BEFORE THE OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

IN THE MATTER OF THE APPEAL OF,	
REGENTS OF THE UNIVERSITY OF CALIFORNIA,	OTA NO. 19064889
APPELLANT.	

TRANSCRIPT OF PROCEEDINGS

Cerritos, California

Wednesday, August 19, 2020

Reported by:
ERNALYN M. ALONZO
HEARING REPORTER

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Transcript of Proceedings, taken at 12900 Park Plaza Dr., Suite 300, Cerritos, California, 91401, commencing at 10:00 a.m. and concluding at 11:24 a.m. on Wednesday, August 19, 2020, reported by Ernalyn M. Alonzo, Hearing Reporter, in and for the State of California.

APPEARANCES:

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

I N D E X

E X H I B I T S

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

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

PRESENTATION

CLOSING STATEMENT

Cerritos, California; Wednesday, August 19, 2020

10:00 a.m.

JUDGE DANG: Good morning everyone.

We're opening the record in the appeal of the Regents of the University California before the Office of Tax Appeals. The case number is 19064889. It is currently 10:00 a.m. on August 19th, 2020.

Consistent with the Governor's Executive Order Number 25-20 to reduce and minimize the spread and risk of Corona virus infection and with the agreement of the parties, this hearing is being conducted via Webex Video Conferencing.

Today's case is being heard and decided equally by a panel of three judges. My name once again is Nguyen Dang, and I will be the lead judge for purposes of conducting this hearing. Also on the panel with me today are Judges Andrew Wong and Joshua Aldrich.

At this time will the parties please state their appearances, beginning with Appellant.

MR. BHOLAT: This is Jacob Bholat representing the Appellant.

JUDGE DANG: Thank you. And CDTFA.

MR. BACCHUS: Chad Bacchus with the Department.

MR. CLAREMON: And Scott Claremon with the

Department.

MR. PARKER: And Jason Parker with the Department also.

JUDGE DANG: Thank you.

As previously discussed at the prehearing conference, the sole issue presented in this case is whether CardioGen-82 is an exempt medicine.

Mr. Bholat, is that correct?

MR. BHOLAT: That's correct.

JUDGE DANG: Thank you.

And CDTFA, is that correct?

MR. BACCHUS: Yes, that is correct.

JUDGE DANG: Thank you.

Prior to the hearing today, the parties were provided with a copy of the Exhibit hearing binder for this appeal. The binder contains Appellant's Exhibits 1 through 6 and Respondent's Exhibits A through G as we have received them.

Mr. Bholat, did you have a chance to review that hearing binder? Does it appear correct to you?

MR. BHOLAT: Yes, it does. Thank you.

JUDGE DANG: And do you have any objections to the admission of this hearing binder into evidence?

MR. BHOLAT: No, I do not.

JUDGE DANG: Thank you.

And CDTFA I'm going to ask you the same questions. Did you receive the binder? Any issues with it?

MR. BACCHUS: Chad Bacchus with CDTFA. Yes, we received the hearing binder, and we do not object to any of the exhibits.

JUDGE DANG: Great. Thank you.

Hearing binder containing the parties' exhibits for the appeal is now admitted into evidence.

(Appellant's Exhibits 1-6 were received in evidence by the Administrative Law Judge.)***

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

Okay. Mr. Bholat, if you're ready to begin with your presentation, you will have 15 minutes.

MR. BHOLAT: Thank you.

PRESENTATION***

MR. BHOLAT: Again, my name is Jacob Bholat. I am representing the Appellant. Thank you for the time and opportunity for us to present our case before the Office of Tax Appeals.

As you stated earlier the Department's decision to ignore FDA's direct classification and the incorrect application of historical rulings remains our single

disagreed issue with the appeals decision dated, May 2nd, 2018. This disagreement stems from the purchase of a drug product made by UCSF Medical Center from Bracco Diagnostics. The drug is marketed under the name CardioGen-82. I will refer to it as RB-82, which is the actual drug name, for this presentation.

This drug meets the requirements of an exempt medicine as a preparation substance when carefully examined under Section 6369 and Regulation 1591. Our submissions and exhibits provides the panel with a logical basis of how this product falls squarely within the definition of an exempt medicine, and why the Department misses the mark on just trying to rely on rulings. They are completely unrelated to how RB-82 is used, sold, and injected into the patient.

First, I would like you to refer to Exhibit A and B, specifically, pages 104 to 107 in the package, which provide FDA approved published information about the drug and support the following undisputed facts. The FDA recognizes CardioGen as an approved injectable radioactive drug with an active ingredient of Rubidium RB-82 Chloride manufactured by the exact retailer for the questioned transaction.

The drug is sold with the following component: Medication, which is absorbed on a stannic side strip used

to hold the drug for delivery; a protective container that encloses the drug and used for storage and handling for the medicine; and an internal components to allow saline in and out of the container and to elute or absorb by means of a solvent, which is a key term, medication from the container via saline solution. The saline solution, along with the RB-82 drug inject into the patient.

The drug has a dosage life maximum of either 17-liters of saline passing through it, or 42 days from initial, or when it reaches a minimum level, whichever occurs first. After that, the medicine is no longer useful and must be disposed of, all within a maximum of 42 days. There is no mechanical, chemical, or other physical process within the container; nor is there any means of making a new product. It's simply absorbed by the saline as it passes through the drug container just before injection into the patient.

The Department in their decision sites and rely on two different annotations; annotation 425.0771 and 425.0765 in determining their tax treatment. Annotation 425.0771 from 1994 relies on Annotation 425.0765, which was from 1977. 425.0071 doesn't provide any real basis for logic around the decision, other than referring to the 1977 decision. Both of these decisions predates the revision of Regulation 1591 where Section A9A was added to

rely on FDA classification purposely. They are the medical experts and provide guidance to the industry, which is why Regulation 1591 was updated to help taxpayers and the Department.

Now, let's look carefully at the logic behind Annotation 425.0764 and why it should not be used here. This ruling equates to question products which have a half-life of several decades to X-rays and sunlight. These items physically generate a new substance, X-rays, ultraviolet light.

These items do not contain the final medicine injected into the patient. There's a conversion process. These items have a useful life of many, many years or decades. Thus, those question products in that ruling physically generate a new substance over an extended period of time and are reusable, and they should remain taxable.

RB-82 on the other hand, is the final radioactive drug with a finite amount of medication in the delivery container. There is no physical, mechanical, chemical, or any other process of producing a new substance within the container. Rather, the RB-82 drug is stored and then eluted or absorbed by the saline, which is then injected into the patient.

This process was established by the manufacturer

for a safe storage transfer and delivery of a dangerous radioactive drug when exposed to the public. This process is completely different from the annotation cited by the Department. The panel -- this panel should rely on the FDA classification. They are the experts, not the Department.

Now, I would like to refer to Exhibit C, page 17 -- oh, sorry -- page 119. This illustrates how both the RB-82 drug and other accepted intravenous drugs are delivered to patients. The first illustration on the top shows how RB-82 products is delivered. The only item in question is within the red square. All the other items are purchased separately.

The actual medication is within the yellow rectangle inside that red square on the top of the page. The saline simply goes in, dilutes or absorbs the medication, and then is injected directly into the patient. Again, there are no other changes, events, or other steps in this process.

The second illustration on the bottom shows how the normal event of an intravenous drug is delivered through a meter. Primary A would normally be the saline, and secondary B would normally be the exempt drug. Again, that is also in the red box. The saline in this bottom illustration is also mixed with the drug for safe metered

delivery. While the mechanics are slightly different due to the handling of the drug RB-82, the illustration shows no substantial difference.

Both drugs are stored in a container or a bag, have a connection to the IV line and are mixed into the saline diluted for safe delivery, and then injected into the patient. The Department never tried to argue that the bag of medicine is taxable. There is 100 percent certainty that those items qualify as exempt medicine.

RB-82 is exactly like a regular bag of medicine. However, due to the dangerous nature of the radioactive drug, the handling and delivery have to be modified for safety. This slight difference does not make this product different or taxable. Instead, it is a slight modification to an exempt bag of medicine.

Finally, we have provided Exhibits D and E to provide rulings, definitions, and other relevant information as you work through your analysis. This area remains complex for audit. I humbly request that the panel redirect the Department to rely on expert FDA information, rather than trying to go it alone.

I would like to conclude and ask the panel to take a fresh look at this case. Historically, the Board served as a great avenue for taxpayers to present alternate perspectives. I hope the OTA will continue this

tradition. I also ask for consideration for precedential treatment so that the Department is guided to look to the FDA first and not try to ignore without any basis.

This concludes my opening statement. I'll try to answer any questions to the best of my ability. Thank you.

JUDGE DANG: Thank you, Mr. Bholat.

At this time I'd like to ask my co-panelists if they have any questions for you, beginning with Judge Aldrich.

JUDGE ALDRICH: I don't have any questions at this time. Thank you.

JUDGE DANG: Judge Wong, do you have any questions?

JUDGE WONG: I do have a few questions. Mr. Bholat, the first question is what is Strontium SR-82?

MR. BHOLAT: Sorry. Pardon me. Can you repeat that question? I couldn't hear you. I forgot I had it on mute.

JUDGE WONG: Sure. This is Judge Wong. My question is what is Strontium SR-82?

MR. BHOLAT: Strontium SR -- so when the manufacturer makes the product, they have a process where they create the medicine, and then they store it on that strip of oxide within the container. So when they -- when

they give it a scientific name, they got to -- they've got the name of the SR-82, which is ultimately the RB-82. So what happens is, as the drug pass goes through it, it picks up the drug, and that's injected.

JUDGE WONG: So is Strontium 82 the same as -- you said -- is it the same as Rubidium chloride RB-82? What's the difference, or are they the same?

MR. BHOLAT: So the -- as the RB -- as the SR, the Strontium, is actually placed in the container, it is -- it is a -- it is the same drug. It is just in a more stable format of that drug. So it'll last longer within the container. Once the saline goes in and picks it up, what happen is it picks up a very small amount, which is RB-82. Because it is a -- because, obviously, you can't deliver a huge amount of radiation to the patient.

So as it picks up the RB-82 or the -- yeah, the RB-82, that's the drug that's actually injected into the patient. So it's actually just running through a filter -- or through the system where it's absorbing it. And it's absorbing it through -- through within the container. The SR-82 is what holds the RB-82.

JUDGE WONG: So SR-82 holds the RB-82?

MR. BHOLAT: Correct.

JUDGE WONG: This is Judge Wong again. So when

the CardioGen-82 is delivered to your client, it contains the Strontium 82 or the Rubidium chloride?

MR. BHOLAT: The RB-82 and the SR-82 is one and the same. It's just a different format. It's like, basically, when you buy a drug and when the pharmaceutical company may buy a drug, they might -- they'll buy a large volume of it, or they'll buy a bigger component of it.

And then they will want to titrate it and bring it down to a deliverable amount where they can deliver it to the patient. So the SR-82 is the bulk amount, and the RB-82 is titrated metered down amount of what is delivered to the patient.

JUDGE WONG: This is Judge Wong. Could you explain what titration means?

MR. BHOLAT: So titration is -- so when -- titration is basically a process where the medical professional is going to determine how much medication, what dosage level they're going to deliver to the patient. So they receive it at -- they buy it at a certain volume of potency. And when they deliver it, they don't want it -- they obviously don't want to deliver the potent medication because then it would do more damage than good.

So what they have to do is they mix it with the saline to get it down to portions that's deliverable to the patient. If you look at the illustration we gave you

on Section B, the same thing happens with the drug. The drug is mixed in with the saline, and then it is basically metered down to a safe and deliverable amount.

If too much is given, then what happens is it can actually damage the veins in the process of delivering medication because it would expose the body to more chemical than it can take.

JUDGE WONG: Okay. Thank you. I just have one more question about your Exhibit E. That is the -- it seems to contain a container theory of non-taxability. Can you elaborate on that?

MR. BHOLAT: Can you repeat that? I didn't quite understand.

JUDGE WONG: Sorry. Look like 1589 -- sorry. It looks Exhibit E involves, like, some sort of container theory of relating to Regulation 1589. Can you elaborate on that theory?

MR. BHOLAT: So there was -- included in the package of exhibits, there are little rulings that basically says a container takes the characteristics of the product within what is sold. So if I have a set medicine that's included in a container, and I have a bag and I have tubes and connection devices to it in order to deliver the medication, those other nonmedication container items don't change the taxability of the

product.

What happens is the product inside is exempt. Therefore, the container takes the characteristic of the product and remains exempt. And that actually -- the ruling that I provided actually goes even further. It said even if an item is preloaded and implanted or injected into the patient, even if it's an instrument, those items are exempt.

And that has been historically proven with various products from staplers to stents being implanted to a lot of different products. I think the Department has always allowed those types of things, and has ignored the container as a nonissue when determining the tax treatment.

JUDGE WONG: I have no further questions at this time.

JUDGE DANG: This is Judge Dang speaking. Just a few brief questions for you, Mr. Bholat. I was listening to your explanation to Judge Wong's question regarding the relationship between Strontium SR-82 and Rubidium -- I'm sorry -- RB-82. And I'm wondering, as I was looking through Exhibit B, which I believe was the product data information sheet, I wasn't able to find any support for that explanation that you had given Judge Wong.

I'm wondering if there's any language in that

data sheet you can point to that might explain the relationship between SR-82 and RB-82?

MR. BHOLAT: So I'm looking. There's a long -- I'm trying to find a --

JUDGE DANG: This is Judge Dang again. I just don't have technical expertise in this area. And at least upon my reading, it appears that SR-82 might be some type of reagent -- more similar to reagent than the actual, you know, drug that's injected into the patient. And I believe you mentioned earlier that --

MR. BHOLAT: So --

JUDGE DANG: I'm sorry. Let me finish. And I believe the reason for that is because of the highly -- as you mentioned earlier, the highly radioactive nature of SR-82 as compared to CB-82.

MR. BHOLAT: This is Jacob. That is correct. What happens is that radio -- as you may know, and we're not experts here. But radiation has what's called a half-life. And so what a half-life is, basically, the amount of time that it stays in the current format that it's in.

So when radiation is delivered to a patient, they want to have it as titrated down as possible. And they want it to be in the body as -- for as minimal amount of time as possible for the safety of the patient.

So when they manufacture the product, they have to manufacturer the medicine to the point where it can be packaged, delivered to the medical facility, stored with the medical facility ready for usage, and then be able to inject into the patient. So the SR-82 is a longer termed version of the same version of the RB-82. So the SR-82 has a half-life of I think a couple of weeks or something like that. It may be a few months.

The RB-82, when it's titrated out, has a half-life of a few minutes. Basically, what happens is that because it's titrated down so much, it doesn't have a longer life. Now, I would have to go through and -- I mean, it's a very complex analysis that has to be put together. I'm sure I can go through and find and provide cites and information to provide that information to you. But I would probably have to do it after the fact.

JUDGE DANG: This is Judge Dang speaking. I guess my confusion when I'm looking at this data sheet is I'm unable to see whether or not this is more similar to, say, diluting the product down, which case it's the same product just more in a diluted form versus you've now changed the chemical substance that's being injected into the patient.

Is there anything -- you can take a minute if you would like. Is there anything in this data sheet or any

of the other exhibits that you submitted that might indicate it's the former rather than the latter?

MR. BHOLAT: So if you go to page 109, when you go to the testing process, it says -- on the middle of the page, it says when they're going through and they are evaluating, they're testing the material before the -- so they have to -- the person who is doing the delivery has to evaluate the level of medicine in the product, and also has to make sure the product is safe for use for the patient and has enough medication.

So they go through a testing process. And it goes through the formula of how the conversion happens or how the dilution and titration happens. And it provides information of how the relationship of the SR-82 and RB-82 is. There's a lot of information in here on that conversion. I'm not sure that it answers the exact question of what you're looking for.

If you go down to page 110, it gives you the mathematical formula of the conversion of what the limits are. It also, on page 110, provides you the physical decay chart of how long the product decay from RB-82 to SR-82 and how long RB-82 is usable out in the open.

In the container it has a longer life because it's stored, it's sealed. It's in a leaded container. Once it's outside of that container, now all of the

elements within the air and everything else increases that dissipation or radioactive process.

I'm not sure that answers your question, but there's a lot of information in this FDA published information. And if you go back to -- and I would go back to Exhibit A. When you look at the actual FDA product of how it's setup, they're looking at -- when they define -- first of all, they have it classified in the Orange Book, which is where they keep all of their drugs.

They have it classified as the active ingredient of Rubidium RB-82. They have the product name as CardioGen-82. That's the name of the prescription. Again, it is defined by the FDA as an injectable injection. Not defined in the FDA as a piece of equipment or some type of reagent as you said or anything like that. It is defined specifically as an injectable injection as a drug within the Orange Book, which is how they -- where they classify their drugs.

JUDGE DANG: Thank you. This is Judge Dang again. And that leads me to my final question for you, Mr. Bholat. Were you able to find anything under the rule-making file or any legal authority perhaps that suggest that we should be applying the FDA definition of drug here rather than, I guess, the plain and ordinary meaning of the word drug?

MR. BHOLAT: Well, I think the primary place you're going to look at is 1591A9A where it tells you that the FDA should be used for identifying what an exempt medicine is. And that language was added much later to these rulings; more recently, actually, and probably within the last few years. And that language was added because the Department consistently wanted to ignore the FDA.

And there were -- the actual issues in that particular revision was related to cosmetic implant. And what happened was a lot of times cosmetic implants are used because -- for reconstructive surgery. And the Department was always saying, no those items are not exempt because it's cosmetic. It's not -- there's no medical purpose.

And the revision was added to say, no Department, you can't make that decision. That decision rule should be made by the FDA. And in that scenario and in that situation, the Department was instructed to look at the FDA first. So that's probably the strongest area that I would rely on.

JUDGE DANG: This is Judge Dang. Thank you for your responses.

Co-panelists, did you have any questions before we turn it over to CDTFA? Judge Aldrich?

JUDGE ALDRICH: Not at this time. Thanks.

JUDGE DANG: Thank you. Judge Wong?

JUDGE WONG: This is Judge Wong. I have no questions at this time.

JUDGE DANG: Okay. Thank you.

And CDTFA, if you're ready to begin you'll have 15 minutes for your presentation.

MR. BACCHUS: Thank you.

PRESENTATION***

MR. BACCHUS: This is Chad Bacchus with the Department.

This hearing involves two separate and distinct items. The first is CardioGen-82, which is a medical device that generates Rubidium RB-82 Chloride. And the second is Rubidium RB-82 Chloride, which is a chemical compound that's injected into the human body. Throughout my presentation I'll refer to the first as CardioGen-82 and the second as Rubidium chloride.

According to the prescribing information sheet found in Exhibit D, CardioGen-82 is a closed-system used to produce Rubidium chloride for intravenous use. Exhibit D also explains that Rubidium chloride is a radioactive diagnostic agent indicated for Positron Emission Tomography imaging.

The information sheet also states that the CardioGen-82 should only be used with a specific infusion system designed for use with CardioGen-82 and capable of accurate measurement in delivery of doses of Rubidium chloride. The CardioGen-82 safety data sheet found in Exhibit E -- I should say the Department's Exhibit E -- states that CardioGen-82 contains Strontium SR-82 and SR-85, which are absorbed on a hydrous stannic oxide column, which is encased in a lead shield and surrounded by a plastic container.

Strontium SR-82 has a half-life of 25 days, and Strontium SR-85 has a half-life of 65 days. When sterile pyrogen-free sodium chloride injection is used to elute the CardioGen 82, the diagnostic agent Rubidium chloride is created. The Rubidium chloride decays with a physical half-life of 75 seconds. Once the Rubidium chloride is produced, it is injected into the patient to evaluate myocardial perfusion. Which is to say it helps detect coronary failure.

Revenue and Taxation Code Section 6369, which is interpreted and implemented by regulation 1591, exempts from sales and use tax gross the receipts from the sale of and the storage use or consumption of medicines. Regulation 1591(a)(9)(A) states that, "Medicine means any product fully implanted or injected in the human body or

any drug when such is approved by United States Food and Drug Administration to diagnose, cure, mitigate, treat, or prevent any disease, illness, or medical condition regardless of ultimate use."

(a)(9)(B) states that, "Medicines also 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 that use."

Regulation 1591(c)(2) states that, "The term medicines does not include articles that are in the nature of instruments, apparatus, contrivances, appliances, devices, or other mechanical or physical equipment or article or the component parts and accessories thereof."

Regulation or -- Regulation 1591(b) gives some exceptions to this general rule for devices that do meet the definitions of medicines, including permanently implanted devices, prosthetic devices, orthotic device, and programmable drug infusion devices.

Initially, while we want to acknowledge that we are not scientist, and we are not doctors; so we must rely on the information provided by the manufactures of these products to help us determine whether an item qualifies as a medicine under the sales and use tax law.

Based on the information provided by the manufacturer here, which is Bracco, and can be found in Department's Exhibits D and E. An external saline solution, meaning a solution that is not contained within the CardioGen-82, is introduced into the CardioGen-82 and reacts with the radioactive material housed inside the CardioGen 82. Which as we've heard, is the Strontium SR-82 and SR-85.

Now, this creates a new chemical compound of Rubidium chloride. It is the Rubidium chloride that is injected into the human body for the purpose of diagnosis. There is no dispute that the Rubidium chloride itself qualifies as a medicine, because it is a substance that is fully injected into the human body for the purpose of diagnosing a medical condition.

However, it's not the sale or use of Rubidium chloride that is at issue in this appeal, rather, it is the sale of the CardioGen-82. As for the CardioGen 82, we note that the manufacturer information states only that the CardioGen 82 is a generator of Rubidium chloride. The CardioGen 82 houses one component of the compound needed to create the exempt Rubidium chloride.

Therefore, it's a necessary part of the process of producing the exempt medicine, but by itself does not meet the definition of a medicine. The CardioGen 82 is

not fully implanted or injected into the human body and is not a substance or preparation intended for external or internal application to the human body. The CardioGen 82 is a medical device that's not permanently implanted and is not a prosthetic, orthotic, or a programmable infusion device.

Therefore, the CardioGen 82 is excluded from the definition of medicines under Regulation 1591(c)(2). Regulation 1591(a)(9)(A) does state that, "Medicines include any drug or biologic when such is approved by the United States Food and Drug Administration to diagnose, cure, mitigate, treat, or prevent any disease, illness, or medical condition.

We acknowledge that the Food and Drug Administration has approved a drug named CardioGen 82. However, based on the information found on the FDA website, the active ingredient of the FDA approved drug, CardioGen 82, is listed as Rubidium chloride RB-82. And the dosage form or route is listed as an injectable. While the name of the FDA approved drug is listed as CardioGen 82, based on the information available, it is our understanding that the FDA actually approved Rubidium chloride, which is consistent with the Department's position.

The actual CardioGen 82 is not a drug or

biologic. It is a device, and it cannot be injected into the human body. This result is consistent with how the Department has historically treated radionuclide generators, like the CardioGen 82. For example, annotation 425.0071 dealt with a similar radionuclide generator that is at issue here.

Based on the information provided to the legal Department at that time, that the backup letter to the annotation was written, that taxpayer stated that the generators are constructed on the principle of growth relationship between a long-lived parent radionuclide and its short-lived daughter radionuclide.

The parent is attached to an exchange column, which decays to a short-lived daughter radionuclide. The daughter then can chemically separate from the parent by solvent that is pulled through the generator. In that case, the parent was molybdenum-99 and the daughter was technetium-99m. In this case, the parent radionuclide would be the Strontium SR-82 or 85, at which decays to the daughter RB-82, Rubidium 82.

The process -- going back to the backup letter to the annotation, the process produces technetium-99 pertechnetate, a radio pharmaceutical injected into a patient as agents in brain, thyroid, salivary gland, and other imaging processes. The result from that letter is

Annotation 425.0071, which states, "While the products of a generator may be classified as medicines under proper conditions, the generators themselves are nothing more than a piece of equipment and are not with the definition of medicine for sales and use tax purposes." The similarities with that backup letter and with the CardioGen 82, basically, the processes are exactly the same.

The generator is shipped with the Strontium SR-82 attached to the column, and that decays to RB-82, Rubidium RB-82, which when that is eluted with the saline solution produces Rubidium chloride. Chloride being the definition of the solvent that comes through and attaches itself to the daughter radionuclide.

And then as for Appellant's contention that the CardioGen 82 qualifies as an exempt container, we heard about that right at the end, and Appellant's Exhibit E he attached a letter from the legal Department; we note that Regulation 1589(b)(1)(D) exempts from tax, containers sold or leased with the contents if the sales price of the contents are not required to be included in the measure of the sales tax or the use tax.

To be considered an exempt container, the contents of the CardioGen 82 would have to be exempt from tax. However, as previously stated, the contents of the

CardioGen 82 include Strontium SR-82 and Strontium SR-85, neither of which are exempt from tax. While Rubidium chloride is exempt from tax, that chemical compound does not exist until an external saline solution is introduced into the CardioGen 82. Therefore, the CardioGen 82 is not sold or leased with contents that are exempt from tax and cannot be characterized as an exempt container.

Based on the foregoing, CardioGen 82 is a medical device that through an elution process generates the exempt medicine Rubidium chloride. CardioGen 82 is not an exempt medicine and does not contain or house an exempt medicine.

And I think Scott is going to give some more background on Regulation 1581(a)(9)(A).

MR. CLAREMON: Yeah. Thank you. This is Scott Claremon. I just want to comment. Can everyone hear me? I just want to make sure before I -- okay.

Just comment on a few of the responses that Appellant has made. Firstly, as Mr. Bacchus pointed out, you know, this is our understanding based on the similarity with this Annotation 0071, and the information that's been provided is that, you know, Strontium is a radionuclide -- nucleotide that is -- that is a different element than Rubidium 82, which is a different -- to Judge Dang's question, it's a different -- it is a

different substance than Rubidium chloride.

So we disagree with the characterization of the Appellant that this is the same as -- I think you used the word titrating or diluting a medicine for injection into a body. There are -- there's -- there is a different chemical compound that's attached. It decays into a different chemical compound. And then when it is eluted, which is a specific type of chemical reaction, it creates a third chemical compound, which is what is produced in the body.

So we disagree with the characterization that this is the same as any sort of IV medication. We also note -- again, Mr. Bacchus noted the similarity between essentially the exact same process which is described in that annotation. Which is our longstanding position, and the fact that there's always been IV medication at the time -- like, throughout the time that annotation has been in effect.

So it's always been our position that this not -- that because of these specific chemical processes that are taking place with this type of generator, it's not the same thing as your standard IV medication. To speak to Regulation 1591(a)(9)(A), Appellant is correct that it was specifically focused on cosmetic surgery, specifically, breast implants and Botox.

The issue there wasn't a disagreement over whether those things constitute a medicine or not. The issue there was there was no disagreement that those did constitute medicines -- word medicines -- when used for certain purposes. When used post-mastectomy, a breast implant is medicine. For certain uses, Botox is a medicine. For other uses, they're not a medicine. For other uses when they're used cosmetically, they're not.

So the issue there was how to deal with a product that could be used as a medicine, but also is not a medicine. And you could see from the structure of that sentence, the key point is one, it says, "Except when" -- it starts with, "Except where taxable for all uses as provided in(c)."

First, it's saying if something is never a medicine, we're not going to deal with this. And the most important point is the last part of the sentence which says that it -- it says, "It is a medicine regardless of ultimate use." So the main thing that (a)(9)(A) did in Regulation 1591, was it said that if you have something that is a medicine for some uses, we're going to consider it a medicine regardless of ultimate use.

So it's not -- it was not designed to settle disputes over what is or is not a medicine. Yes, it contains -- in -- in coming up with that rule, it contains

statements about, you know, what's coming and medicine that are -- that are approved by the USDA or FDA are -- are some of the things that are covered in that rule. But it wasn't intended to change the analysis of what constitutes a medicine, and it certainly would not change the analysis here where you have something that is not used as a substance or as an excluded device.

So we do not -- so we do not think that the implementation of (a)(9)(A) of Regulation 1591 changes the analysis of the annotation. Which, yes, it did precede it, but that's been the longstanding analysis. And we don't think regulation 1591(a)(9)(A) had any effect on that analysis. Thank you.

JUDGE DANG: Thank you. This is Judge Dang speaking.

Let me turn to my co-panelists at this time to see if they have any questions. Judge Aldrich, do you have any questions for CDTFA?

JUDGE ALDRICH: Hi this is Judge Aldrich. Can you give me an example of what might be exempt of 1591(b)(6)? Is that something like, for example, a diabetic insulin device? Would that be something that is worn and infusing medicine?

MR. CLAREMON: Yeah. That's a specific example like an insulin -- the type of insulin device that's worn

on the body would be considered exempt medicine under (b)(6). As you can see from that definition it says it has to be worn on or in the body. And, yeah, an insulin injection device is an example.

JUDGE ALDRICH: Okay. And so, I mean, the crux of the dispute here seems like -- and I'll give the both of you the opportunity to correct me if I am wrong -- is that the Department is drawing a distinction between whatever comes out of the product, right, and is ultimately injected versus the piece of equipment or device or medicine, however you determine, that the saline solution is being passed through, right. Whereas, the Appellant is saying, no, the medicine is one and the same. This device or medicine, depending how you analyze it, is what should be tax exempt; is that correct?

MR. BACCHUS: Right. The Department's understanding of Appellant's arguments is that the radioactive -- the radionuclide, which is contained within the generator, is the medicine. And it's just the saline solution that elutes the radionuclide. It's just a way to get that medicine into the human body.

And he uses the example of the IV. And as we have pointed out in our presentation, Mr. Claremon in his explanation is that the Department sees those things as completely separate chemical compounds or chemical

reactions that the Strontium SR-82, which decays to the Rubidium RB-82, those are not medicine.

The medicine is only created once the saline solution passes through and harvests the RB-82 and creates a third chemical compound, a third solution of the Rubidium chloride. And it's the Rubidium chloride which is injected and which is the medicine because it is injected into the human body to diagnose a medical condition.

JUDGE ALDRICH: So the Rubidium chloride, if I were able to dry that out into a powder and put it into some sort of a vile and that is then, like, reconstituted later in that same exact chemical format, that might be a medicine. But in this instance, because it's claimed -- it's changing its chemical structure through these processes, it's not?

MR. BACCHUS: Again, it's hard for us to -- to deal in hypothetical situations and to try to figure what would and not be because there are various facts to consider. But in this case, with these facts, because the Rubidium chloride, which is final product, is not contained within the generator, it is a process of something that is created through the facts after the saline solution has eluted the radionuclide. That is -- and that is the process, and it's not -- it's created

until after the fact.

And it's different having a medication in an IV bag that is diluted with saline solution and is injected into the human body. We believe it's a completely separate and --

JUDGE DANG: Mr. Bacchus, I'm sorry to interrupt you. Mr. Claremon, would you mind muting your mic, please. We're getting quite a bit of feedback.

MR. CLAREMON: Oh, I'm sorry.

JUDGE DANG: Thank you.

I apologize, Mr. Bacchus. Please continue.

MR. BACCHUS: That's okay.

And just to repeat the -- we think it's the IV, the dilution of a medicine for -- for IV purposes is different -- a different process than what is taking place with the CardioGen 82 where the saline solution is eluting or harvesting a radionuclide and creating new chemical compound which then can be injected into the human body.

JUDGE ALDRICH: I don't have any further questions. I'm going to turn it back over to Judge Dang.

JUDGE DANG: This is Judge Dang. Judge Wong, did you have any questions for CDTFA?

JUDGE WONG: This is Judge Wong. I had a couple questions. First one, just for the record, to clarify the record and make clear, what does elution mean?

MR. BACCHUS: Right. Elution, if you look on -- I think it's concluded in some of the Appellant's -- in one of the Appellant's exhibits, also in the manufacturing process. It's a process whereby a saline solution removes a -- the saline solution removes an item -- in this case a radionuclide -- removes a piece of it to create -- and it creates an eluate, which is what it's called, which is a liquid type of -- it's basically a liquid.

It's, essentially, mostly saline solution with some of that radioactive material and allows that material to be safely injected into the human body without causing too much radiation for the body.

JUDGE WONG: This is Judge Wong. One more question. If you know, Strontium SR-82 or SR-85 used by the FDA for anything?

MR. BACCHUS: Not to our knowledge.

MR. CLAREMON: This is Mr. Claremon. I believe that from reading the materials in this case and the backup letter to the annotation, I believe the issue is that Strontium it's the -- it's the useful life of the daughter makes it medically suitable, as opposed to the longer life of the parent. So you wouldn't inject something that last that long into the body. Whereas, the daughter, since it decays faster is medically useful.

I think some of the materials that have been provided in the safety materials, it does indicate that there will be some Strontium that is in the solution, like trace amounts. And that's the danger when, I believe, in terms of balancing the elution reaction is making sure you don't get excess Strontium. One of the dangers, at least, appears to be that you don't get excess Strontium in that Rubidium chloride solution. But I believe that the answer is that it's the short-life of the daughter is what makes it medically useful, as opposed to the long-life of the parent.

JUDGE WONG: Got it. Thank you. And just to clarify, the position is that saline solution is pumped into the CardioGen 82 generator, a chemical process takes place and out comes the RB-82 chloride injection; is that correct?

MR. BACCHUS: Correct.

JUDGE WONG: Thank you. No further questions.

JUDGE DANG: This is Judge Dang. I believe a follow-up on Judge Aldrich's earlier question; I believe a second component of Appellant's argument was that if the FDA approved CardioGen 82 as a drug that, it should be exempt from tax. I'd like to get the Department's response to that.

MR. BACCHUS: Sure. This is Chad Bacchus with

the Department. Our response is that the FDA did not approve CardioGen 82 the device as a drug. It approved Rubidium chloride as the drug but named it CardioGen 82 based on the name from the manufacturer. So, again, the FDA list the active ingredient as Rubidium chloride RB-82, which is consistent with the Department's position that Rubidium chloride is an exempt medicine.

And -- and the FDA also states that the form or the way to administer the FDA approved drug is through injection. So the Department's position is that there's no way that CardioGen 82 the generator is an FDA approved drug as an injectable because it cannot be injected. We believe -- the Department believes that it was -- that the naming -- the FDA naming the drug CardioGen 82 is causing unnecessary confusion.

That it's -- that you should -- we should actually be looking at what -- what it actually is that's being approved, which is the Rubidium chloride RB-82, as specified in the FDA materials.

JUDGE DANG: Thank you. Let's assume for the moment that the FDA did approve this product, the generator CardioGen 82 as a drug or that the product meets the definition in the Food and Drug in a cosmetic act as a drug, what would be the Department's position be there? Would it still be taxable, or would it be exempt in that

case?

MR. BACCHUS: Again, it's difficult for the Department to engage in hypothetical questions just because we deal with facts that are in front of us. Again, as Mr. Claremon pointed out with the 1591(a)(9)(A) came about, it didn't change the way we look at what products or items qualify as medicine. It's products that did qualify as medicines for certain circumstances. It then expanded to allow those products to be characterized as medicines no matter what the ultimate use was.

So the Department would look at whether for sale and use tax purposes under the sales and use tax law, the Department would look at whether the item qualified as a medicine in general. And then -- and then if it did, then 1591(a)(9)(A) would then expand that. And no matter what the use was, it would then be allowed -- then we would find that it was a medicine under 1591(a)(9)(A).

MR. CLAREMON: And this is Mr. Claremon. I would add sort of in response to that question. I mean, this is a unique -- I -- we -- as we've said. This is somewhat of a unique situation, and it is -- there is a little confusion with how the FDA approval is labeled.

If -- but I think generally, if something is approved -- something is a drug and is approved as a drug in which -- which is substance of preparation which is

approved as a drug, there's not going to be a lot of room between it being a medicine under 1591(b)(1) one drug or preparation -- excuse me -- 1591(a)(9)(B), a drug or preparation -- of substance preparation that is used to diagnose and something that's also a medicine under (a)(9)(A).

So I mean, generally the answer is going to be if it was truly a substance for preparation that was approved by the FDA for -- as a medicine, we would consider it to be a medicine too. But I don't think there's generally going to be a lot of room between those two definitions. There's this kind of unique facts of this case where you have, what we think is some -- is somewhat confusing, somewhat imprecise labeling here because as Mr. Bacchus said, the facts are that this product is not Rubidium chloride.

So the FDA has approved it and has given it the name CardioGen 82 and said that the active ingredient is Rubidium chloride, but the facts and as all the evidence, shows, that when this is sold it does not contain Rubidium chloride, and it does not produce Rubidium chloride until the elution solvent is put through it.

So we think -- in response to your question, we think the answer will be generally be that something that's approved as drug by the FDA will also be a drug

under our law. This is a unique situation with these facts.

JUDGE DANG: Thank you, Mr. Claremon. I think my concern was I took a quick peak at the Food, Drug, and Cosmetic Act. It seems as though the definition of what the FDA may consider to be a drug is far more expansive than what we would typically use here with regards to sales and use tax law.

If that were the case, and CDTFA were to lose on this factual issue, we need to proceed, I think, to the legal question of whether or not FDA's determination of whether TPP is a drug or not, would controlling in this case. Do you have a response for that?

I'm sorry, Mr. Claremon. I'm sorry. You're still muted.

MR. CLAREMON: I'm sorry. Can you repeat that question again so I can make sure I heard it correctly?

JUDGE DANG: Yes. This is Judge Dang again. My question was that if CDTFA, as you've expressed the labeling is pretty confusing in this case, and my concern is that if CDTFA were to lose on the factual issue here and we were to find that the FDA approved the entire device as a drug, based on my quick look at the Food, Drug, and Cosmetic Act, it seems like the FDA uses a much broader definition of drug than would typically applied

under the sales and use tax law; and I'm wondering, if that were the case and we were to find that CardioGen 82 was an FDA approved drug, the entire device, is the FDA's determination of what's a drug in this case, would that be controlling as to the tax ability of this product?

MR. CLAREMON: You know, I'm not sure I can, you know, give a broad answer as to how this regulation should be, you know, hypothetical in response, how this regulation should be interpreted. Certainly 1591(a)(9)(A) does state that something -- a drug approved by the FDA as such is medicine. So I don't know how broadly that would -- as I said, I don't think there is much room between something that is considered a drug or a biologic under the FDA law versus what we would consider to be substance of preparation that is a medicine.

So I don't know how broadly that would affect other items. But our indication is that -- but certainly, the regulation states that a drug that's approved by the FDA is a medicine. I mean, that -- that's what the definition states. Our understanding here is that the drug here is Rubidium chloride.

JUDGE DANG: Thank you. This is Judge Dang speaking again.

At this time I'd like to turn it over to Mr. Bholat for your rebuttal. You'll have five minutes if

you're ready to begin.

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

REBUTTAL STATEMENT***

MR. BHOLAT: First I'd like to point you to the closing. I wanted to address a few of the issues that the Department brought up, if I may. The number one issue I keep hearing of, and the Department has never failed to answer this because they're trying to play the expert and outsmart the FDA. They claim that the device generates, creates, harvests, whatever term they want to use.

When you look at the specific language within the FDA approval, and in our Exhibit B that is the actual label. That's not an imprecise labeling as it was laid out. That is specific approved FDA labeling of this device. And in this -- this elaborate discussion that they go through, there's only one term that's, used, and that is elute. And that's very important because all elution is, is it means that it is being absorbed by a solvent. There's no chemical reaction as has been stated.

The Department has failed consistently to provide us with any type of an example what chemical process, what mechanical process, what physical process, what any process that the device uses to convert one item to

another. All that's simply happening is the saline is injected inside the container. It is eluted or absorbed. So, basically, what happens is the saline goes in, it elutes it, and it absorbs it and then it injects it.

The manufacture product SR-82 is a longer life product, but it's essentially the same thing. The RB-82 is a broken down shorter-life radioactive chemical that is for the delivery. Under the Department's logic of saying well, adding saline creates a chemical reaction and, therefore, makes the drug taxable. Then in our illustration of exhibit, when the primary, which is the saline, the secondary which is the medicine, when they meet, they again in that situation, they're diluting the drug.

Why? Because the drug is too -- the drug in the bag is too dangerous to deliver to the patient. If they injected that drug directly to the patient, that patient's body would react to it negatively, and it would do more harm than good. Same scenario here. There is no difference. The only difference is that the container is built so that the product is more stable.

A simple bag would not keep the drug stable. It would not keep it safe. It would not be able to -- they would not be able to transport it. They would not be able to use it. It would not be able to have as needed basis.

If they were manufacturer RB-82 and sell it as is, they'd have to use it within a few minutes. Well, how are they going to get it from point A to point B ready for patient use? The Department continues to use the term generate, harvest, or create, but it fails to provide any logic or any basis or any facts of what the container does other than absorbing the medicine through saline.

The other thing that I want to talk about is 425.0071. That ruling and decision is highly flawed. All it does is it takes a look at the previous ruling from 1977, that says, hey, that 1977 ruling said this product was taxable. Therefore, we're going to say this product is taxable. It doesn't do anything else. You can read the background, and I've read it myself.

What it fails to realize is that those two products are completely differently. In the 1977 ruling, those radioactive material had half-lives of decades. They're manufactured in a process, or they wouldn't be around for years. The hospital or the medical professional wouldn't be able to use that product for a very long period of time. Here we have a product that's good for roughly five weeks. We're not talking about years. We're talking about weeks, and that's at our maximum.

The reason why they manufacture it that way is

because that's the only way they can get it from point A to point B, to the patient. So we are trying to equate an instrument, an equipment, a sunlamp, and X-ray machine to a medicine. And that's a flawed regulation or ruling -- sorry. And it fails to take anything into consideration when it does that analysis. All it does is say those 1977 rulings that say this product was taxable, therefore, that product is taxable. There's no other analysis done.

The next thing I would like to address, 1591(a)(9)(A) is -- specifically says the FDA is the primary place where you should go and look for answers. We as a Department are not experts. I'm not an expert. The FDA is. So the language in (a)(9)(A) is very specific. It says if the FDA classifies something as a drug, it should be treated as a drug.

Mr. Claremon said that cosmetics are taxable. That is not true. A cosmetic implant is exempt, and it remains exempt after (a)(9)(A). The reason why is because the Department does not want to be able -- does not want to have the need to look at patient records. They're not allowed to. So there was a broad application for all implants, whether it was cosmetic or not. They were deemed to be exempt. And there was no further analysis done.

Finally, I think that I wanted to talk about all

this -- this whole concept of a third product. I don't -- I'm sure where this came from. The Department is saying that the saline mixed with an RB-82 is now a third product. That -- that to me makes no logical sense. There's no basis or fact to that. So that's kind of the response that I have.

As far as any conclusion remarks, again, I want to say that the Department has narrowed their vision to only look at the rulings that should not be used for this drug. A huge question that they've failed to answer is what proof or fact makes them decide RB-82 is an instrument -- or CardioGen is an instrument and not a drug.

The logic of this panel should use as follows: The FDA classifies it as a drug. The FDA provides the active ingredient within this the drug. They don't provide any distinction. In their Orange Book, they're saying it's a drug. They're saying the propriety name is CardioGen 82. The active ingredient is Rubidium chloride. Their publication and their labeling, which goes through a very significant process of approval, specifically says that it's eluted, which means absorbed.

The active ingredient is mixed with the saline after elution and injected. There's no conversion of any type within the container. There's no physical, no

chemical, no mix, or any other process. It simply goes in, absorbs the medicine, leaves the container, goes into the patient. Nothing else happens.

The Department cited rulings that relate the products to a long-term reusable item for decades. I mean, we're talking these products have a half-life of -- in the 1977 ruling, specifically talks about half-lives of 28 and I think it was 35 years. This one through RB-82 have a half-life of 42 days maximum within the container.

The Department cited rulings that analyzed the products. They use some type of mechanical, physical, chemical process to create a new substance. We're not creating a new substance. All we're doing is taking a product manufactured by the manufacturer, good for 6 to 7 weeks. We're titrating it down to a deliverable dosage. RB-82 is made at the facility -- the manufacturer's facility, packaged into a container, and then it is eluted, titrated, and delivered into the patient via a saline injection.

This product is exactly as a bag of exempt medicine modified only for safe handling, delivery, and processing of a dangerous drug. This tunnel vision has led the Department to making a mistaken decision back in 1977 and again, they're trying to do it today. This is a very unique product. This is a very unique situation.

One of the questions that the panel brought up is does -- if the FDA -- if we were to take the broad FDA definition, would that change it?

I don't think we need to go there. Because the FDA classifies this as a drug. They're classifying the amount of the material inside the container as a drug. The outside of it is all container, and everything else is all of the delivery.

In the Exhibit E that we provided, we provided a ruling back from 2012 which dealt with the delivery of a stent. And in that stent there's a delivery system; catheter, it's preloaded, it's ready to go. All the doctor has to do is take that device, place it into the body, release -- pump up the stent so that it's ready for delivery. Then once it's placed, they remove the device, and they toss the device. Well, that device is not taxable because a stent is exempt, implanted.

That device is deemed to be a container even though it does much more than a container. It actually process of the delivery. So I don't think we need to go to the point of saying, well, if the FDA approves it as a drug, we have to look at it as drug. If the FDA approved the item within the CardioGen container as a drug, then that container, that whole device should be exempt.

Thank you for your time and consideration.

That's kind of the end of my rant. I apologize.

JUDGE DANG: Thank you, Mr. Bholat. This is Judge Dang speaking.

Before we conclude, I'd like to ask my panel members one last time whether they have any further questions, starting with Judge Aldrich.

JUDGE ALDRICH: No further questions. Thank you.

JUDGE DANG: Thank you. Judge Wong?

JUDGE WONG: This is Judge Wong. I did have one last question for Mr. Bholat. In your Exhibit F there's, like, a sheet about the CardioGen 82. You had mentioned that Rubidium RB-82 is not generated. But it seems to say on the top of that CardioGen 82 -- and underneath it, it says Rubidium RB-82 generate. Can you address that?

Mr. Bholat, I think your muted or I can't hear you.

MR. BHOLAT: Sorry. I was on mute, and I was talking.

To answer your question, the product is marketed as a process where they generate, and they use the term generate. And when you look at the actual process of what it does and how it explains it, all it's saying is that it's an absorption process. It's not any type of a generating manufacturing process. There is not internal component that happens. There is no chemical reaction

that happens between the saline and the device or the medicine. All it is absorbing it.

And if you read through the FDA labeling, the entire process talks about elution. And I fall back to that term because that term -- and it's defined in one of our exhibits. It's defined as absorbed by a saline -- by a solvent. The solvent here is safe. So there's no chemical process. There's no conversion. There's just simply an absorption. And so that's the process, but the term generator is there. That is, I think, what's causing the Department to misinterpret the application of this process.

JUDGE WONG: Thank you. No further questions.

JUDGE DANG: This is Judge Dang. I'd like to thank everyone for their presentations. The record is closed, and this matter will be submitted for decision. The panel will meet and deliberate on the arguments and evidence that's been presented to us. And we will endeavor to send you our written opinion within 100 days from today. I'd like to thank everyone once again. This hearing is now adjourned.

(Proceedings adjourned at 11:24 a.m.)

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