Membership in this group research project remains open, and Semiconductor Research Corporation intends to file additional written notification disclosing all changes in membership.

On January 7, 1985, Semiconductor Research Corporation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on January 30, 1985 (50 FR 4281).

The last notification was filed with the Department on March 22, 1994. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on April 20, 1994 (59 FR 18830).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 95–29496 Filed 12–4–95; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Transguide System Media Services Software Project

Notice is hereby given that, on August 23, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute (''SwRI'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are: Harte-Hanks Television KENS-Channel 5, San Antonio, TX; KISS Radio of San Antonio, Ltd., San Antonio, TX; KMOL-Channel 4, San Antonio, TX; KSAT-TV12, San Antonio, TX; KSMG, San Antonio, TX; KTFM, San Antonio, TX; KTSA, San Antonio, TX; San Antonio, TX; San Antonio Express News, San Antonio, TX; Southwest Research Institute, San Antonio, TX; and State of Texas, acting by and through the Texas Department of Transportation, San Antonio, TX.

The purpose of the venture is to facilitate the transmission of information for the Texas Department of Transportation Operational Control Center of the TransGuide System to media outlets through the development of personal computer based software which will list current traffic incident scenarios, list current scheduled lane closures and provide a display of a high level and schematic map of the major highways and road segments where the TransGuide System is active in Bexar County.

Membership in the program remains open, and SwRI intends to file additional written notifications disclosing all changes in the membership or planned activities.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 95–29504 Filed 12–4–95; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Affordable High Performance Computing Cooperative Arrangement

Notice is hereby given that, on June 29, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Pratt & Whitney Division of United Technologies Corporation has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of a cooperative arrangement known as the ''Coordinated Research Agreement for Development of Affordable High-Performance Computing'' (the ''AHPC''). The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are: United Technologies Corporation, Hartford, CT; The Massachusetts Institute of Technology, Cambridge, MA; CFD Research Company, Huntsville, AL; Platform Computing Company, Newbury, MA; The Research Foundation of the State University of New York, Amherst, NY; and The MacNeal-Schwendler Corporation, Los Angeles, CA.

The purpose of the AHPC is to pursue a coordinated research and development effort leading to development of affordable distributed computing software for use in design of advanced aircraft engine components, while providing technology for commercial and military uses.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 95–29497 Filed 12–4–95; 8:45 am]

BILLING CODE 4410–01–M

Drug Enforcement Administration

[Docket No. 94–10]

Michael J. Roth, M.D.; Continuation of Registration

On October 27, 1994, the Deputy Assistant Administrator (formerly Director), Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Michael J. Roth, M.D. (Respondent), of Santa Monica, California, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AR8354425, under 21 U.S.C. 824(a)(4) and deny any pending applications under 823(f), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that:

(1) During the period March 1988 through December 1989, the Respondent prescribed, administered, and dispensed excessive amounts of controlled substances to a single patient, including Demerol, Dilaudid, Xanax, Ativan, Percordan, Tylenol with Codeine, Valium, Percocet, Methodone, and Doriden, without a legitimate medical purpose and while not acting in the usual course of professional practice;

(2) During the same time period, the Respondent further prescribed narcotic drugs to the same narcotic dependent patient for the purpose of maintenance treatment, and engaged in detoxification treatment of that patient without holding a separate DEA registration to conduct a narcotic treatment program; and

(3) During the period January 1991 through February 1993, the Respondent prescribed excessive amounts of controlled substances to two patients, including Chloral Hydrate, Ativan, Dalmane, Tylenol with Codeine, and Fiorinal, without a legitimate medical purpose and while not acting in the usual course of professional practice.

On November 19, 1993, the Respondent, through counsel, filed a timely request for a hearing. On February 23, 1994, the case was consolidated for hearing with *Michael S. Gottlieb, M.D.*, Docket No. 93–53, and *William J. Skinner, M.D.*, Docket No. 93–39. Following prehearing procedures, a hearing was held in Los Angeles, California, on March 29–30 and May 10–12, 1994, before Administrative Law Judge Paul A. Tenney. At the hearing both the Government and the Respondent called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On October 17, 1994, Judge Tenney

issued his Findings of Fact, Conclusions of Law, and Recommended Ruling, finding that the Respondent's registration was not inconsistent with the public interest, and recommending that no action be taken with respect to the Certificate of Registration of Respondent, Dr. Roth. The Government filed exceptions to his decision, and the Respondent filed responses to the Government's exceptions. On December 12, 1994, Judge Tenney transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and the filings of the parties, 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 opinion of Judge Tenney, and 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.

The Deputy Administrator finds that the Respondent is licensed to practice as a physician and surgeon in the State of California. The DEA's allegations concern the Respondent's treatment of two patients, ''Patient A'' and ''Patient B.'' Patient A had a number of significant physical conditions which caused severe pain, including pressure on the nerves from cervical degenerative joint disease; degenerative osteoarthritis of the lumbar vertebrae above a previous area where fusion surgery had been performed; spinal stenosis which occurs when the spinal canal narrows, in some cases putting pressure on a nerve; severe temporal mandibular joint degenerative disease; compression fracture of the patient's spine at L–1 and L–2; and trochanteric bursitis of the hip.

During the time period of March through October 1988, the government contended that the Respondent prescribed controlled substances to Patient A for other than a legitimate medical purpose. During this period, Dr. Skinner was the primary treating physician for Patient A. The Respondent and Dr. Michael Gottlieb were partners in a medical practice in Los Angeles, and Dr. Gottlieb would care for Patient A when Dr. Skinner was not available, and the Respondent cared for Patient A when neither Dr. Skinner nor Dr. Gottlieb was available. Respondent testified that he did not keep independent medical records of the patient while he was in partnership with Dr. Gottlieb, but when he issued prescriptions to Patient A, he followed the medical regimen established by Dr. Gottlieb and Dr. Skinner.

During the period of March 26, 1988, through October 13, 1988, the Respondent prescribed Schedule II controlled substances to Patient A on 13 occasions, and Schedules III through V controlled substances to Patient A on 23 occasions. The Respondent testified that when Patient A was in acute pain, he would prescribe Percodan, but that he would then try to taper her off that substance once the acute pain diminished. In July 1988, Patient A suffered a fall and injured her back. Dr. Gottlieb admitted the patient to the hospital on July 25, 1988, with a diagnosis of severe degenerative disc disease with marked fact hypertrophy from L3 to S1, a history of sciatica and foot drop, premature atrial contractions, and degenerative disc disease of the cervical spine. Dr. Gottlieb noted on the patient's history that she was currently using Percodan, Ativan, and Xanaz. Percodan, a Schedule II controlled substance, contains oxycodone and aspirin; Ativan, a Schedule IV controlled substance, contains lorazepam; and Xanaz, a Schedule IV controlled substance, contains alprazolam. Upon admission to the hospital, Dr. Gottlieb ordered, and Patient A was given, 150 milligrams (mg.) of Demerol and 1 mg. of Ativan. Demerol is a brand name for meperidine hydrochloride and is a Schedule II controlled substance.

On July 26, 1988, following a CAT scan, Dr. Joyce issued a report, writing that Patient A had a mild compression fracture at L1, mild stenosis at L2–3, moderate stenosis at L3–4, and a post-posterior bony fusion from L4 to the sacrum. Patient A was discharged on August 18, 1988, and the Respondent ordered administration of 100 mg. of Demerol, and then issued a prescription 70 Percodan. On August 25, 1988, the Respondent prescribed 20 Percodan and 5 Dilaudid. Dilaudid is a brand name of hydromorphone hydrochloride and is a Schedule II controlled substance.

During the period from September 1, 1988, to October 13, 1988, the Respondent prescribed to Patient A 210 Percodan and 300 mg. of Demerol. On September 29, 1988, Patient A was admitted to the hospital by Dr. Skinner, and she was discharged on October 4, 1988, with a diagnosis of a compression fracture, osteoporosis, and congenital scoliosis. On October 17, 1988, Patient A was again admitted with a complaint of severe left leg pain, and on October 23, 1988, she was discharged with the diagnosis of acute back pain secondary compression fracture of L1, acute lumbosacral spinal sprain and strain secondary to severe osteoarthritis at L2–3 with neuroforaminal narrowing, sciatica (resolved) and osteoporosis with high risk of possible spontaneous hip fracture. On October 31, 1988, Patient A was admitted to the Betty Ford Clinic with an initial diagnosis of opiate, alcohol, sedative, and amphetamine dependent (continuous), and she was discharged on December 10, 1988.

As Judge Tenney noted, ''[t]here is a 'debate' or difference of opinion between those specialized in addiction medicine and those in pain management regarding the use of narcotics for the treatment of severe pain.'' He also noted that Dr. Smith and Dr. Ling, the Government expert witnesses, were primarily experts in addiction medicine, and Dr. Margoles and Dr. Brechner, the Respondent's expert witnesses, were primarily experts in pain management. Dr. Smith and Dr. Margoles agreed that there exists a difference of opinion within the medical community as to the appropriate level of prescribing of controlled substances for the treatment of chronic pain patients. Also significant is the fact that the opinions of Dr. Brechner, Dr. Dodge, Dr. Horacek, and Dr. Woods were supported by either their personal examination, treatment, or both, of Patient A, during the relevant time period, whereas the opinions of Dr. Smith and Dr. Ling were based upon their review of Patient A's treatment records and relevant prescription documentation.

On March 3, 1990, Dr. Smith wrote in a report for the District Attorney: ''[the] spectrum of medications [prescribed to Patient A] was not justified by the medical pathology and, in fact, the medications caused the patient far more harm than benefit. The dosage of medication was clearly excessive and the duration over the several month period as outlined in the medical records was both excessive and not justified by the medical pathology.'' He concluded that ''[a]s a result of this analysis it is my opinion then, that Dr. Skinner and his colleagues were not prescribing a narcotic medication primarily for the management of pain but, in fact, were maintaining her addiction.'' During the hearing before Judge Tenney, Dr. Smith testified, after reviewing the quantities of controlled substances prescribed on selected dates, that those quantities were excessive in light of the standard therapeutic dosage. He then adopted the conclusion reached in his 1990 letter to the District Attorney.

Dr. Ling, a medical expert in the areas of neurology, psychiatry, addiction, and pain medicine, opined that, based upon his review of Patient A's treatment record and pharmacy records, the Respondent's prescribing practices

during 1988 did not meet the standard of care of the average practitioner. He stated, ''If this was the only records there [were], then I don't think it meets the standard of care.'' He also testified that, in 1988, the standard of care was not to prescribe a large amount of narcotics, for such practice could result in the patient's developing a tolerance to a controlled substance: ''You'd be treating the tolerance. You'd be treating addiction, you're no longer treating the [diagnosed medical condition].'' Further, Dr. Ling recommended that a physician treating a patient with a potential drug dependency problem should consult with a specialist in drug addiction. Both Dr. Smith and Dr. Ling concluded that Patient A was an addict who was opiate dependent and benzodiazipine dependent.

The Respondent presented evidence from consulting physicians, who had concluded that Patient A was not an addict, but that she was dependent upon controlled substances to treat her chronic and sometimes acute pain. Specifically, after having reviewed Patient A's medical history and having interviewed her twice, Dr. Margoles, a medical expert in pain management, testified, that throughout the years 1986 to 1988, Patient A had experienced intractable pain as a result of numerous medical problems and degenerative changes. He concluded that Patient A was a chronic pain patient, as opposed to an opioid abuser, and that she sought and was given medications to control her pain, not for euphoria. He found that, although Patient A received an increase in amounts of opioids prescribed for her use, such an increase resulted from the severity of her pain, not addiction. ''It was obvious that the medication was being used to keep her going in her professional career.'' Also, he noted that there was no evidence in the patient's records that she sought drugs in order to obtain euphoria, no evidence of abstinent syndrome, nor clinical or laboratory evidence of toxicity. Dr. Margoles testified that the lack of toxicity evidence meant that the ''patient obviously tolerated the medication that she had, that was used in her case, and evidently benefitted her and [that] she had no toxic side effects * * * no slurred speech, inability to have cognitive speech, straight speaking.''

As to the Respondent's specific involvement in 1988, Dr. Mangoles also opined that the 13 prescriptions Dr. Roth wrote during a seven month period were needed to control the patient's pain problems. He also noted that the Respondent appeared ''to be tapering her down all the time,'' and that such tapering was within the usual course of professional practice. Dr. Smith agreed with Dr. Margoles concerning the propriety of tapering Patient A, under the circumstances. Further, Dr. Margoles testified that the Respondent ''acted in good faith and prescribed medication that was adequate for a given diagnosis and following good faith examination.''

Finally, Dr. Margoles noted that in the 1980's, guidelines were established in prescribing controlled substances for chronic conditions. These guidelines were endorsed by various medical and legal groups, to include the California Board of Medical Quality Assurance and the California Bureau of Narcotic Enforcement. Dr. Margoles testified that the Respondent's prescribing to Patient A met these standards. Thus, he concluded that the Respondent prescribed controlled substance in the appropriate course of his professional conduct, and not for the purpose of maintaining Patient A's condition as an addict.

Also, the Respondent produced an affidavit from Dr. Dodge, a consulting neurosurgeon involved with the treatment of Patient A from 1986 through 1988, who wrote:

> In my opinion, although the amounts of drugs were large compared to the average patient, they were necessary in order to treat the patient's pain. Although the patient clearly had a drug dependence problem, I do not believe the pain was controllable by other means besides narcotics. The amounts of narcotics tended to increase at the time of the acute events . . . Dr. Skinner and the other physicians responsible for her care always attempted to minimize the amounts of drugs that she took and sought to detoxify her from those drugs when the acute phase of pain and muscle spasm from the injuries passed.
>
> In my opinion, Dr. Skinner and the other physicians responsible for her care did not violate the standard of practice in prescribing narcotic analgesics to this patient.

Further, in an affidavit, Dr. Woods, a neurologist who treated Patient A from January 1987 to January 1988, made similar observations as Dr. Dodge, and concluded: ''In my opinion, Dr. Skinner and the other physicians responsible for her care did not violate the standard of practice in prescribing narcotic analgesics to this patient, in that the drugs were prescribed to control the patient's pain not to maintain her addiction.''

As to the legitimacy of the quantities of the controlled substances prescribed, Dr. Brechner, a medical expert in the field of pain management and anesthesiology, testified that in 1988 he was consulted concerning an aspect of Patient A's treatment, for he had performed a facet block procedure to aid in the diagnosis of the source of Patient A's back pain. In the course of performing that procedure, he administered narcotic analgesics, observing that Patient A had ''an extraordinary tolerance to narcotics, even when potentiated with the tranquilizers.'' Dr. Brechner also noted that Patient A suffered from severe chronic pain and from periods of acute, intractable pain. Dr. Brechner concluded that Patient A had received narcotics prescribed in amounts that were ''extraordinary compared to the average patient,'' because of her extreme tolerance for narcotics, and that she needed the narcotics in the amounts prescribed in order to control her pain. He testified that prescribing the narcotics in lower doses was not effective, and thus, she was not ''over-dosed.''

Also, Dr. Brechner testified that alternative means of treatment were tried to control Patient A's pain, but that he did not believe such treatment was effective alone in treating the pain resulting from her acute pain-inducing incidents, such as the automobile accident or the fall down the stairway. Finally, Dr. Brechner testified that the doctors treating Patient A prescribed narcotics for a legitimate medical purpose, to treat her pain, and not to maintain her condition as an addict.

Further, Dr. Skinner, the Medical Director of St. John's Chemical Dependency Center from 1981 to 1990, and a medical expert in chemical dependency, testified that he had begun treating Patient A at the Respondent's request in 1983. Dr. Skinner testified extensively about the acute pain incidents experienced by Patient A through 1988, the consulting physicians' diagnoses resulting from these incidents, and the various narcotic and non-narcotic treatment regimen implemented to control her pain. He also stated that there was no evidence that drug intoxication caused any of Patient A's acute events, and that he had made an extra effort to insure her lack of toxicity throughout his treatment of her. Further, Dr. Skinner testified that all narcotics were either administered in the hospital or under the supervision of a private duty nurse selected by him from the nursing staff of the Chemical Dependency Center at Saint John's Hospital, and that the nurses were familiar with Patient A's case, her tolerances, and with treating patients who had Patient A's type of problems. As a result of his treatment of Patient A, Dr. Skinner concluded that she was not an addict: ''She did not demonstrate typical findings of addiction behavior. * * * never did she evidence toxicity, never did she evidence any abstinence

withdrawal syndrome, and never did she evidence, while under my care at home or in the hospitals, any evidence of street-like drug seeking behavior.''

The Respondent also testified before Judge Tenney, stating that Patient A was ''opiate dependent'' or ''opiate reliant,'' but not addicted. ''I don't feel she was addicted to the medication from the point of view that she needed the medication every so many hours as an addict would for maintenance of the use of the drug. But she relied on the medication to take away her pain. In that sense, I'm saying she was reliant on the medication. But she could go days without having medication, even weeks, when her pain wasn't bad. Then the pain would get bad and she was reliant, again, on the medication to take away the pain.'' He concluded by stating that, although he was not the primary treating physician during 1988, he issued prescriptions in good faith and as part of the regimen established by her primary treatment physicians. Further, he affirmed that he did not issue any prescriptions for the purpose of enabling Patient A to reach a state of euphoria.

As to his prescribing practices during 1991 through 1993, the Respondent testified that Patient A complained that her pain was causing her insomnia. He first referred Patient A to the sleep clinic at Cedars Sinai Hospital, but she did not follow up on that referral. Next, the Respondent consulted with the director of that clinic and used the treatment regimen he suggested to try to provide Patient A relief from both her insomnia and her pain. The recommended regimen involved trying to rotate insomnia medications to determine what medication would provide Patient A relief. He prescribed benzodiazepines, to include Restoril, Prosom, Chloral Hydrate, and Dalmane. The Respondent testified that he would give Patient A three prescriptions at one time for small dosages of different substances, stating ''the reason that we gave her the three medications at one time was to give her the alternative to try one and if one didn't work to try a second.'' The Respondent testified that he cautioned Patient A about the addictive nature of these substances, and Patient A affirmed that she was just trying to get some sleep so she could work. The Respondent affirmed that it was never his intention that Patient A would take all three prescribed medications at the same time, and that ''[Patient A] knew absolutely that that wasn't the indication.'' Finally, the Respondent testified that he was prescribing these substances in good faith to assist Patient A in trying to obtain some sleep, not to obtain a state of euphoria.

Dr. Margoles agreed with the Respondent, testifying that Patient A needed the medications prescribed during this time period to control her pain and to help her sleep, given the pain she was experiencing. Dr. Smith, however, testified generally about sedative-hypnotic dependence, and, after reviewing the prescriptions issued during 1992 through 1993, he concluded that the Respondent's prescriptions to Patient A were beyond therapeutic use and were issued for the purpose of sustaining her addiction. However, undisputed in the record was the Respondent's testimony that Patient A's medical records reflecting his treatment of her during this time period had been stolen from the Respondent's office. Acknowledging the lack of medical records, Dr. Smith admitted that if he had been able to review the medical records ''[he] could have a better understanding of what was going on in the physician's mind and whether it was appropriate prescribing.''

However, the Respondent submitted letters written between September 1990 and February 1993, reflecting his referral of Patient A to other physicians for consultation. Dr. Ling, after reviewing the consulting physician's opinions, conceded that the letters supported the Respondent's opinion that Patient A suffered intractable pain during this time period. Dr. Ling also testified that he did not see any overall strategy for the treatment of Patient A, but he conceded that, lacking the medical treatment record, he could not render an opinion as to whether the Respondent's medical practices were consistent with the skill and knowledge of the average practitioner.

Also in dispute was the adequacy of the medical treatment records for Patient A during the 1988 time period. The Respondent testified that, since he shared a practice with Dr. Gottlieb, he had not kept a separate medical record, but rather he had followed the treatment regimen of Dr. Gottlieb and Dr. Skinner. Dr. Smith testified that Dr. Gottlieb's treatment records did not meet the usual medical standard of practice regarding prescription of controlled substances. Yet Dr. Brechner also reviewed Patient A's treatment records provided by Dr. Skinner and Dr. Gottlieb, as well as the hospital records, and he testified that the acute and chronic medical conditions were well documented in the medical records. Also, Dr. Margoles testified that the records sufficiently supported the Respondent's prescribing practices, for Dr. Gottlieb's records included diagnoses and a treatment plan for Patient A. Finally, there was no expert witness testimony to establish that the Respondent's recordkeeping practices, under the circumstances, failed to meet the usual medical standard.

As to Patient B, the Government's attorney stated on the record that ''the government will really not submit any argument to the issue of . . . whether Patient B had legitimate medical conditions that were being treated,'' but noted that the Respondent's recordkeeping practices as to Patient B were deficient. Patient B's medical chart was of record, and in it the Respondent had listed several diagnoses, including ''migraine v. cluster'' headaches and insomnia. The Respondent also testified that a cluster headache could incapacitate someone and could cause insomnia. Three times in June, twice in July, and once in September 1992, the Respondent prescribed Fiorinal, a barbiturate containing butalbital, a Schedule III controlled substance, for Patient B's headaches. For Patient B's insomnia condition, the Respondent prescribed Prosom, a triazolobensodiazepine derivative, which is a Schedule IV controlled substance. The Respondent also testified that Patient B's medical problems were documented in his medical record, and that given the small amount of medication prescribed for Patient B, he felt it was not relevant to go into a long, lengthy work-up for this patient.

Dr. Margoles testified that Fiorinal was a medication that was used to control cluster headaches, and that the Respondent prescribed this medication to Patient B in appropriate dosages. He also testified that the Prosom was prescribed to Patient B in appropriate dosages to help him sleep, and that there was no evidence in the medical records that Patient B sought either of these medications for the purpose of euphoria. Therefore, he concluded that the medications were prescribed for a legitimate medical purpose and in the appropriate course of normal medical practice.

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of 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 or 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., Docket No. 88–42, 54 FR 16422 (1989).

In this case, factors two, four, and five are relevant in determining whether the Respondent's continued registration would be inconsistent with the public interest. As to factor two, the Respondent's ''experience in dispensing * * * controlled substances,'' and factor four, the Respondent's compliance with ''Federal, State, or local law,'' the Government contends that during the periods March through October 1988, and 1991 through 1993, the Respondent prescribed controlled substances in the treatment of Patient A not for a legitimate medical purpose and not in the usual course of his professional practice, in violation of State and Federal law. Specifically, the Government argues that controlled substances were prescribed to Patient A during these periods to maintain her addiction, and that the amount of narcotics prescribed far exceeded what Patient A needed for pain relief.

An ''addict'' is defined in 21 U.S.C. 802(1) as ''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 [one's] addiction.'' There was no dispute that very high doses of narcotic analgesics were administered to Patient A, but the evidence also demonstrated that she had a high tolerance to the controlled substances and required this dosage to effectively treat her pain. Patient A's medical records and the statements and testimony of medical experts establish that Patient A had several injuries and was plausibly experiencing severe and chronic pain. Further, the evidence did not adequately establish that Patient A was an ''addict.'' No evidence was presented to show that Patient A had acted to ''endanger the public morals, health, safety, or welfare,'' or that she had a compulsion to use drugs, had lost control over the drugs, or that she continued to use the drugs in spite of adverse consequences. Also, medical testimony was presented to establish that, although considered, there was no evidence of abstinent syndrome, slurred speech, inability to have cognitive speech, nor clinical or laboratory evidence of toxicity. However, there was expert testimony to establish that use of the controlled substances helped Patient A to function and participate in her professional activities in spite of chronic pain. Although the Respondent did not deny that Patient A had a chemical dependency, he testified that he was not prescribing controlled substances to Patient A to maintain an addiction, for she did not present any addictive behavior to him. Therefore, the Deputy Administrator concurs with Judge Tenney's finding that Patient A is a chronic pain patient being maintained on opioids for treatment of pain, and that she is not an ''addict.''

The Government also asserted that the Respondent's practices violated California Health and Safety Code Sections 11153 and 11154. Pursuant to Section 11153(a), a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice,'' and a prescription issued ''for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment * * * but for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use'' would not be a legal prescription pursuant to this section. Section 11154 provides in relevant part that ''[e]xcept in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person * * * which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance. * * *''

The Respondent asserted that prescribing in good faith was an absolute defense to an allegation of violation of these provisions. Dr. Ling testified that he accepted that the Respondent believed Patient A was in pain, and that he was treating her in good faith. Dr. Margoles also testified to the Respondent's good faith treatment of Patient A.

The Deputy Administrator agrees with the conclusion of Judge Tenney, that the Respondent did not violate these State code provisions. See *People* v. *Lonergan,* 219 Cal.App.3d 82, 90 (1990) (acting in ''good faith,'' as defined by California Health and Safety Code 11210, exempts a physician from criminal liability under the provision of 11153). In response to the Government's exceptions relevant to the standard applicable in this administrative proceeding, the Deputy Administrator also finds that the preponderance of the evidence establishes that the Respondent prescribed controlled substances to Patient A for a legitimate medical purpose while acting in the usual course of his professional practice, and thus, he did not violate the cited State law.

Next, the Government asserted that the Respondent performed detoxification or maintenance treatment of a narcotic drug-dependent patient without obtaining a registration for that purpose in violation of Federal law. Pursuant to 21 U.S.C. 802(30), ''detoxification treatment'' is

> The dispensing for a period not in excess of one hundred and eighty days of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. (Emphasis added).

Further, the statute defines ''maintenance treatment'' as the dispensing, ''for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.'' 21 U.S.C. 802(29) (emphasis added). However, the applicable implementing regulation states in pertinent part:

> This section is not intended to impose any limitations on a physician * * * to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or * * * to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

21 C.F.R. 1306.07(c).

The preponderance of the evidence supports a finding that the Respondent was tapering the drugs prescribed to Patient A after acute pain resolved. Dr. Ling, as well as others, testified that such tapering would be appropriate under such circumstances. Further, the record does not establish that Patient A experienced ''adverse physiological or psychological effects incident to withdrawal'' nor that, in fact, Patient A exhibited behavior consistent with the finding that she was an ''addict.'' Therefore, the Deputy Administrator agrees with Judge Tenney that the

''Respondent made a reasonable effort to manage the patient's intractable pain and limit the use of controlled substances in terms of treatment of [Patient A's] other medical conditions, and did not prescribe controlled substances primarily to wean the patient from dependence on narcotic analgesics.'' Thus, the Respondent was not maintaining Patient A's addiction nor detoxifying Patient A without a proper registration.

Next, the Government asserts that the Respondent violated 21 C.F.R. 1306.04 and California Health and Safety Code 11168, 11190, and 11191, by failing to keep adequate medical records in the course of his treatment of Patient A during 1988, and 1991 through 1993. The primary treatment records during 1988 were the records of Dr. Skinner and Dr. Gottlieb, and there was no dispute that Dr. Roth did not maintain separate treatment records recording his treatment of Patient A during this time period. Although Dr. Smith testified that Dr. Gottlieb's records were inadequate, Dr. Margoles and Dr. Brechner testified that the records sufficiently supported the Respondent's prescribing practices, for Dr. Gottlieb's records included diagnoses and a treatment plan for Patient A. Further, the Respondent testified that he merely followed the treatment regimen of Dr. Gottlieb and Dr. Skinner when he ''covered'' for them in treating Patient A. No expert witness testimony was presented to discredit the Respondent's professional practice of recordkeeping under these circumstances.

As to the records from 1991 through 1993, the Respondent testified, and no evidence was presented to the contrary, that Patient A's treatment records covering his treatment of her during this time period were stolen from his office. Further, the Deputy Administrator concurs with Judge Tenney's finding that the Respondent's explanation for the missing records was credible. Given the loss of these medical records, the hearing record is devoid of evidence sufficient to establish the inadequacy of the Respondent's contemporaneous recordkeeping practices. Thus, the Deputy Administrator agrees with Judge Tenney's conclusion that the inadequacies of the medical records were not clearly supported.

As to factor five, ''such other conduct which may threaten the public health and safety,'' the Government argued that the Respondent's pattern of prescribing to Patient A caused a threat to the public health and safety. As Judge Tenney noted, this is an unusual case for it involved the Respondent's prescribing practices for a single patient, and no evidence was provided to show a pattern of excessive prescribing to any other patients. Further, as to that single patient, the Deputy Administrator concurs with Judge Tenney's finding that the ''overriding purpose of [the] Respondent's prescribing practices was the treatment of Patient A's pain,'' a legitimate medical purpose. Also, a relevant factor in determining the public's interest is the nature of the Respondent's current practice, for the Respondent testified that the majority of his patients in 1994 were living with AIDS and in many cases in need of controlled substances to relieve their incurable pain. In the balance, the Deputy Administrator finds that it is in the public interest for the Respondent to retain his DEA Certificate of Registration.

Yet the Deputy Administrator notes with concern the large quantities of controlled substances prescribed to Patient A over an extended period of time. However, 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. Given this dispute, the Deputy Administrator is reluctant to conclude that the Respondent's prescribing of controlled substances to Patient A lacked a legitimate medical purpose or was outside the usual course of professional practice. It remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of Federal and State law. Here, the preponderance of the evidence established that the Respondent so acted.

Therefore, the Deputy Administrator finds that the public interest is best served by taking no action with respect to the continued registration of the Respondent. 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 21 C.F.R. 0.100(b) and 0.104, hereby orders DEA Certificate of Registration AR8354425, issued to Michael J. Roth, M.D., be, and it hereby is, continued, and that any pending applications, be, and they hereby are, granted. This order is effective January 4, 1996.

Dated: November 24, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–29487 Filed 12–4–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

November 29, 1995.

The Department of Labor has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (P.L. 104–13, 44 U.S.C. Chapter 35). Copies of these individual ICRs, with applicable supporting documentation, may be obtained by calling the Department of Labor Acting Departmental Clearance Officer, Theresa M. O'Malley ((202) 219–5095). Comments and questions about the ICRs listed below should be directed to Ms. O'Malley, Office of Information Resources Management Policy, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–1301, Washington, DC 20210 within 30 days from the date of this publication in the Federal Register. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OAW/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 10325, Washington, DC 20503 ((202) 395–7316). Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 219–4720 between 1:00 p.m. and 4:00 p.m. Eastern time, Monday through Friday.

Agency: Bureau of Labor Statistics.

Title: Application for BLS Occupational Safety and Health Statistics Cooperative Agreements.

OMB Number: 1220–0149.