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December 28, 1993

Re: X-----
 Vascular/Lymphatic Limb Devices

Dear X-----,

As you remember from our telephone conversation the other day, EA Auditing has requested that the Legal Division answer your opinion request. By memorandum dated November 18, 1993, we were sent your letters of November 4, 1993 to EA Auditing explaining the function of the devices which your client sells, and of November 16, 1993, to Senior Tax Auditor Paul G. Jungkeit on whether or not the devices your client sells support the affected limb. Attached to your November 4 letter were brochures explaining the operation of the Lympa Press Mini and the Multicom 500 Peristaltic Gradient Sequential Compression System and a reprint from LXVIII Archives of Physical Medicine and Rehabilitation (July 1987) describing the Legging Orthosis. You also enclosed pictures of the results if the condition is left untreated. Since you did not identify the tax payer, this letter does not constitute specific written advice to the taxpayer under Revenue and Taxation Code Section 6596. Rather, it constitutes general comments regarding the applicability of California Sales and Use Tax Law to a set of hypothetical facts.

OPINION

A. Sales and Use Tax Generally

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes an excise tax, computed as a percentage of gross receipts, upon all retailers for the privilege of selling tangible personal property at retail in this state. (Unless otherwise state, all statutory references are to the Revenue and Taxation Code.) “[I]t shall be presumed that all gross receipts are subject to tax until the contrary is established. The burden of proving that a sale of tangible personal property is not a sale at retail is upon the person who makes the sale ..” (§ 6091.) “Exemptions from taxation must be found in the statute.” (“Market St. Ry. Co. v. Cal. St. Bd. Of Equal. (1953) 137 Cal.App.2d 87, 96 [290 P.2d 201.]”) The taxpayer has the burden of showing that he clearly comes within the exemption.” (Standard Oil Co. v. St. Bd. Of Equalization (1974) 39 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

B. Prescription Medicines

Section 6369, interpreted and implemented by Title 28, California Code of Regulations, Regulation 1591 provides that sales of medicine, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales or use tax. (Reg. 1591(a).) Subdivision (b)(1) defines “medicine” to “mean and include any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for such use.” However, Regulation 1591(c)(2) adds that “medicines” do not include “articles which are in the nature of splints, bandages, pads, compresses,

supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof.” (Sales and Use Tax Regulations are Board promulgations which have the force and effect of law.) As a rule, then, items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines.

Regulation 1591(b) does provide that certain items which might otherwise be considered as being devices, etc., are defined as “medicines.” Regulation 1591(b)(4) includes orthotic devices, or their replacements, designed to be worn on the person of the user as a brace, support, or other correction for the body structure. We have consistently interpreted this language to mean that the device must be fully worn on the body of the patient in order to qualify for the exemption.

C: Tax Consequences.

1. Lympha Press Mini, Multicom 500.

These systems share similar characteristics. The patient wears a sleeve or legging which is attached to a pump by a series of hoses. The pump sits on a table or stand and applies pressure gradient therapy to relieve the edema. We previously determined that systems such as these do not qualify as “orthoses” under Regulation 1591(b)(4) because they cannot be fully worn on the body of the patient. Sales of these devices are subject to tax.

2. Legging Orthosis.

The preprint describes this item, in part, as follows:

“The legging orthosis is worn around the lower leg from the knee to the instep. It is constructed entirely of 3.8 cm and 5.1 cm bands of woven nylon loop fastening tape. The length of each band and consequently, each band’s pressure level is independently adjustable. Bands are held closed and compression is maintained by short pieces of hook tape under the front ends of each band.

“Each legging orthosis is immediately custom fitted to the patient.....

“Optimally, the orthosis is removed when the patient goes to bed and put on when the patient first arises....”

The pictures in the offprint indicate that this item is fully worn on the body of the patient. Your letter further indicates that this device may only be obtained by prescription. Once the prescription is issued, a Certified Orthotist employed by your client oversees the fitting of the item and instruction on its use. You also indicated that the Legging supports the venous and lymphatic structure and that it is prescribed when the physician determines that the patient’s limb has lost the ability to function properly without orthotic support.

The function of this item appears to be much the same as that of an anti-embolism stocking which item is specifically listed in Regulation 1591(b)(4) as an example of an orthosis. We are thus of the opinion that the Legging Orthosis qualifies as an orthotic device because it supports the internal leg structure and is fully worn on the body of the patient. As a result, sales of this item are exempt from tax.

I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again.

Sincerely,

John L. Waid
Tax Counsel

JLW:es

Cc: X-----, Paul G. Jungkeit, Senior Tax Auditor

M e m o r a n d u m

425.1105

To: HQ – Legal (MIC:82)

Date: November 18, 1993

From: EA -- Auditing

Subject: X-----

Attached you will find a written request, dated November 4, 1993, from the taxpayer's representative concerning the correct tax application on their sales of Vascular/Lymphatic Limb Orthoses. After contacting the taxpayer's representative by phone, additional information was sent to us on November 16, 1993.

We are forwarding this inquiry to you so you can respond directly to the taxpayer. We appreciate you help in answering this inquiry.

November 4, 1993

State of California
Board of Equalization
Attention Audit Department
28 Civic Center Plaza
Santa Ana, California 92701

Re: Sales Tax Exemption / Prescription Medical Device

Dear Sir or Madam:

We write to request written confirmation that certain medical devices (Vascular/Lymphatic Limb Orthoses with Sequential Support Applicators) sold by our client are exempt from sales tax pursuant to Regulation 1591 of the Sales and Use Tax Regulations. Our analysis of that regulation as it pertains to our client's products follows. For your convenience, we enclose material which describes the products.

Regulation 1591(a)(1) reads as follows:

Tax does not apply to sales of medicines for the treatment of a human being which medicines are prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a registered pharmacist in accordance with law...

VASCULAT/LYMPHATIC LIMB ORTHOSES ARE "MEDICINES"

The first issue we address is whether Vascular/Lymphatic Limb Orthoses (hereinafter referred to as "the ORTHOSES") sold by our client are "medicines" as defined by Regulation 1591(b). We believe the short answer is "yes."

The ORTHOSES are prescribed by physicians for the correction and support of the vascular and lymphatic structures in the arms and/or legs of patients. The ORTHOSES utilize intermittent sequential pneumatic compression of the limbs in the correction and prevention of, among other things, chronic lymphedema, venous stasis, post-thrombotic leg ulcers and postoperative deep venous thrombosis.

The ORTHOSES qualify as "medicines" under Regulation 1591(b)(4) because they are orthotic devices. An orthosis is variously defined as a device which when in contact with the human body improves function.¹ Such a definition precisely describes the design purpose of the Vascular/Lymphatic Limb Orthosis. When the orthosis is in contact with the patient's limb, it corrects the function of the limb by supporting its venous and lymphatic structure. The orthosis is prescribed because the physician has determined that the patient's limb has lost its ability to function properly without orthotic support. We refer you to the enclosed article entitled, *Legging Orthosis for Venous and Lymphatic Insufficiency*.²

¹ Redford Jb (ed): Orthotics Etcetera, Ed. 3. Baltimore, Williams & Wilkins, 1986.

² Archives of Physical Medicine and Rehabilitation, Vol. 68, August 1987.

In view of the foregoing authority and analysis, we believe the ORTHOSES sold by our client qualify as “medicines” under Regulation 1591(b)(4).

THE ORTHOSES ARE AVAILABLE
ONLY BY PRESCRIPTION

The second issue we address is whether the ORTHOSES sold by our client are “prescribed and dispensed on prescription.” This is easily done. Federal law restricts the ORTHOSES to sale by or on the order of a licensed physician. Accordingly, our client cannot sell the product unless it is first prescribed by a doctor.

After a Vascular/Lymphatic Limb Orthosis has been prescribed, a Certified Orthotist employed by our client will meet with the patient either at the physician’s office or at the patient’s home in order to take the measurements necessary to properly fit the product to the patient’s limb. The final fitting of the orthosis takes place at the patient’s home where any additional measurements and adjustments are made. Finally, follow up visits at the patient’s home are made at one week, two week and one month intervals to take measurements and monitor the patients progress and insure the proper fit and use of the orthosis.

In view of foregoing, we believe the ORTHOSES sold by our client are prescribed and dispensed on prescription.

ORTHOTIC DEVICES NEED NOT BE DISPENSED
BY A REGISTERED PHARMACIST

The final issue we address is whether the prescription is filled by a registered pharmacist in accordance with law. We refer you to Regulation 1591(i) which provides:

Orthotic and prosthetic devices ... furnished pursuant to the written order of a licensed physician or podiatrist, shall be deemed to be dispensed on prescription within the meaning of paragraph (a)(1), whether or not the devices are furnished by a registered pharmacist.

In view of the clear meaning of section (i), we believe that our client need not be a registered pharmacist to sell these systems without sales tax.

CONCLUSION

In view of the foregoing, we believe that the ORTHOSES sold by our client are exempt from sales tax. If you agree, we would sincerely appreciate written confirmation from you for our records. If you disagree, however, please contact the undersigned at your earliest convenience so that we may discuss the issue.

Your professional courtesy and cooperation are greatly appreciated. Should you have any question or comments or if you require additional documentation, please do not hesitate to call.

Very truly yours,

Enclosures.

X-----