STATE OF CONNECTICUT

OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

Declaratory Ruling

Final Decision

Docket Number:	**07-30991-DCR**
Project Title:	**Declaratory Ruling to answer the following question:** **"***Whether dental providers in Connecticut may acquire and operate an i-CAT Cone Beam 3D Dental Imaging System without prior certificate of need approval?***"**
Statutory Reference:	**Connecticut General Statutes Sections 4-176, et seq and Section 19a-639 (c)**
Hearing Date:	**August 29, 2007**
Hearing Officer:	**Commissioner Cristine A. Vogel**
Decision Date:	**December 3, 2007**
Staff:	**Melanie Dillon**
Intervenors	Imaging Sciences International Connecticut State Medical Society Connecticut Ear, Nose & Throat Society Radiological Society of Connecticut, Inc. Xoran Technologies, Inc. Neurologica Corporation

Background & Procedural History

On June 12, 2007, Imaging Sciences International ("ISI") filed a Petition for Declaratory Ruling with the Office of Health Care Access ("OHCA"). The question presented was whether dental providers in Connecticut may acquire and operate an i-CAT Cone Beam 3D Dental Imaging System ("i-CAT") without prior Certificate of Need ("CON") approval.

Prior to the filing of ISI's Petition for Declaratory Ruling, ISI and Marianne Urbanski, DMD, filed CON determinations regarding the acquisition of the i-CAT. On December 8, 2006, OHCA determined that ISI's i-CAT is a scanner similar to the other scanners and equipment requiring CON approval and therefore, providers wishing to acquire and operate an i-CAT must receive CON authorization from OHCA. (*Certificate of Need Determination Report Number 06-30814-DTR, December 8, 2006*). OHCA simultaneously issued a determination report to Marianne Urbanski, DMD, concluding that CON approval would be required for Dr. Urbanski to acquire and operate an i-CAT in her private dental office. (*Certificate of Need Determination Report Number 06-30852-DTR, December 8, 2006*).

The University of Connecticut Health Center, School of Dental Medicine ("UCHC School of Dental Medicine") also sought a determination during the same time period with respect to acquisition of a Hitachi CB Mercuray Maxillofacial Digital Imaging System ("Mercuray"). The Mercuray utilizes cone beam volumetric tomography to acquire images of patients who require bony maxillofacial imaging. Thus, it utilizes technology similar to that of the i-CAT. On December 7, 2006, OHCA concluded that the UCHC School of Dental medicine required CON approval to acquire and operate the Mercuray. (*Certificate of Need Determination Report Number 06-30866-DTR, December 7, 2006*). Subsequently, the UCHC School of Dental Medicine sought and received CON approval on May 31, 2007 to acquire and operate the Mercuray. (*University of Connecticut Health Center, School of Dental Medicine, Acquisition and Operation of a Hitachi CB Mercuray Maxillofacial Digital Imaging System, Docket Number 06-30866-CON, May 31, 2007*).

Through its Petition for Declaratory Ruling, ISI now seeks a ruling from OHCA regarding whether dental providers are required to obtain CON approval prior to acquiring and operating an i-CAT. Although OHCA already addressed this issue through the aforementioned CON determinations and CON decision, OHCA proceeded with providing notice of ISI's Petition for Declaratory Ruling to all interested parties and scheduled a public hearing for August 29, 2007 pursuant to the request of ISI and General Statutes § 4-176. Additionally, OHCA published notice of the declaratory ruling proceedings in the Connecticut Law Journal on July 24, 2007.

On July 27, 2007, ISI, the Connecticut Ear, Nose & Throat Society (ENT Society), the Connecticut State Medical Society ("CSMS"), and the Radiological Society of Connecticut ("RSC") filed petitions for status in the declaratory ruling proceeding. Xoran Technologies ("Xoran") filed a request for an extension of time within which to request status as a party and/or intervenor and OHCA extended Xoran's deadline for requesting status until August 13, 2007.

OHCA designated ISI and RSC as intervenors with full rights of participation and designated the ENT Society and CSMS as intervenors with limited rights of participation on August 2, 2007. Xoran filed its petition for status on August 13, 2007 and OHCA designated Xoran as an intervenor with full rights of participation on August 16, 2007. Pursuant to the Regulations of Connecticut State Agencies § 19a-643-38, NeuroLogica Corporation ("NeuroLogica") filed a Petition for Status as an intervenor as well as the prefiled testimony of Eric Bailey, Ph.D, President and CEO of NeuroLogica on August 24, 2007. OHCA designated NeuroLogica as an intervenor with limited rights of participation on August 28, 2007.

On August 27, 2007, RSC filed an Objection to the Request of Intervenors to Expand the Scope of the Declaratory Ruling Proceeding to include all specialty CT scanners, such as the MiniCAT and CereTom. OHCA proceeded with the hearing on the Petition for Declaratory Ruling on August 29, 2007. Prior to hearing testimony from the intervenors, OHCA heard argument on RSC's Objection to the Request of the Intervenors to Expand the Scope of the Declaratory Ruling Proceeding. Following argument from all parties on the objection, OHCA sustained RSC's objection and thereby declined to expand the scope of the declaratory ruling to include all physicians wishing to acquire low-cost, specialty CT scanners. Accordingly, OHCA advised all intervenors to refrain from offering testimony in support of expanding the scope of the proceeding and indicated that testimony regarding similar pieces of equipment would be allowed only to the extent that it was relevant to the issue of whether dental providers may acquire and operate an i-CAT without prior CON approval.

Discussion

Through its Petition for Declaratory Ruling, ISI claimed that the i-CAT is more similar to a traditional x-ray device in that it is solely designed to take high density images of bone and teeth whereas a CT, PET, PET/CT and MRI are designed to take or acquire low and high density images of the skeletal system, organs, tissues and metabolic processes and arteries. (*Petition for Declaratory Ruling, July 12, 2007, p. 12*)**.** ISI nonetheless conceded through its petition and testimony that the i-CAT utilizes computed tomography to acquire an image. (*Petition for Declaratory Ruling, July 12, 2007, p. 13; Testimony of Edward Marandola, August 29, 2007*)**.** Despite conceding that the i-CAT is a CT scanner, ISI continued to distinguish the i-CAT from "conventional CT scanners" by asserting that the i-CAT emits a significantly lower radiation dose than conventional CT scanners and that it utilizes a cone-beam x-ray source as opposed to a fan beam radiation source. (*Petition for Declaratory Ruling, July 12, 2007, p. 13; Testimony of Edward Marandola, August 29, 2007*)**.** ISI also asserted that OHCA should not regulate the acquisition and operation of i-CAT imaging systems by dental providers as it has a tradition of not regulating dental providers. (*Petition for Declaratory Ruling, July 12, 2007, p. 14; Testimony of Joel L. Rosenlicht, DMD, August 29, 2007*)**.** ISI further argued that the i-CAT does not utilize new technology. (*Petition for Declaratory Ruling, July 12, 2007, pp.15-16*).

RSC countered that OHCA has jurisdiction over physicians, dentists and their respective practices to the extent that they acquire certain imaging equipment regulated pursuant to General Statutes § 19a-639 (c). (*Prefiled Testimony of Marc Glickstein, M.D., pp. 4, 7***)**. RSC also asserted that § 19a-639 (c) focuses on the equipment rather than the person or provider making the acquisition. (*Prefiled Testimony of Marc Glickstein, M.D., p. 5).* RSC testified that § 19a-

639 (c) applies to anyone who acquires a CT scanner or similar equipment utilizing technology that is new or being introduced to the state and that dental providers fall under this section when they acquire imaging equipment. (*Testimony of Marc Glickstein, M.D., August 29,* 2007). According to RSC, the i-CAT is a CT scanner because it acquires data through the use of an x-ray beam, which acquires two-dimensional images that are reconstructed using computer software that applies algorithms to raw data to produce 3-D images in high resolution. (*Prefiled Testimony of Marc Glickstein, M.D., p. 8*). RSC noted that the distinguishing features of the i-CAT, including the type of beam, patient position, lower radiation dose, scan times and training requirements, are merely a function of the specific generation of equipment being used and have no bearing on whether the i-CAT is a CT scanner. (*Prefiled Testimony of Marc Glickstein, M.D., p. 9*). RSC also noted that ISI provided no evidence that the geometry of a beam source is determinative of whether a device is a CT scanner and that existing CT manufacturers are in the process of developing cone beam CT scanners for general medical use. (*Prefiled Testimony of Marc Glickstein, M.D., pp. 9-10).* RSC stated that a CT scanner basically requires an x-ray source, a detector, a gantry and a computer to generate the image. (*Testimony of Marc Glickstein, August 29,* 2007). Therefore, RSC testified there is no question that the i-CAT is a CT scanner based upon the images from the i-CAT that were included in the articles and publications submitted by ISI. (*Testimony of Marc Glickstein, M.D., August 29, 2007*).

Alternatively, RSC argued that i-CAT is similar equipment utilizing technology that is new to the state of Connecticut, especially given the fact that ISI has said that the i-CAT "has already been sold. . . . to more than one facility since 2004" in Connecticut. (*Prefiled Testimony of Marc Glickstein, M.D., p. 11; see also, Petition for Declaratory Ruling, p.4*). From a policy perspective, RSC asserted that the i-CAT is not the only specialty CT scanner that could be viewed as potentially falling outside OHCA's jurisdiction, as there are many specialty units coming on the market. (*Prefiled Testimony of Marc Glickstein, M.D., pp. 13-14*). Additionally, exempting the i-CAT would allow providers to make judgment calls with respect to whether similar imaging equipment requires CON approval and could eventually lead to the proliferation and overuse of the i-CAT and similar specialty CT scanners. (*Prefiled Testimony of Marc Glickstein, M.D., pp. 12-15*).

CSMS argued that exempting the i-CAT from the CON process would not contradict the legislative intent behind the CON requirement in § 19a-639 (c) in that the i-CAT is not substandard equipment and the use of the i-CAT will not compete with hospital services. (*Prefiled Testimony of Matthew Katz, Executive Director, CSMS, pp. 2-3*) The ENT society similarly testified that the i-CAT is not substandard equipment, that it gives the same high quality image as a larger more expensive CT Scan and it is not competitive with hospital services. (*Prefiled Testimony of Steven Levine, M.D., pp. 3-5*). Additionally, the ENT society testified that the CON process discourages providers from purchasing the i-CAT and therefore, acts as barrier to prevent improved quality equipment from entering the marketplace. (*Prefiled Testimony of Steven Levine, M.D., pp. 6-7*).

Xoran claimed that the CON requirements limit Connecticut physicians and patients from the opportunity to use low-dose radiation scanning. (*Prefiled Testimony of Matthew Jordan, pp. 4-5*). Xoran asserted that specialty CT scanners, such as the i-CAT are of lower cost and use lower radiation and therefore, could easily be identified and exempted from the CON process.

(*Prefiled Testimony of Matthew Jordan, pp. 5-6*). Xoran proposed exempting specialty CT scanners provided they are below $400,000 and have a peak power output of 5 kilowatts or less. (*Prefiled Testimony of Matthew Jordan, p. 6; Prefiled Testimony of Susie Vestevich, Esq., pp. 7-8*). Xoran also testified with respect to the differences between a specialty CT scanner and traditional CT scanners, including the lower radiation dose; the use of "spatial resolution" to capture hard bone images rather than using "contrast resolution" to capture soft tissue images; and the pre-set safety protocols of a specialty CT scanner. (*Prefiled Testimony of Susie Vestevich, Esq., pp.5-7*).

Dr. Eric Bailey, President and CEO of NeuroLogica, stated that he led the team of design engineers that developed the first commercial multi-slice CT machine. (*Prefiled Testimony of Eric M. Bailey, Ph.D., p. 1*). He also led the design of key subsystems and eight complete systems for the first medical multi-slice systems. (*Prefiled Testimony of Eric M. Bailey, Ph.D., p. 1*). Dr. Bailey testified that he personally "built the guts of just about everybody's CT system that is out there." (*Testimony of Eric M. Bailey, Ph.D., August 29, 2007*). Dr. Bailey testified that any scanner that is beyond a single slice system has cone beam mathematics that are involved in reconstructing images; therefore, all CT scanners are essentially cone beam devices. (*Testimony of Eric M. Bailey, Ph.D., August 29, 2007*). Although there was testimony from the various intervenors with respect to whether the i-CAT and other specialty CT scanners are CT scanners, Dr. Bailey testified that "these are all CT scanners." (*Testimony of Eric M. Bailey, Ph.D., August 29, 2007*).

Although Neurologica supported the petition of ISI and agreed that low cost, high quality imaging equipment should not require CON approval, it was noted that the exemption from CON for the specialty CT scanners should not be limited to dentistry and a specific brand name. (*Prefiled Testimony of Eric M. Bailey, Ph.D., p. 2; Testimony of Eric M. Bailey, Ph.D., August 29, 2007*). Accordingly, Dr. Bailey testified that any ruling by OHCA exempting specialty CT scanners from the CON process should be broad enough to encompass all providers and types of specialty CT scanners or there should be no exemption at all. (*Testimony of Eric M. Bailey, Ph.D., August 29, 2007*).

Rationale and Decision

General Statutes § 19a-639 (c) provides in relevant part: "Each person or provider, other than a health care or state health care facility or institution subject to subsection (a) of this section, proposing to purchase, lease, accept donation of or replace . . . . (2) a CT scanner, PET scanner, PET/CT scanner or MRI scanner, cineangiography equipment, a linear accelerator or other similar equipment utilizing technology that is new or being introduced into the state, shall submit a request for approval of any such purchase, lease, donation or replacement pursuant to the provisions of subsection (a) of this section. . . . " The plain language of § 19a-639 (c) indicates that "***each person or provider***" proposing to acquire "a CT scanner, PET scanner, PET/CT scanner or MRI scanner . . . or other similar equipment utilizing technology that is new or being introduced into the state, ***shall submit a request for approval*** of any such purchase, lease, donation or replacement…." (*Emphasis added.*) OHCA finds that dentists are providers or

persons and to the extent that they acquire any of the equipment enumerated in § 19a-639 (c) they are required to apply for a CON prior to such acquisition.

Section 19a-639 (c) lists "CT scanner" as one of the pieces of imaging equipment that requires CON approval prior to its acquisition by a person or provider. Testimony from ISI and Xoran focused on the differences between specialty CT scanners, including the i-CAT, and "conventional" CT scanners. Although OHCA understands and appreciates that there are distinguishing characteristics between the specialty CT scanners and "conventional" scanners, there is no such distinction in § 19a-639. Section 19a-639 is devoid of any language that limits the term "CT scanner" to only include "conventional" CT scanners. RSC and NeuroLogica both testified that the i-CAT and the other specialty CT scanners in the marketplace are CT scanners. Additionally, neither ISI nor Xoran presented any evidence that the i-CAT or any of the specialty CT scanners are ***not*** CT scanners. In fact, ISI conceded both through its petition and testimony that the i-CAT utilizes computed tomography to acquire an image. Moreover, Xoran clearly recognizes that the i-CAT as well as other specialty CT scanners are currently included under the present language of § 19a-639 (c) as it proposed a statutory change to exempt specialty CT scanners by reinstating the dollar threshold, which was eliminated in 2005 pursuant to Public Act 05-93, and by adding language regarding peak power output. Accordingly, OHCA finds that the i-CAT is a CT scanner that requires a person or provider to obtain CON approval prior to acquisition pursuant to § 19a-639 (c).

Based upon the foregoing, OHCA concludes that pursuant to § 19a-639 (c) dental providers in Connecticut are required to obtain CON approval prior to acquiring and operating an i-CAT Cone Beam 3D Dental Imaging System. Although it utilizes cone beam technology, emits a lower radiation dose, has a lower peak power output and costs less than a "conventional" CT scanner, the i-CAT is a CT scanner within the meaning of § 19a-639 (c) as the statute does not distinguish between specialty CT scanners and "conventional" CT scanners.

All of the foregoing constitutes the final ruling of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

Signed by Commissioner Vogel on December 3, 2007

_____
Cristine A. Vogel
Commissioner