

TESTIMONY OF

Ed Marandola
Imaging Sciences, Inc.

**BEFORE THE
PUBLIC HEALTH COMMITTEE**
Friday, March 12, 2010

House Bill 5447 “An Act Concerning the Certificate of Need Process”

Senator Jonathan Harris, Representative Betsy Ritter and distinguished members of the Public Health Committee, my name is Ed Marandola of Imaging Sciences, Inc. (ISI). Thank you for the opportunity to testify today in support of House Bill 5447 “An Act Concerning the Certificate of Need Process.”

Introduction

By way of background, I am one of the founders and past-President of ISI. ISI developed a device named the i-CAT, which is the leading dental Cone Beam imaging device in the world. In 2005, Cone Beam imaging in dentistry was a 10 million dollar business and today it is a 500 million dollar global business. In 2005 there were only 4 manufacturers of Cone Beam imaging and today there are 30 manufacturers. ISI’s distribution in 2005 of the i-CAT was limited to North America and today we are providing this equipment to dentists in over 30 countries across the globe.

I am here specifically to discuss Section 5(b)(17), of HB 5447, regarding the proposed exemption for the acquisition of cone-beam dental imaging equipment by a dentist licensed pursuant to chapter 379.

Today, the State of Connecticut is the only state, in the Union, where dental Cone Beam CT (CBCT) is not being sold and, in part or in whole, this is due to the regulatory hurdles currently in place. In the absence of dental CBCT, dentists are forced to use panoramic and intraoral devices to make diagnosis. These lesser imaging modalities reduce the quality of care for Connecticut patients.

The purpose of providing comment today is not to debate Connecticut’s CON laws, at large, rather it is to consider a very specific section of CON regulation related to the practice of dentistry. When the Connecticut General Assembly considered what types of imaging equipment should be subject to certificate of need (CON) review, dental imaging equipment and the practice of dentistry were not deemed to be subject to CON review. As technology advanced, Cone Beam imaging became available, and unfortunately, the Office of Health Care Access (OHCA) has deemed this modality to be similar to CT scanning modalities. The existing statutes never contemplated the inclusion of the Cone Beam imaging because it did not exist at the time the

statutes were created. We argued this point a few years ago, in a declaratory ruling process before OHCA; the Agency did not find in our favor at that time, but OHCA is recommending an exemption today. Like, X-ray, ultrasound and other similar modalities that OHCA exempts, we are here to request relief for Cone Beam imaging for dentistry.

Impact on Quality of Care

The ALARA (as low as reasonably achievable) principles are used by hospitals and imaging centers. Medical CT scanners expose patients to higher doses of radiation when compared with the lower doses of dental CBCT. Thus, patients in the State of Connecticut are forced to receive higher radiation doses for these dental images. Patient positioning for a medical CT is not ideal for dental imaging. Dental patients should be imaged in the sitting or standing position for accurate dental relationships. Hospitals and imaging centers do not have these positions available to dental patients. Moreover, metal scatter artifacts from dental amalgams (fillings) and implants are higher in medical CT than in dental CBCT causing problems to image quality as it relates to dental anatomy. Additionally, dentists require smaller voxel (slices) sizes than most medical CT images provide. Also, CT imaging software for use in dental models and impressions, which are needed for treatment planning, are not provided by most hospital imaging centers.

It can be demonstrated that dental panoramic images are more difficult to read than CBCT images. In fact, many times diseases are found in a panoramic image only after a CBCT image is taken. New dental applications are being developed on the basis that CBCT is available to dentists. Currently, these new applications are not available to patients in Connecticut. Examples include Sure Smile™ orthodontic treatment and Nobel Guide™ for implant planning.

Impact on Patient Access

Traditional dental imaging is part of the dental practice. Imaging centers and hospitals do not provide comprehensive services to private dental practices. For example, if a patient requires a panoramic radiograph, the patient must often be referred to a dental specialist. Dentists provide patients with dental imaging as part of the dental procedure. For example, during a root canal, images are taken in order to accurately provide treatment. Similarly, dental CBCT images can be taken immediately post-surgery to determine accurate placement of dental implants. These methods could not be provided without imaging in the dental office. These low cost dental CBCT offer a logical return on investment by allowing for greater patient convenience, improved patient care, and increased doctor productivity.

The law today creates access issues for the patient. A provider who does not have CBCT in its office has to refer patients to medical CT devices. This requires patients to access care unnecessarily in two separate locations resulting in unnecessary delay and a gap in care. The time it takes to schedule the patient and the time it takes the patient to work the additional appointment into their own schedule inevitably results in patients not receiving a continuum of care that should be readily available to them in their dentists' office.

Impact on Healthcare Costs

The impact on healthcare costs has not been considered with respect to dentistry because most

information comes from medical insurance payers (either private or Medicare), which exclude dentistry or provides very limited dental coverage. Today patients' pay for the majority of scans used by dental CBCT. These scans are generally not covered by Insurance. Hospitals and private radiology practices do not provide dental imaging services. Hence, dental imaging is not presently part of the services normally controlled/governed by CON regulations. Consequently, if dental CBCT's were deregulated it would not adversely affect the finances of hospitals or private radiology practices.

The capital cost of cone beam imaging device for dentist is significantly less than the cost of medical CT devices resulting in less cost to the provider and more importantly the patient.

Conclusion

In the dental health care system, dental CBCT is an essential diagnostic tool that provides clarity that currently panoramic radiographs are unable to capture. Dental CBCT devices do not compete with medical CT scanners, have no affect on the medical healthcare system, and should therefore be exempt from the CON process.

I thank you for the opportunity to testify today, and I respectfully urge you to support an exemption from CON for CBCT.