEA ''cannot lawfully determine and enforce a national medical standard of care.'' Exceptions at 11. Respondent further contends that because ''*Gonzales* directs that the states retain the power to set parameters on the practice of medicine, [and he] produced evidence that his prescribing practices conformed with Ohio law,'' DEA cannot act against his federal registration. *Id.* Relatedly, Respondent argues that whether he ''did or did not conform his conduct to the mandates of Ohio law is a question for the State Medical Board of Ohio—not DEA.'' *Id.* at 12. Respondent's argument that he was in compliance with the Ohio regulations is not factually correct; his contention that the Agency is exceeding its authority and usurping the State's role in regulating the practice of medicine is also mistaken.

As found above, Respondent's testimony that he complied with Ohio law was not credible. Under Ohio law, ''when utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts that may not be appropriate when treating other medical conditions, a practitioner shall'' perform:

> [a]n initial evaluation of the patient * * * and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and *an appropriate physical examination.*

Ohio Admin. Code R. 4731–21–02(A) (emphasis added).

There is ample evidence that Respondent failed to obtain adequate histories and perform adequate physical exams including the testimony of Dr. Kennedy and the DI's review of Respondent's patient files which found that there was no documentation of a physical exam in 900 of the files as required by Ohio law. This conclusion is also supported by the testimony regarding the interview of DC, who obtained three controlled-substance prescriptions from Respondent without the latter having performed a physical exam.

Moreover, the Ohio regulations require that ''[t]he practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain.'' Ohio Admin. Code R. 4731–21–02(A)(4)(a). Furthermore, ''[t]he practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this'' provision.[37] *Id.* With respect to the six deceased patients, there is no credible evidence that Respondent had them evaluated by specialists [38] or relied on reports that a specialist had prepared ''within a reasonable period of time'' before diagnosing them as having intractable pain. *Id.* R. 4731–21–02(4)(b).

Respondent argues that while Dr. Kennedy ''claim[ed] to be aware of the Ohio guidelines,'' he was ''painfully unfamiliar with the controlling state standards.'' Exceptions at 12 (citing Tr. 1202–03). While it is true that much of Dr. Kennedy's testimony focused on the Kentucky guidelines, he also testified that ''there is no significant variation between the'' Ohio standards and the Kentucky guidelines. Tr. 1203. Moreover, when Dr. Kennedy offered to display the Ohio provisions to the court and explain how Respondent ''violated the Ohio Code,'' Respondent's counsel declined to pursue this line of questioning. *See Id.* Furthermore, in his report, Dr. Kennedy made clear that he had reviewed and was generally familiar with the Ohio standards for treating intractable pain (as well as other professional standards such as those issued by the Federation of State Medical Boards). GX 74, at 2; *see also* Tr. 1075 (expressing opinion that Respondent knew better because of ''the guidelines that were published by the

[37] The practitioner is not ''required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by a specialist.'' Ohio Admin. Code R. 4731–21–02(A)(4)(b). The practitioner must, however ''obtain and review all available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain.'' *Id.* Moreover, under this regulation, the practitioner is required to ''maintain a copy of any record or report * * * on which [he] relied.'' *Id.*

[38] While there is evidence in a progress note dated 8/11/04 that D.P. had been referred to the Cleveland Clinic, the note does not indicate what the referral was for and when it occurred. At the time, D.P. had been seeing Respondent since April 2003.

State Medical Board of Ohio [and] the Kentucky Board of Medical Licensure that were well circulated'').

Respondent further argues that I should reject Dr. Kennedy's testimony because ''it was clear that he had not studied the chart * * * and was unable to harmonize his criticism of [Respondent's] care with the actual patient record then in front of him.'' Exceptions at 11. Respondent then argues that Dr. Kennedy ''admittedly worked from summaries, print-outs, and other documents created by the government or himself, based on pharmacy records—without any meaningful review and reliance on the patient record itself.'' *Id.*

Respondent does not, however, support these contentions with any citations to the record. *See* 21 CFR 1316.66. Moreover, in both his report and testimony, Dr. Kennedy made clear that for each of the patients, he had ''reviewed records obtained from [Respondent's] office'' including his ''clinical records.'' *See also* GX 74, at 1–2; *see also* Tr. 1068. While it is true that Respondent showed that he had performed a physical exam on K.R. at apparently her first visit (which also coincided with when he started working for Tri-State), he made no such showing with respect to the other five patients. Moreover, even with respect to K.R., Respondent did not establish that he complied with the Ohio standards and maintained a valid doctor-patient relationship with her.

Indeed, Respondent offered no testimony specific to his treatment of the six deceased patients and did not submit their patient files into the record. Accordingly, I adopt Dr. Kennedy's opinion that Respondent ''distributed prescriptions for oxycodone and other controlled substances not for a legitimate medical purpose and beyond the usual course of professional practice.'' GX 74, at 3.

Respondent further argues that the Agency is acting ''in direct contravention to *Gonzales*'' because it ''sought to pass judgment upon the medical care [he] rendered.'' Exceptions at 11. Relatedly, Respondent contends that whether he complied with Ohio law ''is a question for the State Medical Board of Ohio [and] not DEA.'' *Id.* at 12.

It is true that in enacting the CSA, Congress did not adopt a federal standard for determining whether a valid doctor-patient relationship exists. Rather, on this issue, the CSA recognizes the traditional role of the States in regulating the practice of medicine. *See Gonzales*, 546 U.S. at 270. The CSA therefore looks to state law in determining whether there is a valid doctor-patient relationship. *United Prescription Services*, 72 FR at 50407; *Dispensing and Purchasing Controlled-Substances over the Internet, 66 FR at 21182–83.*

Determining whether Respondent established and maintained a valid doctor-patient relationship with the six deceased patients under Ohio law is thus a necessary and permissible incident of determining whether Respondent complied with the prescription requirement of Federal law. *Cf.* 21 U.S.C. 823(f)(4) (directing consideration of applicant's ''[c]ompliance with applicable State * * * or local laws relating to controlled substances''). Whether Respondent complied with Ohio law in prescribing controlled substances is thus not only a question for the Ohio Medical Board, but also a question for the Attorney General, who has been entrusted with the authority under Federal law to determine whether the granting of a registration to dispense controlled substances is consistent with the public interest. *See Id.* section 823(f); *Id.* § 824(a) (granting Attorney General authority to revoke a registration where a registrant has committed acts inconsistent with the public interest). DEA's reliance on Ohio's medical practice standards thus does not exceed this Agency's authority as set forth in Gonzales.[39]

Accordingly, Respondent's arguments are without merit. Because the evidence establishes that Respondent lacked a ''legitimate medical purpose'' and acted outside of ''the usual course of his professional practice'' in distributing numerous controlled-substance prescriptions to the six deceased patients (and others), he violated Federal law. This conclusion provides reason alone to conclude that granting his application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

The Record Keeping Violations

The record also contains extensive evidence that Respondent violated Federal law by failing to keep proper records for the controlled substances that were ordered and dispensed under his registration at Tri-State. Respondent agreed that his registration could be used to order and dispense controlled substances for Tri-State's customers. Tr. 1550. As the record establishes, Respondent agreed to this because numerous pharmacists were questioning his prescriptions and refusing to fill them. Tr. 1428–29. Moreover, Respondent told Denise Huffman what drugs to order. *Id.* at 543.

Respondent rapidly became the largest practitioner-purchaser in the nation of oxycodone, a schedule II controlled substance which is highly sought after by drug-abusers, and which commands top dollar in the illicit market. As found above, his purchases dwarfed that of other Ohio-based practitioners who purchased the drug. Moreover, Respondent also became—by a wide margin—the largest Ohio-based practitioner-purchaser of combination hydrocodone/apap drugs.[40]

Respondent proceeded to order hundreds of thousands of dosage units of these drugs (136,000 dosage units of oxycodone between 8/18/03 and 12/30/03; 222,600 dosage units of hydrocodone between 7/24/03 and 12/30/03)[41] which he distributed, and was required to maintain purchasing, inventory and dispensing records. *See* 21 U.S.C. 827(a); 21 CFR 1304.03(b) (requiring dispenser to keep records); *see also* 21 CFR 1304.11 (requiring initial and biennial inventories), *id.* 1304.22(c) (requiring maintenance of receiving and dispensing records). When, however, on December 30, 2003, Agent Kinneer of the Ohio State Board of Pharmacy inspected Tri-State, he found that the clinic had not made any entries in several controlled-substance dispensing logs in more than four months. *See* GX 11, at 2; GX 12, at 5. Respondent was thus already repeatedly violating Federal law.

[39] By contrast, *Gonzales* did not involve reliance on a State's medical practice standards but the issuance of an interpretive rule, unsupported by a grant of Congressional authority, which would have barred conducted permitted by state law. *See* 546 U.S. at 274–75. Moreover, as Gonzales recognized, prior to 1984, ''the Attorney General was required to register any physician who was authorized by his State [and] could only deregister a physician who falsified his application, was convicted of a felony relating to controlled substances, or had his state license or registration revoked.'' *Id.* at 261. In 1984, however, the CSA was amended to grant ''the Attorney General the authority to deny a registration to an applicant 'if he determines that the issuance of such registration would be inconsistent with the public interest.'' '*Id.* (quoting 21 U.S.C. 823(f)). Respondent's prescribing practices are therefore properly considered in this proceeding.

[40] The record further establishes that Respondent also ordered large quantities of hydromorphone, another schedule II controlled substance, 21 CFR 1308.12(b)(1), and several benzodiazepines, which are schedule IV controlled substances. *Id.* 1308.14(c). During the 2005 search, there were also no records documenting the handling of these drugs.

[41] As found above, in 2004, Respondent ordered 457,000 dosage units of oxycodone and 263,500 dosage units of hydrocodone/apap. Moreover, during the little more than eight months of 2005 when he worked at Tri-State, Respondent ordered 414,000 dosage units of oxycodone and 168,500 dosage units of hydrocodone.

Thereafter, in January 2004, Respondent represented to the Ohio Board that ''[a]ll log books are current and up to date and are being kept current.'' GX 11. He also stated that ''[a]ll controlled medication being dispensed * * * is being logged as it is filled.'' GX 11.

Notwithstanding Respondent's representations to the state board, on June 7, 2005, DEA investigators could not find any dispensing logs for the year 2004, and Denise Huffman admitted that there were no such logs. Tr. 670. Under Federal regulations, however, Respondent was required to maintain these records for a period of two years. *See* 21 U.S.C. 827(b). Moreover, given the circumstances in which the 2005 logs were not at the clinic but were later provided to the Government only after copies of the patient files were given to the clinic (following the search), and that the logs appeared to be brand new, it is most unlikely that these were accurate records. In any event, the various dispensing logs were required to be maintained at the clinic. *See* 21 CFR 1304.04(1). Respondent thus repeatedly violated Federal law by failing to maintain the required records and did so over a sustained period of time. It is no defense that Respondent delegated this responsibility to Ms. Huffman.[42] Tr. 1511.

Aggravating these violations is the fact that he ordered extraordinary quantities of various highly abused controlled substances and that there is no way—given the wholly deficient recordkeeping—to determine where these drugs have gone. Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances. Given the extraordinary quantities of controlled substances which Respondent ordered and his complete lack of accountability for them, it is likely that most of these drugs were diverted. Respondent's failure to maintain accurate records (assuming that they were ever accurately maintained beyond August 2003,[43] *see* GX 11, at 2), provides a further reason—which is sufficient by itself—to conclude that granting him a registration would ''be inconsistent with the public interest.'' 21 U.S.C. 823(f).

At the hearing, Respondent testified that ''as far as I was concerned, as far as my knowledge of Ohio law, Federal law, standards of care of pain management, and anything else I could find, I had done nothing wrong, and was following absolutely prescribed procedures that I should in every respect.'' Tr. 1439. I beg to differ. As the record shows, Respondent is an egregious violator of the CSA's requirements with respect to both his prescribing practices and compliance with the Act's recordkeeping requirements.[44] And even assuming—given the remedial purpose of proceedings under section 303—that there could be circumstances in which an egregious violator of the Act might convincingly establish that he has reformed, Respondent has offered no credible evidence to demonstrate that he can be entrusted with a new registration. Accordingly, I conclude that granting Respondent's application for a new registration would be ''inconsistent with the public interest.''[45] 21 U.S.C. 823(f).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Paul H. Volkman, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective June 27, 2008.

Dated: May 16, 2008.

Michele M. Leonhart,

Deputy Administrator.

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[42] As I have previously explained, when a registrant authorizes another person to perform acts under his registration, he is responsible for that individual's misuse of the registration and failure to perform required acts. *See Rose Mary Jacinta Lewis*, 72 FR 4035, 4040 (2007); *see also Summer Grove Pharmacy*, 54 FR 28522, 28523 (1989).

[43] While Agent Kinneer stated in his report that during his February 2004 visit, Respondent and Alice Huffman gave him dispensing logs, no such logs were found during the June 2005 search.

[44] There is also evidence in the record that Respondent told a patient (J.R.) to sell a drug (Soma) if he did not take it. Tr. 42 & 104. While Soma is not controlled under Federal law, the evidence is nonetheless probative of Respondent's intent.

[45] In light of the extensive evidence of Respondent's misconduct, I conclude that it is unnecessary to make findings regarding the remaining factors.

MERIT SYSTEMS PROTECTION BOARD

Agency Information Collection Activities; Proposed Collection

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), the U.S. Merit Systems Protection Board (MSPB) announces that it is planning to submit a request for a three-year extension of an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Before submitting this ICR to OMB for review and approval, MSPB is soliciting comments on specific aspects of its information collection activities as described below.

DATES: Written comments must be received on or before June 27, 2008.

ADDRESSES: Submit written comments on the collection of information to Dr. Dee Ann Batten, Merit Systems Protection Board, 1615 M Street, NW., Washington, DC 20419.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Dr. Dee Ann Batten at (202) 653–6772, ext. 1411.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. The MSPB intends to ask for a three-year renewal of its Generic Clearance Request for Voluntary Customer Surveys, OMB Control No. 3124–0012. Executive Order 12862, ''Setting Customer Service Standards,'' mandates that agencies identify their customers and survey them to determine the kind and quality of services they want and their level of satisfaction with existing services.

In this regard, we are soliciting comments on the public reporting burden. The reporting burden for the collection of information on this request is estimated to vary from 5 minutes to 30 minutes, with an average of 15 minutes, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. In the estimated annual reporting burden listed below, the reason that the annual number of respondents differs from the number of total annual responses is that the latter figure assumes a 60% response rate. Our experience has been that fewer than 60% of those invited to participate in our voluntary customer surveys avail themselves of that opportunity.

In addition, the MSPB invites comments on (1) Whether the proposed collection of information is necessary for the proper performance of MSPB's functions, including whether the information will have practical utility; (2) the accuracy of MSPB's estimate of burden of the proposed collection of information, including the validity of the methodology and assumptions used;