# LOUISIANA STATE BOARD OF MEDICAL EXAMINERS



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In the Matter of

EDWARD C. KEITH, M.D.

FINAL DECISION

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A formal administrative hearing was convened before the Louisiana State Board of Medical Examiners ("Board") on December 9, 1981 to adjudicate alleged, specified violations of the Louisiana Medical Practice Act by Edwawrd C. Keith, M.D. ("Dr. Keith"), to-wit: "[p]rescribing, dispensing, or administering habit-forming or other legally controlled substances in other than a legal or legitimate manner," La. Rev. Stat., Title 37, Section 1285(6), and "[p]rofessional or medical incompetency," La. Rev. Stat., Title 37, Section 1285(12). A quorum of the Board was present. Dr. Keith was present in proper person, having waived representation by legal counsel.

Upon consideration of the evidence presented, pursuant to La. Rev. Stat., Title 49, Section 958, the Board renders the following findings of fact, conclusions of law, and decision.

## Findings of Fact

1

Dr. Keith is a physician duly licensed by the Board to practice medicine in the state of Louisiana. By virtue of state licensure and Federal registration, he is authorized as a practitioner, to prescribe, dispense and administer controlled substances. At all times material to the conduct and activities which this administrative proceeding concerns, Dr. Keith was so licensed and authorized and, while a full-time resident in family medicine at Charity Hospital, engaged in the practice of medicine in New Orleans, Louisiana.

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Dr. Keith conducted a general practice primarily in an office located within one New Orleans area pharmacy from July, 1980 through April, 1981. Occasionally, Dr. Keith worked in one of three other area pharmacy clinics and he conducted this practice three days per week, approximately three hours each day. Dr. Keith estimates that initially 95% of his patients were seen for weight control at the pharmacy clinic. As

described by Dr. Keith, he did an initial history and physical examination on weight control patients after which either he or an assistant obtained the patients' blood pressure, weight and height. Dr. Keith testified that he did not perform diagnostic testing nor did he routinely perform urinalyses on weight control patients.

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Dr. Keith's program consisted, essentially, of the prescription of an anorexiant medication, Preludin (phendimetrazine hydrochloride), 75 mg.; Desoxyn (methamphetamine hydrochloride), 15 mg.; or Biphetamine (resin complexes of amphetamine and dextroamphetamine), 20 mg., one tablet to be taken each day. Dr. Keith also stated that he counseled patients and provided them with printed diet sheets.

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An investigation was conducted by the Office of Narcotics and Dangerous Drugs ("NDD") of the Louisiana Department of Health and Human Resources into the Schedule II prescription files of seven New Orleans pharmacies. In the course of the investigation, NDD agents seized 421 prescriptions for controlled scheduled substances written by Dr. Keith from July, 1980 to April, 1981. Of this number, the prescriptions were

primarily written for the Schedule II controlled substances of the amphetamine or sympathomimetic amine class and within this class 248 prescriptions were written for Preludin, 75 mg., representing 5,723 dosage units; 60 prescriptions were written for Desoxyn, 15 mg., representing 1,721 dosage units; and 40 prescriptions, representing 1,159 dosage units of Biphetamine, 20 mg., were also written. The investigation revealed that in the course of one day, Dr. Keith wrote 22 prescriptions, representing 561 dosage units of Schedule II controlled substances.

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Further analysis of the seized Schedule II prescriptions revealed several instances on which Dr. Keith wrote prescriptions for either Desoxyn, Preludin, or Biphetamine, or a combination thereof, for patients within days of writing an identical prescription for the same patient, thus allowing the patient access to several times the prescribed daily dosages over extended periods. In one instance, Dr. Keith prescribed 60 tablets of Biphetamine, a Schedule II controlled substance, to a patient on a single visit.

6

The evidence also established that Dr. Keith maintained several patients on Preludin, Desoxyn, Biphetamine, or a com-

bination of the three, for periods of time substantially in excess of 12 weeks. While Dr. Keith testified that the prescriptions were intended to assist in the control of the patient's weight, "maintenance" of weight is less than an adequate or acceptable medical justification for prescribing Preludin, Desoxyn or Biphetamine. One of the records produced by Dr. Keith reveal that the patient in question did not lose but, in fact, gained weight over the course of Dr. Keith's treatment.

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The evidence also established that Dr. Keith failed to employ less hazardous substances in his treatment therapy; rather, he consistently prescribed Preludin, Desoxyn or Biphetamine, all Schedule II substances, as the primary mode of treating obesity.

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Desoxyn, Preludin and Biphetamine are sympathomimetic amines with pharmacological actions similar to the amphetamines, acting as central nervous and cardiovascular system stimulants. Their exclusive indication is as an appetite suppressant or anorexiant therapy in the management of

exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, exercise, and behavior modification.*

9

In prescribing Preludin, Desoxyn or Biphetamine, a physician must be cognizant of their contraindications, possible adverse side effects and potential dangers and weigh such risks against the limited usefulness of the substances. Preludin, Desoxyn or Biphetamine, thus, may produce untoward cardiovascular and central nervous system stimulation. These substances may also produce tachyphylaxis and tolerance, which appears in most patients with administration of the drug over four to six weeks. Continued administration beyond such a term carries a substantial risk of physical or psychological dependence.

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Preludin, Desoxyn and Biphetamine, like the amphetamines and other stimulant drugs, have been extensively abused. Such

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*Desoxyn and Biphetamine are also indicated in the treatment of hyperkinetic children. There was no evidence, however, that Dr. Keith was treating any hyperkinetic children with Desoxyn or Biphetamine.

drugs are stimulants of preference among drug abusers. Preludin, in particular, is water soluble, and its stimulatory effect may be enhanced by parenteral administration, or injection, in lieu of oral administration. In the estimate of a narcotics investigative officer, the current illicit market value of a single tablet of Preludin is approximately $18 to $25, while the retail price currently charged by pharmacies in filling prescriptions is approximately 30¢ to 35¢ per tablet. Because of their known high potential for abuse, Preludin, Desoxyn and Biphetamine are controlled by both state and Federal law as Schedule II substances. LSA-R.S. 40:964; 21 C.F.R. § 1308.12.

11

Dr. Carl King, Assistant Professor of pharmacology at the Louisiana State University Medical School, was qualified as an expert in pharmacology and medical education as it relates to pharmacology. In Dr. King's opinion there is no pharmacological justification for prescribing Preludin, Desoxyn or Biphetamine due to the substantial risk of addiction, drug abuse and side effects accompanying their use. As additional reasons for avoidance of these substances, Dr. King cited their popularity among abusers and the availability of perhaps less dangerous substances for use in the treatment of obesity.

12

A typical second year medical student would be aware that Preludin, Desoxyn and Biphetamine should be avoided, due to the dangers accompanying their use. Even the manufacturers of the drugs warn of rapid tolerance, requiring ever-increasing dosages, as well as drug dependency and drug addiction.

13

In reviewing the prescriptions written by Dr. Keith, Dr. King testified that there was no pharmacological or medical justification for the prescribing of Preludin, Desoxyn or Biphetamine in the quantity and with the frequency that Dr. Keith prescribed and, if used at all, these substances should only be given on a short-term basis and certainly not more than a few weeks. Further, Dr. King testified that there was absolutely no pharmacological or medical justification for prescribing Preludin, 75 mg., Desoxyn, 15 mg. or Biphetamine, 20 mg. in such a manner that the patient had access to more than one tablet per day during the period for which they are prescribed.

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Dr. Brobson Lutz, a physician Board certified in the area of internal medicine and practicing in New Orleans, was

qualified as an expert in internal medicine as it relates to the treatment of obesity. Dr. Lutz testified that approximately 15% to 20% of his patients are seen for the treatment of obesity. In the treatment of weight control patients, Dr. Lutz testified that he does not prescribe Schedule II anorexiant substances due to the rapid development of tolerance, side effects, and potential for abuse.

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Further, in Dr. Lutz's opinion, it is contrary to good medical practice to prescribe Preludin, Desoxyn or Biphetamine, as part of a weight control program, on the patient's initial visit; rather, if sympathomimetic amines are to be used at all, Dr. Lutz testified that there are less dangerous substances which could be employed and which do not carry the abuse potential of Preludin, Desoxyn or Biphetamine.

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In reviewing the prescriptions written by Dr. Keith, Dr. Lutz testified that there was no medical justification for the prescribing of Preludin, Desoxyn or Biphetamine in the quantity and with the frequency that such were prescribed and, if used at all, such should only be given on a short-term basis. Furthermore, he testified that there was absolutely no medical

justification for prescribing Preludin, 75 mg., Desoxyn, 15 mg. or Biphetamine, 20 mg. in such a manner that a patient had access to more than one tablet per day during the period for which they are prescribed.

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The Board finds as a matter of medical fact, consistent with the opinions of experts who testified in this matter and the unanimous teachings of the medical authorities that Preludin, Desoxyn and Biphetamine cause rapid tolerance, are highly addictive and should be avoided because of their potential for abuse. The Board further finds that there is no conceivable medical justification in any case for the prescribing of Preludin 75 mg., Desoxyn 15 mg. or Biphetamine 20 mg. in excess of one tablet per day or for the continuous prescribing of Preludin, Desoxyn or Biphetamine in excess of 12 weeks.

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In his defense, Dr. Keith testified that he did not knowingly prescribe controlled scheduled substances to patients who would abuse the medication and, that if patients did not lose weight he would discontinue the medication. Further, Dr. Keith testified that he was attempting to convert a practice, consisting almost entirely of weight control patients, to a

general medicine practice. By the time he discontinued his pharmacy practice, Dr. Keith stated that only 30% to 40% of the patients were being seen for weight control. Finally, Dr. Keith testified that he was aware of the potential for abuse of Preludin, Desoxyn, and Biphetamine, as well as the dangers in using anorexiants generally; nevertheless, it was his opinion that these substances could be continuously prescribed as long as there was weight loss.

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The Board finds wholly unsupportable the contention that Schedule II anorexiants, such as Desoxyn, Preludin or Biphetamine, may be prescribed for as long as the patient loses weight. This contention not only discounts the dangers and inadvisability of the use of these substances in the first place, but it is inconsistent with the plain language of the indications of the drugs' manufacturers, the recommendations of all available medical authorities and the opinions of the experts who testified in this proceeding. Such a contention is antithetical to common medical sense. Indeed, sound medical practice would dictate that prescriptions for such medication be restricted to a period of time not to exceed 12 weeks under any circumstances.

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Dr. Keith further testified that the conditions under which he worked in the drug store clinics made it difficult to keep accurate profiles and records of patients. Therefore, he was not always aware of what medication a patient had been on or the length of time they had received it.

## Conclusions of Law

Based on the foregoing Findings of Fact, the Board concludes, as a matter of law, that:

1

Preludin (phendimetrazine hydrochloride), Desoxyn (methamphetamine hydrochloride), and Biphetamine (resin complexes of amphetamine and dextroamphetamine) are controlled substances under Louisiana and Federal law. LSA-R.S. 40:964; 21 C.F.R. § 1308.12.

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State and Federal law, recognizing the substantial hazards inherent in controlled substances,* uniformly condition their

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*A drug is classified as a Schedule II controlled dangerous substance upon a considered, empirical finding that "[t]he drug or other substance has a high potential for abuse" and "[a]buse of the drug or other substance may lead to severe psychological or physical dependence." The definition is identical under Federal and Louisiana law. 21 U.S.C. § 812(b)(2)(A), (C); LSA-R.S. 40:963(A), (C).

use by physicians on strict adherence to statutes and regulations governing records, security, and the form of and cause for prescriptions. Federal regulations, for example, provide that:

> A prescription for controlled substances to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual scope of his professional practice. . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 390 of the Act (21 U.S.C. 829) and the . . . person issuing its shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a). A virtually identical policy is embraced by Louisiana law.*

Thus, the law severely circumscribes a physician's privilege to make controlled substances available by explicitly requiring that a prescription may be issued (1) only within the usual scope of a physician's professional practice, (2) only for a legitimate medical purpose, and (3) only when the physician is acting in good faith in the administration of a

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*LSA-R.S. 40:961(30) defines "prescription" as a written request for a drug or therapeutic aid issued by a licensed physician . . . for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.

bona fide treatment of a physical, mental or bodily ailment. Together, these requirements make it clear that controlled substances licensure and registration do not license a physician to disregard the demonstrated abuse and dependency-inducing potential of dangerous drugs. When a physician does so, he can no longer claim that the treatment is bona fide or that his prescription is issued in good faith with medical justification.

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As a matter of course, Dr. Keith has indiscriminately issued prescriptions for controlled substances without legitimate medical basis or justification and not in the good faith administration of a bona fide treatment for a physical, mental, or bodily ailment. In issuing such prescriptions, Dr. Keith was prescribing legally controlled substances in other than a legal or legitimate manner and, therefore, just cause exists for action against his license as provided by LSA-R.S. 37:1285(6).

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Dr. Keith's explanation for those prescriptions written in excessive frequency is indicative of medical incompetence in that respect. Dr. Keith's explanation that prescribing Preludin, Desoxyn or Biphetamine for periods in excess of three

months was medically justified, as long as a patient was losing weight, is an additional indicator of medical incompetence.

Dr. Keith's failure to keep adequate patient records and failure to take adequate precautions to prevent abuse of Scheduled II controlled substances further supports a conclusion of medical incompetency. Accordingly, just cause exists for action against his license as provided by LSA-R.S. 37:1285(12).

## Decision

Considering the foregoing,

IT IS ORDERED that the license of Edward C. Keith, M.D. to practice medicine in the State of Louisiana, as evidenced by Certificate No. 15287, be, and the same is hereby, suspended for a period of three (3) months from December 18, 1981 and will remain on probation for a period of three (3) years.

IT IS FURTHER ORDERED that Edward C. Keith, M.D. surrender his Federal and State controlled substances permits for a period of one (1) year from December 18, 1981.

IT IS FURTHER ORDERED that any violation of the probationary terms, conditions, and restrictions set forth herein shall be deemed just cause for the suspension or revocation of

the medical licensure of Edward C. Keith, M.D. or for such other disciplinary action as the Board deems appropriate, as if such violations were enumerated among the causes provided in LSA-R.S. 37:1285.

New Orleans, Louisiana, this 9 day of February, 1982.

LOUISIANA STATE BOARD OF
MEDICAL EXAMINERS

By: Charles B Odom M.D.
CHARLES B. ODOM, M.D.
President