BEFORE THE OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

IN THE MATTER OF THE APPEAL OF,	
ANGIODYNAMICS, INC.,	OTA NO. 19075004
APPELLANT.	

TRANSCRIPT OF PROCEEDINGS

Cerritos, California

Tuesday, September 22, 2020

Reported by:
ERNALYN M. ALONZO
HEARING REPORTER

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IN THE MATTER OF THE APPEAL OF, ANGIODYNAMICS, INC., APPELLANT.	OTA NO. 19075004

Transcript of Proceedings, taken at 12900 Park Plaza Dr., Suite 300, Cerritos, California, 91401, commencing at 11:35 a.m. and concluding at 12:31 p.m. on Tuesday, September 22, 2020, reported by Ernalyn M. Alonzo, Hearing Reporter, in and for the State of California.

APPEARANCES:

Panel Lead:	ALJ ANDREW WONG
Panel Members:	ALJ NGUYEN DANG ALJ JOSHUA ALDRICH
For the Appellant:	JACOB BHOLAT
For the Respondent:	STATE OF CALIFORNIA DEPARTMENT OF TAX AND FEE ADMINISTRATION AMANDA JACOBS SCOTT CLAREMON JASON PARKER

I N D E X

E X H I B I T S

(Appellant's Exhibits 1-7 were received at page 6.)

(Department's Exhibits A-D were received at page 7.)

PRESENTATION

CLOSING STATEMENT

Cerritos, California; Tuesday, September 22, 2020

11:35 a.m.

JUDGE WONG: We are now going on the record.

We're opening the record in Appeal of AngioDynamics, Inc., before the Office of Tax Appeals and OTA Case Number 19075004. Today is Tuesday, September 22, 2020. The time is 11:35 a.m. We're holding this hearing by video conference. The location, for the record, is technically Cerritos, California.

I'm lead Administrative Law Judge Andrew Wong, and with today are Judges Nguyen Dang and Josh Aldrich. We are the panel hearing and deciding this case.

Individuals representing Appellant, please identify yourselves and spell your names for the record.

MR. BHOLAT: My name is Jacob Bholat. That's J-A-C-O-B. Last name is B as in boy, H-O-L-A-T. Thank you.

JUDGE WONG: This is Judge Wong. Thank you.

Individuals representing the California Department of Tax and Fee Administration, which I will refer to as CDTFA, please identify yourselves, and spell your names for the record.

MS. JACOBS: This is Amanda Jacobs, A-M-A-N-D-A-J-A-C-O-B-S, for CDTFA.

MR. CLAREMON: And this is Scott Claremon, S-C-O-T-T, last name C-L-A-R-E-M-O-N.

MR. PARKER: And this is Jason Parker J-A-S-O-N, last name Parker, P-A-R-K-E-R.

JUDGE WONG: This is Judge Wong. Thank you.

We are considering one issue today, whether Port-a-Cath systems qualify as exempt medicines.

Mr. Bholat, is that correct?

MR. BHOLAT: This is Jacob Bholat. That is correct.

JUDGE WONG: This is Judge Wong. Thank you.

CDTFA, is that a correct statement of the issue?

MS. JACOBS: Amanda Jacobs. That's correct.

JUDGE WONG: This is Judge Wong. Thank you.

Appellant has identified and submitted proposed Exhibits 1 through 7 as evidence. Appellant has no other exhibit to offer as evidence, and CDTFA has no objections to them. Therefore, Appellant's proposed Exhibits 1 through 7 will be admitted into the record as evidence.

(Appellant's Exhibits 1-7 were received in evidence by the Administrative Law Judge.)

CDTFA has identified and submitted proposed Exhibits A through D as evidence and has no other exhibits as evidence, and Appellant has not objected. Therefore, CDTFA's proposed Exhibits A through D will also be

admitted into the record as evidence.

(Department's Exhibits A-D were received in evidence by the Administrative Law Judge.)

Appellant has no witnesses, and CDTFA also has no witnesses.

Appellant you have 15 minutes. Please proceed with your presentation.

PRESENTATION

MR. BHOLAT: Thank you. This is Jacob Bholat representing the Appellant. Thank you for the time to present our case before this panel.

The Appellant sold permanently implanted catheters found under Revenue and Taxation Code Section 6369, Regulation 1591, and Regulation 1591.1 and collected tax from its customers. The claim for refund was denied by staff based on the language of Regulation 1591(b)(2), paragraph three. The application of this paragraph in question is unsupported by Revenue and Taxation Code 6369, and the Department's misinterpretation creates structural conflict within the regulation and causes unnecessary confusion.

The panel asks us to provide responses to questions from the prehearing conference discussion. We provided an extensive amount of product literature,

medical information from renowned institutions, including the National Institute of Health and the National MPS Society. Also, we provided historical rulings dating back to 1978 that establishes a consistent administrative interpretation that the six-month test has been the determining fact when distinguishing between a permanent and temporary implant.

This consistent administrative interpretation of six-month rule is a long-standing guideline for over 40 years and was established by the Department and accepted industry wide. The legal basis of using consistent administrative interpretation or construction can be found in numerous court decisions and rulings which include, Salbee (sp) Superior Court 2008, GE versus the State Board of Equalization in 1952, and also on Annotations 220.0211 in 1996, 220.0480 in 1994, 570.0480 in 1951.

The panel also asks us to provide legal basis directing the OTA and CDTFA to accept the Board of Equalization's finalized decision to exempt these exact products sold by the exact same retailer on their October 2017 finalized decision ruling in the Appellant's favor. Section 15570.22 of SB86, the Taxpayer Transparency and Fairness Act of 2017 states the following:

All laws prescribing the duties, powers, and

responsibilities of the Board to which the Department succeeds together with all lawful rules and regulations established under those laws are expressly continued enforced."

Expressly continued enforced, that is a fundamental statement within the landmark legislation, California Code Regulation Title 18 Division 4.1, which provides the legal foundation for the Office of Tax Appeals. Section 30106 transferred the BOE jurisdiction to the OTA over all appeals heard after January 1st, 2018. All prior matters were legally decided by the BOE, unless the decision was not finalized.

Since the hearing was completed in October 2017 and, thus, finalized 30 days later, that decision should be accepted by both the CDTFA and OTA becoming a part of Section 15570.22, which requires that lawful rules regulations are expressly continued as enforce as enacted by the legislature. Ignoring legal jurisdiction of the BOE at that time directly violates the legislature's intent under this Taxpayer Transparency and Fairness Act for continuity, fairness, and protecting taxpayer's rights, and fails to meet the legislature's direct guidance.

Now, I'd like to get into more information about the product. Permanently implanted catheters included in

this refund claim are intended for a long-term implantation and generally implanted between two to six years. You can find that in Exhibit 5. The implant is sutured in place at the port location beneath the skin. The vessel is punctured, and the catheter is sutured in place where the catheter enters the vessel system. Thus, the entire implant is tied into the vascular system as illustrated in Exhibit 4.

Based on Exhibit 3, ports are implanted for patients who require long-term access. These patients are at high risk of collapsing veins and vessels and also infection. The damage would impair normal blood flow in the overall vascular system. The products assist the vascular system by reducing risk from occlusion, which is clotting, blockage, and/or collapse, so that the blood can continue to flow normally; which is the primary function of the vascular system.

The needle no longer enters the vessel or vein, thus, protecting and assisting the patient's vascular system for normal function. It also risk some infection -- sorry. It also reduces the risk of infection for patients who require consistent access to their vascular system by providing an alternative safe access point, which is standard from the vessel to the skin.

This product is surgically implanted in a

separate procedure. Our claim only includes items that were implanted. Any items that are from the skin to the outside of the patient's body are not being claimed. Our basis for exempt treatment. In 2017 the board clearly decided these items are exempt from taxes, permanent implants. The following logic was applied and should be continued enforce to conclude that these items should remain exempt qualified permanent implants, supporting the legislature's intent for continuity.

First, the device has been considered to be permanently implanted if its removal is not otherwise anticipated for more than six months. All parties agree that these products met that qualification, both in the BOE 2017 hearing and all prior appeals related to both cases. Second, Revenue and Taxation Code 6369 exempts as medicines, permanently implanted items that assist the function of the body.

Merriam-Webster defines this as "to give support or aid." Another definition is "an act or action that helps assist does not mean replace." The decision provided by appeals takes an unsupported narrow application of the assist the function concept that is not supported by regulation or law or the accepted definition of these words. The decision claims that unless the catheter conducts blood flow, it does not assist the human

body.

This concept has no basis within the law section or regulation. Regulation 1591 exemptions include, tissue markers, IV and enteral feeding tubes, integral related bags, tubings, filters, locks, tapes, clamps, connectors. Also exempt are wigs and hair pieces under a prescription. All of these items and many numerous others qualify the support and/or assist the human body within the same regulation.

Why then would an implanted catheter used to stabilize and protect the patient's vascular system be excluded. These exempt products listed contradict the mistaken decision -- sorry. These exempt products contradict the mistaken decision's narrow application of assist and/or support.

The appeals decisions conduct blood flow have no basis in law, regulation, or administrative interpretation. Annotation 425.0724, which provides a similar logic, again, provides no legal foundation. The Department relies on the annotation excerpt but fails to fully evaluate the prevailing law Section 6369 and two regulations. In fact, the back-up letter published on the CDTFA's website only provides an analysis of the Port-a-Cath product to a programmable drug infusion device, and has no mention of any analysis on the

permanent implant application.

The published annotation doesn't have any backing of the full response from legal. They likely don't want to publish this because they have no legal basis for this flawed logic. Again, there's no detailed analysis of the permanent implant language. It is a simplistic analysis with no basis in law related to the concept of permanent implant. Yet, it is being used as the bases to the Department's argument.

Regulation 1591.1(b)(4)(B) exempts catheters which are permanently implanted in the human body and assist the function of a natural organ, artery, vein. This item is a permanently implanted catheter which assist the arteries and veins or vascular system. This Regulation 1591.1 clearly exempts this product with no question.

The Department's misinterpretation of Regulation 1591 creates major application issues. Regulation 1591(b)(2) unnumbered paragraph 3 states the following: Implanted articles do not qualify as permanently, in quote, "implanted medicines include but are not limited to," and then it list temporary implants, including the Port-a-Cath system.

Language under subdivision (b)(2) paragraph 3 specifically emphasis the word permanently in quotation.

This language can be interpreted two different ways. The language specifically excludes the items listed in the paragraph, which is the position of the Department, disregarding the emphasized permanent in quotes. Or two, it excludes items which are temporarily implanted and should not be taken as a 100 percent list, which is also clearly stated in the paragraph.

The quotation marks are added as an emphasis to exclude only temporary items, which is our position and consistent with the balance of Regulation 1591, Regulation 1591.1, and Revenue and Taxation Code 6369, then there is a large construction issue with the regulation in a never-ending circular reference. One place that says taxable when taken out of context, two places it provides a clear exemption.

Why do we have this problem in this regulation? The list of examples in paragraph 3 included items that were not permanently implanted at the time the section was added. Pages 7 to 11 of Exhibit 6 provides a historical timeline of the development of this technology. Not until the 1980s was a port implanted permanently for long-term use. So after this period, this paragraph list of items, which included the Port-a-Cath became obsolete.

The Board address this issue to correct it on two occasions. However, the Department continued to violate

the legislator's intent by ignoring these direct mandates. Today the Port-a-Cath systems included in this claim are permanent implants and assist the natural function of the artery system within a patient requiring long-term care in order to prevent long-term difficulties associated with collapsing veins and arteries, damage to their blood system, and increased risk of infection, and a better quality of life.

Next, I would like to go through the historical application of permanent implants. I have served clients in the healthcare industry for over 20 years. Since 2001, higher level decisions of products that were implanted have 100 percent of the time have been determined that permanently implanted items qualify as exempt medicines, going against the Department's various historical positions.

In every case the products being taxable by the Department were exempted by the higher levels. This list includes dental bone screws and abutment, cochlear hearing implants, including external integral components, cosmetic implants, regardless if the procedure is selective or reconstructive, and most recently, monitoring devices in breast tissue markers.

Also in 2017, after an extensive analysis and discussion of this product, was determined to be exempt.

However, the Department chose to ignore that decision. In November 2014, the Business Tax Committee held board meetings in response to the cases related to the breast tissue markers.

The treatment of the permanently implanted Port-a-Cath systems was discussed along with the regulation revision. This product was brought up because at that time those items were being held in abeyance by the Department pending the regulation revision. Based on the business tax committee minutes, this exact paragraph, Section (b)(2) paragraph 3 was modified. And the sentence as stated is that these items in the paragraph here as taxable was removed. This was a step forward in the right direction to remove the conflict, however, it was not enough. The Board recognized this issue and asked the Department to provide clarification in the Audit Manual, which was never done by the Department.

In conclusion, we respectfully request that the OTA determine that Port-a-Caths are exempt permanent implants qualify under Revenue & Taxation Code 6369, Regulation 1591, and Regulation 1591.1. This will also carry through the legislator's intent for continued fairness by accepting the BOE's accurate rightful legal decision. And it will guide the Department to correct the inaccurate language in Regulation 1591(b)(2) paragraph 3.

This paragraph should be modified to clearly guide the segregation of temporary versus permanent. The list of examples need to be modified to remove this product now that it is confirmed as permanent. This language should be updated also to clarify that this paragraph only applies to temporary implant.

Thank you. This concludes my opening statement.

JUDGE WONG: This is Judge Wong. Thank you, Mr. Bholat.

I will now turn to my panel to see if they have any questions. Judge Aldrich, do you have any questions for Appellant?

JUDGE ALDRICH: Yeah, I have a couple of questions. So you referenced a prior claim, and I understand that was a claim that was filed April 25, 2012; is that correct?

I can't hear you. I'm sorry. You muted yourself.

MR. BHOLAT: Could you repeat that question because I didn't hear you very clearly.

JUDGE ADLRICH: Okay. So during your opening argument you referenced a prior claim that went to decision and ultimately to a hearing. And are those the decisions in the hearing notes referenced in the exhibits? So I have that as a decision issued August 9th, 2016, with

a hearing date of October 24th, 2017.

MR. BHOLAT: That was a Board of Equalization hearing in October of 2017.

JUDGE ALDRICH: Yeah. Is it your position that's a precedential decision, or is it not?

MR. BHOLAT: I don't think we tried to address that question. I think we bring it up and reference it because the -- the higher body decided that. I think our position is that, if you look at the way legislation was set up, there was the concept of continued to enforce. And so when you look at the legislation to enact the Department's structure and the OTA's structure, there was a transition that was made. And the October 2017 decision was finalized.

And within that decision, which is a public decision, there's also guidance to the Department to take corrective action. However, that was never taken. So clearly the Board, which had the legal right to make that decision directed the Department to make corrections and ruled in our favor. Whether there's a direct legal answer of yes, this is a, you know, an absolute decision and you have to follow it, I'm not -- I'm not qualified to make that decision.

But I think what we've done is presented as much facts as we can in terms of information and laws and rules

that support the position that that decision should have been carried forward.

JUDGE ALDRICH: Okay. Thank you. No further questions at this time.

JUDGE WONG: This is Judge Wong. Thank you.

Judge Dang, do you have any questions for Appellant?

JUDGE DANG: This is Judge Dang. I do have one question for you, Mr. Bholat. I'm wondering if you could please show me where in the record it demonstrates that the Port-a-Cath is indicated with patients with either collapsed veins or some other form of blood flow issue?

MR. BHOLAT: So you're looking at a situation where it is a -- so you have a patient who has a long-term access requirement. And you have a situation where the medical staff understands that the person is going to have repeated access to the vessel -- vascular system. So this is an implant that's put in place as a preemptive measure to avoid that generally.

Now, if a patient has a -- has already a collapsed vein or has that issue, they're going to put that in. However, I don't think the product literature says, oh, you should put this in after the fact. It's put -- generally, it's put in as soon as they determine that this person is going to need repeated long-term

access.

JUDGE DANG: Thank you, Mr. Bholat. So just to make sure my understanding is correct, this is more of a preventative measure. So it's just in the sense that it prevents issues from continued access to the vein or artery, but not in essence medicine to correct preexisting conditions for that.

MR. BHOLAT: Sorry. This is Jacob. I would say, yes. But I also would say it's not a situation where they're not -- if there's already a damaged vessel, they're not going to not put it in. So if the patient is already having problems, and they put this port in after the fact, that's still the same scenario. It's going to be that patient needs continuous access for long periods of time. And so the reason they put it in is to avoid that damage. Because once the damage occurs, now you have a problem where the vascular system no longer functions properly. So therefore --

JUDGE DANG: Thank you. This is --

MR. BHOLAT: I'm sorry.

JUDGE WONG: I'm sorry. Thank you. This is Judge Dang again. So would it be fair to say, in your opinion, that another use of catheter is access to the artery or vein, the more permanent access?

MR. BHOLAT: Is it a very -- it is a part of the

process, so I would say yes. I think to look at it and say it's only an access point would be unfair to the -- would be a misrepresentation of the true intent of that product. The true intent of the product is to make sure that patient has proper blood flow through their body. And they go through a special procedure of implanting this in a separate procedure. It's not part of, like, when the patient is in the bed.

They will take them in to have a separate procedure done. They'll do the implantation. They suture the items into the skin. They suture the item into the catheter, which -- or into the vessel where the catheter enters. So they are sealed in both places. And so it's basically a connection or an extension of the vascular system to the skin and so at that point, rather than the needle going into -- directly into the vessel where it's going to cause damage.

The consistent access to it is going to cause it to damage. It's going to cause it to collapse. And so what they'll do is -- the whole concept of this product is to protect the vascular system, so that when they have the access point, which is a flexible rubber cover -- it's probably silicone. But every time it's accessed, it is self-healed. It self-closes. And so it's basically an extension from the vascular system to the skin.

JUDGE DANG: Thank you so much. I have no further questions at this time.

JUDGE WONG: This is Judge Wong. Thank you. I had one question for Appellant. Mr. Bholat, the Board decision that you're referencing involve the same taxpayer, same product. But was it for a prior claim period? It's not the claim period at issue; is that correct?

MR. BHOLAT: This is Jacob Bholat. I apologize. I forgot to announce myself. Yes, that is correct. It was for the prior I think two or three-year period to this claim; and the exact same product, exact same customer, exact same vendor. Everything was exactly the same.

JUDGE WONG: This is Judge Wong. Thank you. I have no further questions.

Now we turn to CDTFA for their presentation. They have 20 minutes.

You may proceed.

PRESENTATION

MS. JACOBS: This is Amanda Jacobs for CDTFA.

Appellant is seeking a refund of sales tax reimbursement collected and remitted to CDTFA on behalf of its customer, the University of California San Francisco Medical Center or SFMC, on its sale of port catheters or

Port-a-Caths.

It's undisputed that the medical devices were purchased by SFMC, and that Appellant charged and collected sales tax reimbursement from SFMC on these sales. It has never been disputed that port catheters were used for drug infusion. The only issue is whether Port-a-Caths when used for drug infusion qualifies as medicines for purposes of the exemption.

Under the Revenue & Taxation Code Sections 6012 and 6051, sales tax applies to a retailer's gross receipts from the retail sale of tangible personal property in this state, unless the sale is specifically exempt or excluded from a taxation by statute. Section 6369, which is interpreted and implemented by Regulation 1591, exempts from sales and use tax the gross receipts from the sale of and the storage use or consumption of medicines as defined if they're dispensed or otherwise provided to the patient for certain specified circumstances.

As relevant to this appeal, 6369(b)(2) excludes from the definition of medicines articles that are in the nature of splints, bandages, pad, 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.

However, 6369 (c) provides exceptions to that exclusion, including permanently implanted articles that assist the functioning of a natural organ, artery, vein, or limb, and which remain or dissolve in the body. Regulation 1591(b)(2) further clarifies that this exception -- further clarifies this exception and specifically states that Port-a-Cath systems used for drug infusion purposes, quote, "Do not qualify as permanently implanted medicine," end quote.

The statutes granting a tax exemption are strictly construed to avoid enlarging our extending concession beyond the plain meaning of the language used in granting it. See Associated Beverage Co. Versus Board of Equalization, 1990 224 Cal.App.3d 192. Appellant bears the burden of showing it clearly comes from within the terms of the exemption by a preponderance of the evidence. See regulation 35003(a) and Paine versus State Board of Equalization 1982 137Cal.App.3d 438.

Here a port catheter sold by Appellant were used for the purpose of drug infusion. Regulation 1591(b)(2) categorically states that Port-a-Cath systems used for drug infusion purposes do not qualify as permanently implanted medicines. This is consistent with several other definitions set forth in 1591(b), including orthotic devices in (b)(4) and prosthetic devices in (b)(5), which

also list items that do or do not meet the definition. But there's no difference here.

This provision is not subject to an interpretation of Port-a-Cath's use for drug infusion purposes could meet the definition of medicines in subdivision(b)(2). Therefore, it's not necessary to assess whether these devices fail to meet the specific element of Regulation 1591(b)(2). The Department must be faithful to its own regulations, which are quasi legislative and have the force and effect of law. See California Teachers Association versus California Commission on Teach Credentialing 2003, 111Cal.app.4th 1001.

Furthermore, as the Office of Tax appeals has recognized in precedential opinion in the matter of the Appeal of Alfred Jake Talavara, OTA does not have an authority to declare a CDTFA regulation invalid or refuse to follow it; Case No. 1801185. These facts alone are sufficient to deny Appellant's claim. However, to address Appellant's contentions today and to respond to the panel's request made at the prehearing conference, we will discuss the specific elements of the definition set forth in 1591(b)(2).

Revenue and Taxation Code 6369(c)(2) states that medicine include articles permanently implanted in the

human body to assist the functioning of any natural organ, artery, vein, or limb, and which remain or dissolve in the body. Regulation 1591(b)(2) clarifies that an article is considered to be permanently implanted if its removal is not otherwise anticipated.

Thus, to be considered permanently implanted for the purposes of the exemption, the medical device must both one, assist the functioning of any natural organ artery, vein, or limb; and two, remain or dissolve in the body such that its removal is not anticipated. As to the first element, the device at issue fails. When used for the purpose of drug infusion, a Port-a-Cath does not assist the functioning of a natural organ, artery, vein, or limb.

The purpose of a vein is to conduct blood flow. According to the materials Appellant provided, the purpose of a Port-a-Cath is to act as a portal into the vein for ease of access into the vascular system. In Appellant's Exhibit 3, page 21 in the exhibit binder and highlighted by Appellant, we find the port catheter is inserted into a blood vessel to deliver therapy from the port body into the bloodstream. Dispersal of drugs is not the vein's natural function.

Later on page 23, the literature states that the most frequent use of the port is for, quote, "vein

access". It defines this as a way of entering certain blood vessels in the body. Intravenous access is not a natural function of the human body. As such, Port-a-Cath systems used for drug infusion purposes, whether or not they remain or dissolve in the body, would be excluded from the definition of medicines under subdivision (b)(2) because they do not assist the functioning of any natural organ, artery, vein, or limb.

This has been a long-standing position of the Department as evidence by Annotations 425.0724 and 425.0247. Appellant argues that Port-a-Cath systems used for drug infusion purposes were explicitly excluded from regulation 1591(b)(2) only because they were only deemed to be implanted for less than six months. These annotations, which predate the amendment adding the specific exclusion of Port-a-Cath systems, show that this is incorrect.

The panel requested we address whether Port-a-Cath are permanently implanted and whether sales and use Tax Annotation 425.0163 applies in this case. We presume the panel wants us to address the second element of 1591(b)(2), whether or not this device remains or dissolves in the body such that its removal is not anticipated. Appellant's device appears to be intended to remain in the body beyond six months.

However, as already discussed, Port-a-Caths are specifically excluded as permanently implanted device by regulation. And even if they were not specifically excluded, in order to qualify as a permanently implanted article for purposes of the exemption, the device must meet both elements. Which this device does not.

Finally, we have provided the rule making documents for the most recent amendments to regulation 1591, and specifically subdivision (b)(2), including the second discussion paper and formal issue paper 14-006 as Exhibit C and D. These exhibits show that Mr. Bholat recommended amendments to the final paragraph of Regulation 1591(b)(2), the paragraph in which Port-a-Cath systems are specifically excluded from the exemption.

His recommendation included both a suggestion to remove this specific exclusion for Port-a-Cath systems used for drug infusion purpose, and to add an additional phrase to (b)(2) indicating items specified as not constituting permanently implanted medicines are taxable only, quote, "If intended for temporary implantation," end quote. See Exhibit C, PDF pages 114 and 135 to 136 and Exhibit D, pages 161 and 164.

In other words, Mr. Bholat recommended amendments that would have made explicit what he is arguing today. His recommendations were rejected by the Board. In

professing of his proposed amendments and consistent with Annotations 425.0724 and 425.0247, the issue paper states, quote, "Some of the items listed in the paragraph," -- that's the final paragraph of 1591(b)(2) -- "failed to meet the definition of medicine contained in subdivision (b)(2) not because they are not permanently implanted, but because they do not assist the functioning of a natural organ, artery, vein, or limb." See Exhibit D, page 161.

Appellant argues that these items support the natural functioning of arteries, veins, and blood vessels by providing support so that they do not collapse or become damaged. And, therefore, argues that they do assist in the functioning of a natural organ, artery, vein, or limb. We again note that the Regulation 1591(b)(2) specifically states that Port-a-Cath systems used for drug infusion purposes do not qualify as permanently implanted medicines.

Therefore, it should not be necessary to assess whether these devices fail to meet a specific element of 1591(b)(2). However, a review of Appellant' the product materials also shows that the only reason the veins would become damaged or collapse is the repeated access to the bloodstream. And the purpose of a Port-a-Cath is to allow repeated access without damage. Again, intravenous access is not a natural function of the human body.

Appellant references to other devices such as breast tissue markers. However, while Port-a-Cath were specifically excluded from subdivision (b)(2) by definition, breast tissue markers are specifically included, as also explained in Exhibit C and D. Appellant also argues that the removal of the formal final sentence, quote, "The sale or use of these types of items would be subject to tax," end quote, from subdivision (b)(2) could allow this product to be exempt.

However, as Exhibit D shows, that sentence was removed to clarify the specific articles that do not qualify as permanently implanted medicines under (b)(2) may meet the definition of medicines under a different subdivision. See Exhibit D, pages 158 and 161. Removal of that sentence had no effect on the applicability of subdivision (b)(2) to those items.

Finally, as requested by the panel, we address whether OTA is bound by any prior Board of Equalization decision in this matter. To be clear, there has been no prior Board of Equalization decision in this matter. We presume this is a reference to the BOE's October 24, 2017, oral hearing related to a refund claim for the period January 1, 2009 to June 30th, 2011. That matter is not before us today. This is a new refund claim for a different period for tax paid on different transactions.

Therefore, OTA has jurisdiction to hear and decide this appeal with the authority granted to it by Rules For Tax Appeals Section 30103 subdivision (b). Appellant presented argument as to why the Board's decision should be accepted by CDTFA and OTA and references Government Code Section 15570.22. However, this is not a matter of continuing lawful rules and regulations. Nor is this a matter of overturning a prior decision by the Board of Equalization.

Furthermore, an administration decision, even when involving the same taxpayer, may not be relied upon as precedent unless it is so designated by the agency. See Government Code Section 11425.60(a) and see Sheet Metals Workers Association -- International Association Local Union Number 104 versus Rea 2007 153.Cal.app4th 1071. Even former Section 5551(b)(4) of Board of Equalization Rules For Tax Appeals in effect at the time of the 2017 oral hearing stated, quote, "Non-precedential opinions may not be cited as precedent in any manner or other proceeding," end quote.

No precedential opinion followed the October 24th, 2017, oral hearing. As such the outcome is not precedent and by law cannot be relied upon as such. We also note that in the 2017 hearing, the Board failed to follow its own regulation as required of it by California

law. See Newco Leasing, Incorporated versus State Board of Equalization 143 Cal.App3d 120, cite 124; which states, the BOE's interpretation of the legislative must be reasonable, and the Board must be faithful to its own regular regulations.

In summary, the port catheter sold by Appellant were used for the purpose of drug infusion. Regulation 1591(b)(2) unambiguously states that Port-a-Cath systems used for drug infusion purposes do not qualify as permanently implanted medicines. Even if they were not specifically excluded by regulation, they do not assist the functioning of a natural organ, artery, vein, or limb. Therefore, Port-a-Cath systems used for drug infusion purposes do not qualify as medicines for purposes of the exemption.

Appellant has not met its burden of proving these transactions are entitled to exemption from sales tax and a refund is not warranted. For these reasons we request the appeal be denied.

Thank you.

JUDGE WONG: This is Judge Wong. Thank you.

I'll now turn to my co-panelists for any questions for CDTFA. Judge Aldrich, do you have any questions?

JUDGE ALDRICH: I do not at this time. Thank

you.

JUDGE WONG: This is Judge Wong. Thank you.

Judge Dang do you have any questions?

JUDGE DANG: This is Judge Dang. I do have a question for you, Ms. Jacobs. The second sentence of subdivision (b)(2), it states that an article is considered to be permanently implanted if its removal is not otherwise anticipated. You had mentioned on several occasions that CDTFA must be faithful to its own regulations. I'm wondering if perhaps you know the rationale for why -- for the policy or CDTFA's position today that something is permanently implanted if it remains -- if it's anticipated to remain in the body for a period of at least 6 months, given the language here on this subdivision?

MS. JACOBS: I'm not sure I understand the question.

MR. CLAREMON: This is Mr. Claremon. I think as a general principle, often six-month timeline is substituted for a law that sets forth a permanent or -- or no timeline at all. For instance, when something is being presumed to be used in California, it's generally we -- we -- the -- the rule of thumb we use colloquially is forever equal six months, basically. So often you will see a six-month test applied to a timeline that's

essentially permanent.

JUDGE DANG: This is Judge Dang speaking. And thank you for that explanation. Would it be appropriate to use a colloquial, as you put it, definition when the -- it appears we have a technical definition here, the regulation, that permanent means no removal anticipated?

MR. CLAREMON: Yeah, I'm not -- I mean, I'm not sure about the question of appropriateness. You know, as the annotation states, the general rule is that if something is intended to remain in the body for more than six months, we consider it to meet this test. Or I'm not -- I don't know if we can respond to the appropriateness of that annotation.

JUDGE DANG: This is Judge Dang. Thank you for your response. I don't have any further questions at this time.

JUDGE WONG: This is Judge Wong. Thank you.

Now, we turn back to Mr. Bholat for rebuttal and closing remarks.

You have 10 minutes. You may proceed.

CLOSING STATEMENT

MR. BHOLAT: Thank you. This is Jacob Bholat.

So first I wanted to address some of the items that Ms. Jacobs brought up. I don't think we in any way

have intention of contradicting or questioning the OTA's jurisdiction in this case. We do cite that prior case again, because it's the exact same product, exact same customer, exact same retailer. The only difference is the period of time.

Due to the transition that October 2017 decision was not afforded the time to update the regulation. However, when you read the language of the discussion of the Board members, they actually advise the Department that they should take this matter up and to further make clarifications in the regulation. However, because of the transition of power, that process was never taken up.

Related to the breast tissue markers that Ms. Jacobs cited as being specifically in the regulation, that regulation update was done because of a Board position where it exempted the product. And in that situation the Department argued that because that marker -- all the marker does is it's placed inside the human body. It is marking a location, and that's all it's done.

It's done in cancer patients so that when the physicians or medical staff goes back to evaluate future changes of that -- of the cancer and evaluate the status of it, they know where that cancer was located. So clearly in that position, that also supports that the

permanent implant in itself should be deemed to be exempt.

The -- Ms. Jacobs assertion that the -- in the 2014 regulation revision that our recommendations were rejected, is partially true. We recommended that the regulation be revised to exclude that product from the list of temporary implants. However, the Board didn't deem that they had the jurisdiction in that situation to make that decision. So what they did do was, they did strike out the sentence that says this item is subject -- these items are subject to sales tax to provide clarification.

They also asked and requested that the Department make revisions in the audit manual to help provide clarification. Again, that was not done. Further backing up their position in 2017, three years later, their analysis in this same scenario with the same products when we brought them up was to rule in favor of the Appellant. So clearly their recommendation, their decision was that anything permanently implanted is exempt from tax. The Board's slicing and dicing of what is and is not, is not accurate.

The other thing that I would like to point out, which is a language issue that Ms. Jacobs used in her reading of Regulation -- or sorry -- Revenue & Taxation Code 6369 Section(c)(2). It says -- Section (c) says

notwithstanding subdivision (b) medicines as used in this section mean and include any of the following. And I'm reading this specifically out of the language. It says, bone screws, bone pins, pacemakers, and other articles other than dentures, permanently implanted in the human body to assist the function of any natural organ, artery, vein, or limb, which remains or dissolves in the body.

In her presentation, she split the word natural in the position of the word natural. Her argument was is that it doesn't assist the natural function. That's not what the law section says. It actually says the natural organ. So it doesn't say that it has to assist the natural function. It only has to assist any function within the body. I that think the Department's continued argument that it has to conduct blood flow. It is clearly not supported anywhere in the regulation, anywhere in the law section.

In fact, that position contradicts everywhere else in Regulation 1591. And, in fact, 1591.1 specifically exempts permanently implanted catheters with no exception. So if you take the Department's position that well, because specifically the language taken out of context in paragraph 3 of (b)(2) is taken out of context, it says this item was taxable, well then it conflicts directly with 1591.1. It conflicts directly with

Revenue & Taxation Code 6369. It conflicts directly with Regulation 1591(b), the first part.

And the definition, the permanent, I think we've already gone through. I don't think anybody argues that. So when we look at their analysis, they keep coming back to well, it's specifically excluded. However, when you read the paragraph, the words permanently are in quotation, and that's to provide emphasis. And the emphasis is that items that are not permanently implanted are subject to tax.

Nobody argues with that position. If it's in there for less than six months, it doesn't qualify as an implant. It may qualify somewhere else, but it doesn't qualify as an implant. When you look at all of the items listed in that paragraph, all of them are temporary implants. At the time they were all temporary implants when that section was added to the Regulation. However, as we point out in our presentation earlier, in the 1980 that technological evolution changed.

And so, therefore, that portion of leaving that item in that list became obsolete. And so it needs to be removed, which is what we've been trying to do for the last four years or five years. And so when we look at that, the only revision that needs to be made in the Regulation, in my opinion -- and I've been doing this a

long time, and I have analyzed tens of thousands of products. And that is that that product needs to be removed because it's no longer a temporary implant.

That section and that paragraph needs to be strengthened to clearly establish that permanent implants are exempt and temporary ones are not. And that's what that caveat that paragraph should be at. So I wanted -- what I wanted to do is to, again, go back to the structure of Revenue & Taxation Code 6369. In that section the ultimate goal is defining a permanent implant.

That language as I read earlier provides a very clear description of a permanent implant. It says notwithstanding subdivision (b), and then it goes to list bones screws, bone pins, various other thing permanently implanted in the human body to assist the function of any natural organ, artery, vein, or limb, and which remains or dissolves in the body. The Department's decision discusses standards to meet that term, permanent.

Within the language of the law, there's no distinction, qualification, or exemption to permanently implanted item that is administered to a patient under a prescription other than dentures. They only have one exclusion. They define permanently implanted exempt, only exclusion they give is dentures. The law section uses the term notwithstanding subdivision (b), which defined in the

dictionary, as in spite of. Which, again, clearly indicated a legislator's intent to exempt all permanent implants, ignoring subdivision(b) limitations when it comes to a permanent implant.

The application of Regulation 1591(b)(2), paragraph 3, should be construed only to exclude temporary implants and nothing else. As Judge Dang had said earlier -- asked a question earlier; if an item is permanently implanted, it goes into the spirit of law that that item is an exempt medicine, period. The term permanent has been agreed and accepted as six months or longer. The examples in the regulation language, paragraph 3, were used to illustrate potential temporary products at that time. This should not include any implanted items that remain in the body for more than six months through technological evolution.

Now, that the product has changed, it should be removed from that list. The position to tax a permanent implant is not supported by the Law Section 6369 in any way possible. Whatever the regulations says, the law sections is clear. The Department has conceded for over four years, since this case has started, that these Port-a-Cath are implanted for more than six months. Thus, they are permanently implanted in the patient. I already went through all this.

I'm reading through my notes, so forgive me. The discussion during the BTT to remove that specific sentence where I stated the items were subject to sales tax, that's an important step forward because it helps provide clarity to the application of that paragraph within the Regulation. But the Department didn't carry through the mandate to provide further guidance in the audit manual.

Again, the lack of any exception in Law Sections 6369 and the language clearly indicates that any item qualified under Regulation 1591 or 1591.1 and implanted for more than six months meets the exemption of a permanent implant.

Finally -- and I don't know we've said this over and over again, there's a major conflict within the Regulation 1591 and 1591.1, if this paragraph is taken out of context as the Department --

JUDGE WONG: This is Judge Wong. Mr. Bholat, sorry for interrupting. Your 10 minutes are up, if you could just finish up. I know you said finally, but if -- I'll give you, like, 30 seconds to finish up.

MR. BHOLAT: Perfect. Regulation 1591 clearly exempts permanently implanted catheters -- sorry. Regulation 1591.1 clearly exempts permanently implanted catheters, no limitation, no exception. The only exception is dentures, and that's it. Paragraph 3 when --

again, when taken out of context, it creates a conflict within the law and within the regulation -- within Regulation 1591.1. And it makes no sense when it is applied the way the Department is applying it.

Thank you, again, for the presentation and the extra time.

JUDGE WONG: Thank you, Mr. Bholat. This is Judge Wong.

Now I'll turn to my co-panelists for any final questions. Judge Aldrich, do you have any questions?

JUDGE ALDRICH: This is Judge Aldrich. I don't have any final questions.

JUDGE WONG: This is Judge Wong. Thank you.

Judge Dang, do you have any final questions?

JUDGE DANG: This is Judge Dang. Thank you, Judge Wong. I do not have any final questions.

JUDGE WONG: This is Judge Wong. Thank you. I also have no final questions.

Accordingly, this concludes the hearing. The record is closed, and the case submitted today. The Judges will meet and decide the case base on the exhibits presented and admitted as evidence.

We will send both parties our written decision no later than 100 days from today. The hearing is now adjourned. Hearings for today are adjourned until

tomorrow at 10:00 a.m. Thank you all.

And now we're off the record.

(Proceedings adjourned at 12:31 p.m.)

HEARING REPORTER'S CERTIFICATE

I, Ernalyn M. Alonzo, Hearing Reporter in and for the State of California, do hereby certify:

That the foregoing transcript of proceedings was taken before me at the time and place set forth, that the testimony and proceedings were reported stenographically by me and later transcribed by computer-aided transcription under my direction and supervision, that the foregoing is a true record of the testimony and proceedings taken at that time.

I further certify that I am in no way interested in the outcome of said action.

I have hereunto subscribed my name this 1st day of October, 2020.

_____
ERNALYN M. ALONZO
HEARING REPORTER