

COMMONWEALTH OF MASSACHUSETTS**Suffolk, ss****Board of Registration
in Medicine****Adjudicatory Case No.
04-35-XX****In the Matter of****Joseph Py, D.O.****CONSENT ORDER**

Joseph Py, D.O. ("the Respondent") and the Complaint Counsel agree that the Board of Registration in Medicine ("the Board") may issue this Consent Order, in lieu of convening an adjudicatory proceeding, with all the force and effect of a Final Decision within the meaning of 801 CMR 1.01(11)(d). The Respondent admits to the findings of fact described below and agrees the Board may make conclusions of law and impose a sanction as set forth below.

FINDINGS OF FACT

1. The Respondent was born on October 30, 1956. He is a 1984 graduate of the New England College of Osteopathic Medicine. He has been licensed to practice medicine in Massachusetts since January 15, 1997, under certificate number 152684. He is also licensed to practice medicine in the State of Maine. His primary area of practice is Family Medicine and he has been certified in Family Practice by the American Osteopathic Board of Family Practice. The Respondent currently practices medicine in Amesbury, Massachusetts and in the State of Maine.

2. On November 14, 2002, the Respondent entered into a Consent Order with

the Maine Board of Osteopathic Licensure ("the Maine Osteopathic Board"). The terms of the Consent Order provided that between April 2001 and November 2002, the

Respondent treated patients with IV H₂O₂ (hydrogen peroxide) therapy under a protocol approved by the International Bio-Oxidative Medicine Foundation ("IBOMF"). The consent form that he used included language that IV H₂O₂ therapy was regarded as experimental. The consent form also required patients to release the Respondent from any legal responsibility for harm resulting to them from the use of IV H₂O₂ therapy. The latter requirement did not comply with FDA regulations pertaining to experimental studies 21 C.F.R. §50.20.

3. Along with the consent form, the Respondent gave his patients a document entitled "Side Effects of Peroxide Therapy". The concluding paragraph of this document stated: "Question: If there was nothing wrong with you and you took peroxide therapy for no reason at all, would it be harmful? Absolutely not! It would act like a tune-up to your body." The document did not specifically identify conventional alternatives for the conditions being treated and it did not enumerate the risks of failing to pursue other more proven treatments. The document also contained the following representation: "It is believed in your case that IV H₂O₂ therapy is proper under these criteria and will quite probably improve the condition for which you are under treatment, and your overall health from its use. However, you must understand no one can or does guarantee or warrant the results in any manner."

4. Prior to beginning IV H₂O₂ therapy with a patient, the Respondent spoke with patients about IV H₂O₂ therapy and he provided patients with articles, materials and studies related to IV H₂O₂ therapy and its administration. Additional, more technical

materials were made available to patients whenever they wanted more information about

IV H₂O₂ therapy and he would speak with patients about these materials and answer any

other questions they had about IV H₂O₂ treatment. The Respondent asked each patient to acknowledge in writing that he or she had read and understood the material. None of the material provided or offered related to scientifically controlled human studies or to the efficacy of this therapy for the specific conditions being treated, except one study regarding influenza.

5. Based upon the foregoing, the Maine Osteopathic Board determined that the Respondent did not demonstrate compliance with 32 M.R.S.A. §2591-A(2)(F) by requiring patients to sign a release of liability as part of the informed consent before IV H₂O₂ therapy would be administered and by providing literature and other information to patients, in connection with the informed consent and the study, that could have been misunderstood by patients regarding the efficacy of IV H₂O₂ therapy. 32 M.R.S.A. § 2591 provides that the Maine Osteopathic Board may discipline a licensee for unprofessional conduct if the licensee violates a standard of professional behavior that has been established in the practice for which the licensee is licensed.

6. In the Consent Order, the Respondent and the Maine Osteopathic Board agreed that if the Respondent ever used IV H₂O₂ therapy on patients again, he would use consent forms approved by the Food and Drug Administration ("FDA") and the Maine Osteopathic Board. The Respondent also agreed that he would not require any patient to waive any legal rights in order to receive IV H₂O₂ therapy. He further agreed that if a study was required by the FDA, he would use a consent form that complied with FDA regulations and that if a study was not required by the FDA, his consent form would

include information about a) the patient's condition; b) other potential and alternative courses of treatment for the condition; c) the risks of not pursuing conventional treatment; d) information that no clinical trials have demonstrated the efficacy of IV H₂O₂ treatment for the patient's medical condition; e) information on the reasonably foreseeable risks that the patient can expect from the therapy. The Respondent further agreed that if he used IV H₂O₂ treatments in the future, he would be subject to monitoring by the Maine Osteopathic Board. He also agreed to reimburse the Maine Osteopathic Board for the costs of their investigation. A copy of the Consent Order between the Respondent and the Maine Osteopathic Board is attached as Exhibit A and incorporated by reference into this pleading.

7. On November 14, 2002, the Maine Osteopathic Board issued a First Amendment to Consent Agreement and Board Order. In this document, the Maine Osteopathic Board acknowledged that the Respondent had represented to them that he had no intention of using IV H₂O₂ therapy in the future. The Maine Osteopathic Board ordered that the Agreement between them and the Respondent would terminate on November 14, 2004, provided that the Respondent did not use IV H₂O₂ therapy in his practice or violate any other conditions of the November 14, 2002 Consent Agreement during that period of time. A copy of the First Amendment to Consent Agreement and Board Order is attached as Exhibit B and incorporated by reference into this pleading.

8. The Respondent also used IV H₂O₂ therapy on patients in the Commonwealth of Massachusetts under the same protocol that he used it in the State of Maine.

CONCLUSIONS OF LAW

The Respondent has violated 243 CMR 1.03(5)(a)(12), in that he has been disciplined by another jurisdiction for reasons substantially similar to those set forth in G.L. c. 112, § 5 or 243 CMR 1.03(5), specifically 243 CMR 1.01(5)(a)(18), by engaging in misconduct in the practice of medicine.

SANCTION

The Respondent agrees to a license restriction that he will not use IV H₂O₂ therapy in the Commonwealth of Massachusetts. This sanction is imposed as a resolution to Board of Registration in Medicine Docket No. 03-639.

EXECUTION OF THIS CONSENT ORDER

The parties agree that the approval of this Consent Order is left to the discretion of the Board. The signatures of the Respondent, his attorney, and Complaint Counsel are expressly conditioned on the Board accepting this Consent Order. If the Board rejects this Consent Order in whole or in part, then the entire document shall be null and void; thereafter, neither of the parties nor anyone else may rely on the Consent Order. As to any matter this Consent Order leaves to the discretion of the Board, neither the Respondent, nor anyone else acting on his behalf has received any promises or representations regarding the same.

The Respondent waives any right of appeal he may have resulting from the Board's acceptance of this Consent Order.

The Respondent shall provide a complete copy of this Consent Order, with all exhibits and attachments, if any, within ten (10) days by certified mail, return receipt requested, or by hand delivery to the following designated entities: any in-state or out-of-state hospital, nursing home, clinic, other licensed facility, or municipal, state, or federal

JUN 16 2004 3:02PM EUKLEY RICHARDSON GELINAS

No. 3282 P. 7/7

facility at which he practices medicine; any in-state or out-of-state health maintenance

organization with whom he has privileges or any kind of association, any state agency,

in-state or out-of-state, with which he has a provider contract; any in-state or out-of-state

medical employer, whether or not he practices medicine there; and the state licensing

boards of all states in which he has any kind of license to practice medicine. The

Respondent shall also provide this notification to any such designated entities, which he

becomes associated with for the duration of this Consent Order. The Respondent is

further directed to certify to the Board within ten (10) days that he has complied with this

directive.


The Board expressly reserves the authority to independently notify, at any time,

any of the entities designated above or any other affected entity, of any action it has

taken.


Joseph Py, D.O.

Respondent


Katherine Robertson

Respondent's Counsel


Muriel Ann Finnegan

Complaint Counsel

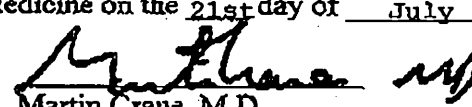
6/16/04
Date

6/21/04
Date

6/22/04
Date

Accepted by the Board of Registration in Medicine on the 21st day of July

2004.


Martin Crane, M.D.
Chairman

Notified by Certified Mail 7/21/04 JT

COMMONWEALTH OF MASSACHUSETTS

Suffolk, ss

Board of Registration
in MedicineAdjudicatory Case No.
04-35-XX

In the Matter of)

Joseph Py, D.O.)

STATEMENT OF ALLEGATIONS

In Board of Registration in Medicine (the Board) Docket No. 03-369, the Board has reason to believe that Joseph Py, M.D. (the Respondent) has been disciplined by the State of Maine for unprofessional conduct.

BACKGROUND

The Respondent was born on October 30, 1956. He is a 1984 graduate of the New England College of Osteopathic Medicine. He has been licensed to practice medicine in Massachusetts since January 15, 1997, under certificate number 152684. He is also licensed to practice medicine in the State of Maine. His primary area of practice is Family Medicine and he has been certified in Family Practice by the American Osteopathic Board of Family Practice. The Respondent currently practices medicine in Amesbury, Massachusetts and in the State of Maine.

FACTUAL ALLEGATIONS

2. On November 14, 2002, the Respondent entered into a Consent Order with the Maine Board of Osteopathic Licensure ("the Maine Osteopathic Board"). The terms of the Consent Order provided that between April 21, 2001 and November 14, 2002, the

Respondent treated patients with IV H₂O₂ (hydrogen peroxide) therapy under a protocol approved by the International Bio-Oxidative Medicine Foundation ("IBOMF"). The consent form that he used included language that IV H₂O₂ therapy was regarded as experimental. The consent form also required patients to release the Respondent from any legal responsibility for harm resulting to them from the use of IV H₂O₂ therapy. The later requirement did not comply with FDA regulations pertaining to experimental studies at 21 C.F.R. § 50.20

3. Along with the consent form, the Respondent gave his patients a document entitled "Side Effects of Peroxide Therapy". The concluding paragraph of this document stated: "Question: If there was nothing wrong with you and you took peroxide therapy for no reason at all, would it be harmful? Absolutely not! It would act like a tune-up to your body." The document did not specifically identify conventional alternatives for the conditions being treated and it did not enumerate the risks of failing to pursue other more proven treatments. The document also contained the following representation: "It is believed in your case that IV H₂O₂ therapy is proper under these criteria and will quite probably improve the condition for which you are under treatment, and your overall health from its use. However, you must understand no one can or does guarantee or warrant the results in any manner."

4. Prior to beginning IV H₂O₂ therapy with a patient, the Respondent spoke with patients about IV H₂O₂ therapy and he provided patients with articles, materials and studies related to IV H₂O₂ therapy and its administration. Additional, more technical materials were made available to patients whenever they wanted more information about IV H₂O₂ therapy and he would speak with patients about these materials and answer any

other questions they had about IV H₂O₂ treatment. The Respondent asked each patient to

~~acknowledge in writing that he or she had read and understood the material. None of the~~

material provided or offered related to scientifically controlled human studies or to the efficacy of this therapy for the specific conditions being treated, except one study regarding influenza.

5. Based upon the foregoing, the Maine Osteopathic Board determined that the Respondent did not demonstrate compliance with 32 M.R.S.A. §2591-A(2)(F) by requiring patients to sign a release of liability as part of the informed consent before IV H₂O₂ therapy would be administered and by providing literature and other information to patients, in connection with the informed consent and the study, that could have been misunderstood by patients regarding the efficacy of IV H₂O₂ therapy. 32 M.R.S.A. § 2591 provides that the Maine Osteopathic Board may discipline a licensee for unprofessional conduct if the licensee violates a standard of professional behavior that has been established in the practice for which the licensee is licensed.

6. In the Consent Order, the Respondent and the Maine Osteopathic Board agreed that if the Respondent ever used IV H₂O₂ therapy on patients again, he would use consent forms approved by the Food and Drug Administration ("FDA") and the Maine Osteopathic Board. The Respondent also agreed that he would not require any patient to waive any legal rights in order to receive IV H₂O₂ therapy. He further agreed that if a study was required by the FDA, he would use a consent form that complied with FDA regulations and that if a study was not required by the FDA, his consent form would include information about a) the patient's condition; b) other potential and alternative courses of treatment for the condition; c) the risks of not pursuing conventional

treatment; d) information that no clinical trials have demonstrated the efficacy of IV H₂O₂

~~treatment for the patient's medical condition; e) information on the reasonably~~

foreseeable risks that the patient can expect from the therapy. The Respondent further agreed that if he used IV H₂O₂ treatments in the future, he would be subject to monitoring by the Maine Osteopathic Board. He also agreed to reimburse the Maine Osteopathic Board for the costs of their investigation. A copy of the Consent Order between the Respondent and the Maine Osteopathic Board is attached as Exhibit A and incorporated by reference into this pleading.

7. On November 14, 2002, the Maine Osteopathic Board issued a First Amendment to Consent Agreement and Board Order. In this document, the Maine Osteopathic Board acknowledged that the Respondent had represented to them that he had no intention of using IV H₂O₂ therapy in the future. The Maine Osteopathic Board ordered that the Agreement between them and the Respondent would terminate on November 14, 2004, provided that the Respondent did not use IV H₂O₂ therapy in his practice or violate any other conditions of the November 14, 2002 Consent Agreement during that period of time. A copy of the First Amendment to Consent Agreement and Board Order is attached as Exhibit B and incorporated by reference into this pleading.

8. The Respondent also used IV H₂O₂ therapy on patients in the Commonwealth of Massachusetts under the same protocol that he used it in the State of Maine.

LEGAL BASIS FOR PROPOSED RELIEF

A. Pursuant to 243 CMR 1.03(5)(a)(12), the Board may discipline a physician upon proof satisfactory to a majority of the Board that the physician has been disciplined by another jurisdiction for reasons substantially similar to those set forth in G.L. c. 112, §

5 or 243 CMR 1.03(5). Specifically, pursuant to 243 CMR 1.01(5)(a)(18), the Board

may discipline a physician for engaging in misconduct in the practice of medicine.

The Board has jurisdiction over this matter pursuant to G.L. c. 112, §§5, 61, and

62. This adjudicatory proceeding will be conducted in accordance with the provisions of

G.L. c. 30A and 801 CMR 1.01 et seq.

NATURE OF RELIEF SOUGHT

The Board is authorized and empowered to order appropriate disciplinary action, which may include revocation or suspension of the Respondent's license to practice medicine. The Board may also order, in addition to or instead of revocation or suspension, one or more of the following: admonishment, censure, reprimand, fine, the performance of uncompensated public service, a course of education or training or other restrictions upon the Respondent's practice of medicine.

ORDER

Wherefore, it is hereby ORDERED that the Respondent show cause why he should not be disciplined for the conduct described herein.

By the Board of
Registration in Medicine,



Martin Crane, M.D.
Chairman

Dated: July 14, 2004

Notified by certified Mail 7/21/04 JT