

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.

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). 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 CFR 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 patient's use of controlled substances in terms of treatment of [Patient A's] other medical conditions, and did not prescribe controlled substances to her primarily to wean her from dependence on narcotic analgesics." Thus, the Respondent was not maintaining Patient A's addiction nor detoxifying Patient A without a prior registration.

Finally, the Government argued that from March 1986 through October 1988, the Respondent failed to keep adequate medical records of his treatment of Patient A, and thus, his prescriptions were not issued for a legitimate medical purpose nor in the usual course of professional practice in violation of 21 CFR 1306.04, and California Health and Safety Code Sections 11168, 11190, and 11191. Yet the Government failed to cite to any specific inadequacies of the Respondent's records in either their proposed findings of fact or in the exceptions filed to the Administrative Law Judge's recommended decision.

Pursuant to 21 CFR 1304.03(c), a "registered individual practitioner is not

required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual." Further, a "registered individual practitioner is not required to keep records of controlled substances listed in [Schedules II through V] which are administered in the lawful course of professional practice unless the practitioner regularly engaged in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered." 21 CFR 1304.03(d). Here, the Respondent prescribed controlled substances to Patient A, but the record does not indicate that he "regularly dispensed" those substances to her nor that he prescribed them "in the course of maintenance or detoxification treatment." The Deputy Administrator thus agrees with Judge Tenney's conclusion that "the Government failed to prove that Respondent kept inadequate records. No violation of the Federal statute is found."

As for violations of State law, California Health and Safety Code Section 11190 provides that a practitioner who issues a prescription of a controlled substance classified in Schedule II must make a record for each transaction which shows the name and address of the patient, the date of the transaction, the "character, including the name and strength, and quantity of controlled substances involved", and the pathology and purpose for which the prescription was issued. The Government did not cite to any specific instances where the Respondent failed to provide this required information. Thus, after reviewing the record, the Deputy Administrator agrees with Judge Tenney's conclusion that the "DEA did not prove that there were recordkeeping violations by a preponderance of the evidence."

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. In the balance, the Deputy Administrator finds that it is in the public interest for the Respondent to retain his DEA Certificate of Registration.

However, the Deputy Administrator notes with concern the large quantities of controlled substances prescribed to Patient A over an extended period of time. Yet 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 the 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 CFR 0.100(b) and 0.104, hereby orders DEA Certificate of Registration AS7287534, issued to William F. Skinner, M.D., be, and it hereby is, continued, and that any pending applications be, and they hereby are, granted. This order is effective January 8, 1996.

Dated: November 30, 1995.

Stephen H. Greene,

*Deputy Administrator.*

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## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Records Schedules; Availability and Request for Comments

**AGENCY:** National Archives and Records Administration, Office of Records Administration.

**ACTION:** Notice of availability of proposed records schedules; request for comments.

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