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STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

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Executive Director

October 6, 1993

Re: [No Permit Number]
Esophageal Dilators

Dear REDACTED TEXT,

I am responding to your letter dated August 19, 1993, to the Legal Division. You asked for a letter ruling regarding the application of sales or use tax to your client's sales of esophageal dilators. Since you did not identify the taxpayer, 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.

I. FACTUAL BACKGROUND

You describe the product the sales of which are at issue as follows:

"XYZ Company, our client, manufactures and markets dilators. This product is sold to gastroenterologists, hospitals, and clinics. The dilator is a thin cylindrical instrument filled with mercury in order to make it liable and flexible. The dilator is reusable after sterilization and has a shelf life of approximately three years.

"Generally the product is used by gastroenterologists to dilate the esophagus so that the patient's esophagus functions normally (i.e. allows the patient to eat and drink normally). Reasons for dilating the esophagus include the following:

"1. Assist doctors during surgery (e.g. if a procedure requires the esophagus to be dilated).

"2. On an outpatient basis for treatment of:

- throat cancer patients
- esophageal strictures (abnormal narrowing of the passage)
- esophageal injuries
- esophageal rings or webs (thin circular mucosa shelves)
- scleroderma (hardening or thickening of esophagus due to abnormal tissue growth)

You further indicate that, although the dilator may be used to assist doctors during surgery, it is more generally used on an out-patient basis for treatment or repair of the esophagus. From the fact that the device is reusable, we presume that it is inserted into the patient's esophagus to treat the conditions and then removed.

II. 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 stated, 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. Rv. 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." Sub-division (b)(2) includes articles permanently implanted in the human body to assist the functioning- of, as distinguished from replacing all or any part of, any natural organ, artery, vein , or limb, and which remain or dissolve in the body. Regulation 1591(b)(5) includes prosthetic devices and their replacement parts designed to be worn on or in the person of the user to replace or assist in the functioning of a natural part of the human body.

C. Tax Consequences.

There is, unfortunately, no single answer to this question. You indicate that some of these instruments are used temporarily during surgery. When used in such a way, these items are in the nature of devices, appliances, etc., excluded from the definition of "medicines" by Regulation 1591(c)(2). Sales of esophageal dilators for use during surgery are subject to tax.

You aver that, by analogy to exempt sales of catheters used for drainage through an artificial opening in the skin (See, Reg. 1591(j), the esophageal tubes are prosthetic devices. We

do not agree. First of all, sales of drainage catheters inserted into artificial openings are subject to a specific exemption. (See, § 6369(g).) Second, the exemptions for permanently implanted items and for prostheses are two separate exemptions. Former section 6369(c)- now sub-divisions (c) (1) & (2)- was enacted partially to confirm the board's existing interpretation that the definition of "medicines" as originally enacted did not encompass either items implanted in the body to assist the functioning of a natural body part or external prostheses. The legislature made permanently-implanted articles exempt without disturbing the Board's interpretation as to the original meaning of the law. In 1977, Section 6369(c)(4) was enacted exempting the sales and use of certain prostheses. Thus, prostheses are to be distinguished from implants. While a prosthesis may be partially inserted into a patient, they are worn on the outside of the patient's body.

Your description of esophageal dilators indicates that they, to be used, must be implanted in the patient. Therefore, sales of such items, if exempt at all, are exempt only if the item is permanently implanted. We have previously concluded that, to be considered "permanently implanted," the item must be implanted with the intent that it remain in place for at least six months - i.e., the item was intended to be "permanently" implanted even if for some reason it had to be removed sooner. We have assumed that the dilator is implanted temporarily in the patient only for as long as necessary to properly dilate the esophagus and then removed. Under that assumption, then, esophageal dilators are appliances, devices, etc. excluded from the definition of "medicine" under Regulation 1591(c)(2) with the result that sales of such items are subject to tax.

For your information, I have included a copy of Regulation 1591. 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

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Enclosure: Reg 1591