SAFEGUARDS:

Information contained in the system is maintained in accordance with DFBP procedures. Manual information in the system is safeguarded in locked file cabinets within a limited access room in a limited access building. Access to manual files is limited to personnel who have a need for files to perform official duties. Operational access to information maintained on a dedicated computer system, is controlled by levels of security provided by password keys to prevent unauthorized entry, and an audit trail of accessed information. Access is also limited to personnel who have a need to know to perform official duties.

RETENTION AND DISPOSAL:

Data is maintained for current and prior years in a master file. Data is not destroyed, but maintained for historical purposes.

SYSTEM MANAGER(S) AND ADDRESS:

Director, DFBP, Office of Justice Programs, 810 Seventh Street, NW, Washington, DC 20531.

NOTIFICATION PROCEDURE:

Same as above.

RECORD ACCESS PROCEDURES:

A request for access to a record from the system shall be in writing, with the envelope and letter marked ''Privacy Access Request.'' Direct the access request to the System Manager listed above. Identification of individuals requesting access to their records will include fingerprinting (28 CFR 20.34).

CONTESTING RECORDS PROCEDURES:

An individual desiring to contest or amend information maintained in the system should direct the request to the System Manager listed above. The request should state clearly and concisely the information being contested, the reasons for contesting the information, and the proposed information amendment(s) sought.

RECORD SOURCE CATEGORIES:

Sources of information contained in the system are Federal and State courts, individuals convicted of certain drug offenses, individuals convicted of defense-contract related felonies, United States Attorneys, and Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 99–11662 Filed 5–7–99; 8:45 am]

BILLING CODE 4410–CJ–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated January 27, 1999, and published in the **Federal Register** on February 10, 1999, (64 FR 6684), Isotec, Inc., 3858 Benner Road, Miamisburg, Ohio 45342, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Aminorex (1585)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
2,5-Dimethoxyamphetamine (7396).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (7405).	I
4-Methoxyamphetamine (7411)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
N-Ethyl-1-phenylcyclohexylamine (7455).	I
Dihydromorphine (9145)	I
Normorphine (9313)	I
Acetylmethadol (9601)	I
Alphacetylmethadol Except Levo-Alphacetylmethadol (9603).	I
Normethadone (9635)	I
3-Methylfentanyl (9813)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylecgoning (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Levo-Alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The firm plans to use small quantities of the listed controlled substances to produce standards for analytical laboratories.

DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Isotec, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Isotec, Inc. on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: April 26, 1999.

John H. King,

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

[FR Doc. 99–11693 Filed 5–7–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 96–41]

Paul W. Saxton, Continuation of Registration

On July 15, 1996, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) issued an Order to Show Cause to Paul W. Saxton, D.O. (Respondent) of Sandy, Utah, notifying him or an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AS9420059 and deny any pending applications for renewal of such registration as a practitioner pursuant to 21 U.S.C. 823(f) and 824(a)(4), for reason that his continued registration would be inconsistent with the public interest.

By letter dated August 15, 1996, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Salt Lake City, Utah on March 4 through 7, 1997; March 17 through 19, 1997; and June 23 through 27, 1997, before Administration Law Judge Gail A. Randall. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing counsel for both parties submitted proposed findings of fact, conclusions of law and argument. On October 6, 1998, Judge Randall issued her Opinion and Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's DEA Certificate of Registration be continued with no adverse action being taken. No exceptions were filed by either party to the Administration Law Judge's Decision, however on November 5, 1998, Respondent filed an Application for Attorney's Fees and Expenses. Thereafter, on November 19, 1998, Judge Randall transmitted the record of these proceedings to the then-Acting Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Recommended Rulings, Findings of Fact. Conclusions of Law and Decision of the Administration Law Judge. His adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

As a preliminary matter, the Deputy Administrator finds that Respondent's Application for Attorney's Fees and Expenses filed on November 5, 1998, was premature. Pursuant to 5 U.S.C. 504 and 28 CFR 24.101, *et seq.*, such a request may only be filed after a party has prevailed in an action brought by DEA. Since this final order is the final agency action in this matter, Respondent's request was premature and is therefore denied.

The Deputy Administrator finds that Respondent has been practicing osteopathic medicine since 1979, and since about 1990, the primary aspect of his practice has been the treatment of pain.

The Utah agency responsible for issuing licenses to professionals received complaints concerning Respondents in July 1988, January 1989 and August 1993. Following an investigation of these complaints, no action was taken against Respondent. Respondent however did admit that he prescribed anabolic steroids for muscle enhancement until sometime in 1992. In 1992 he was told by state and Federal investigators that this practice became illegal in the State of Utah in 1990 and federally in February 1991. There is no evidence that Respondent has prescribed anabolic steroids for muscle enhancement after being advised that such practice was illegal.

In January 1994, the state agency received a complaint from a pharmacist that Respondent had prescribed six different controlled substances to one individual on January 10, 1994. As a result, the state agency and DEA initiated an investigation of Respondent. Investigators obtained patient prescription profiles from local pharmacies. Then on November 30, 1995, the investigators executed an administrative inspection warrant at Respondent's office during which the investigators seized 38 patient charts. Also during execution of the administrative inspection warrant it was discovered that Respondent has purchased controlled substances but had not maintained a log or other record, other than the patient charts, indicating the disposition of the drugs, nor had Respondent conducted a biennial inventory of the controlled substances that he had purchased.

Next, the Government had an expert in pain management and the proper use of controlled substances review 18 of the 38 patient medical records that were seized from Respondent's office. After reviewing these records the Government's expert concluded that there are ''consistent patterns supporting the contention that [Respondent] has been inappropriately and excessively prescribing controlled substances, particularly opioids.''

Since Respondent's patients that are at issue in this proceeding were supposedly being treated by Respondent for chronic pain, there was extensive evidence presented by both the Government and Respondent regarding the treatment of chronic pain patients. The Government's expert defined chronic pain as ''pain which has been present for over 6 months.'' He stated that pain is subjective and therefore a physician has to rely on a patient's complaints of pain. He further stated that the source of an individual's pain may never be identified. The Government's expert acknowledged that using opioids to relieve chronic pain is a legitimate medical practice and that some patients may require opioids for the rest of their lives to control chronic pain. He testified that once a diagnosis was made, a physician should start with the most benign medications at the least dose and increase the dose or change the medication as needed. According to the Government's expert there does not appear to be an arbitrary upper dosage limit for most opioids, however increasing dosage levels may not be appropriate if the pain is not responding to the opioids because ''[m]any types of pain are not responsive to opioids. * * * Regardless of what dose.'' Nevertheless the Government's expert testified that:

> [M]ost chronic pain patients are never going to be pain free. * * * But I think if their pain is managed at a level where they can function where the pain isn't a big issue in their life anymore, then that's considered reasonable control. * * * [But] there are a lot of other treatment options that would be used before opioids would be tried.

Two experts testified on behalf of Respondent. The first, an expert in family practice with chronic pain patients comprising the predominant portion of his practice, defined intractable pain as ''[p]ain that has resisted all reasonable efforts to eliminate the source or to eliminate the symptoms.'' He testified that there is no ceiling on the use of controlled substances in the treatment of chronic pain, and that the dosage and length of therapy are irrelevant as measurements to determine the quality of medical treatment received by chronic pain patients. This expert further testified that a physician should not reduce the levels of a patient's medications if the patient's pain is being managed, and that it is appropriate to prescribe combinations of controlled substances since different medications work for different levels of pain and there are varying effective time spans for various medications. It was the opinion of this expert that physicians are afraid to prescribe narcotics for fear of prosecution by regulatory agencies.

Respondent's other expert witness was qualified as an expert in family practice with a subspecialty in pain management and opioid treatment. He has published numerous articles regarding the treatment of chronic pain patients. According to this expert, there is a difference of opinion on the medical profession regarding the use of opioids in the management of chronic pain, with two differing approaches classified as the therapeutic school, to which Respondent and his experts belong, and the dependency school, to which the Government's expert belongs. The field of pain management is a controversial issue with the treatment policy evolving within the medical profession.

According to this expert, the measure of successful treatment of a chronic pain

patient is whether the patient has experienced an increase in his/her level of comfort and function and has an improved quality of life. A physician has to trust his/her patient and individualize the treatment. There is no ceiling or upper limit on the use of opioids and in determining whether a dosage level is adequate for a chronic pain patient one should not look at the number of pills consumed, but should look at the functioning level of the patient. The expert further testified that prescribing combinations of drugs meets the standards of the therapeutic school since a patient might use one type of drug for light pain and another type for more severe pain.

Respondent also introduced into evidence a copy of a document written in 1997 by the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) entitled ''The Use of Opioids for the Treatment of Chronic Pain,'' (hereinafter referred to as ''Consensus Statement''). One conclusion of the Consensus Statement is that ''[p]ain is often managed inadequately, despite the ready availability of safe and effective treatments,'' because impediments ''to the use of opioids include * * * fear if regulatory action.'' The Consensus Statement also provided guidance for regulatory agencies for determining accepted principles of practice for the use of opioids for chronic pain patients. The Consensus Statement indicated that in initially evaluating a patient a complete history and physical examination should be conducted. The treatment plan should be individualized and should include different types of treatment modalities. Consultation with a specialist in pain medicine or with a psychologist may be warranted. The Consensus Statement further provided that ''[t]he management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.'' Review of treatment efficacy should occur periodically and complete documentation is essential.

Respondent testified that his treatment objectives for his chronic pain patients are (1) to improve the patient's quality of life; (2) to increase the patient's level of comfort; and (3) to increase that patient's ability to function. He further testified that when he diagnoses a patient with chronic pain, he uses the ''stepladder approach'' to prescribing medication, starting with noncontrolled substances, then Schedule III and IV controlled substances, and then if necessary Schedule II controlled substances. In treating his chronic pain patients, Respondent also uses other modalities in conjunction with his prescribing of controlled substances.

After reviewing the 18 patient records, the Government's expert provided an opinion regarding the appropriateness of Respondent's prescribing of controlled substances for each patient and regarding a number of general inadequacies he found in Respondent's treatment of his chronic pain patients. However, in rendering this opinion the Government's expert did not examine any patient personally; did not interview any of the patients; did not obtain a medical history; and did not discuss the information in the charts, or the lack therefor, with Respondent, the treating physician.

According to the Government's expert, Respondent's treatment of the patients was inadequate because the patients entering into treatment with Respondent received inadequate evaluations and diagnosis, since Respondent provided a general physical examination rather than an examination tailored to the patient's specific pain complaint. However, the Government's expert admitted at the hearing that he could not decipher the meaning of some of Respondent's abbreviations found in the patient records. The Government's expert was also of the opinion that Respondent's treatment was inadequate because he simultaneously prescribed similar medications without medical justification, allowing the patient to determine which of the overlapping medications to take, and he made no attempt to reduce or control medication doses responsive to the patient's condition. In addition, Respondent prescribed controlled substances to several patients known by him to have ongoing substance abuse or psychiatric problems, with some patients actually having recently completed substance abuse treatment, which according to the Government's expert made continued controlled substance use suspect. Further, the Government's expert found that if Respondent's prescribing of controlled substances for family members was not blatantly illegal, it was at least ethically prohibited. The Government's expert also concluded that Respondent appeared reluctant to seek help from other medical specialists outside of his area of expertise; failed to correlate treatment with the patient's improvement or lack of improvement; and failed to use other modes of treatment other than prescribing controlled substances.

The Government's expert testified that based upon his review of the patient records, ''I do not believe that there was sufficient diagnosis or basis for the prescribing of the substances prescribed by [Respondent].''

Respondent's first expert reviewed Respondent's patient charts, read the report of the Government's expert, and discussed the patient charts with Respondent. He concluded that in his opinion, Respondent was thorough in his diagnosis, that he adequately examined the patients, and that he had maintained adequate charts. In his opinion, Respondent's prescribing was well within the standards of reasonable medical care; his monitoring of the patients' medications was adequate; his evaluation of each patient on a regular basis was adequate; and his prescribing of narcotic analgesics was forlegitimate clinical reasons.

Respondent's other expert testified concerning Respondent's treatment in general and specifically regarding Respondent's treatment of eight of the patients at issue. In rendering his opinion, he reviewed the patient charts and discussed the patients' treatment with Respondent. According to this expert, Respondent met the standard of care in his treatment under the therapeutic school treatment approach for chronic pain patients. However, the expert acknowledged that Respondent's practices were not without flaws. In his opinion, Respondent did not document his initial findings regarding the medical history and physical examination in the recommended detail when making his chronic pain diagnostic evaluation of his patients; he did not consistently consult previous treating physicians; while he discussed the risks with his patients, to include acetaminophen toxicity, he did not chart the possible side effects in all of the medical records; and although he did consult with specialists in many instances, Respondent could have utilized consultants more consistently in his patients' care. During his testimony, this expert stressed the need for thorough documentation stating that ''there should be clear-cut indications in the medical record that [the patient's] function is better with the medications. And if it's not, then the doctor puts himself at risk if he doesn't document sufficiently in the record that the patient actually is doing better.''

However, this expert also testified that Respondent had a working diagnosis for each patient which justified the prescribed medications; had an adequate treatment plan documented in his patient charts; saw his patients frequently to monitor their progress; prescribed controlled substances in compliance with applicable law; and maintained quite

adequate records after the sparse initial visit entries. He further testified that in his opinion, Respondent's prescribing practices were appropriate.

In her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, Judge Randall went into great detail regarding the medical problems and treatment of the patients at issue in this proceeding. She discussed the prescription profiles, the information contained in the patient charts, the experts' testimony, Respondent's testimony, and the testimony of some of the patients. Since the Deputy Administrator is adopting Judge Randall's findings of fact in their entirety, there is no need for him to reiterate them. However, the Deputy Administrator makes the following general findings regarding Respondent's treatment of the patients at issue.

In general, the patients at issue suffered from a variety of problems including headaches, low back pain, pain in other parts of their bodies, sleep disturbances, multiple sclerosis, and depression. These patients were seen by Respondent at least monthly, and sometimes weekly. At virtually every visit, they were prescribed a combination of several different controlled substances, as well as other medication. Respondent explained the use of these medications, warned of the dangers of misusing the medications, and adjusted the medication regimen periodically to find the best combination of drugs. In addition, these patients received other forms of treatment such as osteopathic manipulations, traction, physical therapy, trigger point injections, range of motion exercises, transcutaneous electric nerve stimulation, and training in the proper use of body mechanics.

Respondent prescribed large quantities of controlled substances to these patients on a regular basis; however, he appeared to monitor his patients' use of the medications. He would not refill a prescription without seeing the patient. If Respondent became concerned about the amount of controlled substances being consumed by a patient, he would evaluate whether the patient appeared coherent and able to function. Respondent would perform liver toxicity tests to determine whether a patient was consuming too much acetaminophen and when a patient would experience a side effect from a drug, Respondent would discontinue the medication. Respondent assisted one patient in tapering off all medication, however the patient's pain became intolerable and Respondent resumed prescribing controlled substances for the patient.

A couple of the patient charts indicate that Respondent performed an impairment evaluation using the American Medical Association guidelines. Respondent also referred many of these patients to specialists, such as neurologists or psychiatrists, or to pain clinics. For the most part, these specialists confirmed Respondent's diagnosis, however, several of the specialists expressed concerns regarding the amount of controlled substances being prescribed by Respondent to the patients. Reports from these specialists, including those that expressed concerns, are included in the patients' charts. Two of Respondent's patients were referred to the pain clinic where the Government's expert was the medical director. In neither instance did the Government's expert contact Respondent to learn of the patient's history, however the Government's expert testified that there was no medical standard requiring such contact. One patient left the clinic because he could not afford to continue his treatment there. The other patient was tapered off his medication while at the clinic, but when the clinic could not manage the patient's pain, he was put back on narcotics. According to this patient, the clinic encouraged extensive daily exercise and meditation, however he further testified that this was not realistic if one has a job given the time constraints.

According to the Government's expert there were a number of ''red flags'' in Respondent's charts which should have alerted Respondent to the fact that these drugs were not being used for a legitimate medical purpose. First, some patients were involved in a number of accidents, however Respondent was not always told of them. On one occasion, a patient was arrested for driving under the influence of drugs. Respondent regulated the patient's medication, but after the patient's second arrest, Respondent refused to prescribe any more medication unless the patient signed a written promise not to drive while taking the medication. Second, a number of the patients were being treated by other doctors. In some of these instances, Respondent was not aware of the other doctors' treatment. According to Respondent and the patients, if he was made aware of the other treatment, he would discuss the situation with the patients and indicate that they could have only one treating, physician. Third, on several occasions' Respondent was contacted by pharmacists, a home health care nurse and/or insurance carriers regarding the large amount of controlled substances being prescribed to patients. Respondent credibly testified that he took these concerns into consideration when treating the patients. Fourth, one of Respondent's patients was sharing drugs with a family member and another with a friend. Also two of Respondent's patients had allegedly altered prescriptions. With all of these patients, Respondent advised them that this behavior was unacceptable and if it continued they would no longer be his patients. In fact, Respondent did ultimately stop treating one of them. Fifth, the spouse of one of Respondent's patients told Respondent of her husband's past drug problems and that he faked pain and exhibited drug seeking behavior. Respondent met with the patient and his wife to discuss this situation and determined that the patient had chronic pain and needed the medication. Respondent's expert testified that a family member's concerns should be addressed, but often a family member needs to be educated that just because a person is taking a large number of controlled substances does mean that the person is an addict or abuser. Sixth, one of the patient charts indicated that the patient lost several prescriptions, however Judge Randall found that the patient credibly testified that he never lied to Respondent in order to obtain more prescriptions. Seventh, Respondent resumed prescribing controlled substances to a patient after he completed drug detoxification treatment. According to Respondent, he evaluated the patient and determined that he still suffered from chronic pain and needed the medication. Finally, one of Respondent's patients was hospitalized for an amphetamine overdose. Respondent's expert testified that this was a ''big red flag'' but if the patient had chronic pain, she was entitled to relief.

The concerns of the Government's expert have been discussed generally above. The Government's expert expressed specific concerns regarding each of the patients. Most notable is the expert's disagreement with Respondent's continued prescribing of acetaminophen-based products to a patient who developed hepatitis. In fact, Respondent's expert indicated that he would have altered the prescriptions for this patient once it was learned that she had hepatitis.

As discussed above, one of Respondent's experts found that Respondent's patient chart were lacking details regarding his initial evaluation and diagnosis, however the expert found Respondent's treatment reasonable and prescribing appropriate.

The expert found that the prescribing of a combination of drugs at the same time is appropriate because each drug has specific indications. The expert also opined that prescribing beyond the recommended doses found in the Physician's Desk Reference (PDR) is not acting outside the standard of care because the PDR is merely a guide.

A number of Respondent's patients testified at the hearing in this matter. In addition, Respondent introduced letters from 99 of Respondent's patients. Essentially, these patients indicated that before seeing Respondent they could not function due to their chronic pain. Some indicated that they had been to other doctors but nothing worked to relieve them of their pain. However, they all indicated that due to Respondent's treatment, including the prescribed medications, their level of comfort has increased and their quality of life has improved. Some indicated that they were now able to work full-time and others indicated that they were able to participate in family activities and life in general. Several of the patients indicated that they had stopped taking medications for a period of time, but the pain was intolerable and they had to resume taking narcotics prescribed by Respondent. One patient indicated that it was his goal to ultimately be drug-free, but he does not want to be drug-free and disabled. Regarding the combination of prescriptions issued by Respondent, a number of the patients stated that they take different drugs depending on the severity of the pain and never take the drugs simultaneously. In addition, a number of patients indicated that Respondent did not tell them to take their prescriptions to different pharmacies to avoid suspicion. In fact, Respondent encouraged them to establish a relationship with one pharmacy and take all of their prescriptions to that pharmacy to be filled.

The Government also introduced into evidence at the hearing the testimony of two pharmacists and statements from 13 other pharmacists regarding their concerns about Respondent's controlled substance prescribing. One pharmacist testified that Respondent's prescribing placed the health and overall well-being of his patients at risk. He was concerned about the number of prescriptions issued by Respondent, the frequency of the prescriptions and the toxicity associated with taking those prescriptions. He further testified that he filled the prescriptions of other physicians who treat chronic pain, but they did not write as many controlled substance prescriptions as Respondent. He also indicated that when he expressed his concerns to Respondent regarding prescriptions issued to three patients who lived together, Respondent ''basically * * * told me that he was the doctor, I was the pharmacist. * * * He was very flippant about the way that he told me off, basically just to mind my own business, that I had no reason to be calling him.'' The other pharmacist testified that he had concerns regarding some of Respondent's prescriptions; that he contacted Respondent regarding these concerns; but that he never refused to fill any of Respondent's prescriptions.

As to 10 of the pharmacists' statements, the Deputy Administrator agrees with Judge Randall's finding that they were ''(1) lacking in foundational information about the declarants' credentials, (2) so lacking in factual specificity about the events related, and (3) so vague as to what was said to the Respondent and what he replied, that, without the declarants' testimony and opportunity for cross-examination, . . . these statements [are] worth very little weight in this matter.''

The other three pharmacists' statements also lacked foundational information about the pharmacists' credentials other than that they were licensed at some point. One pharmacist expressed general concerns about three specific patients and that these concerns were raised with Respondent. However there was no information in this statement as to when these concerns were raised with Respondent and what specifically Respondent was told about the patients' behavior at the pharmacy. Another pharmacist indicated that he no longer fills Respondent's prescriptions, but he also indicated that he never called Respondent to voice his concerns. This pharmacist also named a specific patient however there was no other evidence presented linking this patient to Respondent. The third pharmacist described his experiences with a specifically named patient, however there was no evidence linking the behavior of this patient with conduct by Respondent. As with the other statements, Judge Randall concluded and the Deputy Administrator agrees that these statements are entitled to little weight.

Respondent testified at the hearing about the pharmacists' concerns stating that, ''The captain of the ship is the physician, the buck stops here. I'm the ultimate individual because I'm the individual who prescribes the medication. Therefore, I take into consideration what the pharmacist says, but it's my responsibility to prescribe the medication.''

Respondent acknowledged at the hearing that between December 1993 and September 1995, he had ordered multiple dosage units of controlled substances that he either took himself or gave to family members for their documented medical conditions, or that were to be used for emergency situations in his office.

Respondent admitted at the hearing that in 1995 he had not maintained a complete and accurate record in a formal log of controlled substances he dispensed in his office, and that he had not taken a biennial inventory of controlled substances prior to November 1995. However, Respondent introduced evidence at the hearing that in December 1995, he began maintaining a log which reflects his controlled substance dispensing, and he also introduced a copy of his in-office inventory of controlled substances as of January 2, 1996.

A former member of the Utah medical examining board who was also the president of the state osteopathic association from 1984 to 1991, testified that he has known Respondent since 1974; that Respondent has a reputation in the medical community as being skilled in the practice of osteopathic medicine; that he has referred his patients to Respondent for treatment; that it is appropriate for a physician to maintain controlled substances in his office for treating family members; and that Respondent's professional charges were reasonable within thee osteopathic community.

Respondent testified at the hearing that between 1994 and 1997, he took three courses on pain management which consisted of guest lectures ''who were considered 'authorities' in the pain treatment and how these individuals managed their chronic intractable pain patients.''

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to 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.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. See *Henry J. Schwarz, Jr., M.D.*, 54 FR 16,422 (1989).

It is the Government's position that factors two, four and five apply in this case. Because of his failure to keep proper records, Respondent was unable to account for large quantities of drugs that he had ordered. He prescribed large quantities of controlled substances to individuals who he knew or should have known abused the drugs. In addition, he prescribed controlled substances to patients without adequate justification for the prescribing. Respondent ignored the concerns of pharmacists and other health care professionals thereby threatening his patients' health and safety. The Government further argued that Respondent violated state law by prescribing controlled substances for family members and by prescribing anabolic steroids for muscle enhancement. It is the Government's position that Respondent's cavalier attitude towards the handling of controlled substances places his patients at risk.

Conversely, Respondent contends that the Government has failed to establish a factual basis for the revocation of his DEA registration. It is Respondent's position that there were problems with the Government's investigation and that the Government's expert was not provided adequate information in order to render a meaningful opinion regarding Respondent's treatment of his patients. The Government took 38 out of over 500 patients charts and then only had its expert review 18 of the charts. The pharmacists' statements were too general to be used against him. Also, the Government failed to link any patient abuse of the prescriptions to any conduct, or lack thereof, by Respondent. It is Respondent's position that he prescribed controlled substances to his patients for legitimate medical purposes and that his failure to maintain records in the form prescribed by DEA does not warrant revocation in this case. Respondent contends that his medical practices pose no danger to the public health and safety, but that his patients will be in danger if his registration is revoked and they can no longer obtain controlled substances to enable them to continue functioning as productively as possible.

Regarding factor one, there is no evidence in the record that the state licensing board has taken any action against Respondent's license to practice medicine or handle controlled substances. Likewise regarding factor three, there is no evidence in the record that Respondent has been convicted of any controlled substance related offense.

However, factors two and four, Respondent's experience in dispensing controlled substances and his compliance with applicable laws relating to controlled substances, are relevant in determining whether Respondent's continued registration is in the public interest. Pursuant to 21 CFR 1306.04, prescriptions for controlled substances must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

The Government alleged that Respondent's prescribing to the patients at issue in this proceeding, as well as to his family members was not for a legitimate medical purpose. First, in support of its position the Government argued that Respondent's prescribing exceeded the recommended amounts and length of time set forth in the PDR. However, DEA has previously held that the PDR is not binding on a physician. *See Margaret E. Sarver, M.D.*, 61 FR 57,896 (1996). The Deputy Administrator agrees with Judge Randall's conclusion that exceeding the recommendations in the PDR may warrant further investigation but it does not, in and of itself, make the prescriptions not legitimate.

Second, the Government contended that there was inadequate diagnosis and evaluation to justify Respondent's prescribing of controlled substances. According to the Government's expert, there was insufficient information in the patient charts to warrant the prescriptions and Respondent did not refer the patients to specialists. One of Respondent's experts agreed with the Government's expert testifying that in his opinion the patient charts were lacking in detail regarding Respondent's initial evaluation and diagnosis, and on two occasions he would have referred the patients to specialists. But Respondent's expert also testified that subsequent entries in the patient charts were sufficient and that Respondent did refer other patients to specialists. Judge Randall concluded and the Deputy Administrator agrees that based upon a review of the patient charts, as well as, Respondent's testimony, the patients' testimony and statements, the experts' testimony, and reports from specialists found in the charts, the preponderance of the evidence supports a conclusion that the prescribing was justified.

Third, the Government argued that Respondent failed to reduce the dosage levels prescribed and that his prescribing was not responsive to the patients' medical conditions. All of the experts testified that there is no upper limit on the use of narcotics in the treatment of chronic pain. Respondent's experts testified that dosage levels should not be reduced so long as the amount of drugs prescribed are effectively managing the patient's pain; that Respondent's prescribing was responsive to the patients' medical conditions; and that the amount of pills prescribed alone should not be the test for determining whether the prescriptions are legitimate. Rather, one should look at whether the amount of drugs prescribed are enabling the patient to function. Respondent monitored his patients' use of controlled substances by seeing them at least monthly, and according to Respondent none of his patients were over-medicated. There is no evidence in the record that any of Respondent's patients were addicts. The term ''addict'' is defined in 21 U.S.C. 802(1) to mean, ''any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.'' To the contrary, Respondent's patients testified and/or submitted statements indicating that because of Respondent's treatment they are able to be functioning members of society.

Fourth, the Government argued that Respondent improperly prescribed controlled substances to patients who had recently completed substance abuse treatment. But, the Government witness and the Consensus Statement both indicated that it is not illegal to prescribe narcotics to these patients, but that a physician should use extra caution in so prescribing. The record indicates that Respondent evaluated these patients and determined that they still suffered from chronic pain requiring narcotics. Respondent monitored these patients' use of controlled substances.

Fifth, the Government contended that Respondent improperly prescribed controlled substances to family members. However, there is no evidence that it is illegal to do so.

Finally, the Government argued that Respondent improperly prescribed similar controlled substances simultaneously. But Respondent testified that he uses the stepladder approach to prescribing controlled substances. Therefore, he may prescribe a relatively weak opiate and a stronger opiate so that he patient can take the medication that correlates with his/her level of pain. Respondent's experts testified that this approach to prescribing meets the standard of care followed by the therapeutic school in the treatment of chronic pain. Different drugs work differently for different people, and since pain is subjective, the physician has to trust his patients.

The Government questioned the trustworthiness of a number of Respondent's patients, including one who indicated that he lost prescriptions; two who shared their drugs with others; those who went to other doctors at the same time that they were being treated by Respondent; and one whose spouse indicated that he faked pain to get prescriptions. However, Respondent investigated the claims, discussed the claims with the patients, made judgments as to whether or not to believe the patients, and carefully monitored any future behavior.

The Deputy Administrator agrees with Judge Randall's conclusion that based upon a review of the patient charts, Respondent's testimony, the patients' testimony and/or statements, and the experts' testimony, the preponderance of the evidence supports a conclusion that Respondent prescribed controlled substances for a legitimate medical purpose.

However, the Deputy Administrator finds that Respondent did prescribe anabolic steroids for muscle enhancement when it was illegal to do so. As Judge Randall stated, ''[t]he Government is legitimately concerned about the Respondent's failure to remain current with the law concerning anabolic steroid prescribing. It is the registrant's responsibility to know the state of the law affecting his profession, and 'I didn't know' does not justify the Respondent's unlawful prescribing of anabolic steroids in 1992.''

In addition at the time of the investigation in this matter, Respondent failed to keep complete and accurate records of his controlled substance handling as required by 21 U.S.C. 287 CFR 1304.04 and 1304.21. However, according to Respondent he has properly maintained the required records since 1995.

As other conduct which may threaten the public health and safety under factor five, the Government asserted that Respondent failed to acknowledge warnings of local pharmacists; failed to obtain information from other physicians treating a patient at the same time as Respondent; failed to alter his prescribing in response to a hospice nurse's concerns; failed to deny controlled substance prescriptions to an individual after he completed drug treatment; and improperly continued to prescribe acetaminophen to a patient after she was diagnosed with hepatitis.

The Deputy Administrator concurs with Judge Randall's conclusion that Respondent's treatment of the patient with hepatitis did place the patient's health at risk. However, the Deputy Administrator also agrees with Judge Randall that the Government's other concerns did not place his patients or the public health and safety at risk. He considered the concerns of the other health care professionals and the fact that a patient had just completed drug treatment in determining the appropriate treatment for a patient. While it may have been prudent for Respondent to contact other physicians who treated his patients, this is not required and no evidence was presented to indicate that the health and safety of his patients or the general public was endangered by his failure to do so.

After reviewing the record in this matter, Judge Randall noted, ''[w]ithout a doubt, the Government had legitimate concerns as a result of its initial investigation of the Respondent and his prescribing practices.'' The Deputy Administrator finds it noteworthy that even one of Respondent's experts testified that Respondent's documentation was lacking and that lack of sufficient documentation places a physician at risk. However, despite the large number of prescriptions issued by Respondent, the pharmacists' concerns, and the evaluation of the Government's expert, the Government has failed to prove by a preponderance of the evidence that Respondent's continued registration would be inconsistent with the public interest. As a result, Judge Randall recommended that no action be taken against Respondent's registration.

In evaluating this case, it is apparent that there is disagreement within the medical community regarding the use of controlled substances in the treatment of chronic pain. As Judge Randall noted, ''DEA is in a difficult position, for it is asked to determine appropriate prescribing practices in a treatment area in which the medical profession is not in accord: the treatment of chronic pain patients.'' However, DEA has previously held that it is not DEA's role to resolve this disagreement. In *William F. Skinner, M.D.*, 60 FR 62,887 (1995), the then-Deputy Administrator found that, ''the conflicting expert opinion evidence presented leads to the conclusion that the medical community has not reached a consensus as to the appropriate level of prescribing of controlled substances in the treatment of chronic pain patients. * * * It remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of the Federal and State law.''

Here, the Government's evidence is outweighed by the testimony of Respondent and his experts, the patients' testimony and statements, and the patient charts.

While it is true that Respondent prescribed anabolic steroids for muscle enhancement and did not maintain proper records of his controlled substance handling, revocation of his registration is not warranted. Respondent admitted that his prescribing of anabolic steroids was illegal. However, he ceased such prescribing immediately upon learning that it was illegal and has not prescribed anabolic steroids for muscle enhancement since. Judge Randall stated, ''[a]lthough this corrective action does not justify the Respondent's failure to remain current in the law, * * * his actions show his desire and willingness to comply with the law in the prescribing of controlled substances.''

Respondent also clearly did not maintain adequate controlled substances records, but he accepted responsibility for his inadequate recordkeeping and now maintains complete and accurate records. Here Judge Randall stated, ''[a]gain, the Respondent's remedial efforts do not justify his prior failure to comply with record-keeping requirements, but such efforts do demonstrate that the DEA has certainly acquired this Respondent's attention. His response has been to take affirmative action to correct his prior mistakes.''

The Deputy Administrator finds it significant that Respondent has taken several courses since the investigation of his practice concerning pain management and handling controlled substances. As Judge Randall noted, ''although such remedial actions do not justify the Respondent's prior lack of knowledge, it does demonstrate his sincerity in updating his credentials, consistent with his current medical practice.''

The Deputy Administrator agrees with Judge Randall that based upon the record as a whole, no adverse action is warranted against Respondent's DEA Certificate of Registration. However, the Deputy Administrator notes that the

treatment of chronic pain patients is a difficult business. Since pain is mainly subjective, physicians must rely heavily on the complaints of patients. Because of this, physicians must be ever vigilant for evidence of diversion of controlled substances for other than legitimate medical purposes.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 C.F.R. 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AS9420059, previously issued to Paul W. Saxton, D.O., be, and it hereby is, continued with no adverse action being taken.

Dated: May 3, 1999.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 99–11580 Filed 5–7–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on March 2, 1999, Sigma Aldrich Research Biochemicals, Inc., Attn: Richard Milius, 1–3 Strathmore Road, Natick, Massachusetts 01760, made application by renewal to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cathinone (1235)	I
Methcathionone (1237)	I
Aminorex (1585)	I
Alpha-Ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
4-Bromo-2, 5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
2, 5-Dimethoxyamphetamine (7396).	I
3, 4-Methylenedioxyamphetamine (7400).	I
N-Hydroxy-3, 4-methylenedioxyamphetamine (7402).	I
3, 4-Methylenedioxymethamphetamine (7405).	I
1- [1- (2-Thienyl) cyclohexyl] piperidine (7470).	I
Heroin (9200)	I
Normorphine (9313)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Benzoylecgonine (9180)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Metazocine (9240)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
levo-alphacetylmethadol (9648)	II
Fentanyl (9801)	II

The firm plans to manufacturer the listed controlled substances for laboratory reference standards and neurochemicals.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than (60 days from publication).

Dated: April 26, 1999.

John H. King,

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

[FR Doc. 99–11692 Filed 5–7–99; 8:45 am]

BILLING CODE 4410–09–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

May 5, 1999.

TIME AND DATE: 10:00 a.m., Thursday, May 13, 1999.

PLACE: Room 6005, 6th Floor, 1730 K Street, NW, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following:

1. *Secretary of Labor* versus *Newmont Gold Co.*, Docket Nos. WEST 97–164–RM, etc. (Issues include whether the judge correctly determined that (1) citations should be dismissed based on their failure to state reasonable abatement times and (2) 30 CFR § 56.14107 cannot be applied to require supplementation of factory installed guards on haul trucks, and that the exception is subsection (b) applied.)

TIME AND DATE: The meeting will commence following upon the conclusion of oral argument in the case which commences at 10:00 a.m. on Thursday, May 13, 1999.

PLACE: Room 6005, 6th Floor, 1730 K Street, NW, Washington, DC.

STATUS: Closed [Pursuant to 5 U.S.C. § 552b(c)(10)].

MATTERS TO BE CONSIDERED: It was determined by a unanimous vote of the Commission that the Commission consider and act upon the following in closed session:

1. *Secretary of Labor* versus *Newmont Gold Co.*, Docket Nos. WEST 97–164–RM, etc. (*See* oral argument listing, *supra,* for issues.)

Any person attending an open meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2796.160(d).

CONTACT PERSON FOR MORE INFO: Jean Ellen, (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll-free.

Sandra G. Farrow,

Acting Chief Docket Clerk.

[FR Doc. 99–11890 Filed 5–6–99; 3:58 pm]

BILLING CODE 6735–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Leadership Initiatives Advisory Panel

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Leadership Initiatives Panel, International section, to the National Council on the Arts will be held on May 19, 1999. The panel will meet from 8:15 a.m. to 9:00 a.m. in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications and proposals for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by applicants. In accordance with the determination of the Chairman of May 14, 1998, these sessions will be closed to the public pursuant to subsection