OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

In the Matter of the Appeal of:	) OTA Case No. 19064889
	) CDTFA Account No. 019-154365
REGENTS OF THE UNIVERSITY OF CALIFORNIA	) CDTFA Case ID 1013574
	)
	)
	)

OPINION

Representing the Parties:

For Appellant: Jacob Bholat, Representative

For Respondent: Chad Bacchus, Tax Counsel IV
Scott Claremon, Tax Counsel IV
Jason Parker, Chief of Headquarters Operations

N. DANG, Administrative Law Judge: Pursuant to Revenue and Taxation Code (R&TC) section 6901, the Regents of the University of California (appellant) appeals a decision issued by respondent California Department of Tax and Fee Administration (CDTFA)[1] denying a portion of appellant's refund claim for 2006 through 2010 (claim period).

Office of Tax Appeals Administrative Law Judges Nguyen Dang, Andrew Wong and Josh Aldrich held an oral hearing for this matter in Cerritos, California, on August 19, 2020.[2] At the conclusion of the hearing, the record was closed, and this matter was submitted for decision.

ISSUE

Whether CardioGen-82 (a radionuclide generator) is an exempt medicine?

[1] Sales and use taxes were formerly administered by the State Board of Equalization (BOE). In 2017, functions of BOE relevant to this case were transferred to CDTFA. (Gov. Code, § 15570.22.) For ease of reference, when referring to acts or events that occurred before July 1, 2017, "CDTFA" shall refer to BOE.

[2] The oral hearing was noticed for Cerritos, California, but conducted electronically by video conference due to COVID-19.

FACTUAL FINDINGS

1. During the claim period, appellant reported and paid use tax to CDTFA in connection with its purchase and use in California of CardioGen-82.
2. CardioGen-82 is a closed system that produces rubidium-82 chloride injection (RB82), a radioactive intravenous solution used in connection with positron emission tomography for medical diagnostic purposes.
3. CardioGen-82 is marketed as an RB82 "generator" and is composed of a shielded container housing strontium-82. When sodium chloride solution is passed through the container, strontium-82 is transformed into rubidium-82. RB82 is a mixture of sodium chloride solution and rubidium-82. Under normal conditions, RB82 does not contain strontium-82.
4. In comparison to rubidium-82, which has a half-life of 75 seconds, strontium-82 is highly radioactive with a half-life of 600 hours. Excess radiation exposure may occur when the patient is exposed to residual strontium-82. This requires daily testing of CardioGen-82 to ensure that any residual strontium-82 levels are within prescribed limits prior to RB82 being administered to patients.
5. Appellant filed a timely claim for refund asserting (among other things) that its use in this state of CardioGen-82 was not subject to tax because it is an exempt medicine. CDTFA denied the portion of appellant's refund claim pertaining to CardioGen-82, finding that while RB82 is an exempt medicine, CardioGen-82 itself is a non-exempt device used to produce that medicine.[3]

DISCUSSION

The use, storage or consumption of prescription medicines in this state is exempt from tax when prescribed, furnished or sold under certain conditions. (R&TC, § 6369(a)(1)-(6).) It is undisputed that appellant meets these conditions, and therefore, we need not elaborate upon them here. The sole issue presented for our consideration is whether CardioGen-82 is an exempt medicine within the meaning of the Sales and Use Tax Law.

[3] CDTFA approved and denied other items pertaining to appellant's refund claim which are not at issue here.

The term "medicine" means 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 commonly recognized as a substance or preparation intended for that use.[4] (R&TC, § 6369(b); Cal. Code Regs., tit. 18, § 1591(a)(9)(B).)

A taxpayer seeking an exemption from tax bears the burden of proving that the statutory requirements for the exemption have been satisfied. (*Paine v. State Bd. of Equalization* (1982) 137 Cal. App.3d 438, 445.)

Appellant's claim that CardioGen-82 is an exempt medicine is premised on its belief that rubidium-82 and strontium-82 are essentially similar in purpose and form, and that rubidium-82 should be viewed as merely a less radioactive form of strontium-82. Appellant explains that due to rubidium-82's exceedingly short radioactive half-life, it cannot be manufactured for storage and transport to the customer. Instead, it must be stored in a longer-lived form, namely strontium-82, which then spontaneously decays to rubidium-82 when removed from CardioGen-82 using a sodium chloride solution. Appellant asserts that should we find strontium-82 to be nontaxable, the shielded container itself would also be exempt from tax pursuant to California Code of Regulations, title 18, section (Regulation) 1589(b)(1)(D).

We are not persuaded that, for sales and use tax purposes, strontium-82 and rubidium-82 should be viewed similarly. The record plainly indicates that the former is not intended for intravenous injection. As stated in the product's prescribing information, excess radiation exposure occurs when strontium-82 levels exceed prescribed limits and daily testing for residual strontium-82 is required prior to administering RB82 to patients. This indicates, in no uncertain terms, that strontium-82 is a toxic substance and not one intended for application to the human body.

Further, rubidium-82 and strontium-82 are isotopes relating to two entirely separate and distinct chemical elements with greatly differing radioactive half-lives. Although the exact process by which one becomes the other is not described in any of the product literature provided by the parties, clearly, strontium-82 must be transformed into rubidium-82 prior to injection into the patient. This indicates that strontium-82's immediate use is to produce RB82, which is consistent with the product being marketed as an RB82 "generator."

[4] Medicines also includes a broad swath of products such as orthotic and prosthetic devices which are not at issue here. (See R&TC, § 6369(c)(1)-(6); Cal. Code Regs., tit. 18, § 1591(b)(1)-(6).)

Alternatively, appellant has also argued that the United States Food and Drug Administration's (FDA's) approval of CardioGen-82 as a drug product automatically qualifies it as an exempt medicine pursuant to Regulation 1591(a)(9)(A).

The language appellant relies upon states that except where specifically excluded, medicines include "any drug or any biologic, when such are approved by the [FDA] to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use … ." (Cal. Code Regs., tit. 18, § 1591(a)(9)(A).) Although the word "drug" and its plural form appear over 20 times in this regulation, it is only within this subdivision that it is referenced in terms of FDA approval, which lends some support for appellant's position.[5] However, in examining this language more carefully, it is unclear whether the word "drug" actually refers to the FDA's classification and approval of an item as a drug (i.e., an FDA-approved drug product), or whether it refers to the FDA's approval of an item which would ordinarily be considered a drug for sales and use tax purposes.

For items which are commonly recognized as a drug, there is likely to be no meaningful distinction. Items such as penicillin for example, are unquestioningly a drug for both FDA regulatory as well as sales and use tax purposes. However, RB82 is an unusual case in that medical providers are unable to purchase RB82 directly. Due to its short radioactive half-life, RB82 must be contemporaneously produced from CardioGen-82 at the time it is administered to patients. From a health and safety standpoint, it is understandable that CardioGen-82 would fall within the FDA's regulatory purview as a drug. In contrast, for sales and use tax purposes, medicines are generally those items directly applied to the human body. (See R&TC, § 6369(b).) It appears from the regulatory language that this distinction was not considered by CDTFA.

Case law warns of the dangers of indiscriminately applying definitions and concepts from other areas of law. "Like many tax statutes, the sales tax law employs relatively artificial, relatively self-contained, concepts. If it utilizes popular meaning or concepts from other fields of law, it does so only by force of its own objectives and definitions. … To pursue the will-o'-the-wisp of definitions, concepts and distinctions from other areas of law—where they are shaped by purposes and by social and economic factors unrelated to sales taxation—leads to false goals. The coverage of the sales tax law is shaped by its own provisions and definitions and, where

[5] For the reasons specified below, we ultimately reject this position. Consequently, we do not address whether CardioGen-82 might also be considered a non-exempt "device" within the meaning of Regulation 1591(c).

these are unclear, by applying its own perceived policies and concepts. [Fn. omitted.]" (*King v. State Bd. of Equalization* (1972) 22 Cal.App.3d 1006, 1010-1011.) This warrants further investigation to verify whether appellant's interpretation is in keeping with the regulatory purpose and provisions of the Sales and Use Tax Law.

In determining whether an item is a drug for regulatory purposes, the FDA looks to specific, technically defined terms as found in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.). Title 21 United States Code section 321(ii)(1)-(2) states that the term "compounded positron emission tomography drug" means a drug that "exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images … and includes any nonradioactive reagent, reagent kit, ingredient, *nuclide generator,* accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such drug." (Italics added.) The fact that the FDA views CardioGen-82 as a drug is also evidenced by its listing in the FDA's "Orange Book" of approved drug products. (21 U.S.C. § 321(dd) [the term "drug product" means a drug subject to regulation by the FDA].)

We apply the general rules of statutory construction to ascertain the meaning of the word "drug" for sales and use tax purposes. It is well established that the rules of statutory construction apply equally to the interpretation of administrative regulations. (*Hoitt v. Dept. of Rehabilitation* (2012) 207 Cal.App.4th 513, 523.) In construing a regulation, the primary purpose is to "ascertain the intent of the administrative agency that issued the regulation." (*Ibid.*) The most reliable indicator of that intent is the words of the regulation themselves, given their usual and ordinary meaning. (See *People v. Lawrence* (2000) 24 Cal.4th 219, 230.) Every word, phrase, sentence, and part of a regulation should be given significant consideration in discerning its purpose. (See *Curle v. Superior Court* (2001) 24 Cal.4th 1057, 1063.) However, that language is not examined in isolation, but in the context of the regulatory framework as a whole to determine the scope and purpose of the regulation and to harmonize its various parts. (See *Sierra Club v. Superior Court* (2013) 57 Cal.4th 157, 165.) Where the regulatory language is open to more than one reasonable interpretation, courts may look to extrinsic sources, such as the regulatory purpose, legislative history and public policy for guidance. (See *id.* at p. 166.)

The word "drug" is not expressly defined within the Sales and Use Tax Law. In the absence of a technical definition, we apply the plain meaning rule; that is, we look "to the plain

meaning of a word as understood by the ordinary person, which would typically be a dictionary definition." (*Hammond v. Agran* (1999) 76 Cal.App.4th 1181, 1189.) Black's Law Dictionary (11th ed. 2019) defines "drug" in relevant part as a *substance* intended for use in the diagnosis, cure, treatment or prevention of disease. R&TC section 6369(b) makes clear that "medicines" include only those substances or preparations intended for application to the human body, suggesting that the word "drug," which is a type of substance, should be interpreted in a similarly narrow fashion. This notion is further bolstered by the language of Regulation 1591(b)(1) interpreting that statute, which states that "preparations and similar substances" include drugs such as penicillin and other commonly recognized items which are applied to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease. As we find above, CardioGen-82 fails to meet this definition.

We also look to the legislative history for further guidance; specifically, the rulemaking file containing CDTFA's final statement of reasons for promulgating subdivision (a)(9)(A), which states:

"In Section 6369, subdivision (b), the Legislature has provided that the term 'medicines' means '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 commonly recognized as a substance or preparation intended for that use [emphasis supplied].' Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of 'medicines.' Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease. The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles (e.g., certain implants) prescribed or furnished under subdivision (c) of Section 6369.

"The Board concluded an amendment was needed because Board auditors were erroneously assessing tax on sales of prescription items used to treat medical conditions. Specifically, auditors had questioned nontaxed sales of certain items that have a medical purpose when the auditors suspected that the eventual application of the specific item sold was for cosmetic purposes (i.e., for a purpose that is wholly unrelated to the treatment of a medical

condition). The Board has concluded that making a determination as to whether or not an item is sold for an exempt purpose when the item is susceptible to a dual use would improperly require auditors to investigate doctors' practices and question their professional judgment and would require auditors to examine patient records in derogation of the doctor-patient privilege.

"Subdivision (a)(9) – new subdivision (a)(9)(A) [is] added to clarify that certain items approved by the FDA to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition are considered a medicine, except for items excluded from the term 'medicines' in subdivision (c) … ." (Cal. Reg. Notice Register 2006, No. 30.)[6]

It is evident from the legislative history that CDTFA did not intend to exempt all FDA-approved drug products from tax, nor did it consider the situation where an FDA-approved drug product was not intended for application to the human body. Rather, the purpose of this regulatory amendment was to address the concern that CDTFA's auditors were substituting their judgment in place of medical professionals in determining the ultimate disposition and use of an item. There is no language suggesting that CDTFA intended to expand the definition of the word drug to include products which are not applied to the human body or that it should be interpreted by reference to the Federal Food, Drug, and Cosmetic Act. Had CDTFA intended to utilize definitions from other areas of law, it could have easily done so. (See, e.g., Cal. Code Regs., tit. 18, § 1620(b)(5)(A)1 [defining the term "California resident" by specific reference to section 516 of the Vehicle Code].)

Finally, we address the interpretive rule that exemptions from tax are to be strictly construed against the taxpayer. (See *Garret Corp. v. State Bd. of Equalization* (1961) 189 Cal.App.2d 504, 509.) That is to say, any doubt concerning the applicability of an exemption is to be resolved against that exemption. (*American Hospital Supply Corp. v. State Bd. of Equalization* (1985) 169 Cal.App.3d 1088, 1092.) Here, we decide between two interpretations of the word "drug." Appellant's position, which would include items not intended for application to the human body and draws from other areas of law for support, is not only the more expansive interpretation, but it finds no support in the legislative history or in the overall context of the Sales and Use Tax Law pertaining to medicines. We acknowledge that while there are sound policy reasons for creating a bright-line rule that would exempt all FDA-approved drug products, we lack the legislative authority to implement such a rule. (Cf. *Garret Corp. v.*

[6] The rulemaking file is also available from CDTFA upon request.

State Bd. of Equalization, *supra*, at p. 512 [stating that "[c]ourts must take a statute as they find it; if its operation results in inequality or hardship, the remedy is with the Legislature"].)

In considering all the foregoing, we resolve this regulatory ambiguity by finding that CardioGen-82, despite FDA approval, is not a "drug" within the meaning of Regulation 1591 because it is not a substance intended for use by internal or external application to the human body.

HOLDING

CardioGen-82 is not an exempt medicine.

DISPOSITION

We sustain CDTFA's action denying the portion of appellant's refund claim pertaining to CardioGen-82.

DocuSigned by:
Nguyen Dang
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Nguyen Dang
Administrative Law Judge

We concur:

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