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Kenneth Koehler, DC Prins Bernhardstratt 54 Noordwijk 2202 LJ Netherlands

Dear Dr. Koehler:

In recent days the International Chiropractors Association (ICA) has, in addition to your communication, been contacted by a record number of its more than one-hundred members in The Netherlands who have expressed concern over the potential for arbitrary limitations or restrictions on proven, evidence-based and safe chiropractic procedures. As a professional society dedicated to professional and clinical excellence for its members and the chiropractic profession worldwide and to fully exploring both the potential and the limitations of chiropractic science, ICA is deeply concerned about any poorly informed or ill-considered action that would, ultimately, result in denying patients of all ages necessary, clinically effective and safe care.

Throughout its nearly one-hundred years of continuous operation, the ICA has sought to obtain objective, science-based consideration of all public policy questions related to chiropractic art, science, philosophy and practice. It is ICA's hope that it is, indeed, objectivity and a factual, responsible consideration of all aspects of any such question that will determine the final outcome of any public policy decision in any jurisdiction.

On the issue of upper cervical adjusting, including its appropriateness, safety and clinical effectiveness, we can only point to the vast and growing clinical and research record that documents its safety and effectiveness. A detailed and referenced selection of some of the key research resources have been provided as exhibits to this letter. I would specifically like to point to an additional landmark study titled, "Upper Cervical Vertebral Subluxation in Multiple Sclerosis Subjects with Chronic Cerebrospinal Venous Insufficiency: A Pilot Study," by Sandro Mandolesi, MD, Giuseppe Marceca, MD, Stephen Conicello, DC, and Eriece Harris, DC, published just several days ago. (Journal of Upper Cervical Chiropractic Research, September 23, 2013.) This paper highlights the serious nature of the research behind upper cervical procedures and the wide range of often very serious conditions for which such care is indicated.

It is also important to note that every state in the United States, every province of Canada and dozens of nations around the world recognize upper cervical procedures as vital elements of chiropractic practice and place no limitations or restrictions thereon.

ICA strongly supports full-spine care, including upper cervical procedures as clinically indicated. ICA has come to this position on the basis of an extensive review of both the clinical research record, the outcomes and safety data over the past several decades and the teaching experience offered at chiropractic colleges and in the post-graduate process through ICA's Council on Upper Cervical Care. It is also fair and responsible to look at such procedures in comparison to the effectiveness and safety record of other professions.

The chiropractic profession maintains a vigilant watch on safety and clinical effectiveness issues and conducts an on-going evaluation of all healthcare literature related to issues of safety and relative risk. The findings of those efforts are widely disseminated throughout the chiropractic profession and are well understood by chiropractic practitioners. It is certainly within the interests of the chiropractic profession to honestly and immediately address any valid risk factor. We believe this responsibility is incumbent on all health care professionals. In the analysis process, ICA has reviewed all clinical research on this issue and feels that the summary attached as Exhibit 1 serves as the best evidence for the position outlined herein.

One of the most significant measures of the incidence of injury in any health profession is the malpractice record. In this litigious society, consumers, supported by an increasingly aggressive legal profession, do not hesitate to seek compensation even in the case of the slightest perceived injury. The ICA has maintained its own chiropractic malpractice program, and the actuarial record, covering tens of millions of patient visits over many decades, profoundly refutes the assertion that stroke risk is frequent or common. Indeed, that actuarial record is a resounding testament to the safety of the chiropractic adjustment, even in terms of possible stroke risk. This safety record is reflected in chiropractic malpractice premiums in the United States, which average approximately \$2,000 for \$1 to \$5 million in coverage. This is a striking difference from the premiums paid by medical doctors, which can reach the \$500,000 mark or more in some specialties.

Likewise, the state regulatory bodies created by the various US state legislatures to protect the public maintain records on charges of injury by consumers. In the US State of Connecticut, for example, news report recently stated: "According to the Connecticut Board of Chiropractic Examiners, which disciplines chiropractors, the state public health department received 57 complaints about chiropractors between Jan. 1, 2002 and Dec. 31, 2006. That's 1 percent of the 4,941 complaints the department received for all licensed Medical professionals. Of the 57 complaints, the board issued 15 disciplinary orders." This record is comparable to that in other states.

ICA fully recognizes that any health care delivery system is not without risk and that all consumers must explore to their personal satisfaction and understanding the risks and dangers associated with any and all health care surgical procedures, treatments, chemical interventions, etc., both diagnostic and therapeutic. The safety record of the

chiropractic profession is demonstrably exceptional and stands as one of the primary outcome elements that distinguishes chiropractic procedures from the medical model.

All health care professionals must make consumer and patient safety a paramount concern. When the level of risk is quantifiable and significant, providers have a responsibility to offer that data to patents and potential patients. What constitutes a significant level of risk is open to a diverse range of opinions and interpretations; however, to pinpoint risk requires that exact data on causality needs to be present. That causality factor is simply not present and even the coincidental occurrence of injury from upper cervical procedures applied by chiropractors is exceptionally rare, perhaps no more than one per 3 million neck adjustments.

In many health care situations, a casual, coincidental relationship between a procedure and an adverse event can and is easily mistaken for causality. We believe that the research record indicates that there are, indeed, cases where an individual suffers from an adverse event in conjunction with, but not caused by a chiropractic intervention and even these cases are rare. This being the case, how should a concerned and ethical professional proceed? Is it appropriate and reasonable to require a professional to provide a warning on an event for which the causality link is not present? How is a consumer supposed to interpret a warning based on a parade of imaginary horribles, rather than on a sound, actuarial statement of anticipated risk? Finally, what is the intent of those who, even in the face of the compelling research record and the lack of evidence other than a rare coincidental intersection between an upper cervical chiropractic procedure and some level of injury, are seeking to restrict such procedures? ICA has no data on which to base any response to this specific question but it does need to be asked.

Medical researchers frequently misunderstand the critical differences between specific chiropractic adjustments and cervical manipulation. Doctors of chiropractic are highly trained in the use of the adjustment, which is the specific and scientific application of directional force to facilitate the reduction of nerve interference. Manipulation is the forceful passive movement of a joint beyond its active limit of motion. Since manipulation doesn't imply the use of precision, specificity or the correction of nerve interference, it is not synonymous with chiropractic adjustment.

Many of the cases cited by medical researchers as being "chiropractic treatments" were actually spinal manipulations rendered by non-chiropractic practitioners. According to a research report by Terret, A. (Vertebral stroke following manipulation) and referenced in the *Journal of Manipulative and Psychological Therapeutics*, "manipulations" administered by King Fu practitioners, GPs, osteopaths, physiotherapists, a wife, a blind masseur and an Indian barber had been incorrectly attributed to chiropractors. (7)

A multitude of systematic distortions and biases may affect the results and conclusions drawn from case-control studies. Other criteria must be used to determine whether an association is actually *causative* because an association, no matter how strong, does not prove causation. At this point in time due to the rarity with which VBA's occur, experimental evidence in humans and prospective cohort studies examining the hypothesis that chiropractic adjustments cause stroke - *do not exist*.

ICA understands the emotion, the complexity and the confusion that surrounds these issues at times but believes that the research and actuarial record on this matter demonstrate the exemplary safety record of the chiropractic profession, and that chiropractic adjustments administered by licensed doctors of chiropractic pose no demonstrable, significant risk of strokes and therefore should not be restricted or banned.

ICA will be happy to answer any questions or provide any additional documentation or supporting research should you so request.

Please know we deeply respect and appreciate your concern over these matters and share your commitment to a responsible dialogue and objective outcome of any public policy question that may impact so many current and future chiropractic patients.

Sincerely Yours,

Michael S. McLean, DC, FICA

President

MSM/nip

CC: ICA Board of Directors

Affiliated College Presidents Members in The Netherlands