

**STATE BOARD OF EQUALIZATION**

1020 N STREET, SACRAMENTO, CALIFORNIA
(P.O. BOX 942879, SACRAMENTO, CALIFORNIA 94279-0001)
(916) 324-5589

June 12, 1989

Ms. G--- P---
Accounting Department
P--- D--- Inc.
XXX --- --- Road
--- ---, -- XXXXX

Re: SC – XX-XXXXXX

Dear Ms. P---:

This is in response to your letter of March 28, 1989. You have requested our opinion regarding the correct application of tax to various items sold by your company. You have also requested information regarding the various tax rates and the procedure for filing tax refunds.

As we understand it, P--- D--- has two principal product lines. The Port-A-Cath which are totally implantable port and intravenous catheter systems used for single injections, or continuous infusion and Computerized Ambulatory Drug Delivery Pumps (CADDP) which provide a system for administering medication.

Revenue and Taxation Code Section 6369 (c) (6) provides that “programmable drug infusion devices” are considered medicines as that term is used in Section 6369. We are of the opinion that Computerized Ambulatory Drug Delivery pumps qualify as programmable drug infusion devices under Section 6369 (c) (6) and your sale of CADDP is exempt from tax. The Port-A-Cath system is not exempt from tax because it is not a programmable drug infusion device. It merely serves as a port for the injection of medicine.

According to the literature you supplied, the Port-A-Cath can also be used in conjunction with a programmable battery pump which meters out the drug. This pump would be considered a programmable drug infusion device.

We are enclosing a copy of our pamphlet “Tax Tips for District Taxes” for your reference. The pamphlet explains the various tax rates now in effect in California.

You have also requested information regarding the procedure to be followed in filing a claim for refund with the State Board. Revenue and Taxation Code Section 6904 provides:

“Every claim shall be in writing and shall state the specific grounds upon which the claim is grounded.”

Claims for refund for tax previously paid on sales of drug infusion devices should be addressed to the Board of Equalization, Attention Audit Review and Refund Unit, P.O. Box 942879, Sacramento, California, 94279-0001.

If you have further questions concerning this matter, please write this office again.

Very truly yours,

Mary C. Armstrong
Senior Tax Counsel

MCA:cl

Enclosure

bc: Out-of-State District Administrator

**STATE BOARD OF EQUALIZATION**

1020 N STREET, SACRAMENTO, CALIFORNIA
(P.O. BOX 942879, SACRAMENTO, CALIFORNIA 94279-0001)
(916) 324-3828

December 14, 1990

Ms. J--- P---
Senior Accountant
P--- D--- Inc.
XXX --- --- Road
--- ---, -- XXXXX

Re: SC – XX-XXXXXX

Dear Ms. P---:

Senior Tax Counsel Mary C. Armstrong has forwarded your letter of October 19, 1990, to me for a response. You have requested that we reconsider our previous opinion, expressed in Mrs. Armstrong's letter of June 12, 1989, that the sales of P--- D---'s product, Port-A-Cath, are subject to sales tax.

1. FACTUAL BACKGROUND

In your letter, you described the operation of the Port-A-Cath (hereinafter "the product") as follows:

"The Port-A-Cath consists of two-to-three components which are implanted in the body, they are the portal, the catheter and, depending on the model, a catheter connector. A huber, noncoring needle is used to access the port. The Port-A-Cath is permanently implanted into the body to maintain venous access. Without this system, the patient may suffer from collapsed veins making it impossible to receive any medication which would normally be injected into the vein."

The brochure you sent, in Section 1., Introduction, the brochure you sent described the product as a "totally implantable [device] designed to permit repeated access to the venous circulation." In Section 2., Indications for Use, the brochure states that use of the product is indicated "when a patient requires repeated venous access for injection or infusion therapy and/or blood sampling."

II. OPINION

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. 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. State Bd. of Equalization (1974) 29 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

Section 6369 generally provides that the gross receipts from the sales of prescription medicines, sold for certain uses and under certain conditions, are exempt from sales tax. Section, 6369(b)(2) excludes from the definition of “medicines” articles in the nature of, among other things, apparatus, appliances, or devices. Section 6369(c) provides that certain items, which might otherwise be considered as being apparatus, etc., are defined as “medicines”. Section 6369(c)(2) includes articles permanently implanted in the body to assist the natural functioning of a vein. Section 6369(c)(4) includes prosthetic devices and their replacement parts designed to be worn in the person of the user to assist the functioning of a natural part of the human body, with certain exceptions.

“In interpreting particular words, phrases or clauses in a statute, it is a cardinal rule that the entire substance of the statute or that portion relating to the subject under review should be examined in order to determine the scope and purpose of the provision containing such words, phrases or clauses.” (West Pico Furniture Co. v. Pacific Finance Loans (1977) 2 Cal.3d 594, 608 [86 Cal.Rptr 793, 469 P.2d 665].) “Generally, the same rules of construction and interpretation which apply to statutes govern the construction and interpretation of rules and regulation of administrative agencies.” (Cal. Drive-In Restaurant Assn. v. Clark (1943) 22 Cal.2d 2878, 292 [140 P.2d 657, 147 A.D.R. 1028].)

The plain language of the above statutes indicates that the articles covered by Sections 6369(c)(2) and (4) are not exempt merely because they are implanted in the body. To be considered a medicine, the prescription sales of which are exempt from sales tax, the item must be sold for the purpose of replacing or assisting the functioning of a natural part of the human body. The passage from your letter as well as the passages from the brochure quoted above emphasize that the purpose of the product is to provide venous access when repeated injections are prescribed. To that end, they support the vein, which presumably gives the incidental benefit of maintaining blood flow.

In analyzing the taxability of the sales of items of tangible personal property where the availability of an exemption is keyed to the property’s use, as here, we have always looked to the primary purpose for which the property is sold. If that purpose causes the sale of the property to

be taxable, the sale is taxed even if the property renders an incidental benefit which, if it were the primary purpose, would render the sale non-taxable.

Thus, we reiterate our previous conclusion, as expressed in Mrs. Armstrong's letter, that the product is not a medicine but rather an appliance, device, etc., as it is sold primarily for use as a port for repeated injection of medicines. Its sales are therefore subject to California sales tax.

Please remember that exemptions from tax are controlled by the language of the statute providing the exemption. The Board may not expand through administrative decision the scope of an exemption beyond that provided by the statute. (Agricultural Labor Relations Bd. v. Superior Court (1976) 16 Cal.3d 392, 426 [128 Cal.Rptr. 183, 546 P.2d 687]; Am. Distilling Co. v. St. Bd. of Equalization (1942) 55 Cal.Ap.2d 799, 805 [131 P.2d 609].)

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

Very truly yours,

John L. Waid
Tax Counsel

JLW:es
0033E

**STATE BOARD OF EQUALIZATION**

1020 N STREET, SACRAMENTO, CALIFORNIA
(P.O. BOX 942879, SACRAMENTO, CALIFORNIA 94279-0001)
(916) 324-3828

February 20, 1991

Ms. J--- P---, Senior Accountant
P--- D---, Inc.
XXXX --- --- Road
--- ---, -- XXXXX

RE: SC – XX-XXXXXX

Dear Ms. P---:

I am writing this in response to your letter to me of January 7, 1991. You are requesting that we reconsider our opinion, as expressed in my letter of December 14, 1990, that the Port-a-Cath system does not qualify as a prescription medicine under Regulation 1591.

The information which you previously supplied and which you re-affirmed in your letter indicates that the Port-a-Cath system is sold primarily for the purpose of chemotherapy infusion. The cannula for the system are permanently implanted.

We cannot agree with your assertion that, in cancer cases, the patient's vein is for the purpose of getting chemotherapy agents into the body rather than for blood flow. The natural function of the vein remains the maintenance of blood flow. Delivery of the chemotherapy agent into the vein may facilitate rapid dispersal of the vesicant drug, but rapid dispersal of drugs is not the vein's natural function.

Annotation 425.0530, "Miscellaneous Medical Supplies," is not on point. My review of the opinion letter supporting that annotation indicates that the letter was written to interpret the effect of then-recently-amended Section 6369(c) on the sales of hemodialysis products, mainly blood tubing sets. That section, as discussed in my previous letters, requires that an article be permanently implanted in the human body to assist the function of a natural part of the body. The exemption does not derive from the fact that the article is permanently implanted but from the fact that it assists a natural function. As noted above, we are of the opinion that delivery of chemotherapeutic agents is not a natural function of a blood vessel.

Therefore, we cannot alter the opinion expressed by myself in two previous letters to your company, and as also expressed by Senior Tax Counsel Mary C. Armstrong in a letter to Ms. G--- P--- of P--- D---'s accounting department dated June 12, 1989. Sales of the Port-a-Cath system for drug infusion purposes are not exempt from tax. Your letter, however, indicates that 5% of the sales of the Port-a-Cath system are not for chemotherapy infusion. If any of those sales meet the criteria set forth in our previous letters, then they would be 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
3743I

**STATE BOARD OF EQUALIZATION**

1020 N STREET, SACRAMENTO, CALIFORNIA
(P.O. BOX 942879, SACRAMENTO, CALIFORNIA 94279-0001)
(916) 324-3828

April 26, 1991

Ms. J--- P---
P--- D---
XXXX --- --- Road
--- ---, --- XXXXX

RE: SC – XX-XXXXXX

Dear Ms. Pribyl:

I am writing in response to your letter to me of March 14, 1991. You have once again requested that the Board staff reconsider its opinion that the Port-a-Cath system does not qualify as a prescription medicine under Sales and Use Tax Regulation 1591. That opinion has been expressed in three previous letters: one from Senior Tax Counsel (Specialist) Mary C. Armstrong to Ms. G--- P--- dated June 12, 1989, and two from me to you dated December 14, 1990, and February 20, 1991.

I. FACTUAL BACKGROUND

You describe P--- D---'s business as follows:

“P--- D--- is regulated by the Food and Drug Administration; all products contain warning labels restricting the device to sale by or on the order of a physician. The Port-a-Cath, being a fully implantable device, would be obtained through a surgeon only.”

You attached to your letter a copy of a letter to me by a person you describe as a “medical expert”, G--- S--- M---, M.D., dated March 1, 1991. I had received Dr. M---'s letter on March 10, 1991. He describes the function of the Port-a-Cath as follows:

The Port-a-Cath was designed to enable repeated access to the vascular system while minimizing circulation. Many anti-cancer drugs are highly irritant and, if injected directly into a peripheral vein, can result in spasm of the vessel wall and thrombosis.

Consequently, in patients who have received a course of anti-cancer treatment it is common to find that many of the superficial arm veins are permanently damaged and non-functional. By enabling irritant drugs to be injected into the larger central veins in the chest where blood flow is greater and dilution occurs more rapidly, the Port-a-Cath preserves the function of the peripheral veins.

In some patients, not always those with cancer, implantation of a Port-a-Cath is indicated because repeated venous access is otherwise not possible. Quite simply, suitable veins cannot be reliably found. In this instance the Port-a-Cath is acting as a substitute for a peripheral vein.

II. OPINION

Prosthetics is the art or science of replacing or assisting, by artificial means, body parts that are missing or defective. (Dorland's Illustrated Medical Dictionary, 24th Ed., P.1230.) Additionally, as I pointed out in my previous letters, the Board staff has long held the position that catheters, tubing, and cannulae used to administer medication are not themselves "medicines" as that term is used in Regulation 1591.

As I also demonstrated, the Board staff is of the opinion based on the above principles, that, merely because a device is prescribed by a physician for treatment of his patient, is implanted in the patient, and happens to assist the function of a natural part of the human body while accomplishing the purpose for which it was prescribed, it still does not qualify as a "prosthesis" under Regulation 1591(b)(5). Rather, the device must be worn on the person of the patient for the purpose of replacing or assisting a body part to perform its natural function.

Dr. May's letter only serves to re-confirm our previous conclusion that the Port-a-Cath is implanted in the patient for the purpose of administering medication. The first sentence of the portion of Dr. May's letter quoted above makes this function clear: "The Port-a-Cath was designed to enable repeated access to the vascular system while minimizing discomfort to the patient and trauma to the circulation." The device is not, then, implanted for the purpose of replacing a vein or assisting existing veins in which the blood flow is impaired, but for the purpose of providing a suitable place into which anti-cancer drugs can be injected.

Dr. May further indicates that, in some cases, the Port-a-Cath is implanted because veins are suitable for repeated injections cannot be found. This representation further reinforces our conclusion that the device is prescribed for the purpose of administering medication. It is thus patent that, although the Port-a-Cath may be in the body for a long period of time due to the protracted nature of chemotherapy, the device is implanted in order for the chemotherapy to take place, and the need for the device lasts only so long as does the need for treatment.

We therefore repeat our previous conclusion that the Port-a-Cath is an appliance, instrument, device, etc., and so excluded from the term "medicine" pursuant to Regulation 1591(c)(2). Sales of this product are therefore subject to tax.

In your letter, you requested that the Board re-consider its decision on this matter. This letter, and those previous, represent the opinion of the Board legal staff and not the Board itself. Your letter indicates that you may wish to appeal this matter. Enclosed you will find a copy of Board of Equalization Pamphlet No. 17, "Appeals Procedures", which should answer any questions you may have about the appeals process.

In reviewing my previous letters I note that I neglected to send you a copy of Regulation 1591. For your information, I have enclosed it. 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

3824I

Enclosure: Regulation 1591