STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

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In Re:)

SOURCE PLASMA DONATION CENTERS,)Date: January 25th, 2024

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Department of Public Health

410 Capitol Avenue

Hartford, CT 06106

HEARING

Held before:

TYRA PELUSO
Hearing Administrator

(Transcription from electronic recording.)

APPEARANCES

FOR THE STATE OF CONNECTICUT, DEPARTMENT OF PUBLIC HEALTH

DEPARTMENT OF PUBLIC HEALTH - STATE OF CONNECTICUT
410 CAPITOL AVENUE
HARTFORD, CT 06106

(Whereupon, the proceedings were commenced.)

MS. PELUSO: -- here with us in the conference room, if they could just either nod or give (unintelligible.)

Okay, thank you. I did have a few announcements.

Good morning, this hearing is being held by the Department of Public Health in accordance with Sections 4-168a-1f and 4-168b of the Connecticut General Statutes.

The purpose of the hearing is to allow all interested persons the opportunity to verbally comment on the proposed regulations pertaining to Source Plasma Donation Centers (unintelligible) Subsection B of Section 19a-565 of the Connecticut General Statutes as amended by Section 9 of Public Act 23-31, proposed Regulation No. 2023-039.

The hearing is being recorded, and for the record today, it is January 25th, 2024, and the time is now 10:07.

I'm just double-checking the audio. If people can hear, you can nod. Okay, I'm getting a nod.

My name is Tyra Peluso. I'm assisting to facilitate today's hearing on behalf of the Department of Public Health. At this time, I will explain how the hearing will proceed and set out some ground rules.

First, please, keep in mind that the purpose of the hearing is for the Department to receive and listen to public comments. There will be no discussion or debate allowed.

Each person providing comment is going to be allotted two minutes. We will keep track of the time, and when the time is up, I will notify you. I'd ask that you finish your sentence and leave the floor so that everyone who wishes to speak will have a chance to do so.

Those attending in-person and wishing to speak should have signed up on the sign-in sheet at the entrance. Individuals will be permitted to speak in the order in which they signed up in-person or on the sign-in sheet or on to the Zoom meeting. We will alternate between those attending in-person and those attending on Zoom.

I ask that you, please, mute (unintelligible), if any, before proceeding to make your comments. For those attending via

Zoom, I will call upon the individuals in the order each person signed up and ask -- or provide you with the opportunity to speak. You are not required to speak during the meeting.

As a reminder, if you have not submitted written comments and wish to do so, you may submit your comments to the Department for consideration via the E-regulation system or by sending an email to Dante Costo, and I will provide her email address, and that deadline is February 2nd at 11:00 p.m., and you should reference the matter in the subject line.

That email address is Dante, d-a-n-t-e.c-o-s-t-o@ct.gov.

And I will now have our first speaker.

MR. BILL SPEAR(PH): I know there are a number of people on Zoom. Do you (unintelligible).

MS. PELUSO: (Unintelligible). You may (unintelligible).

MR. BILL SPEAR(PH): Oh, okay.

MS. PELUSO: So I'll ask you to go first. Can you, please, state your name for the record?

(Due to the poor quality of the audio of the speaker below, full transcription of his testimony is not possible.)

UNIDENTIFIED SPEAKER: Sure.

I'm Bill Spear with the Department of (unintelligible).

MS. PELUSO: Okay (unintelligible.) Okay, thank you.

UNIDENTIFIED SPEAKER: First, I would like to thank the Department for working with us (unintelligible) in Connecticut. I've stated in Public Act 2258, the goal is to align state law and federal law on the high level of (unintelligible) safety. During the Department's review, as required by Public Act 2358, we've shared evidence, including a peer-reviewed study, that shows the federal standards provide a high level of public safety. (Unintelligible) recently did a similar review and (unintelligible) federal law.

This is why we are surprised by the barriers found in the proposed regulations (unintelligible). These policies and procedures (unintelligible), we expected there would be at least three centers open by now. This would have

meant (unintelligible) revenue in each of the communities where the centers would have been located. Unfortunately, this has not occured, unless the regulations (unintelligible) these barriers and (unintelligible).

Regulations require a center to have a (unintelligible) blood-banking experience. This language has been carried over from the old regulations. This requirement is not allowed in federal law, nor (unintelligible). We hope it will be removed, like the regulation that requires a physician on-site (unintelligible).

A review has shown there are 22 physicians with this type of experience in this state. This is not a requirement found in other states. Most of the other 45 states where plasma is donated require a director to have experience in (unintelligible) requirements (unintelligible) DPH has in the proposed regulations. Most of the other states require the director to be responsible for (unintelligible) requirements found in federal law.

We would ask that you amend the regulation to allow them to have responsible physician requirements found in 21 (unintelligible).

The CPR ratio is made administratively difficult given it includes individuals not actively donating plasma. Federal requirements (unintelligible) one individual on-site with CPR training. We would ask that you consider changing the regulations to the federal law.

There are testing requirements found in the proposed regulations (unintelligible) plasma. We ask that you eliminate those testing requirements (unintelligible) covered by (unintelligible). We ask that the (unintelligible) section of the proposed language clarify the (unintelligible) with the federal law on (unintelligible).

Lastly, the reporting requirement is (unintelligible). DPH (unintelligible) we would that you consider having it (unintelligible).

I thank you for your attention and I'm happy to answer any questions.

MS. PELUSO: Thank you very much for those comments. We will move on to the individuals that are online.

I have a Matt Prentice, if you would like to speak. I'll allow the opportunity to introduce yourself, so you can go ahead and do so.

MR. PRENTICE: Sure, can you hear me?

MS. PELUSO: Yes, thank you. You can start your two minutes now. Thank you.

MR. PRENTICE: All right, great, good morning. My name is Matt Prentice and I'm the director of state policy with the Immune Deficiency Foundation, or IDF. IDF advocates to improve the diagnosis, treatment, and quality of life for people with Primary Immunodeficiencies, or P.I. Individuals with P.I. have one of the over 450 rare disorders in which a person's immune system fails to function properly. In Connecticut alone, there are an estimated 2,700 people diagnosed with P.I. and many more undiagnosed.

Most people with P.I. can live healthy, productive lives if they receive lifelong immunoglobulin or I.G. replacement therapy. However, because I.G. derives from human plasma, the P.I. community relies upon an adequate number of plasma donors, and importantly, an appropriate number of donation centers across the country.

The need for plasma and plasma-derived products grows each year and studies show that the federal standards in place for plasma donation provide a high level of donor safety.

On behalf of individuals with P.I., IDF encourages the Department to ensure that the regulations in place do not create unnecessary operational barriers for plasma donation centers in the state.

I thank you for your attention to this issue.

MS. PELUSO: Okay, thank you for your comments. I do have another individual. I have a Ryan T. There was just no last name.

Ryan T, if you would like to speak, I'll give you a few seconds to unmute yourself.

Okay, looks like we have another individual -- okay, we'll go on to the next individual.

I have an Eva Quinley. If there is an Eva Quinley on the line that would like to speak, you can unmute yourself and I will start the two minutes.

MS. QUINLEY: Okay, thank you -- thank you very much for the opportunity to comment on your proposed regulations for proposed plasma collection centers. I'm the global head of regulatory at CSL Plasma and the senior director of laboratory operations. We sincerely

appreciate your continued commitment to regulations that will support the establishment and growth of plasma donations in the State of Connecticut by modernizing regulations to align more closely with well-established federal regulations.

As a subsidiary of CSL Bearing, a global biotherapeutics company, CSL Plasma operates more than 320 plasma centers, including one in the State of Connecticut.

The plasma collected at our centers is used by CSL Bearing for the sole purpose of manufacturing plasma-derived life-saving therapies. We will provide detailed, written comments on our requested revisions, but I would like to highlight a few.

First of all, the draft regulations that the proposed center director have a license in the state of Connecticut as well as minimum of one year in blood-banking or equivalent experiences of concern. This requirement is more difficult to meet as there are very few individuals in the whole country that meet this kind of requirement, and most of those are employed in hospitals.

As a former instructor of blood-banking

physicians, the experience that they have is mainly dealing with transfusion medicine, management of patients receiving blood, not in the collection process, itself. So it is an unnecessary requirement to have that one year of blood-banking experience.

We ask that Department revise the regulation to have the qualification be that the physician is licensed in the State of Connecticut only. This is the standard that we find in most of the states in which we operate.

We also ask for greater specification around the delegation of duties of director. We would appreciate the opportunity to work with the Department to have that delegation more reflective of the federal standards and clearly define what is delegated to physician (unintelligible) to and what could be delegated to other appropriately-trained individuals.

In the proposed regulations, there is a requirement for reporting of adverse events and other things. This, we believe, is very burdensome and we would ask that this be reduced or even eliminated from the regulations.

The newly-proposed regulation reference

testing that does not really apply to plasma collection, but is instead more applicable to whole blood collection and the recovered plasma that comes from those collections. We ask that that those references be removed.

And finally, the requirement to have two individuals for every 10 donors in the center, CPR-trained is a bit burdensome for the fact that a donor is defined as anybody that is in the donor center and it would be very difficult for us to be able to maintain two per -- two per every 10 donors that are present. We ask that be revised to just two per every center at all times.

I thank --

MS. PELUSO: That is two minutes.

MS. QUINLEY: Yes, thank you for your time.

MS. PELUSO: I will thank you for your comments, and we will move on to the next individual.

I have Alexis Boroskov(ph). I'm not sure, Alexis, if you wanted to speak. I will give you a moment to unmute yourself.

MS. BOROSKOV(PH): Hello, I will defer to Vlasta Hakes from Grifols, if that is okay. I

will not be speaking on this issue. I am just listening in.

MS. PELUSO: Okay, and I do have.

MS. BOROSKOV(PH): Okay, I was just listening in.

MS. PELUSO: Okay, and I do have that name on here.

Vlasta, if you wanted to unmute and provide a comment (unintelligible). Do you want to unmute?

MS. VLASTA HAKES: Yeah, definitely.

MS. PELUSO: I'll start the two minutes. Thank you.

MS. VLASTA HAKES: Thank you, thank you and good morning, everyone. Thank you for this opportunity. I'm sorry I can't be there in-person. I had mechanical issues on my flight this morning, so I am still in DC.

But I want to thank the Department for all their efforts in drafting the regulations concerning Source Plasma Donation Centers.

Grifols is a global healthcare company and they -- we are trying to open up a center in Connecticut. We have been working with Grifols -- sorry, Grifols has been working with

Connecticut for the last four years on this issue.

Grifols proudly serves over 45,000 donors a day across our plasma donor network. We have centers in over 290 -- we have 290 centers in over 40 states, including Massachusetts, Rhode Island, Pennsylvania, and Maine.

More recently, we have been trying to meet the proposed regulations that DPH has released. We have been having issues identifying a physician who meets those qualifications and responsibilities, particularly the issue of the one year of blood-banking experience.

We submitted our initial application in October with a physician that was licensed in Connecticut and met the federal guidelines. We also provided additional information to the Department later about the issues we've had identifying the physician, as well as if there was any other experience that they would accept and submitted an official waiver. DPH denied the waiver in December, and to-date, the Department has not responded to Grifols' request of whether the qualifications are acceptable.

We have communicated with over 70 physicians

and have been unable to find one.

According to the American Medical Board of Medical Specialists, there are only about 22 physicians that might qualify in Connecticut. This requirement should be modernized, as New York has done recently.

Today, plasma donation is fully-automated. Plasma donor centers are not performing blood-banking activities nor collecting any products that would be used for direct transfusion. Grifols cannot open a Source Plasma Donor Center until we have an approved physician. We have asked that DPH adjust the physician qualification requirements to align with the requirements of other states, be licensed in Connecticut, and meet the federal guidelines.

We have a completed facility at a $3.2 million initial investment in Connecticut that was ready to be opened in May of 2023. This facility could be contributing $5 million annually to the local community, but instead, it is closed while we are waiting to align with DPH.

Patients are -- are depending on this plasma that is coming from this -- that could from this center and we have donors that are ready to

donate. We'd also be employing about 50 people.

So, again, we ask that DPH consider this and the other comments to help make the issue of opening up a plasma center in Connecticut easier as aligned with other states in the area.

Thank you and I appreciate the opportunity to comment.

MS. PELUSO: Thank you for those comments. Perfect timing. Awesome, thank you.

I'll move on to the next individual.

I have a Dr. T. Simon. I'm not sure if you intended to speak today. If you would like to unmute yourself, I'll allow you a few seconds to do so.

MR. T. SIMON: Okay, thank you very much. I'm a medical consultant of VPTA. I've been with CSL Plasma as a senior medical director, and relevant to my testimony on this issue of the -- of a plasma center medical director, I'm trained and board-certified in both internal medicine and blood-banking transfusion medicine, and I've also served for 25 years on the American Board of Pathology Blood-Banking Transfusion Medicine Test Development Advisory Committee, which is responsible for the board certification in blood

banking, and my view is that blood bank experience requirement is unnecessary for donor safety and center compliance and is an impediment to Source Plasma Donor Centers in the state.

The difference is that blood center medical directors deal not only with donor suitability issues, but also with physicians and hospitals related to the utilization of blood products, and also, oversee immunohematology testing in the blood center.

By contrast, in plasma centers, the medical directors don't deal with the utilization of product and no products are collected for direct transfusion, and the testing that is done, the hematocrit and the protein, is not immunohematology. In fact, when we do hire physicians with specialty of transfusion medicine, blood-banking, we have to assure that they are adequately-trained in general medicine to oversee the health assessments we perform.

So I believe the medical director qualification should follow the requirements of the federal regulations combined with the specific state requirement. That would require the physician be licensed to practice medicine in

the State of Connecticut, be certified in cardiopulmonary resuscitation, a requirement you have, and then meet federal requirements to serve as a responsible physician for a plasma donor center and a laboratory director for a laboratory of moderate complexity related to the protein determination. Then each program -- each company would have a training program for the medical director, and he or she cannot assume full responsibility until they have been trained on the relevant procedures concerning the determination of donor eligibility, collection of blood, and blood components and the return of red cells.

And this is comparable to what the state of New York has done. They've just dropped that blood -- blood bank director qualification and they now allow qualifications such as I have just described.

So thank you for the opportunity to present my testimony and I hope we can proceed to open up in Connecticut with the new requirements for the medical director being changed for what they are in the current regulations.

Thank you.

MS. PELUSO: Thank you for those comments. I will move on to the next individual.

I have a Jim, and I apologize if I'm mispronouncing this, Jim Paolino or Paulino, if you would like to speak, I'll give you a moment to unmute yourself.

Okay, seeing -- seeing none, I will move on.

The next individual is Diana Delphine(ph). Again, I'm not sure if I'm mispronouncing that. You could unmute if you would like to speak. If you would unmute yourself, please.

MR. DELPHINE(PH): I have no comments.

MS. PELUSO: There was a Karen Buckley. Karen, if you would like to speak, you can unmute yourself.

MS. KAREN BUCKLEY: Hi, good morning. I'm just listening to the hearing today. I work for CHA and we will be submitting comments after this hearing.

MS. PELUSO: Okay, thank you so much.

MS. KAREN BUCKLEY: Thank you for your time.

MS. PELUSO: Okay, thank you.

I have a Heather Pratt. Heather, if you would like to speak, you can unmute yourself.

MS. HEATHER PRATT: Yes, good morning, I'm

from Ket(ph) Plasma, LLC and I have no comments at this time. I'm just listening in.

MS. PELUSO: Okay.

MS. HEATHER PRATT: Thank you.

MS. PELUSO: Thank you very much.

I have a Keisha Barrett. Keisha, if you would like to speak, you can unmute yourself.

MS. KEISHA BARRETT: Thank you, yes. I'm with CSL Plasma, but no, I do not have any comments. I'm just listening in on the hearing.

Thanks.

MS. PELUSO: Okay, thank you.

And earlier, I called on a Ryan T. I also have a Ryan listed. I'm not sure if that's the same Ryan or if it's a different Ryan. I don't have a last name. If you would like to provide comment, you can unmute yourself.

MR. RYAN: Yeah, hey, hi. How's it going? No comment. Just here listening and monitoring and listening to the information.

MS. PELUSO: Okay, thank you for letting me know that.

Okay, I have a Betsy Jeff(ph). Betsy, if you would like to speak, you can unmute yourself, please.

MS. BETSY JEFF(PH): Hi, I'm with New York Blood Center. I do not have a comment.

MS. PELUSO: Okay, again, thank you.

I -- I believe I am going to mispronounce this last name. I have a Katharina Rothwangl. If you would like to speak, Katharina, you can unmute yourself.

MS. KATHARINA ROTHWANGL: Hi, thank you so much. I'm with Biolife Takeda. No comments. Our comments will be covered by Roger.

Thank you.

MS. PELUSO: Okay, thank you so much.

Okay, Roger BRisner, Brinser, I'm sorry if I'm mispronouncing that. Roger, you can unmute yourself.

MR. ROGER BRINSER: No, you did fine. Thank you very much.

Yeah, I would like the opportunity to comment. I appreciate this opportunity. I will do my best to keep it at two minutes or less. I tend to ramble on, but thank you.

My name is Roger Brinser, head of our regulatory affairs for Biolife Plasma Services.

Biolife is an industry-leading plasma donation network that's part of Takeda, one of

the world's largest biopharmaceutical companies. There's a growing demand for plasma-derived therapies to treat patients, many who live in Connecticut, with rare, chronic, and complex diseases. Plasma-derived therapies can only be produced using human plasma from healthy individuals collected at a plasma donation centers.

Biolife Takeda currently operates 270 Biolife Plasma Donation Centers in the United States. We operate five New England-based centers in Massachusetts, that -- and are exploring opportunities for additional centers in the region, including New York.

The safety and well-being of donors and patients is of utmost importance. Takeda is committed to delivering the safest donation process from start to finish.

We are requesting that the Department amend Section 19a-36D-5, personnel requirements and qualifications, and in particular, Section C-3, which describes the qualifications of the center director.

Physicians with this type of blood blanking are extremely rare -- extremely rare, as you've

already heard. Either the medical supervision requirements described in 21-CFR-635 -- 630.5, excuse me, should be recognized as sufficient to meet the qualifications or the Department should clearly define experience and training that is acceptable.

Source Plasma collection organization invest significant time and energy in training licensed physicians in order to provide appropriate medical oversight and the training programs should be deemed as adequate.

Connecticut's unique provisions require a special -- requiring a specialized physician make it difficult to find such a candidate with a center director and significantly limits the opening of plasma donation centers in Connecticut.

According to the center director qualification requirements, consistent with federal -- excuse me, amending the center of director qualification requirements consistent with federal regulations would provide Tekada with a level of certainty needed to move forward to explore securing long-term leases, planning for capital investments, and starting the process

to recruit for employees.

For background, it usually takes 12 to 18 months to open each center, and this process requires significant planning that Takeda resources an investment in advance.

Takeda has additional comments regarding proposed regulation concerning Source Plasma Donation Centers. These include the numerous and confusing references to blood, classification of adverse events, according to nationally-recognized standards, and the burdensome quarterly reporting requirements, which have limited value.

These will be addressed in our written response to the pro -- proposed regulation.

Thank you for your time and I'm happy to answer any questions you might have.

MS. PELUSO: Thank you very much for your comments. (Unintelligible.)

I have another individual, as well, Kenneth, and I'm sorry if I'm mispronouncing this, Kenneth Price(ph), if you would like to speak, you can unmute yourself.

I would just like to offer: I don't believe I missed anyone that is not on the Zoom. Is

there anyone that I have not called on, if you would like the opportunity to comment, would you, please, unmute yourself and let me know your name? I'll a -- a few minutes -- I'll wait a few seconds to make sure I didn't miss anyone.

Okay, I'm not seeing anyone.

I would like to thank everyone for their comments. Did you want to -- (unintelligible.) Okay, we're just going to see (unintelligible) that we haven't overlooked anyone and (unintelligible).

Thank you.

Okay, I will -- I wanted to, again, thank all of you for taking the time today to provide comments. I know this is an important topic.

I did want to note: I understand that the volume may not have been perfect on today's Zoom call, but I did want to let everyone know that there is on Zoom -- that today's public hearing has been recorded and we will be posting this to the regulations record so that you -- there will also be a transcript, as well. So everyone should be able to refer to that.

And if you have not submitted written comments or you do want to provide written

comments based on listening back to the recording and reading the transcript, you can submit your comments to the Department for consideration via the E-regulation system or by email, and I understand you did put that email address into the chat box because I know the volume may not be adequate.

Again, the deadline for the comments is February 2nd at 11:00 p.m., and please, reference the subject matter in the line -- subject line, rather.

Again, thank you very much for taking the time to participate today, and we will be -- undo the public hearing at this time.

MR. ROGER BRINSER: Thank you.

MS. VLASTA HAKES: Thank you.

MS. KATHARINA ROTHWANGL: Thank you.

(Whereupon, the proceedings were concluded.)

CERTIFICATE

I hereby certify that the foregoing 28 pages are a complete and accurate transcription to the best of my ability of the Hearing re: Source Plasma Donation Centers held on January 25th, 2024.

Melissa Zamfir, Transcriber

Date: February 5th, 2024