(1) *Type of information collection:* Extension of a previously approved collection.

(2) *The title of the form/collection:* Claims Under the Radiation Exposure Compensation Act.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* none. Civil Division, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households; *Other:* none.

Information is collected to determine whether an individual is entitled to compensation under the Radiation Exposure Compensation Act, 42 U.S.C. 2210 note (1994). Applicants include individuals who resided near the Nevada Test Site; former underground uranium miners; and, individuals who participated onsite in an atmospheric nuclear test.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 914 annual respondents at 2.5 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,285 annual burden hours.

If additional information is required contact: Mrs. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: September 22, 1998.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 98–25798 Filed 9–25–98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 95–54]

Paul J. Caragine, Jr., Grant of Restricted Registration

On July 10, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Paul Caragine, M.D., (Respondent) of Denville, New Jersey, notifying him of an opportunity to show cause as to why DEA should not deny his application for registration as a practitioner under 21 U.S.C. 823(f), as being inconsistent with the public interest.

By letter dated September 6, 1995, Respondent, through counsel, filed a request for a hearing, and following prehearing procedures, a hearing was held in Newark, New Jersey on June 25, 26 and 27 and November 19, 20 and 21, 1996, before Administrative Law Judge Mary Ellen Bittner. 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 March 31, 1998, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that Respondent's application for a DEA Certificate of Registration be denied. On April 17, 1998, Respondent filed exceptions and objections to Judge Bittner's opinion and on May 4, 1998, the Government filed its response to Respondent's exceptions. Thereafter, May 8, 1998, Judge Bittner transmitted the record of these proceedings to the Acting Deputy Administrator.

The Acting Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final ordered based upon findings of fact and conclusions of law as hereinafter set forth. The Acting Deputy Administrator adopts, the findings of fact and conclusions of law set forth in the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, except as specifically noted below, but does not adopt the Administrative Law Judge's recommended ruling. 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 Acting Deputy Administrator finds that Respondent received his medical degree in 1971 from what is now the University of Medicine and Dentistry of New Jersey, and first become licensed to practice medicine in New Jersey in 1973. He has practiced orthopedic medicine in various locations throughout the State of New Jersey. According to Respondent he has treated approximately 15,000 patients over a 20-year period.

In 1988, a New Jersey state agency initiated an investigation of Respondent based upon information from a pharmacist about prescriptions Respondent had issued to two individuals. Thereafter, a state investigator collected and reviewed controlled substance prescriptions issued by Respondent to 11 patients.

Based upon the investigator's review, the New Jersey Medical Board (Medical Board) held an informal hearing on November 27, 1991, regarding Respondent's prescribing practices. Respondent testified at that hearing that he believed in using pain killing drugs for patients who needed them to function. However, Respondent also stated that, ''I'm a lot stricter and tougher about this than I was. I mean, as I look back I realize that I was really too lenient with all these people. * * * I must appear to be a fool and I'm setting myself up here by going along with all these people, going along with all these stories. * * * No more. In the last three years I've had a really exemplary record. I'm very careful. I'm not so easy to get drugs out of like I use[d] to be.'' Respondent emphasized that only two of the patients at issue were still under his care and that he had told them that he would stop prescribing controlled substances to them on April 1, 1992. Respondent further asserted that ''there are no new people out there who represent future problems for this board or for me,'' and that ''I want the board to know that I really made an effort to clean up my act and not be permissive. My only past sin was being too gullible and too charitable.'' When asked what had prompted the change, Respondent stated that, ''It just occurred to me after a period of time that this couldn't be right.''

During this same time period, a local police department received information in August 1991 that two individuals were suspected of distributing narcotics. A subsequent survey of area pharmacies revealed that Respondent had issued most of the controlled substance prescriptions for these individuals. A review of the prescriptions showed, among other things, that one of the individuals obtained 480 dosage units of Vicodin, a Schedule III controlled substance, between August 22 and September 23, 1992, pursuant to prescriptions and refills authorized by Respondent. On October 2, 1992, a search warrant was executed at the individuals' apartment, during which investigators discovered marijuana, marijuana paraphernalia, 88 prescription vials (86 of which were empty), a prescription for Percocet written by Respondent and postdated October 7, 1992, and notes indicating drug distributions. Approximately 85–90% of the prescription vials indicated that they were authorized by Respondent.

The individuals were interviewed following their arrest for among other things, possession of marijuana and drug paraphernalia. One of the individuals admitted that she had filled

prescriptions from Respondent at one pharmacy and had then called him, said that she had lost a prescription, and had him authorize another prescription by telephone at a different pharmacy. The other individual admitted that he was addicted to controlled substances and stated that he sold controlled substances prescribed to him by Respondent.

On October 14, 1992, Respondent was interviewed by state and DEA investigators. According to the investigators, Respondent told them that he knew from the beginning of his treatment of the one individual that the patient was addicted to prescription drugs. At the hearing in this matter, Respondent disputed that he told this to the investigators, however Judge Bittner found the investigators to be more credible than Respondent. Respondent also admitted to the investigators that he issued the postdated prescription, but that he did so to save the individual the expense of another office visit and to better control his intake of controlled substances.

On July 12, 1993, a complaint was filed with the Medical Board seeking the temporary suspension and permanent revocation of Respondent's medical license on grounds that he had excessively prescribed controlled substances, issued prescriptions for controlled substances before the supply previously dispensed to the patient should have been exhausted, failed to maintain medical records on patients to whom he prescribed controlled substances, continued to prescribe narcotic analgesics to a patient after she was hospitalized for treatment of an overdose of these medications, and issued postdated prescriptions. Following a hearing, the Medical Board issued an order temporarily suspending Respondent's license to practice medicine effective August 25, 1993, and suspending his authority to handle controlled substances as of August 11, 1993, on grounds that Respondent had inappropriately prescribed controlled substances to 14 patients. As a result of the Medical Board's action, Respondent surrendered his previous DEA Certificate of Registration on August 16, 1993.

Subsequently, the Medical Board issued a supplemental complaint alleging that Respondent inappropriately prescribed controlled substances to two more individuals. Following a hearing, a state administrative law judge issued an initial decision dated June 29, 1994, finding that the patients at issue had serious problems which may have resulted in legitimate complaints of pain, but that Respondent ignored warning signs which should have alerted him to the dangers of dependency, that Respondent did not control the dispensing of controlled substances, and that the record supported a conclusion that each of the patients was drug dependent. The Judge concluded that Respondent's treatment of these patients constituted gross malpractice, gross negligence and gross incompetence, professional incompetence, and professional misconduct, and that revocation of Respondent's medical license was therefore justified.

On August 11, 1994, the Medical Board issued a Final Order adopting the administrative law judge's findings of fact (with minor exceptions) and conclusions of law. However, the Medical Board found that there was no evidence that Respondent's conduct was ''infected by improper motive, such as desire for profit, or complete disregard for patient well-being.'' Accordingly, the Medical Board concluded that instead of revocation of his medical license, the appropriate sanction was a two year suspension, retroactive to August 11, 1993, but with the second year stayed and served as a period of probation. The Medical Board also prohibited Respondent from prescribing controlled substances until it approved a plan for his resumption of such prescribing.

On August 11, 1994, Respondent executed the application for registration with DEA that is the subject of these proceedings. On October 28, 1994, the Medical Board modified its order, permitting Respondent to handle controlled substances if and when he gets his DEA privileges restored provided that for at least one year, he must maintain a log of his prescribing and dispensing; he may not prescribe or dispense more than a 14-day supply at one time to a patient; and he must refer a patient to a pain management specialist for a second opinion prior to completion of 90 days of prescribing or dispensing to the patient.

On February 24, 1994, a civil complaint was filed against Respondent in the United States District Court for the District of New Jersey alleging violations of 21 U.S.C. 842. On March 11, 1996, the parties filed a Stipulation for Compromise Settlement, pursuant to which Respondent agreed to pay $22,500 plus interest. The stipulation provided, among other things, that Respondent did not admit liability or fault and that the complaint would be dismissed with prejudice.

Since Respondent's patients that are at issue in this proceeding were supposedly being treated by Respondent for chronic pain, there was evidence presented by both the Government and Respondent regarding the treatment of chronic pain patients. An expert in pain management testified on behalf of the Government and his report regarding Respondent's patients was admitted into evidence. Respondent offered the report and the testimony before the Medial Board of his expert in pain management. The Government's expert testified that chronic pain is pain from the same etiology that lasts longer than six months. Respondent's expert opined that chronic pain patients are the most difficult patient population to treat, that many of these patients are angry and depressed, and that psychological complications make managing them more difficult.

Regarding the treatment of pain, the Government's expert testified that narcotics do not relive pain, but block the perception of pain in the brain, while non-steroidal anti-inflammatory drugs (NSAIDs) may operate on the source of the pain. According to the Government's expert, narcotic analgesics may be used in conjunction with NSAIDs where the pain is severe; preferably starting the patient on the narcotic first, then prescribing NSAIDs, and then gradually taking the patient off the narcotic and increasing the NSAIDs. Respondent's expert testified in the Medical Board proceeding that narcotics may be an appropriate permanent solution to a patient's pain problem but that ''[i]t's certainly not the first one we consider. Usually it's a choice of last resort, not first.''

Respondent also introduced into evidence at the hearing pages of the Handbook of Pain Management, G. John DiGregorio, M.D., Ph.D., et al. (3rd ed. 1991), which recommends initial treatment of chronic benign pain with NSAIDs. The Handbook further advises that ''[t]he regular use of opioid analgesics in benign pain syndromes is controversial,'' and that

> [p]hysicians who choose to use these types of opioids should be aware of the potential escalation by the patient to stronger types of medication during their treatment program. It is for these reasons that all efforts should be made not to utilize opioid treatment in these types of syndromes. the administration of strong opioids in chronic benign pain syndromes is to be avoided if at all possible, since the resulting problems of tolerance, physical dependence, and drug-seeking behavior are usually more life-disrupting than the pain process itself.

Judge Bittner found that New Jersey law requires that physicians prescribe controlled substances only for legitimate medical purposes in the course of professional treatment and that physicians must take complete histories

and perform physical examinations of patients. In addition, physicians in New Jersey are required to maintain a chart on patients for whom they prescribe controlled substances for pain.

The Government's expert testified that in treating a chronic pain patient, the physician should include both positive and negative findings in a patient's chart, including information for each visit as to whether the pain is better or worse, and whether it is in the same place. Respondent's expert asserted that pain is highly subjective and the physician must rely on the patient's description of pain, family members' reports of it, and how well the patient is able to function.

Because the Government alleged that a number of Respondent's patients were drug dependent, the Government's expert listed some ''red flags'' which should alert a physician to possible drug-seeking behavior. Specifically, the Government's expert testified that drug-seeking patients may complain of symptoms that would normally lead a doctor to consider prescribing controlled substances, express symptoms that are incompatible with the purported injury, try to avoid diagnostic procedures which may show that their conditions do not warrant treatment with narcotics, ask for a controlled substance by name on a first visit, visit physicians some distance from the patient's residence, have a history of problems but no medical records, often have multiple accidents, multiple fractures, or complain of injuring themselves at home or at work, insist on a drug of choice, lose prescriptions or medication, take more medication than directed, request more medication before the previously dispensed supply should have been exhausted, use controlled substances prescribed for others, use controlled substances in combination or with alcohol, or obtain controlled substance prescriptions from multiple physicians or have prescriptions filled at multiple pharmacies. The expert acknowledged however, that many doctors ignore these ''red flags.''

At the hearing in this matter, there was extensive testimony and documentary evidence presented regarding Respondent's treatment of 18 patients, including the prescribing of controlled substances. While the patient charts were not offered into evidence, various witnesses, including Respondent and the Government's expert, used the charts while testifying. In addition, Respondent prepared summaries of his patient records which were admitted into evidence. Further, two affidavits by Respondent in 1990, Respondent's 1991 testimony in the Medical Board's Preliminary Evaluation Committee hearing, the state investigator's 1991 report, and the state administrative law judge's opinion were admitted into evidence without objection. Respondent argues that the Government expert's reports should not be relied upon because the underlying patient records were missing. Judge Bittner rejected this argument noting ''that hearsay is admissible, that [the expert's] reports were referenced in a Government prehearing statement filed in January 1996, and that Respondent had had a substantial opportunity to raise any questions he had about the records on which the report was based.'' The Acting Deputy Administrator agrees with Judge Bittner and also notes that the reports were properly admitted into evidence at the hearing because Respondent's objections to the reports being received into evidence were not based upon the lace of underlying patient records.

In her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, Judge Bittner went into great detail regarding the medical problems and treatment, including the prescribing of controlled substances, of the patients at issue in these proceedings. Since the Acting Deputy Administrator is adopting Judge Bittner's findings of fact in their entirety, there is no need for him to reiterate them. However, the Acting Deputy Administrator makes the following general findings regarding Respondent's treatment of the patients at issue.

Respondent treat R.C. over a period of approximately eight years. Respondent initially saw R.C. for shoulder and elbow pain following a motorcycle accident. On a number of occasions, Respondent performed surgery on R.C.'s shoulder and ring finger where he removed a benign tumor. Throughout the years, R.C. continued to complain of shoulder and finger pain. At various times, Respondent prescribed R.C. Percocet, Talwin, Darvon and Tylenol with codeine #3. For example, between January 2 and January 30, 1985, Respondent prescribed R.C. 335 dosage units of Talwin, and during February 1986, he prescribed 290 dosage units.

A note in the patient file dated August 30, 1982, stated, ''give no more Darvon.'' Another note in R.C.'s patient file dated May 21, 1985, said, ''This is the very last Rx—make it last. Follow exactly as written. If he abuses this one—he's finished with us. complaints from drug store that entire family does narcotic drug [sic].'' However, Respondent continued to prescribe Talwin to R.C., because according to Respondent, R.C. re-injured himself. In September 1986, R.C. sought another prescription from Respondent claiming that his wife washed his pants with the 60 Talwin in them that had been prescribed the day before. In a letter to R.C. dated October 9, 1986, Respondent advised R.C. that ''I am aware of your desire to have more Talwin tablets. It has been brought to my attention by many people, including my secretary, pharmacist and the emergency staff at St. Clare's Hospital that you have grossly abused this drug.'' Respondent further stated that ''to protect my own medical license and to maintain good relations with other doctors and nurses, I have to stop giving you this drug and any other drugs of comparable strength. You certainly have no reason to need this drug anymore anyway. It would be reasonable for you to take lesser medications from time to time, such as Darvocet or Tylenol with codeine: if you wish, I can give you a prescription for those. You will have to obtain Talwin elsewhere.'' Nonetheless, Respondent continued to prescribe R.C. Talwin throughout 1987 following continuing complaints of shoulder pain. In September 1988, Respondent issued R.C. a duplicate prescription after R.C. claimed that he had lost a prescription.

Before Judge Bittner, Respondent testified that although he did not recognize at the time that he was issuing prescriptions that R.C. had a drug problem, he would recognize it now. Respondent further testified that he believed R.C.'s pain warranted the prescribed medications, but that ''I shouldn't have done it. I should have been tougher.''

Respondent treated M.C. from September 1986 to June 1989. Initially, Respondent treated M.C. for back pain and headache resulting from a myelogram. Throughout the years, Respondent treated M.C. following several falls and car accidents for pain down her leg, cervical radiculopathy, and back and shoulder pain. He regularly prescribed M.C. Demerol for pain, Halcion for sleep, and Restoril as a muscle relaxer and for pain. According to Respondent, only Demerol helped M.C.'s pain. Respondent also gave M.C. anti-inflammatories, had her undergo physical therapy and traction, and recommended exercise to strengthen her muscles. Notes in M.C.'s patient file indicated that M.C. sometimes telephoned Respondent requesting prescriptions for pain medication and that pharmacies had called Respondent advising that M.C. was not following the directions on prescriptions and she was attempting to obtain refills of the prescriptions early.

At the hearing before Judge Bittner, Respondent indicated that his prescribing to M.C. helped her, but it also subjected her to possible danger.

Respondent treated patient S.D. from March 28, 1985 through June 30, 1988. Initially, Respondent treated S.D. for chronic low back pain from an old surgery and he and his partner aspirated the site. In 1985, S.D. fractured her ankle and she had surgery to remove scar tissue. S.D. was hospitalized in 1986 for low back pain and in November 1986, she had surgery to remove bone chips. Between July 11, 1985 and June 6, 1988, Respondent prescribed S.D. 240 Demerol, 430 Percodan, 50 Seconal, 475 Percocet, 1,387 Tylenol No. 4, 177 Nembutal, and 260 Tylenol No. 3. Respondent indicated that S.D. had a threshold for pain and that only the drugs prescribed ever helped her. A note in S.D.'s patient file dated August 27, 1987, indicated that S.D. was hospitalized for a drug overdose and that a pharmacy reported that it would no longer serve S.D. since she had seen every doctor in the area in an effort to obtain drugs. Four days after this note was written, Respondent issued S.D. a prescription for Tylenol No. 4

The Government's expert testified that he considered Respondent's prescribing to S.D. ''egregious'' and that it ''jeopardized certainly the welfare and the health and the safety, and even the life of this patient.'' The expert further testified that ''this is not gullibility, this is total irresponsibility in the prescribing of controlled dangerous substances.'' Respondent stated that he ''tried to act in as responsible a way as possible,'' that in the last months he saw her, S.D. asked for less medication, and that he had given her ''a hard time'' with respect to Demerol. Respondent further testified that he was concerned about S.D.'s use of controlled substances because the first time he met her she told him that she needed more medication than most people to achieve the same effect, but that he thought she was being honest. Respondent testified that this incident ''goes to show how oblivious I was to red flags in front of me.''

According to T.K., he was Respondent's patient from 1979 until January 1993. Respondent diagnosed T.K. in 1981 with a complicated form of Osgood-Schlatter's disease which causes inflammation and pain. In addition, T.K. had knee operations in 1983 and 1985, and was treated by Respondent at various times for tennis elbow, gout and tendonitis in the left forearm. Respondent regularly prescribed T.K. both Tylenol with codeine and Doriden without always noting it in the patient chart, and sometimes without seeing the patient. The Government's expert testified that there is no medical justification for prescribing Tylenol with codeine and glutethimide (the generic name for Doriden) in combination. The combination of these drugs is commonly abused because it creates a heroin-like effect. In fact, in 1984, the Medical Board sent a newsletter to all physicians which indicated that barring unusual circumstances there was no legitimate medical indication for prescribing a combination of glutethimide and codeine. Respondent testified that he did not recall receiving this newsletter. After the 1991 hearing before the Preliminary Evaluation Committee of the Medical Board, Respondent continued to prescribe both of these drugs to T.K. T.K. told the state investigator that ''I never felt that the doctor acted in anything but good faith.''

The Government's expert stated that Respondent issued T.K. new prescriptions for Tylenol with codeine before the supply dispensed pursuant to previous prescriptions should have been exhausted. The expert opined that Respondent's prescribing of controlled substances to T.K. was not for a legitimate medical purpose because the prescribed medications were not compatible with the diagnosis of what was wrong with the patient.

Respondent testified that he prescribed Doriden to T.K. because he had a chronic sleep disorder, and that other physicians had prescribed T.K. the drug. He further stated that he never told T.K. to take the Tylenol No. 3 and Doriden together.

G.K. first saw Respondent's partner in January 1990 suffering from back spasms and was prescribed Dilaudid. Respondent than began treating him approximately one year later for chronic back pain. Respondent regularly prescribed G.K. Dilaudid, often issuing a new prescription before the previous one should have run out, and often not noting the prescription in the patient chart. On one occasion, Respondent issued G.K. a new prescription after G.K. represented that he had lost a prescription. The pharmacy reviews revealed that Respondent postdated Dilaudid prescriptions for G.K. on several occasions. There were notes in the file stating that Respondent would not issue any more Dilaudid prescriptions to G.K., yet Respondent continued to do so.

The Government's expert concluded that Respondent prescribed one of the most potent narcotics to G.K. notwithstanding G.K.'s obvious drug-seeking behavior. Respondent testified that G.K. needed Dilaudid for pain and especially to sleep, or else he could not go to work. He further testified that G.K. would improve for a period of time but then would have setbacks. In retrospect, Respondent through that he was lenient with G.K. and that G.K. was a drug-seeking patient.

D.K. initially saw Respondent in August 1982, for injuries that he had sustained in a car accident that had occurred several months earlier. D.K. was a patient of Respondent's for over ten years. He was treated for injuries sustained in five car accidents and other types of accidents. During the course of his treatment, D.K. had two low back surgeries and ultimately used a cane to walk because his knees frequently buckled. According to Respondent, D.K. was the sole support for his three children, so he needed pain medication to be able to keep working. After anti-inflammatory medications did not work, Respondent prescribed D.K. Percodan. Throughout D.K.'s treatment, Respondent regularly prescribed, Tylenol No. 3, Vicodin and/or Percodan for pain, and sometimes prescribed Restoril for sleep and Valium for muscle spasms.

On several occasions, Respondent's records indicated that he intended to either diminish or cease prescribing Vicodin and Percodan to D.K. In a November 1990 affidavit, Respondent stated that ''each time [D.K.] was just about ready to get off habit-forming medicine, that another accident would occur.'' Respondent further stated that he wanted D.K. to go to another physician who might be better at getting him off of all medicine, but that ''I have no evidence of [D.K.] ever abusing medications that I gave him; it was my belief they were so that he could go to work.'' However, Respondent nonetheless continued to prescribe controlled substances after this affidavit.

The Government's expert testified that prescribing two narcotics simultaneously should be intermittent, and not done on a regular basis like Respondent did. The expert further testified that it was his opinion that there was no valid medical purpose for Respondent's prescribing to D.K. in the types and quantities of controlled substances that he did. He emphasized that a physician loses control when he prescribes a large quantity of controlled substances with refills.

Respondent testified that it never occurred to him that D.K.'s accidents may have been related to his use of controlled substances. Respondent further testified that D.K. was one of the

patients he felt he had not handled properly and that he should have been more reluctant to prescribe controlled substances to him.

Respondent began treating D.K.M. following a car accident in 1982. He diagnosed her as having a cervical sprain with radiculopathy and prescribed Talwin and exercises. When the Talwin did not appear to be working, Respondent prescribed D.K.M. Percodan. Over the next ten years, D.K.M. was involved in approximately five more car accidents with some requiring emergency room treatment. She was assaulted by patients during her work as a nurse and by her spouse on several occasions. In addition, she was injured lifting a heavy patient at work, her knees buckled several times causing her to fall, and she broke her ankle following a fall off a truck and later sprained the same ankle. During his treatment of D.K.M., Respondent regularly prescribed large quantities of various controlled substances. For example, between May 4, 1987 and January 20, 1988, Respondent prescribed D.K.M. 415 Percodan, 780 Tylenol No. 3 and 760 Vicodin. In April 1992, Respondent stated that his goal was to get D.K.M. off all medication by July 1992, yet he subsequently issued her a prescription for 100 hydrocodone with APAP with five refills.

Respondent testified that it did not occur to him that D.K.M.'s accidents may have been related to her abuse of controlled substances, but that in retrospect, her multiple injuries were ''red flags.'' The Government's expert testified that none of D.K.M.'s accidents justified prescribing her the quantity of controlled substances that Respondent did and that people who are abusing medication frequently develop falls and injuries in an attempt to obtain more drugs. In addition, D.K.M. allegedly lost prescriptions, which according to the expert is further evidence of drug-seeking behavior. The expert opined that Respondent did not prescribe for D.K.M. for a legitimate medical purpose.

Respondent began testing S.K. in April 1990. S.K. had significant motor weakness of both legs as a result of brain surgery, had severe scoliosis for which she had had a spinal fusion, and needed crutches in order to walk. She first saw Respondent complaining of neck pains and headaches. Respondent diagnosed S.K. as suffering from a cervical sprain. S.K. saw Respondent periodically until February 1993, suffering from continuing pain in the back, hip and groin, headaches and muscle spasms. Respondent prescribe S.K. various controlled substances and anti-inflammatories, and referred her for physical therapy. On two occasions, Respondent prescribed S.K. 100 Vicodin with 5 refills. Respondent testified that he prescribed S.K. such large quantities of Vicodin because he did not expect her condition to change quickly, that orthopedic conditions generally change slowly, and that pharmacists frequently encouraged him to prescribe in quantities of 100 because it is less expensive.

Between June 5, 1989 and May 21, 1990, Respondent issued N.R. 29 prescriptions (6 original prescriptions plus refills) for a total of 1,690 Tylenol No. 3. N.R. was K.D.M's elderly mother and she suffered from advanced arthritis of multiple joints. N.R. was never officially a patient of Respondent's and he did not maintain a patient record for her. Respondent stated that he prescribed for N.R. as a favor and did not charge her. However, Respondent informed D.K.M. that if N.R. wanted prescriptions or treatment in the future she would ''have to become an official patient and be worked up thoroughly with x-rays and other tests, become 'favors' cannot go on forever.'' The Government's expert testified that patent records are not only legally required but are necessary to establish a doctor-patient relationship, to determine the patient's progress or lack thereof, to determine how the patient will respond to treatment, and to protect the physician. It was the Government expert's opinion that the prescriptions issued to N.R. were not for a legitimate medical purpose.

Respondent issued prescriptions to A.R. and C.R., the couple whose house was searched and were later arrested that was discussed above. Respondent did not offer any explanation for the controlled substance prescriptions issued to A.R. Regarding C.R., Respondent first treated him in June 1991 for lumbosacral sprain with radiculopathy stemming from various accidents in 1990 and 1991. Initially, Respondent ordered an MRI, and prescribed 60 Percocet, 100 Xanax with 5 refills, and 60 Valium with 5 refills. In addition, C.R., dislocated his shoulder three times and fell causing more pain. During his treatment of C.R., Respondent prescribed large quantities of Percocet, Xanax and Valium, and prescribed Dalaudid for a period of time. For example, over a 117-day period in 1991. Respondent prescribed C.R. 950 Valium or about 8.1 pills per day. Between February 28 and March 25, 1992, Respondent prescribed C.R. 310 Percocet or about 11.5 pills per day. Respondent almost always issued new prescriptions before the supply from the previous prescription should have run out. On one occasion, Respondent issued C.R. a new prescription after C.R. indicated that he had spilled water on his Percocet causing the pills to dissolve. In addition, Respondent often postdated prescriptions for C.R.

Notes in the patient file dated July 15, 1991, indicated that a pharmacist had called because C.R. was taking more Percocet that directed; that Respondent's partner refused to give C.R. more medication; and that the patient had two herniated discs, a dislocated shoulder and a bad knee and was in great pain and wanted Percocet before his next scheduled visit. Respondent testified that he ended his doctor-patient relationship with C.R. after the local police told him that they suspected that C.R. was a drug dealer and that he cooperated in the investigation. Respondent also testified that the local prosecutor wrote to him thanking him for his help in the investigation of A.R. and C.R.

The Government's expert stated that in his opinion to a reasonable degree of medical certainty, C.R. was addicted to drugs, that Respondent maintained C.R. on controlled substances knowing that he was addicted to them, and that Respondent unlawfully attempted to detoxify a narcotic addict with narcotic medications by telling C.R. to cut down gradually on his use of these medications. The expert further stated that in his opinion, Respondent grossly deviated from the standard of care and the normal doctor-patient relationship by his prescribing to C.R. Respondent testified that he was ''lenient'' with C.R. and that C.R. was ''almost a waking red flag.''

Respondent also treated C.R.'s brother, J.R. for a little over two years beginning in March 1991. J.R. was a garbage man with chronic lumbosacral sprain and a fracture in the lower back that could by itself require surgery and that resulted in other low back ailments to take longer to heal. During the course of his treatment, J.R. also suffered a number of accidents at work which further injured his back. J.R. needed to work to support his family. Respondent regularly prescribed J.R. Percocet and at various times also prescribed him Valium, Xanax and Darvocet. Respondent also referred J.R. for physical therapy. At one point, J.R. was seen by Respondent's partner who also prescribed J.R. Percocet.

At some point during his treatment, J.R. told Respondent that he was a former addict, but felt that he needed the medication for his pain and not because he was addicted. The Government's expert stated that an x-ray report in J.R.'s file did not indicate any

condition that would cause sufficient pain to warrant treatment with Schedule II narcotics in the quantities and over the period of time that Respondent prescribed them.

A review of the prescriptions issued by Respondent to J.R. also revealed a number of postdated prescriptions. Respondent testified that he postdated prescriptions for this patient when his office would be closed on the day the prescription would normally be issued, and that he understood at the time he issued these prescriptions that a pharmacist would not dispense them until the date written on them.

The Government's expert stated that in his opinion, J.R. was addicted to drugs and that Respondent prescribed these drugs to him even though he knows or should have known that J.R. had no medical need for them. The expert further stated that Respondent did not take adequate histories or perform adequate physical examinations of this patient, that Respondent prescribed controlled substances to J.R. without seeing him, that the patient showed obvious drug-seeking behavior and that Respondent knowingly perpetuated J.R.'s addiction. Respondent testified that he did not think that he was lenient with J.R. and did not think that J.R. was a drug-seeking patient.

B.S. was a nurse who first was Respondent's partner in August 1986 after being injured at work. She became Respondent's patient in January 1987 and was hospitalized that month. Over the next six and half years B.S. underwent surgery several times. In October 1992, an MRI revealed a large lesion destroying bone in her back which was probably caused by a bone infection. She subsequently underwent a nine hour surgery. In addition, she was involved in a car accident, fell down some stairs and had a severe asthma attack, all of which exacerbated her neck and back pain.

Respondent prescribed B.S. various controlled substances over the years. On six occasions between January 7 and August 4, 1991, Respondent issued B.S. prescriptions for both Percocet and Demerol for a total of 260 Demerol and 390 Percocet. Following her last surgery, Respondent prescribed B.S. Dilaudid for approximately three and a half months. Over the years, Respondent referred B.S. to a spine specialist, a neurosurgeon, a neurologist and an infectious disease specialist.

Respondent's records revealed that Respondent reissued prescriptions for Percocet to B.S. after her house was burglarized two times, the locker room at her work was robbed, her motel room was robbed while she was on vacation, she spilled some Percocet at a ball game, and her daughter threw some of the drugs away.

The Government's expert opined that three and a half months is a long time for any patient to be routinely taking Dilaudid. The expert reported that Respondent issued prescriptions for Dilaudid to B.S. before her previous supply should have been exhausted, that Percocet and Dilaudid are not normally prescribed in combination, and that they both attach to the same receptor sites in the brain. He concluded that Respondent's prescribing to B.S. was irresponsible and a ''gross deviation from the standard of care in the practice of medicine in New Jersey, or in the United States.'' Respondent testified that he knew B.S. before he began treating her and that he thought she had personal integrity and would not be likely to divert controlled substances.

Respondent began treating C.T. Sr. in 1978 for a knee injury. Respondent treated C.T. Sr. until 1990 for various problems including chronic should pain, cervical and lumbosacral sprain suffered as a result of a car accident, impingement in the shoulder, and pain following surgery on his shoulder and arthroscopic surgery on his knee. C.T. Sr. had a number of work-related accidents and injuries and was hit by a car. During his treatment of C.T. Sr., Respondent prescribed him various controlled substances for pain. Between 1984 and 1990, Respondent issued C.T. Sr. 208 Percocet prescriptions, even issuing two on the same day, one for 21 dosage units and the other for 20. Respondent admitted that after a while, he became suspicious of C.T. Sr.

Respondent often issued C.T. Sr. controlled substance prescriptions before the supply from the previous prescription should have run out. Respondent admitted to this, but testified that he did so because patients' conditions change daily and the directions on the prescription represent the physician's ''best guess and estimate'' as to how often the patient should take the medication.

Respondent began treating C.T. Sr's wife, D.T. in 1979 for pulled muscles and tendonitis of the knee and possible phlebitis. At one point, she was hospitalized and a neurologist diagnosed her as suffering from neuromuscular derangement syndrome. At a later point, D.T. had surgery for scar tissue and thereafter, surgery for a ganglion cyst and inflamed tendons of the left wrist. Over the years, Respondent prescribed large amounts of Percocet to D.T. On one occasion, C.T. Sr. called Respondent and told him that D.T. was suffering from severe back and knee pain, and Respondent issued her a Percocet prescription. Respondent testified that now he would recognize this as ''a rather blatant attempt to try and get some Percodan out of me.''

Respondent issued D.T. prescriptions for Percocet before the supply from the previous prescription should have been exhausted, and would often issue new prescriptions after D.T. represented that she had lost a prescription. While Respondent believed that D.T. clearly had problems with her arm, he ultimately told her to go elsewhere because he was not able to cure her wrist and would not give her any more medication.

According to the Government's expert, Respondent's prescribing to D.T. was not for a legitimate medical purpose. The expert stated that ''[i]t is incomprehensible to think that this physician was not aware of the substance abuse by these patients.'' He further testified that, ''If you don't see a patient and you get asked to fill prescriptions for a patient you haven't seen, and the wife is getting the same medicine and she's fabricating and exaggerating symptoms as he is, that's pretty obvious. I mean, that's not something that you would call gullibility.''

Respondent also issued Percocet prescriptions to C.T. Sr.'s son, C.T. Jr., who was 12 years old when Respondent first began treating him. According to Respondent C.T. Jr. had had major injuries to his right hand five years before, and Respondent issued him prescriptions for flare-ups of severe pain. Respondent did not have any patient record for C.T. Jr., and Respondent indicated that C.T. Jr. was not really a patient of his, but that he issued him the prescriptions as an act of charity because the family could not afford to send C.T. Jr. to see his family physician. Respondent admitted that between July 6, 1985 and February 3, 1990, he issued C.T. Jr. 11 prescriptions for a total of 370 dosage units of Percocet. Respondent testified that although C.T. Jr. was an adolescent, he was physically large so there was no physiological difference between him and an adult with respect to prescribing pain medication.

Respondent stated that in retrospect, many of C.T. Jr.'s complaints were fabricated in order to please his parents who were addicted to Percocet. In one month Respondent prescribed to the father, mother and son a total of 369 dosage units of Percocet.

Respondent first saw E.T. in 1981 when she was hospitalized with diabetes-associated problems. He did not see her again until 1985 when her

family physician referred her to Respondent because she was suffering from intractable diabetic neuropathy and she was taking large quantities of Percodan. Respondent continued to prescribe Percodan to E.T., authorizing 227 dosage units during a five week period in 1985. Ultimately, Respondent referred E.T. back to her family physician stating in a letter that, ''Since I have an [enormous] number of Percodan patient[s] myself, I request that you take this patient back.''

A notation in E.T.'s patient file dated January 22, 1986, indicated that this was the last prescription and the patient was so advised. However Respondent issued her several more prescriptions for Percodan. On one occasion, E.T's husband called and indicated that his wife was in a lot of pain and requested that Respondent issue her a prescription for 25 Percocet to hold her until her next appointment.

The Government's expert testified that E.T. and her husband were exhibiting drug seeking behavior, and that even if E.T. had painful diabetic neuropathy, she could have been treated with non-habit forming medications. The expert did not believe that there was a legitimate medical purpose for the drugs Respondent prescribed for E.T. because Respondent was treating this patient for a condition out of his area of expertise and he was ''simply prescribing controlled drugs for another doctor's patient.''

Respondent began treating E.T.'s husband, J.T. in 1980 for multiple injuries sustained in a car accident in 1977 and for which J.T. had undergone three surgeries. When Respondent first saw J.T. he had an unhealed and draining fracture of his left leg and it was crooked so that he had been unable to walk for three and a half years. Respondent performed several operations on J.T.'s leg and prescribed J.T. mainly Percodan. As an example, Respondent prescribed J.T. 735 dosage units of Percodan between April 1 and August 26, 1982.

Subsequently, J.T. fell, rupturing his Achilles tendon, and later sprained his left ankle and had surgery in New York. By 1986, J.T.'s left leg was worse and it was ultimately amputated in 1987 in New York. The doctors in New York prescribed J.T. MS Contin, so Respondent began prescribing him the drug. Thereafter, Respondent performed a procedure on J.T.'s leg since the wound was still draining. In addition, J.T. experienced severe phantom limb pain. Respondent continued to prescribe J.T. large quantities of MS Contin, even after J.T. appeared to be improving. Respondent referred J.T. to a detoxification center, but J.T. would not go for fear of losing his job. At some point later, J.T. was in a car accident where he injured both knees, his ribs, neck and lower back. Respondent referred J.T. to a neurosurgeon.

Notes in J.T.'s patient file indicated that a neurologist recommended that J.T. be detoxified from MS Contin and a pharmacist had reported that J.T. was using Valium twice as fast as he should. Respondent nonetheless continued to prescribe J.T. MS Contin, Restoril, Percocet and Valium.

The Government's expert noted that J.T. called Respondent's office to obtain prescriptions, sometimes stating that he had lost a prescription or requesting postdated prescriptions. The expert state that ''[t]hese tactics are such an obvious attempt of getting and using more pills than prescribed and it clearly points to the situation where the patient now is in control of the doctor rather than vice versa. * * * I do not believe, in this day and age, that any physician would be that blindfolded to the obvious drugs-seeking behavior.'' The expert noted that J.T. displayed the classic signs of a drug abuser, and concluded that Respondent's prescribing of the types and quantities of controlled substances to J.T. was not for a legitimate medical purpose.

Respondent's expert did not testify in the proceedings before Judge Bittner, but his testimony before the Medical Board was admitted into evidence. The expert emphasized that there has ''never been promulgated clear-cut standards of care in the management of patients with chronic pain who require long-term narcotic medication,'' and that there is no law or regulation specifying how much narcotic medication a chronic pain patient may be prescribed. The expert testified that he was impressed by the ''medical and surgical complexity,'' of the patients at issue in that proceeding and that he concluded that Respondent's prescribing ''mostly does not deviate from the accepted [medical] standards,'' noting that Respondent documented reasons for his prescriptions, he followed the patients carefully over a long period of time and knew the cases well, there was no information of progressive deterioration related to the prescriptions during the time of the prescriptions, and that in all but a few cases, Respondent kept ''fairly decent records.'' The expert testified that the only patient for whom Respondent's prescribing deviated from standard medical care was T.K.

Although not required by the Medical Board, following the suspension of his medical license, Respondent underwent rehabilitative training in late 1993 or 1994 with a physician who is part of the Academy of Medicine of New Jersey, the educational arm of the New Jersey Medical Society. This physician is board certified in psychiatry, psychotherapy, and preventive medicine, and certified in addiction medicine.

The training consisted of six or seven two-hour sessions over a four to six month period during which Respondent and the physician engaged in role playing exercises designed to help with the handling of drug seeking patients. They also reviewed the potency of medications, pain management techniques, how to obtain assistance in dealing with problem patients, and how to recognize ''red flags'' to warn of drug seeking patients. Respondent was given homework assignments and also read material outside of his sessions with the physician. Respondent passed an examination given at the conclusion of the training.

Respondent testified that the course made him better able to handle controlled substances and to handle drug-seeking patients. He further testified that as a result of the course. ''I came to believe that I was an easy mark for patients. I was too believing in everything they said. I didn't try hard enough to decrease potentially habit-forming drugs in a number of cases. * * * Although, at the time I felt I was doing the right thing.''

In retrospect and after his training, Respondent felt that in three or four cases, ''I over-prescribed, with good intentions, but I didn't act prudently in retrospect.'' He testified that he had become more suspicious than he used to be and that he believed that it is not necessarily incorrect to use controlled substances to treat chronic pain but that physicians have more alternatives to controlled substances in treating these patients now.

At the hearing, Respondent acknowledged that he sometimes prescribed additional controlled substances to patients before their previous supply should have been exhausted, but testified that if a patient used up a supply of medication before it should have been exhausted if the directions for use were followed, then he would conclude that the patient had more pain than he thought. Respondent also testified that prescribing two narcotics simultaneously is justified when a physician thinks that the patient can be managed on the weaker drug but prescribes some of the stronger one in case the weaker one does not work. Prescribing the drugs at the same time saves the patient another trip to the physician's office if the weaker

medication does not provide relief. Respondent further testified that the issue of prescribing more than one controlled substance at a time ''comes down to do you trust your patient. And I trusted my patient * * * I was too gullible in certain situations.''

In this proceeding, Respondent was asked about his 1991 testimony before the Preliminary Evaluation Committee that, ''I'm a lot stricter and tougher about this than I was. I mean, as I look back I realize that I was really too lenient with all these people.'' Respondent testified at the hearing before Judge Bittner that he ''was more aware of red flags,'' that ''it was an evolving process,'' and that ''I am more aware today than I was last year.''

Respondent offered into evidence affidavits from colleagues who stated that Respondent's medical treatment of his patients was professional, that he has demonstrated concern and compassion for his patients, that he is highly regarded, that he conducts himself in the best interests of his patients, and one stated that he had never observed Respondent engaging in any unethical conduct. An affidavit from a patient indicated that Respondent was dedicated to treating and improving her condition.

In addition, Respondent offered into evidence the testimony of a colleague at the 1993 Medical Board hearing. The colleague testified that Respondent had an excellent reputation within the orthopedic and general medical communities and that Respondent's standard of care was above reproach. The colleague testified that in his opinion, Respondent ''has exercised appropriate care and concern and appropriate management of [the patients at issue] prior to prescribing any given medication.'' He further stated that there could be reasonable differences of opinion among orthopedists as to the type and amount of medication to prescribe to a given patient. The colleague did testify however that he would not prescribe more than a four-week supply of Schedule II or III medication at one time and that he would ''definitely'' not prescribe narcotics for a patient without maintaining a patient record.

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any application for 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:

(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., 54 FR 16, 422 (1989).

As to factor one, it is undisputed that Respondent's New Jersey medical license has been in effect since August 1994, and in October 1994, the Medical Board permitted Respondent to resume prescribing controlled substances, if and when he is issued a DEA registration, subject to various restrictions for at least one year. The restrictions imposed by the Medical Board include that Respondent must maintain a log of his prescribing and dispensing; he may not prescribe or dispense more than a 14-day supply at one time to a patient; and he must refer a patient to a pain management specialist for a second opinion prior to completion of 90 days of prescribing or dispensing to the patient.

Respondent argues that DEA is bound by the Medical Board's findings. The Acting Deputy Administrator rejects this argument since the recommendation of the state licensing authority is only one of the factors to be considered in determining whether Respondent's registration would be in the public interest. Like Judge Bittner states, ''[i]nasmuch as state authority to handle controlled substances is a necessary but not sufficient condition for DEA registration * * * this factor is not dispositive.'' However, the Acting Deputy Administrator does find it significant that after reviewing Respondent's treatment of the patients at issue, the Medical Board reinstated Respondent's license to practice medicine and his ability to handle controlled substances, albeit with restrictions.

Regarding Respondent's experience in dispensing controlled substances, the Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients.

Judge Bittner concluded that Respondent issued controlled substance prescriptions to two individuals for no legitimate medical purpose. She found that Respondent did not offer any explanation for the fact that between August 22 and September 23, 1992, he prescribed 480 Vicodin to A.R. Judge Bittner stated that ''[w]hen a physician prescribes such an unusually large quantity of a controlled substance, it is reasonable to require him to show that the prescribing was for a legitimate medical purpose.'' Since Respondent did not provide any justification for these prescriptions, Judge Bittner inferred that they were not issued for a legitimate medical purpose. The Acting Deputy Administrator disagrees with Judge Bittner's conclusion. The burden of proof in these proceedings is on the Government, and the mere fact that Respondent prescribed A.R. a large quantity of a controlled substance in and of itself does not warrant the conclusion that there was no legitimate medical purpose for the drugs.

Judge Bittner also found that there was no legitimate medical purpose for the Tylenol with codeine and gluethimide prescriptions Respondent issued to T.K. for approximately nine years. The Acting Deputy Administrator agrees with Judge Bittner's conclusion. In 1984, all New Jersey physicians were warned by a newsletter that ''[b]arring unusual circumstances, there would be no legitimate medical indication for the prescribing of the combination of Glutethimide and Codeine.'' In addition, the Government's expert noted in his report that ''there is no medical rationale for the use of this combination.''

Regarding Respondent's prescribing to the other patients at issue, Judge Bittner found numerous examples of questionable conduct. Respondent prescribed various patients other combinations of controlled substances either simultaneously or within a short period of time. He issued prescriptions to individuals before the quantity obtained pursuant to previous prescriptions should have been exhausted. Respondent postdated prescriptions, and issued prescriptions despite expressions of concern by physicians, pharmacists or others about the quantity of medication the patients were obtaining. Respondent continued to prescribe controlled substances to patients even after he had indicated that he would stop issuing them

prescriptions. He ignored signs that patients were abusing the controlled substances prescribed or were at serious risk of doing so. For example, he continued prescribing to one individual even after learning that the individual had been altering earlier prescriptions. He also ignored the possibility that the multiple accidents and injuries reported by the patients could be drug-seeking behavior.

Judge Bittner also found that ''Respondent failed to appropriately document his treatment and prescribing to a number of patients.'' Significantly, Respondent did not maintain any patient file whatsoever on two of the patients.

Judge Bittner further found that ''Respondent's treatment of various patients also shows a regrettable lack of responsibility * * *.'' As examples, she notes that Respondent prescribed large quantities of certain drugs despite recommendations in the Physician's Desk Reference that they were not to be used for more than a few days; he continued to prescribe controlled substances to an individual after she overdosed; and he prescribed narcotics to an individual after learning that the individual had unsuccessfully attempted detoxification and was severely depressed.

The Acting Deputy Administrator agrees that Respondent's prescribing to these patients appears to be highly questionable. However, the Acting Deputy Administrator is uncomfortable saying that Respondent's prescribing of large quantities of controlled substances or issuing new prescriptions before the previous supply should have been exhausted or prescribing combinations of controlled substances was improper given that these patients apparently had medical problems that caused chronic pain and warranted treatment.

But, Respondent himself admits that he was too lenient regarding the treatment of some of the patients. In addition, the Medical Board, through its adoption of the state administrative law judge's findings, found serious problems with Respondent's prescribing of controlled substances. As the administrative law judge noted, ''* * * the patients in question had, to varying degrees, serious problems which no doubt may have resulted in legitimate pain complaints. The question, however, is one of degree. Respondent ignored obvious dangers of dependency, as evidenced in many instances by what were referred to by petitioner's witnesses as clear ''red flags'' which should have made him suspect. In addition, it is apparent * * * that [R]espondent did not have control of the dispensing of [controlled substances], but prescribed largely in response to communications and complaints from the patients in question, who frequently requested specific medications and dosages of medications, as well as specific dates for prescriptions.'' Further, the Medical Board noted in its 1994 order, ''while we do not condone the manner in which Dr. Caragine prescribed controlled dangerous substances to the patients who were the subject of this action, we do note that the vast majority of those patients were individuals with significant medical problems or illnesses requiring pain management.''

The Acting Deputy Administrator also notes that the Government's expert, in his 1993 report, stated that

> At one point a doctor may be naive or even gullible but when patients continuously call the office for refills, lose their prescriptions, receive pharmacist's reports about refilling prescriptions frequently and knowledge of an individual's addiction by virtue of the fact that the doctor decided to wean them from the medication followed by continuous prescriptions, even after overdose situations, with more [controlled substances], can no longer be brushed aside as gullibility.

Therefore, the Acting Deputy Administrator concludes that even though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding ability to responsibly handle controlled substances in the future.

As to factor three, there is no evidence that Respondent has ever been convicted of charges under state or Federal laws relating to the manufacture, distribution or dispensing of controlled substances.

Regarding factor four, pursuant to 21 CFR 1306.04, prescriptions for controlled substances may be issued only ''for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' As discussed above, the Acting Deputy Administrator finds that the prescriptions to T.K. for Tylenol with codeine and glutethimide were not issued for a legitimate medical purpose. Additionally, New Jersey law requires that physicians maintain patient charts for individuals that are prescribed controlled substances. It is undisputed that Respondent failed to maintain such charts for N.R. and C.T. Jr. Also, it is undisputed that Respondent postdated controlled substances prescriptions for various patients in violation of 21 CFR 1306.05, which requires that''[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued. * * *''

The Government alleged that Respondent detoxified patients without being registered to do so. However, the Acting Deputy Administrator agrees with Judge Bittner that the record does not support a finding that Respondent violated DEA regulations by conducting detoxification treatment without being registered to do so.

As to factor five, Judge Bittner found ''Respondent's current assertions that he will be more responsible in the future are entitled to little weight.'' She noted that Respondent continued his questionable prescribing even after being interviewed in 1990 by a state investigator and after telling the Medical Board's Preliminary Evaluation Committee in 1991 that ''I'm very careful. I'm not so easy to get drugs out of like I use[d] to be,'' and that ''I want the board to know that I really made an effort to clean up my act and not be permissive.'' The Acting Deputy Administrator disagrees with Judge Bittner. In 1994, on his own initiative, Respondent underwent training to better equip himself to handle drug-seeking patients and to more responsibly handle controlled substances. Additionally at the hearing in this matter, when asked about his assurances at the 1991 hearing, Respondent testified that ''I'm a lot stricter and tougher about this than I was. I mean, as I look back I realize that I was really too lenient with all these people.'' He further testified that he ''was more aware of red flags,'' that ''it was an evolving process,'' and that ''I am more aware today than I was last year.''

Judge Bittner concluded that even though ''the patients at issue here are a small fraction of the total number he treated over a twenty-year period[,] * * * that most of these patients suffered chronic pain and that it was difficult to find appropriate treatment for many of them'' Respondent's prescribing ''is most charitably described as irresponsible.'' She further concluded that ''[n]otwithstanding Respondent's testimony that he will be more responsible in the future and that he is rehabilitated by his training * * *, it is clear that Respondent does not yet acknowledge his misprescribing.'' Therefore, Judge Bittner found ''that a preponderance of the credible evidence in this record establishes that Respondent's registration would not be in the public interest'' and she recommended that his application be denied.

Respondent filed exceptions to Judge Bittner's Opinion and Recommended Ruling, and the Government filed a

response to Respondent's exceptions. The Deputy Administrator has carefully considered both of these filings in rendering his decision in this matter. First, several of Respondent's exceptions have already been addressed in this final order such as his argument that the Medical Board's ruling is binding on DEA, that the Government did not provide the records relied upon by its expert in rendering his opinion, and that Judge Bittner improperly found that Respondent prescribed controlled substances to A.R. for no legitimate medical purpose.

Respondent also argued that Judge Bittner failed to consider Respondent's innocent unawareness of errors in judgment; the Medical Board's finding that Respondent had no improper motive in prescribing for his patients; the lack of evidence that Respondent knowingly and intentionally prescribed controlled substances to addicted persons or persons involved in illicit activity; the lack of evidence of any complaints about Respondent's prescriptive practices to any government agency by physicians, patients or staff; and the lack of evidence demonstrating that Respondent sold any drugs or prescriptions to anyone. The Acting Deputy Administrator concludes it is not necessary to prove that any of the above circumstances exist before a registration can be revoked or an application denied. Just because misconduct is unintentional, innocent or devoid of improper motivation, does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and could justify revocation or denial.

Respondent argued that Judge Bittner failed to give proper weight to his previous treatment of patients other than those at issue in this proceeding, to the medical problems of the patients at issue, and to the fact that he voluntarily underwent training. Like Judge Bittner, the Acting Deputy Administrator has considered these facts and has given them the weight he deems appropriate in rendering his decision in this matter. Respondent further argued that Judge Bittner failed to even consider that he cooperated with state officials in their investigation of his patients. The Acting Deputy Administrator has considered Respondent's cooperation, however he does not deem it significant in determining whether Respondent can be trusted to responsibly handle controlled substances.

Respondent also argued that the Government expert did not speak with or examine the patients at issue, nor did he speak with Respondent, his partner or office staff before submitting his report. The Acting Deputy Administrator finds that the expert could render an opinion without taking the steps outlined above, however in rendering his decision in this matter, the Acting Deputy Administrator has taken into consideration what was relied upon by the expert.

Respondent further argues that Judge Bittner failed to find in Respondent's favor regarding specific points when ''DEA presented no evidence and the Respondent presented detailed, uncontradicted evidence.'' The Acting Deputy Administrator is unable to address this exception since Respondent did not provide any specific examples where this may have occurred.

Respondent also contends that the Government did not establish that he knew or should have known that the combination of Tylenol with codeine and glutethimide is highly abused and that Judge Bittner was in error in finding that Respondent prescribed these drugs to be taken in combination. Respondent asserts that he prescribed these drugs separately and never told the patients to take them in combination. The Acting Deputy Administrator finds that it is incumbent upon a DEA registrant to keep abreast of the illicit uses of controlled substances. Here, as early as 1984, physicians in New Jersey were notified that barring unusual circumstances, there was no legitimate medical purpose for these drugs in combination. In addition, the Acting Deputy Administrator finds that it is of little significance that Respondent never actually told the patients to take the drugs together. By prescribing these drugs at the same time, he created the opportunity for abuse once the patient left his office.

Respondent argues that Judge Bittner failed to consider a New Jersey regulation that was in place at the time of the prescribing at issue which addresses the prescribing of narcotic drugs for persons suffering from intractable pain. This regulation suggested that narcotics should be used after no other relief or cure can be found, that practitioners should be alert to new or alternative forms of treatment that may be less addictive, and that the practitioner should periodically either cease the medication, taper the dosage or try other medications in an effort to reduce the propensity for addiction. The Acting Deputy Administrator finds that Respondent's reliance on this regulation to justify his prescribing seems to be misplaced since Respondent did not appear to follow the suggestions set forth.

Finally, Respondent argues that Judge Bittner failed to consider that the issuance of a registration limited to hospital patients only would be in the public interest and whether the Medical Board's restrictions would reduce or eliminate any potentially abusive prescriptive practices. These exceptions have been considered by the Acting Deputy Administrator and will be discussed below.

The Acting Deputy Administrator is extremely concerned by Respondent's prescribing to the 18 patients at issue up until his medical license was suspended in 1993. While there may have been no improper motivation, Respondent ignored many ''red flags'' that should have alerted him to the possible abuse of controlled substances.

But, the Acting Deputy Administrator notes that the patients at issue make up a very small percentage of Respondent's total patient population and that these patients had legitimate medical problems that warranted some form of treatment. In addition, the Acting Deputy Administrator recognizes that the events at issue occurred a number of years ago, and while passage of time alone is not dispositive, it is a consideration in assessing whether Respondent's registration would be inconsistent with the public interest. See *Norman Alpert, M.D.*, 58 FR 67,420 (1993). The Acting Deputy Administrator notes that following his state suspension, Respondent on his own initiative, underwent rehabilitative training to become better educated in controlled substances and how to deal with drug-seeking patients, and the restrictions imposed by the Medical Board on Respondent's handling of controlled substances will limit the chance for improper prescribing. Therefore, the Acting Deputy Administrator concludes that it is not in the public interest to deny Respondent's application for resignation.

However, given the Acting Deputy Administrator's concerns about Respondent's past prescribing to the patients at issue, a restricted registration is warranted. This will allow Respondent to demonstrate that he can responsibly handle controlled substances in his medical practice, yet simultaneously protect the public by providing a mechanism for rapid detection of any improper activity related to controlled substances. See *Steven M. Gardner, M.D.*, Docket No. 85–26, 51 FR 12,576 (1986). For at least one year following the issuance of the DEA Certificate of Registration, Respondent shall be limited to handling

controlled substances for hospital in-patients only. This does not include emergency room handling of controlled substances since some of the prescriptions for the patients at issue in this proceeding were issued when they were seen by Respondent in a hospital emergency room. During that year, Respondent shall take a course in the proper handling of controlled substances. The Acting Deputy Administrator finds this necessary since Respondent received the training discussed in this proceeding approximately four years ago. At the conclusion of one year, or upon the submission to the Special Agent in Charge of the DEA Newark Field Division, or his designee, of evidence of completion of the course, whichever is later, Respondent can then handle controlled substances outside of the hospital in-patient setting with the restrictions ordered by the Medical Board. However, since the Medical Board's restrictions on Respondent's prescribing of controlled substances are to be in place for at least one year after he received his DEA registration, they are really of no consequence because Respondent is limited by DEA to only handling controlled substances for hospital in-patients. Therefore, for two years after Respondent is allowed to handle controlled substances outside of the hospital his registration shall be subject to the following conditions:

(1) Respondent shall maintain a log of his prescribing, administering and dispensing of controlled substances and shall make this log available to DEA personnel upon request. At a minimum, the log shall include the name of the patient, the date the controlled substance is prescribed, administered or dispensed, and the name, dosage and quantity of the controlled substance prescribed, administered or dispensed.

(2) Respondent may not prescribe or dispense more than a 14-day supply of a controlled substance at one time to a patient.

(3) Respondent must refer a patient to a pain management specialist for a second opinion prior to completion of 90 days of prescribing or dispensing to the patient.

According, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the application for registration submitted by Paul J. Caragine, Jr., M.D., be, and it hereby is granted subject to the above described restrictions. This order is effective no later than October 28, 1998.

Dated: September 21, 1998.

Donnie R. Marshall,

Acting Deputy Administrator.

[FR Doc. 98–25827 Filed 9–28–98; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 1945–98; AG Order No. 2179–98]

RIN 1115—AE 26

Extension of Designation of Somalia Under Temporary Protected Status Program

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice.

SUMMARY: This notice extends, until September 17, 1999, the Attorney General's designation of Somalia under the Temporary Protected Status (TPS) program provided for in section 244 of the Immigration and Nationality Act, as amended (Act). Accordingly, eligible aliens who are nationals of Somalia (or who have no nationality and who last habitually resided in Somalia) may re-register for TPS and are eligible for an extension of employment authorization. This re-registration is limited to persons who registered for the initial period of TPS, which ended on September 16, 1992.

EFFECTIVE DATE: This extension of designation is effective September 18, 1998, and will remain in effect until September 17, 1999. The re-registration procedures become effective September 28, 1998, and will remain in effect until October 27, 1998.

FOR FURTHER INFORMATION CONTACT: George Raftery, Residence and Status Branch, Adjudications, Immigration and Naturalization Service, Room 3214, 425 I Street, NW., Washington, DC 20536, telephone (202) 305–3199.

SUPPLEMENTARY INFORMATION:

Background

Subsection 308(b)(7) of the Illegal Immigration Reform and Immigrant Responsibility Act, Pub. L. 104–208, dated September 30, 1996, redesignated section 244A of the Act as section 244. Under this section, the Attorney General continues to be authorized to grant TPS to eligible aliens who are nationals of a foreign state designated by the Attorney General (or who have no nationality and last habitually resided in that state). The Attorney General may designate a state upon finding that the state is experiencing ongoing armed conflict, environmental disaster, or certain other extraordinary and temporary conditions that prevent nationals or residents of the country from returning in safety.

On September 16, 1991, the Attorney General designated Somalia for Temporary Protected Status for a period of 12 months (56 FR 46804). The Attorney General extended the designation of Somalia under the TPS program for additional 12-month periods until September 17, 1998 (62 FR 41421).

Based on a thorough review by the Departments of State and Justice of all available evidence, the Attorney General finds that the ongoing armed conflict in Somalia continues and that, due to such armed conflict, extension of the designation of Somalia for TPS is required.

This notice extends the designation of Somalia under the Temporary Protected Status program for an additional 12 months, from September 18, 1998, to September 17, 1999, in accordance with subsections 244(b)(3)(A) and (C) of the Act. This notice also describes the procedures with which eligible aliens who are nationals of Somalia (or who have no nationality and who last habitually resided in Somalia) must comply in order to re-register for TPS.

In addition to timely re-registrations and late re-registrations authorized by this notice's extension of Somalia's TPS designation, late initial registrations are possible under 8 CFR 244.2(f)(2) for some nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia). Such late initial registrants must have been ''continuously physically present'' and have ''continuously resided'' in the United States since September 16, 1991, must have had a valid immigrant or nonimmigrant status during the original registration period or have had an application for such status pending during the original registration period, and must register no later than 30 days from the expiration of such status or the denial of the application for such status.

An application for TPS does not preclude or adversely affect an application for asylum or any other immigration benefit. Any national of Somalia (or alien having no nationality who last habitually resided in Somalia) who is otherwise eligible for TPS and has applied for, or plans to apply for, asylum, but who has not yet been granted asylum or withholding of removal may also apply for TPS.

Nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia) who have been continuously physically present and have continuously resided in the United States since September 16, 1991, may