

**STATE OF CONNECTICUT
CONNECTICUT BOARD OF CHIROPRACTIC EXAMINERS**

IN RE: PETITION FOR DECLARATORY RULING CONCERNING
 WHETHER THE RISK AND/OR POSSIBILITY OF THE
 OCCURRENCE OF A STROKE OR CERVICAL ARTERY
 DISSECTION AS A SIDE EFFECT SHOULD BE ADDRESSED WHEN
 A CHIROPRACTIC PHYSICIAN OBTAINS INFORMED CONSENT
 FROM A PATIENT PRIOR TO THE PERFORMANCE OF A JOINT
 MOBILIZATION, MANIPULATION, OR ADJUSTMENT OF THE
 CERVICAL SPINE

PETITIONER: CONNECTICUT CHIROPRACTIC ASSOCIATION, INC.

**DECLARATORY RULING
MEMORANDUM OF DECISION**

Procedural Background

On June 2, 2009, the Connecticut Chiropractic Association, Inc. ("the CCA") requested that the State of Connecticut Board of Chiropractic Examiners ("the Board") issue a Declaratory Ruling with regard to the following question:

Whether the risk and/or possibility of the occurrence of a stroke or cervical artery dissection as a side effect should be addressed with a patient when a chiropractic physician obtains informed consent from a patient prior to the performance of a joint mobilization, manipulation, or adjustment of the cervical spine.

On or about July 21, 2009, the Board published notice of the Petition, as required by § 4-176(c) of the Connecticut General Statutes ("the Statutes"). Bd. Exh. 2.

On July 24, 2009, the CCA filed a petition to participate as a Party. Bd. Exh. 3. In August 2009, the Connecticut Chiropractic Council ("the CCC"), the Victims of Chiropractic Abuse ("VOCA"), the Chiropractic Stroke Awareness Group, LLC ("CSAG"), Victims of Irresponsible Chiropractic Education and Standards ("VOICES"), Campaign for Science-Based Healthcare, and Preston H. Long, D.C. filed petitions to participate. Bd. Exh. 5, 7, 9, 21, 23, and 27.

In August 2009, the Connecticut Medical Examining Board ("CMEB"), the International Chiropractors Association ("ICA"), the Chiropractic Stroke Awareness Organization ("CSAO"), the ChiroSecure Chiropractic Malpractice Company ("ChiroSecure"), Michael F. McCormick, Sharon Mathiason and Murray S. Katz, MDCM filed petitions to participate as Intervenors. Bd. Exhs. 11, 15, 17, 19, 25, and 29.

On August 20, 2009, Senator Leonard A. Fasano filed a petition to present oral or written testimony. Senator Fasano's request was granted pursuant to §4-177c(b) of the Statutes. Bd. Exhs. 13, 14.

On September 14, 2009, CCA, CCC, VOCA, and CSAG were granted Party status; CMEB, ICA, CSAO, ChiroSecure, VOICES, Campaign for Science-Based Healthcare, Michael F. McCormick, Preston H. Long, D.C., Sharon Mathiason, and Murray S. Katz, MDCM were granted Intervenor Status pursuant to §4-177a of the Statutes. Bd. Exhs. 4, 6, 8, 10, 12, 16, 18, 20, 22, 24, 26, 28, and 30.

Parties and intervenors submitted pre-filed testimony and pre-filed rebuttal testimony, which they adopted under oath during the hearing, and the witnesses were available for questioning and cross-examination. Bd. Exhs. 32-41, and 43-50.

On September 15, 2009, the Board ordered the matter to be set for public hearing on January 5 and 6, 2010, pursuant to §4-176(e)(2) of the Statutes.

On September 29, 2009, Notice of Declaratory Ruling Proceeding was provided to all interested parties as pursuant to §4-176 of the Statutes. Bd. Exh. 31.

The hearing was held on January 5, 6, 19, and 22, 2010, and was conducted in accordance with Chapter 54 of the Statutes, and §§19a-9-1 through 19a-9-29 of the Regulations of Connecticut State Agencies ("the Regulations"). Attorney Mary Alice Moore Leonhardt appeared on behalf of the CCA, CCC and ICA; Attorney Norman A. Pattis appeared on behalf of the CSAG; and, Attorney Jay Malcynsky appeared on behalf of the VOCA.

This Memorandum of Decision is based entirely on the record and sets forth findings of fact and conclusions of law, and an order. To the extent that the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc. v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

Findings of Fact

1. The standard of care for chiropractors in Connecticut requires that they obtain informed consent before performing any procedure and provide post-treatment instructions. Bd. Exhs. 1, 32, 34, 36, 46-48.
2. "Informed consent" requires, in part, disclosure of the risks associated with a medical or chiropractic procedure to patients so they can make an informed decision whether to undergo the procedure. Bd. Exhs. 1, 32, 34, 36, 46-48. Obtaining informed consent from a patient prior to treatment is a legal duty as well as part of the standard of care. See, Logan v. Greenwich Hospital Association, 191 Conn. 282 (1983) and Duffy v. Flagg, 279

Conn. 682 (2006). The standard of disclosure for informed consent in Connecticut is objective and it does not vary from patient to patient based on what the patient asks or what the patient would do with the information if it were disclosed. The standard for informed consent requires a health care practitioner to “provide the patient with that information which a *reasonable* patient would have found material for making a decision whether to embark upon a contemplated course of therapy.” Duffy at 692, citing Logan v. Greenwich Hospital Association (emphasis in original).

3. The evidence is sufficient to establish that a stroke or cervical arterial dissection is not a risk or side effect of a joint mobilization, manipulation, or adjustment of the cervical spine performed by a chiropractor. Bd. Exhs. 1-26, 28-41, 43-52, 57, 58, 60-63, and 67-74; Tr. 1/5/10, pp. 90-293; Tr. 1/6/10, pp. 36-280; Tr. 1/19/10, pp. 9-264; and, Tr. 1/22/10, pp. 3-330.
4. The likelihood of suffering a stroke following an appointment with a chiropractor is no greater than that following an appointment with a primary care physician. Bd. Exhs. 32, 45; Tr. 1/22/10, pp. 11, 14-17, 27, 49, 100-103, and 113.
5. Chiropractors are required by the standard of care to perform a history and physical examination and if determined that a patient is having a stroke or cervical arterial dissection, refrain from providing care and refer the patient for medical diagnosis and treatment. . Bd. Exh. 32; Tr. 1/5/10, pp. 210, 211; Tr., 1/19/10, p. 47; and, Tr. 1/22/10, pp. 15, 17, 18, 28, and 82, 113, 114, 116, and 117.

Discussion and Conclusions of Law

This Declaratory Ruling addresses whether the risk and/or possibility of the occurrence of a stroke or cervical artery dissection as a side effect should be addressed with a patient when a chiropractor obtains informed consent from a patient prior to the performance of a joint mobilization, manipulation, or adjustment of the cervical spine as the standard of care.

The Board heard the testimony of persons who have suffered a stroke and who allege that joint mobilization, manipulation, or adjustment of the cervical spine was the cause of such stroke, experts, and lawmakers, and carefully reviewed the statistical and analytical data that was admitted into evidence at the hearing. After a careful and thorough review of all of the testimony and documentary evidence admitted at the hearing, the Board concludes that there is sufficient evidence to establish that a stroke or a cervical arterial dissection is not a risk or side effect of a joint mobilization, manipulation or adjustment of the cervical spine. Therefore, the Board finds that in securing informed consent from a patient a chiropractor is not required to address with each patient the risk and/or possibility of the occurrence of a stroke or cervical artery dissection as a side effect of a joint mobilization, manipulation or adjustment of the cervical spine.

As indicated above, informed consent for patients is part of the standard of care for health care professionals in Connecticut and it is also a legal duty which must be met prior to the commencement of treatment. As established by the Connecticut Supreme Court, all healthcare providers in Connecticut are obligated to obtain informed consent from their patients. Logan v. Greenwich Hospital Association, 191 Conn. 282, 292-93, (1983), Duffy v. Flagg, 279 Conn. 682, 687-88 (2006). Informed consent, as it relates to medical or chiropractic procedures, requires the disclosure of the nature of the procedure, the risks, alternatives, and the anticipated benefits. Id. A health care professional is required to provide the patient with information which a reasonable patient would have found material for making a decision whether to pursue a course of therapy. In this matter, the Board focused its review on the element of risk as it relates to informed consent. Specifically, whether stroke or cervical arterial dissection is a material risk or side effect of joint mobilization, manipulation or adjustment of the cervical spine that should be disclosed by chiropractors through informed consent.

The materiality of a risk is determined by weighing the benefits of a procedure, against the frequency and severity of the potential harm. In its review of the materiality of stroke as a risk or side effect of joint mobilization, manipulation or adjustment of the cervical spine, the Board reviewed the outcomes and data presented by the *Cassidy*, *Rothwell* and *Smith* studies, finding that the most compelling evidence was generated by the *Cassidy* study. Bd. Exh. 32. In the *Cassidy* study, entitled *Risk of Vertebrobasilar Stroke and Chiropractic Care: Results of a Population-Based Case-Control and Case-Crossover Study*, by David J. Cassidy, PhD, a source population of 109,020,875 person years from Ontario covered by the Ontario Health Insurance Plan were observed through the collection of hospitalization and practitioner diagnostic coding over nine years. The *Cassidy* study is the largest and most current, peer-reviewed research project conducted on the risk of strokes from joint mobilization, manipulation or adjustment of the cervical spine. The cases and controls were from the same population.

The Board finds Dr. Cassidy to be a particularly well-qualified and credible witness, and the Board relied heavily on his testimony and his study in determining its findings of fact and its conclusions. Bd. Exh. 69. As testified by Dr. Cassidy, the *Cassidy* study utilized the same methodologies as the *Rothwell* study, but involved a much larger population over a significantly longer period of time and expanded the objective to generate data that also compared the risk of stroke associated with primary care as compared to joint mobilization, manipulation, or

adjustment of the cervical spine. Tr. 1/22/10, pp. 97-99. The *Cassidy* study found that vertebrobasilar artery stroke is a “very rare event in the population”, and that there is “no evidence of excess risk of vertebrobasilar artery stroke associated with joint mobilization, manipulation or adjustment of the cervical spine compared to primary care.” Though statistically low, the *Cassidy* study found an “association” between stroke and joint mobilization, manipulation or adjustment of the cervical spine, but did not find an excess risk of stroke when a patient received joint mobilization, manipulation, or adjustment of the cervical spine compared to a patient receiving care from a primary care physician. The *Cassidy* study did not rule out chiropractic adjustments as a cause of strokes, but as Dr. Cassidy credibly testified “this is a study that raises real doubt about the association being a risk...” Tr. 1/22/10, p. 102. The Board, based upon all of the evidence in the record, concludes that a reasonable patient would not have found material a discussion of the “association” between joint mobilization, manipulation, or adjustment of the cervical spine and stroke when making the decision whether to embark upon a contemplated course of joint mobilization, manipulation or adjustment of the cervical spine. The Board finds that a chiropractor in Connecticut does not breach his legal duty or the standard of care if the chiropractor chooses not to discuss the issue of stroke as associated with joint mobilization, manipulation or adjustment of the cervical spine.

In contrast to Dr. Cassidy, Dr. Murray S. Katz, failed to adequately scientifically analyze any of the studies upon which he relied upon in support of his position, nor was he able to articulate any insights into the studies. The methodologies utilized in the studies produced by Dr. Katz were less transparent, and not scientifically based when compared to the *Cassidy* study. Tr. 1/22/10 pp. 221-232. The Board finds that the testimony of Dr. Katz is not credible.

While there is evidence that an “association” exists between stroke or cervical arterial dissection and joint mobilization, manipulation or adjustment of the cervical spine, there is simply not enough evidence to find that joint mobilization, manipulation or adjustment of the cervical spine cause strokes or cervical arterial dissections in patients or that patients are at risk for stroke when a chiropractor performs a joint mobilization, manipulation or adjustment of the cervical spine. Accordingly, the Board finds that based on the Cassidy study and the other documentary evidence and testimonial evidence at the hearing, that a reasonable patient would not find a discussion regarding the risks of stroke “material” when assessing what treatment, if any, to undergo. Statistically, what scant evidence exists of the incidence of stroke following a joint mobilization, manipulation or adjustment of the cervical spine was found primarily in

persons under age 45. As provided in the *Rothwell* study, “[i]t remains to be explained why an association between chiropractic manipulation and [vertebrobasilar accident] was observed only in the young. If an association were to exist, one would expect that it would exist regardless of age.” Bd. Exh. 71.

Without diminishing the compelling and heartfelt testimony of persons who had suffered a stroke and their loved ones, the Board finds that although the evidence is insufficient to establish that a stroke or cervical arterial dissection is a side effect or risk of joint mobilization, manipulation or adjustment of the cervical spine, the evidence *is* sufficient to establish that spinal manipulation on persons who are having an acute stroke or cervical arterial dissection is *not* within the standard of care.

Based on the all foregoing and after a careful review of all of the written evidence and testimony, the Board concludes that the standard of care for Connecticut chiropractors does not require that chiropractors inform patients that a stroke or cervical artery dissection is a risk or side effect of joint mobilization, manipulation, or adjustment of the cervical spine when securing informed consent to such treatment. However, even though stroke or cervical artery dissection has not been established as a risk or side effect of chiropractic adjustments, chiropractors will not be in violation of the standard of care if they chose to discuss these issues with their patients.

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Order

A preponderance of the evidence and the need to protect the public health and safety, all mandate the adoption of each of the following conclusions:

1. The evidence is insufficient to conclude that stroke or cervical artery dissection is a risk or side effect of joint mobilization, manipulation, or adjustment of the cervical spine.
2. Chiropractors are not required to address stroke or cervical arterial dissection as a part of securing informed consent by patients to such treatment.

June 10, 2010



Matthew Scott, D.C., Chairperson,
Connecticut Board of Chiropractic Examiners