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FTC Questions Chiropractor's Claims

Is Koren Publications Just the Beginning?

By Editorial Staff

On January 10, 1995, Tedd Koren, DC, president of Koren Publications, Inc., received a seven-page letter from Sidney Steinitz, senior attorney with the Federal Trade Commission (FTC), to "substantiate" numerous "claims" made in Koren Publications' chiropractic brochures. The claims the FTC were concerned about included 21 statements or "representations" which included:

"Chiropractic treatment was more effective for the wide range of symptoms common in the neurological dysfunction syndrome in which 13 symptom problem area were considered;

"Chiropractic care is significantly more effective than commonly used medications such as Ritalin in treating children;

"Chiropractic care can increase the intelligence (as measured by IQ tests) and scholastic performance of students;

"One study of 63 unvaccinated children between the ages of 8 and 15 who had been under chiropractic care showed that they had 'increased resistance to the common childhood diseases,' - specifically measles, mumps, German measles and chicken pox;

"A...1989 study, which compared the child patients of 200 pediatricians with 200 children who had been under chiropractic care, showed that the health of the children who had seen chiropractors was notably superior to that of children brought up under standard medical care;

"Many studies have shown that the majority of newborns have spinal nerve stress that is threatening their health and in some cases their lives;

"onestudy of 185 men and 87 women showed that spinal 'manipulation' improves respiratory function and in another study of patients with chronic pulmonary disease, a classification that includes bronchitis and emphysema, over 90% reported improvement of symptoms after spinal care;

"In one study of 496 patients who received spinal care, more than 95% experienced relief of general gynecological problems;

"...chiropractic patients were found to have an immune competence 200% greater than people who had not received chiropractic, and 400% greater than those with cancer and other serious diseases."

The letter from the FTC not only requested all documentation substantiating the claims made in the brochures, but "all documentation tending to contradict or disprove" those claims.

While Dr. Koren sent the FTC many packages of information with nearly 400 references, it wasn't long before he realized that it was time to retain attorneys to handle negotiations with the FTC.

In 1997, after much back and forth dealings with the FTC, Dr. Koren was sent an agreement that was negotiated between his attorneys and senior FTC attorney Steinitz. The agreement required that some of his brochures be rewritten to reflect less aggressive positions on the benefits of chiropractic care, particularly where the research was limited.

After Dr. Koren reluctantly signed the agreement, it went to the FTC commissioners for ratification. When he didn't hear anything for months, Dr. Koren became nervous. Finally, the agreement came back. It had been rejected by the commissioners.

Meanwhile, Mr. Steinitz retired from the FTC and was replaced by Mr. Richard Cleland. A new complaint and order was developed and faxed to Dr. Koren's attorneys on April 26, 1998.

The complaint focussed on four Koren brochures:

Cold, Flu and Respiratory Disease

Children and Chiropractic

Healthier Children and Chiropractic

Immunization and Chiropractic

The claims in the brochures that concerned the FTC were:

1. "Chiropractic's role in natural immunity was dramatically demonstrated in 1989 by Ronald Pero, PhD, chief of cancer prevention research at New York's Preventive Medicine Institute, and professor of medicine at New York University. In his initial three-year study of 107 individuals who had been under chiropractic care for five years or more, the chiropractic patients were found to have an immune competence 200% greater than people who had not received chiropractic, and 400% greater than those with cancer and other serious diseases!

2. "A fascinating 1989 study, which compared the child patients of 200 pediatricians with 200 children who had been under chiropractic care, showed that the health of the children who had seen chiropractors was notably superior to that of children brought up under standard medical care.

3. "Two pilot studies conducted in Texas in 1974 and 1975 confirmed what chiropractors have known for years, that spinal adjustments can help children with emotional, behavioral, and neurological problems. The kind of problems helped were asthma, anxiety, low mental stamina, inability to concentrate, hyperactivity, discipline problems, and even low grades and low I.Q.

4. "One study of 63 unvaccinated children between the ages of 8 and 15 who had been under chiropractic care showed that they had "increased resistance to the common childhood diseases," specifically measles mumps, German measles and chicken pox.

5. "According to the PDR (Physicians' Desk Reference): 'Injections of foreign substances -- viruses, toxins, and foreign proteins -- into the bloodstream, i.e., vaccinations, have been associated with diseases and disorders of the blood, brain, nervous system, and skin. Rare diseases such as atypical measles and monkey fever as well as such well-known disorders as premature aging and allergies have been associated with vaccinations. Also linked to immunizations are such well-known diseases as

cancer, leukemia, paralysis, multiple sclerosis, arthritis, and SIDS (Sudden Infant Death Syndrome)."

The FTC apparently focussed on these five claims because they had relatively poor research support. In reviewing the claims, Dr. Koren admitted that the quote from the Physicians' Desk Reference (item 5) had been taken from a secondary source and that he was willing to remove it. The immunity study by Dr. Pero (item 1) was apparently never published by any research journal, but taken from "an edited videotape transcript of an interview with Ronald Pero, PhD." Likewise, the two Texas pilot studies (item 3) were apparently not published in any peer reviewed research journals, but were summarized in 1973 and 1975 issues of the ICA Review.

Interestingly enough, the remaining claims (items 2 and 4) are supported by papers in the spring and summer 1989 issues of the Journal of Chiropractic Research. The study of unvaccinated children (item 4) was a pilot study which used questionnaires to collect the information from DCs in the greater Davenport, Iowa area. In the paper, the authors clearly cited numerous limitations to their pilot study and recommended that "future research on a large scale is needed." The paper supporting the chiropractic vs. medical child patients claim (item 2) was written by two chiropractic students.

Looking at it from the research point of view, John Triano, MS, DC, PhD, commented:

"The fact that a federal agency is investigating and raising concerns about claims of treatment effect is concerning and unfortunate ... but not novel. Similar actions have occurred in Houston, Texas in the case of a medical physician who was working with cancer patients using urine extracts. It has happened in chiropractic in the past two decades with action taken to stop the use of the radiometer device. In neither case did the investigation herald sweeping assault on alternative medicine practices or chiropractic. With this in mind, it may be wise to consider the current circumstances with Dr. Koren before mounting a chiropractic jihad. The case of Dr. Koren's personal entrepreneurial and proprietary activities may or may not warrant defense and mobilization of the profession.

That decision ought to be based on an analysis of the facts and how they are likely to be interpreted by the public we serve, the scientific experts that will independently evaluate the data quoted and our chiropractic brethren. In Dr. Koren's literature, the segments that remain controversial are unfortunate. While the conclusions espoused, perhaps, are attractive and popular to the DC, the experts can and will refute them with ease. In so doing, and directly related to the amount of publicity that may be generated, members of the general public are likely to receive another negative image of the profession based on accusations of using

unsubstantiated claims.

For example, the work of Pero was reviewed in detail with publication to the chiropractic profession through DC in the December 1, 1989 issue by scientists and clinicians experienced both with scientific research methodology and specific experience in immunological research. That review demonstrated that the conclusions reported on Dr. Pero's work were inappropriate and the actual data does not support them. Other adequate health and lifestyle factors were present to explain the results in this subgroup of Pero's overall study. Most telling is the fact that the purported results of enhancement in immunological status through chiropractic has never been published by Dr. Pero in either the chiropractic or medical peer reviewed and indexed literature. Certainly, any of us who have research experience would be aggressively pursuing publication of our work that could effectively make such a documentation.

In the case of the Texas pilot studies, Dr. Koren's quote given above is internally inconsistent. By the very nature of pilot studies, they cannot confirm anything! The term "pilot" is defined by the American Heritage dictionary as "constituting a tentative model for future experiment or development: a. experimental, b. tentative, c. trial." A pilot study is a preliminary (often "down and dirty") look at whether there is reason to study the question further. In the early 1990s, our group at National College performed a pilot study on the treatment of dysmenorrhea for which the results suggested a potential benefit. This led to funding of a full randomized, controlled clinical trial from which we are awaiting the results from the investigators.

The remainder of the controversial claims are similarly afflicted by absence of scientific merit and form a poor foundation for defense. The use of this type of evidence, in today's milieu of recognized methodology for guidelines and protocols of care, is at best naive and worst foolhardy and irresponsible. Perhaps the Koren case is not a clarion call to arms, but a lesson in social responsibility. Perhaps those who are calling for donations to Dr. Koren's legal defense would be better served to invest in donations to chiropractic research so that we may produce effective evidence for what we do.

Dr. Koren is left with two choices: agree to the order or fight his way through various levels of bureaucratic review. And while Dr. Koren has already spent a great deal of money just getting this far, he is reluctant to sign the order.

The order contains a number of stipulations that would prohibit Koren Publications from citing the specified studies. The brochures would also be restricted from making any of the following claims without research studies to substantiate the claim that chiropractic:

1. improves human immune system competence;
2. reduces the incidence in children of ear infection, allergies or tonsillitis;
3. administered to children is effective in the treatment or amelioration of asthma, anxiety, low-mental stamina, inability to concentrate, hyperactivity, discipline problems, low grades, or low IQ;
4. in comparable or superior in effectiveness to vaccinations as a means of preventing common childhood diseases, including measles, mumps, German measles, and chicken pox;
5. administered to children, increases their resistance to common childhood diseases, including measles, mumps, German measles, and chicken pox.

Of greatest concern is a provision that would prohibit Koren from making "any representation ... about the health benefits, performance, or efficacy of chiropractic, or any substantially similar treatment, unless the representation is true, and at the time the representation is made, respondents (Koren) possess and rely upon competent and reliable scientific evidence that substantiates the representation."

In a plea for support, Dr. Koren remarked:

"By attacking what I say in my brochures, the FTC is setting a strict legal standard for all the claims that can be made for all forms of alternative health care in the US, especially chiropractic. Unless supported by research according to their (medical) standards you can only tell patients, by word, advertising or writing that chiropractic may help lower back pain. You can not address neck pain, headaches, whiplash, asthma, fevers, ear infections, sciatica, menstrual problems...nothing, except low back pain.

"All other suppliers of patient education materials, including schools, chiropractic organizations and individual DCs could be constrained by the FTC. This will essentially place a gag order on you, me and

the entire chiropractic and alternative health care practitioners. You will be permitted to practice, but you will not be permitted to tell the chiropractic story.

"The FTC requires 'competent and reliable scientific evidence' to support claims made on advertising or promotional materials. What does that REALLY mean? It means that chiropractic will be judged through the eyes of, and under the standards of, allopathic medicine. It means that even truthful, carefully qualified information about chiropractic (indeed, all alternative health care) will be squelched. It will limit people's ability to choose options in health care. It means we cannot educate the public about legitimate forms of alternative care.

"You cannot tell the public of chiropractic's successes. You cannot tell the public of our one hundred plus years of case studies, outcomes, histories and research. None of it is good enough for the "chiropractic experts" of the FTC or the FTC itself. To them chiropractic is public enemy number one.

"I am not making this up. These people are very serious. The FTC could do what the AMA could not. You are not safe. They could have gone after anyone; I was just first on their list. The noose is around all our necks. We will all hang separately, unless we all hang together. I can no longer fight Goliath alone. I need your help. We need to win; defeat will ultimately destroy our profession. Please, please help us now.

"All contributions will be accounted for and handled in a proper legal manner. We need \$500,000 immediately. Our attorneys are \$400 hour, please help pay as many hours as you can. I'd like Doctors of Chiropractic and anyone interested parties to 'purchase' as many hours of attorney's fees as possible. I appeal to you to purchase at least three hours, more, much more if possible. If you think money is tight now, wait until the FTC regulations are in force. Your ability to attract new patients may be severely curtailed. And if they investigate you, you may never recover. An alternative way to give is to donate \$40 per week (or month if per week is too steep) via credit card. They can send their credit card info to the National Institute for Science, Law and Public Policy, 1424 16th St., NW Suite 105, Washington, DC 20036 or call them at 800-510-0151 and tell them you'd like the funds to continue the FTC Chiropractic Fight."

Among the first to be concerned about the FTC's action were the American Chiropractic Association (ACA) and the International Chiropractors Association (ICA). Each organization is reviewing the potential threat to the profession.

The ICA issued this response: "The International Chiropractors Association is aggressively investigating

recent activities of the U.S. Federal Trade Commission regarding that government agency's efforts to regulate statements made on behalf of chiropractic in patient education and practice promotion material. Specifically, the FTC has taken enforcement steps against a major chiropractic publisher arguing that unsubstantiated claims about the appropriateness of chiropractic for certain conditions have been made and that the making of such claims constitutes misleading and false advertising.

"ICA's legal team has begun a detailed examination of the issues surrounding the FTC action to determine the exact implications for the chiropractic profession at large. ICA is keenly aware of the potential danger of government policies that might unfairly restrict the free exchange of vital health information between patient and doctor and is determined to fight any such policy with all of the political, legal and public relations resources it commands.

"The FTC has stated that claims regarding the effectiveness of health procedures must be validated by "research" before they can be used in "advertising." ICA is deeply concerned that the FTC has singled out chiropractic for unfair and discriminatory treatment in this area. The ICA's Washington staff will be seeking answers from the FTC regarding the treatment of medical advertising and information to make certain that one and only one standard is in place, and that standard is not by design unfair to chiropractors and chiropractic patients.

"ICA is concerned that the chiropractic profession be aware of the recent FTC activities and urges all chiropractic organizations to examine this matter. ICA also stands ready to combine forces with any and all chiropractic organizations in a profession-wide campaign to fight the Federal Trade Commission's efforts should it be determined that such an effort is called for."

The ACA issued this statement:

"The American Chiropractic Association (ACA) is aware of and is closely monitoring the Federal Trade Commission (FTC) action against Dr. Tedd Koren and his company Koren Publications, Inc. The issue at point is whether advertising materials produced and sold by Dr. Koren and his publishing company constitute false and misleading advertising in violation of the Federal Trade Commission Act.

"The ACA views with concern any federal investigation of a doctor of chiropractic. Nevertheless, because of the specific focus of the FTC action and the specific remedies sought, it is the ACA's opinion that at the present time this action does not pose a general threat to the chiropractic profession as a whole.

"However, the ACA will seek to intervene in this or any other matter if it determines that such a threat exists.

After all is said, this incident leaves three questions looming in the minds of most chiropractors:

- Is chiropractic being singled out by the FTC among health care professions?

- Does this current action by the FTC affect all DCs (as Koren contends) or just Koren Publications (as the ACA contends)?

- Would the FTC ever investigate practicing chiropractors who are telling the chiropractic story as they understand it through their many years of chiropractic practice?



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