

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

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

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

As to factor five, "such other conduct which may threaten the public health and safety," the Government argued that

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

Yet the Deputy Administrator notes with concern the large quantities of controlled substances prescribed to Patient A over an extended period of time. However, the conflicting expert opinion evidence presented leads to the conclusion that the medical community has not reached a consensus as to the appropriate level of prescribing of controlled substances in the treatment of chronic pain patients. Given this dispute, the Deputy Administrator is reluctant to conclude that the Respondent's prescribing of controlled substances to Patient A lacked a legitimate medical purpose or was outside the usual course of professional practice. It remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of Federal and State law. Here, the preponderance of the evidence established that the Respondent so acted.

Therefore, the Deputy Administrator finds that the public interest is best served by taking no action with respect to the continued registration of the Respondent. Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 21 C.F.R. 0.100(b) and 0.104, hereby orders DEA Certificate of Registration AR8354425, issued to

Michael J. Roth, M.D., be, and it hereby is, continued, and that any pending applications, be, and they hereby are, granted. This order is effective January 4, 1996.

Dated: November 24, 1995.

Stephen H. Greene,

Deputy Administrator.

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DEPARTMENT OF LABOR

Office of the Secretary

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

November 29, 1995.

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

Agency: Bureau of Labor Statistics.

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

OMB Number: 1220-0149.