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STATE OF WISCONSIN

BEFORE THE MEDICAL EXAMINING BOARD

IN THE MATTER OF THE DISCIPLINARY

PROCEEDINGS AGAINST:

JAMES A. HALIKAS, M.D.,

RESPONDENT. LS9902242MED

FINAL DECISION AND ORDER

The parties to this action for the purposes of Wis. Stats. sec. 227.53 are:

James A. Halikas, M.D.

420 Delaware St., SE # 393

Minneapolis, MN 55455

Wisconsin Medical Examining Board

P.O. Box 8935

Madison, WI 53708-8935

Department of Regulation and Licensing

Division of Enforcement

P.O. Box 8935

Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Medical Examining Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. James A. Halikas, M.D., Respondent, date of birth November 26, 1941, is licensed and registered to practice medicine and surgery in the state of Wisconsin by the Wisconsin Medical Examining Board, pursuant to license number 22000, which was first granted October 27, 1978.

2. Respondent's last address reported to the Department of Regulation and Licensing is 420 Delaware St., SE, # 393, Minneapolis, MN 55455.

3. On May 9, 1998, the Minnesota Board of Medical Practice accepted a Stipulation entered into by Respondent and the Complaint Review Committee of the Minnesota Board of Medical Practice and issued its Order taking disciplinary action against Respondent.

4. By its May 9, 1998 Order, the Minnesota Board of Medical Practice found that Respondent failed to assure the safety and welfare of individuals participating in a drug research study, of which Respondent was the principal investigator, including obtaining informed consent of the individuals prior to their participation in the study.

5. In its May 9, 1998 Order, the Minnesota Board of Medical Practice found:

a. Respondent had extensive experience with drug research studies, having served as principal investigator in over twenty studies from approximately 1982 to that time. Those studies involved the administration of drugs to human subjects. One of Respondent's roles as principal investigator had been to assure the safety and welfare of individuals participating in a study, including obtaining informed consent of the individuals prior to their participation in the study.

b. Since 1984, Respondent had been employed by the University of Minnesota, holding various teaching, research, hospital, and clinical appointments.

c. From 1986 to 1993, Respondent was a member of the University's Institutional Review Board Committee on the Use of Human Subjects in Research ("IRB"). The IRB exists pursuant to federal law and is responsible for, among other things, reviewing drug studies subject to Food and Drug Administration ("FDA") regulation. As a member of the University's IRB for seven years, Respondent was familiar with the procedures and protocol required of principal investigators in FDA regulated drug studies.

d. On June 24, 1992, the FDA informed Respondent that it was assigning an Investigational New Drug ("IND") number to a drug for which Respondent was the sponsor, Gamma-Hydroxybutyrate ("GHB"). The FDA also informed Respondent that as sponsor of GHB, Respondent was responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

e. On September 4, 1992, Respondent submitted to the IRB a document entitled "Amendment 1" in which Respondent proposed using GHB for opium detoxification. Specifically, Respondent proposed targeting a population of Southeast Asian immigrants who had "recurring opiate addiction problems."

f. With Amendment 1, Respondent submitted a copy of the consent form he would provide to patients in the GHB opium addiction study. The form told patients, among other things:

i. The patient would take GHB in addition to "normal treatment."

ii. The patient may experience side effects of GHB. If the patient or staff believed that the patient had gotten substantially worse, participation in the study might be terminated.

iii. Medication would be provided to the patient at no cost.

iv. The patient may decide not to participate or may withdraw consent at any time without any affect on the patient's ability to be treated at the University hospital.

g. On October 7, 1992, the IRB approved the GHB opium detoxification study and the consent form submitted by Respondent.

h. From June 1993 to August 5, 1993, Respondent conducted the GHB opium detoxification study on ten patients, nine of whom were Southeast Asian opium-addicted patients. Most were not proficient in English.

i. As principal investigator for the research study, and as attending physician on the unit involved in the study, Respondent was responsible for assuring that the University of Minnesota's protocols for medical research were followed.

j. Respondent did not obtain signed informed consent from eight patients prior to their entry in the program and their being dosed with GHB. Respondent did obtain signed informed consent forms from three patients after their participation in the study had begun.

k. During the study, several of the patients expressed dissatisfaction with GHB and requested more methadone. In most cases no additional methadone was provided.

l. Respondent failed to abide by the dosing protocol limits for the study. No patient was to receive dosing of GHB higher than 15 mg/kg qid, but two patients were dosed in excess of this protocol on one day each.

m. On approximately August 4, 1993, following a meeting with Respondent prompted by complaints from his colleagues about the conduct of the GHB study, the Head of the Department of Psychiatry told Respondent she thought he should terminate the study. Respondent stopped research activity on the GHB opium study on August 5, 1993, and on August 10, 1993, Respondent notified the IRB that he had stopped the research.

n. Based on allegations against Respondent of serious non-compliance with human subjects regulations

and guidelines, the IRB suspended approval of the GHB study on October 13, 1993, and launched an investigation into Respondent's conduct of the study. The IRB also suspended Respondent's membership on the IRB.

o. On November 4, 1993, in light of its concerns about the risk Respondent might pose to patients in other research projects, the IRB suspended all of Respondent's privileges as a Researcher permitted to study human subjects.

p. On March 11, 1994, following its investigation, the IRB concluded that it could not guarantee the welfare of human subjects in research under Respondent's direction. Therefore, it withdrew Respondent's already suspended privilege to serve as a Researcher directly involved in human subjects research at the University of Minnesota, pending an approved remediation plan. The IRB also told Respondent that his IRB membership, which was suspended on October 13, 1993, would not be reinstated.

q. In light of the 1994 IRB action, the Credentials Committee of the Medical and Dental Staff of the University of Minnesota Hospital and Clinic ("Credentials Committee") decided on February 14, 1995, that Respondent would be issued a letter of reprimand, have his clinical performance monitored for two years, and be restricted from any research involving patients of the University Hospital, except as approved by the IRB. The Credentials Committee specifically based its decision on Respondent's performance in conducting the GHB study, stating that there were "significant shortcomings in regard to adherence to appropriate standards of care, conformance with applicable policy, and supervision of staff for whom [Respondent] was responsible."

6. The Minnesota Board of Medical Practice's May 9, 1998 Order reprimanded Respondent and conditioned Respondent's license to practice medicine and surgery in the state of Minnesota as follows:

a. Respondent was required to provide to the Minnesota Board of Medical Practice proof of compliance with the requirements imposed by the University of Minnesota's Credentials Committee in 1995.

b. For a period of two years following the date of the Order, Respondent will be required to provide the Minnesota Board of Medical Practice with immediate written notification of his involvement in any research study involving human subjects that is approved by the IRB.

c. Respondent was required to obtain a supervising physician approved in advance by the Committee or its designee for each of Respondent's Minnesota clinical practice sites. Respondent is required to meet with the supervising physician monthly and cooperate with the supervising physician in providing any information related to Respondent's clinical practice, including but not limited to allowing access to patient records that the supervising physician may randomly select. Respondent is required to ensure that the supervising physician provides the Minnesota Board of Medical Practice with quarterly reports regarding Respondent's involvement in any human subjects research and Respondent's general conduct with patients. The provisions of this subparagraph apply only to Respondent's Minnesota clinical practice and do not apply to Respondent's clinical activities in teaching or supervising residents.

d. Respondent was required to meet on a quarterly basis with a designated Minnesota Board of Medical Practice member. The purpose of such meetings is to review Respondent's progress under the terms of this stipulation and order.

e. Respondent was required to pay to the Minnesota Board of Medical Practice a civil penalty of $3,500.

f. The conditions remain in effect for a minimum of two years from the date of the Order. At the end of that period, Respondent may petition for an unconditional license upon proof satisfactory to the Minnesota Board of Medical Practice of full compliance with the conditions and Respondent's overall fitness to practice medicine without condition. Upon hearing the petition, the Minnesota Board of Medical Practice may continue, modify, or remove the conditions set out in the Order.

g. Within ten days of the date of the Order, Respondent was to provide the Minnesota Board of Medical Practice with a list of all hospitals and skilled nursing facilities at which Respondent currently had medical privileges and a list of all states in which Respondent was licensed or had applied for licensure.

CONCLUSIONS OF LAW

1. The Wisconsin Medical Examining Board has jurisdiction over this matter pursuant to § 448.02(3), Stats.

2. The Wisconsin Medical Examining Board has authority to enter into this stipulated resolution of this matter pursuant to § 227.44(5), Stats.

3. Respondent, by having had disciplinary action taken against his Minnesota license to practice medicine and surgery by the Minnesota Board of Medical Practice, has committed unprofessional conduct as defined by Wis. Adm. Code § Med 10.02(2)(q) and is subject to discipline pursuant to § 448.02(3), Stats.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED:

1. Respondent, James A. Halikas, M.D., is hereby REPRIMANDED for the conduct set out above.

2. Respondent agrees not to practice medicine and surgery in the state of Wisconsin until Respondent provides the Wisconsin Medical Examining Board or its designee with proof sufficient to the Board that all limitations placed on Respondent's license by the Minnesota Board of Medical Practice have been removed, and Respondent has been notified by the Wisconsin Medical Examining Board that it considers the proof to be sufficient.

3. Respondent shall pay to the Wisconsin Department of Regulation and Licensing, within 30 days of the date of this Order, the sum of $300.00 which represents the partial costs incurred as a result of this proceeding.

The rights of a party aggrieved by this Decision to petition the Wisconsin Medical Examining Board for rehearing and to petition for judicial review are set forth on the attached "Notice of Appeal Information".

Dated this 24th day of February, 1999.

Ronald Grossman, M.D.

Secretary

Medical Examining Board