

Statement of Frank Zolli DC, Ed.D.
On behalf of the
Connecticut Chiropractic Association
Before the Committee on Public Health

SB 90

February 6, 2009

**Senator Harris, Representative Ritter, Distinguished
Committee Members.**

I am Frank Zolli, a Connecticut licensed chiropractic physician and Dean at the University of Bridgeport College of Chiropractic (UBCC).

I am testifying on behalf of the Connecticut Chiropractic Association in opposition to SB90.

The UB College of Chiropractic, and every other chiropractic programs in the United States, is accredited by the Commission on Accreditation of the Council on Chiropractic Education, the federally recognized accrediting agency for the chiropractic profession. In addition, each of these accredited programs is a member of the Association of Chiropractic Colleges (ACC).

Several years ago, the ACC charged a task with the responsibility of defining informed consent guidelines which could be implemented into the curriculum at all member chiropractic programs. Those guidelines were developed, endorsed by the membership and implemented into chiropractic education (a copy of the most recent edition is included for your review).

During their time in school, students receive rigorous training in the basic and clinical sciences, culminating with their clinical experience.

At UBCC, students are taught extensively about the structure and function of the human body. In addition, they are taught about its assessment, diagnosis and treatment. This is done in a variety of courses which provide knowledge and theory, after which they interact with patients to hone their clinical skills.

A critical element in this training is students learning evidence based research. This process allows students to learn the most current information available regarding any subject in the field of health care. Evidence based research is taught by trained, experienced evidence based librarians, and students have access to an extensive array of on line publications, which are utilized throughout their training.

Their clinical training occurs at our campus health center, as well as satellite facilities around the city of Bridgeport, as well as the Veteran's Administration Hospital in West Haven. In all of these facilities, the doctrine of informed consent is practiced.

As defined in the ACC guidelines, patients have the right to know the benefits, risks and options of recommended procedures. This is taught and discussed with students starting in their first semester in the program.

In clinic, interns supervised by licensed chiropractic physicians explain the parameters of informed consent to patients. Once explained to the patient's satisfaction, a document is signed, attesting to his/her consent. The signed document is maintained in the patient's file.

As practiced at UBCC, health care is not something done to a patient. It is a process achieved with a patient. As such, it is critical that a patient know and understand the benefits, risks and options to recommended procedures. It is critical that a chiropractic physician act competently and always in the best interest of his/her patient.

All health care providers who accept the responsibility of helping patients understand the rewards and risks of their actions. Patients, the benefactors of this process, should be aware of the benefits and risks, and understand there are no guarantees of success. Informed consent should be employed for all patients, not only those served by members of the chiropractic profession.

Association of Chiropractic Colleges

INFORMED CONSENT GUIDELINE

The Association of Chiropractic Colleges (ACC) hereby adopts the following guideline for the Doctor of Chiropractic ("Doctor") programs at member institutions. This guideline is not intended to have the force of law, statutory or regulatory. Each program is encouraged to conduct its practice in accordance with the following guideline(s). The recommended protocols will result in greater safety and understanding for patients and program participants. It will assist in minimizing concerns, confusion or misunderstandings regarding the information the patient received before care was delivered.

I. GENERAL PURPOSE

The purpose of this guideline is to address the doctrine of informed consent within the clinical setting and those measures which should be undertaken to comply with that doctrine for the protection of the patient, the doctor, and member institution(s). Recognizing that all care including diagnostic studies and chiropractic care have some potential for causing injury to a patient, it is the recommendation of the Association of Chiropractic Colleges that, prior to performing diagnostic testing and prior to implementing chiropractic procedures, the patient should be informed about the material and inherent risks and common options to the recommended care and the associated risks, including the risk of refusing care. If the patient wishes to continue he/she should give his/her consent. The Doctor should have a record in his/her clinical file documentation which confirms that consent was given by the patient to the diagnostic testing and/or the chiropractic procedure.

The Informed Consent Doctrine stems from the concept that patients have the right to control their body and what happens to it. Therefore, to be in control, they have the right to be informed about the proposed care and the risks associated with it. The Association of Chiropractic Colleges believes when patients, receive appropriate information (informed consent) before undergoing chiropractic care, it will assist in eliminating misunderstandings.

Performance of a particular chiropractic procedure without providing necessary information deprives the patients of an understanding of what they may reasonably expect from such care and does not allow them to understand the inherent risks that they may be taking. It also impairs their fundamental right to make decisions concerning the types of care, if any, they wish to undertake. Consequently, the Association of Chiropractic Colleges has chosen to adopt the guidelines set forth below.

II. WHEN SHOULD CONSENT BE OBTAINED?

THE DOCTOR SHOULD OBTAIN INFORMED CONSENT FROM PATIENTS BEFORE CARRYING OUT ANY DIAGNOSTIC OR THERAPEUTIC PROCEDURE ON PATIENTS.

As noted above, the failure to obtain the informed consent of a patient before performing a particular diagnostic or clinical procedure impairs the right of that patient to decide for him/herself what, if any, care he/she wishes to undergo. As new complaints arise requiring additional evaluation procedures or different care procedures additional informed consent should be acquired from the patient.

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The Doctor providing a particular diagnostic or clinical procedure (not a delegated representative) should disclose and discuss with the patient the elements of informed consent in layman's terms. In turn, the patient should have an opportunity to ask questions to elicit a better understanding of the particular diagnostic or clinical procedure, so he/she can make an informed decision to accept or to refuse a particular course of health intervention.

III. WHO CAN GIVE INFORMED CONSENT?

- (a) THE ADULT PATIENT – When the patient is an adult, the Doctor should obtain consent for testing and care directly from the patient. It is reasonable to assume that an adult patient is capable of giving consent for diagnosis and care, unless there are indications or other known factors that the patient is not mentally competent to understand what is proposed and the potential benefits and risks involved. If the Doctor reasonably believes that an adult patient does not adequately understand what is proposed and the related potential benefits and risks, the Doctor should decline to provide care and should inquire as to whether the patient has a legal guardian or healthcare proxy with the legal authority to make the necessary decisions. This concept extends to a language barrier, handicap or disability which may impede the communication and understanding of the patient.
- (b) THE MINOR PATIENT – When the patient is a minor, the Doctor should obtain the necessary informed consent from the parent or legal guardian of the patient, as a general rule the consent of only one parent is necessary to permit care. There may be certain limited circumstances under which a minor child is considered emancipated and thus can legally and effectively consent for himself or herself. When in doubt, seek legal advice from the member institutions general counsel to confirm that emancipation is in place and thus consent of an adult is not required. Care must be exercised in child custody disputes as to which parent has legal guardianship when making a consent decision on treatment of the minor.

IV. WHAT INFORMATION SHOULD BE DISCLOSED TO THE PATIENT?

The Doctor should disclose to the patient all significant clinical information that the Doctor possesses, which would be material to the decision by that patient whether or not to undergo the proposed procedure. For the consent to be legally effective, the patient must receive sufficient information concerning: the proposed procedure; the potential benefits and risks of the procedure; common alternatives to that procedure, including refusing care and the associated risks. Without this disclosure, an informed decision cannot be made.

In determining what information the Doctor is expected to possess concerning the potential benefits and risks of a particular procedure, the benchmark is the quantum of information possessed by the average Doctor of Chiropractic. Generally viewed as a specialty practice group, Doctors of Chiropractic are usually measured against a statewide (if not national) standard as opposed to a local standard. In other words, the risks associated with not taking an x-ray should not vary depending on where the x-ray is taken and the risks associated with cervical manipulation should not vary depending upon whether the manipulation is performed in a rural or urban area.

In determining what information should be given, the Doctor should share that information which the Doctor knows, or has reason to know, the patient would consider important in making his or her decision about whether to undergo the proposed procedure. In addition, if the "reasonable Doctor" would consider the information important to the patient, that too suggests that disclosure of the risks should be made.

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Because some jurisdictions apply the "reasonable Doctor" standard, whereas others use the "reasonable patient" standard, the safest approach for the Doctor is to disclose material risks which are inherent to the procedure if either a reasonable Doctor would disclose those risks as being material or a reasonable patient would think those risks are material and thus should have been part of his or her decision-making before accepting care.

In determining what information the Doctor should convey to a patient concerning risks involved in a particular procedure or care, the Doctor must take into consideration both: (1) the potential severity of the injury or adverse consequences which may result; and (2) the likelihood that the injury or consequence will occur. No Doctor is required to disclose every single conceivable risk of a proposed procedure, regardless of how remote that risk of injury might be. However, if a certain risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example paralysis or even death, it should be regarded as a material risk requiring disclosure. When in doubt, the Doctor is urged to err on the side of disclosure, rather than non-disclosure, because by erring on the side of disclosure, the Doctor eliminates the frequently surfacing legal/factual question of whether the risk was material.

Do not assume that, because your fellow practitioners do not disclose risks, you will be insulated so long as you are in step with your fellow practitioners. The informed consent doctrine and liability flowing there from stems primarily from a determination of what risks are material and inherent to the procedure and not whether a particular profession, as a profession, chooses not to disclose those risks.

The Doctor is not required to disclose information if the Doctor has good reason to believe that the patient already has the information. Should this be the case, the fact should be noted in the clinical records.

It is important to explain to a patient that the "no care" option is a viable option. The Doctor can strongly recommend that the "no care" option is, in the opinion of the Doctor, dangerous. Nevertheless, in most jurisdictions, a patient can refuse care even when deemed advisable by the prevailing health care community or subspecialty community. If the "no care" option is pursued by the patient, the clinical record should clearly and unequivocally reflect the recommendation of the Doctor and the rejection of that recommendation by the patient.

V. DOCUMENTATION OF PATIENT CONSENT

Many practitioners believe that "informed consent" is more of a process than a documented procedure. The Association of Chiropractic Colleges recommends that the Doctor engage in a thorough, verbal discussion with the patient, thus enabling the Doctor to be in a position to verify that he/she took the time to explain the material risks inherent in the recommended procedures and that the patient consented. Beyond this, the Association of Chiropractic Colleges recommends that the patient execute some document acknowledging that: (a) he/she has been part of an informed consent process; (b) that the material risks have been disclosed to the patient, including a description of those material risks; and (c) that the patient, after assessment, has agreed ("consented") to the procedures understanding any material risks which are inherent to that procedure.

Whereas it is beneficial for the Doctor to have notations in the clinical records reflecting that the patient was advised of the material risks and consented to the treatment, there is no substitute for the patient's written confirmation of those facts. It is the Association of Chiropractic Colleges belief that the profession

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and the public interest are better served by an occasional patient refusing to execute an informed consent acknowledgment form as opposed to having licensed Doctors exposed to claims of informed consent violations when, in fact, informed consent was secured but not irrefutably documented and verified. It is the recommendation of the Association of Chiropractic College's to document the patient's consent to both the diagnostic procedures which the practitioner proposes to use, as well as to document the patient's consent to the "patient care plan" which lists the patient's diagnosis and identifies the particular procedures and/or modalities to be used.

IV. RECOMMENDATIONS

The Association of Chiropractic Colleges (ACC) recommends that:

- (1) A consistent, ongoing training program for all current faculty and faculty clinicians, and a process by which all new faculty are trained in the interim, addressing the elements and process of communication of informed consent be implemented at all member institutions
- (2) A program be incorporated at all member institutions to ensure students learn the concept(s) regarding informed consent by incorporating in the classroom and clinics a process allowing for compliance and educational instruction at every level of the educational encounter.
- (3) A report of findings to the patient that includes all elements of Informed Consent consistent with best practices should be in place at all member institutions.
- (4) The "Informed Consent Guideline" be reviewed and updated as appropriate.
- (5) The ACC required elements of informed consent document be reviewed and updated as appropriate.

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The following represent a reasonably complete set of working documents referenced in the creation of the Informed Consent Policy Guideline though it should be noted that in addition to the list and my fellow task force members, the committee consulted a separate task force at PCC (Dr's Bernard, Hubbard, Kime, Stites and Swank), and several other individuals and groups thought to be knowledgeable in the area:

- American Journal of Law and Medicine, 2006, Rethinking Informed Consent
- Medical Malpractice, Informed Consent and Patients
- AMA, Informed Consent
- Encyclopedia of Everyday Law, Informed Consent
- Ethics in Medicine, Informed Consent
- EMedicine Health, Informed Consent
- American Cancer Society, Informed Consent
- The Law Offices of Carl D. Barnes, California, Informed Consent in Cases of Medical Malpractice
- The Medical Malpractice Information Center, Kerrigan, Estess, Rankin, McLeod & Thompson attorneys at law, Florida, Understanding Informed Consent
- Bioethics, Informed Consent, Maxwell J. Mehlman, J.D.



**UNIVERSITY OF BRIDGEPORT COLLEGE OF CHIROPRACTIC
HEALTH SCIENCES CENTER
CONSENT FORM**

INFORMED CONSENT FOR CHIROPRACTIC TREATMENT

I have been informed of the nature of my disorder(s) and of the nature and purpose of chiropractic procedures and related therapeutics proposed as treatment. I have also been informed of the possible consequences and risks inherent in such treatment. The availability of alternative treatment options has been explained to me. I have been also advised of the possible consequences if I decide not to receive care. I understand that there is no guarantee or warranty for any specific result.

I HAVE READ THE ABOVE PARAGRAPHS AND I UNDERSTAND THE INFORMATION PROVIDED. THIS INFORMATION HAS BEEN EXPLAINED TO ME, AND ALL QUESTIONS WHICH I HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION.

I THEREFORE AUTHORIZE THE UNIVERSITY OF BRIDGEPORT COLLEGE OF CHIROPRACTIC HEALTH SCIENCES CENTER TO PROCEED WITH CHIROPRACTIC CARE AND TREATMENT.

PATIENT'S NAME (PLEASE PRINT) _____

PATIENT'S SIGNATURE _____ DATE _____

WHEN THE PATIENT IS A MINOR OR UNABLE TO CONSENT

The patient is a minor of _____ years of age. Other reason: _____

PATIENT'S NAME _____
(PLEASE PRINT)

NAME OF PERSON LEGALLY AUTHORIZED TO SIGN FOR THE PATIENT:

AUTHORIZED PERSON _____ RELATIONSHIP _____
(PLEASE PRINT)

SIGNATURE OF PERSON LEGALLY AUTHORIZED TO SIGN FOR THE PATIENT:

AUTHORIZED SIGNATURE _____ DATE _____

CONSENT TO EDUCATIONAL OBSERVATION

I realize that the University of Bridgeport College of Chiropractic Health Sciences Center is a teaching facility. As such, I hereby give my consent to allow students and/or faculty to observe my visits and/or treatments at the University of Bridgeport College of Chiropractic Health Sciences Center for educational purposes. I realize that I can terminate this privilege at any time by so informing my supervising clinician.

PATIENT'S (OR AUTHORIZED) SIGNATURE _____ DATE _____

I decline to be observed:
PATIENT'S (OR AUTHORIZED) SIGNATURE _____ DATE _____