

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 facet 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 Xanax. Percodan, a Schedule II controlled substance, contains oxycodone and aspirin; Ativan, a Schedule IV controlled substance, contains lorazepam; and Xanax, 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