27 February 2015

Speakers:

- -Deborah Nucatola, MD, Senior Director of Medical Services, Planned Parenthood Federation of America ("**PPFA**")
- -Deborah VanDerhei, National Director, Consortium of Abortion Providers (CAPS), Planned Parenthood Federation of America ("PPCAPS")
- -Two actors posing as Fetal Tissue Procurement Company ("Buyer")

frame counts are approximate

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PPFA: This is Deb Vanderhei, the director of CAPS.

PPCAPS: Hi.

Buyer: Hello. [Name], good to meet you.

PPCAPS: My pleasure. Thank you.

Buyer: One of our procurement technicians.

PPCAPS: Oh, I saw you in the lobby. As I was racing up to the call.

PPFA: And so I'm actually going to be bringing them in for Alisa Goldberg's cervical preparation presentation.

PPCAPS: Oh good.

PPFA: They're just gonna sit in the back to hear that because it's kind of pertinent.

Buyer: It's kind of relevant. In a big way actually.

PPCAPS: Good.

PPFA: Okay.

PPCAPS: Where are you located at?

Buyer: So we're based in southern California. Long Beach area. Yeah. And unfortunately, what we've been discovering is that pretty much all of the California Planned Parenthood affiliates are already partnered with a tissue procurement organization.

PPFA: Yes they are.

Buyer: So we're having to cast our gaze a little further afield around the country to see who would be good, but basically what we're looking for is affiliates that are going reasonably far into the 2nd trimester, after 20 weeks is good.

PPFA: And not giving digoxin. I'm gonna step out.

Buyer: Not giving digoxin, and reasonably high volume. And so actually Dr. Westhoff had mentioned last night that you're the lady who has at your fingertips all the numbers of kind of who's doing what and how much they're doing.

PPCAPS: Mhm.

Buyer: Because if it's gonna be worth it for us to send somebody, to fly a tech out from California to wherever the site is, once a week, we want to know that there are at least four or more specimens per week that are in our range or higher--

PPCAPS: Four or more?

Buyer: Yeah, four or more is I think what would make it worth it for us.

PPCAPS: And at what gestational age?

Buyer: Anywhere from 16 weeks and above.

PPCAPS: Ok. So do you have any Planned Parenthood contracts right now?

Buyer: We're talking with two affiliates right now. And now we're doing a couple of site visits in the next few weeks.

PPCAPS: Okay.

Buyer: So yeah, we're very new. We've only been around for about a year at this point, we do a lot of adipose tissue collection.

PPCAPS: Great. And do you have any accounts with any independent providers yet?

Buyer: Not yet. The issue with independent providers is--it looked like originally FPA in California was going to be a really good option, but apparently they don't want anything to do with tissue procurement in general.

PPCAPS: Oh, too bad.

Buyer: And they start dig'ing pretty early too, so that's another issue.

PPCAPS: Oh they do.

Buyer: Yeah. And then as far as independents in other states, it's something that we've talked about and it's something I'm a little hesitant to go too far with just because there's so many issues with like people closing down and stuff like that, we don't want to start a relationship that is not going to be sustainable, you know if it's a clinic that ends up closing down in like the next year or so, that's just not helpful.

PPCAPS: Mhm. It's a big investment for you to make--

Buyer: Yeah. Exactly, so that's why.

PPCAPS: Yeah, I can understand that. Well, but there are some that will likely not close down, so if you have any questions about them, I'm fairly familiar with most of them so I'm happy to offer my two cents.

Buyer: That would be great. Yeah if there's someone in mind that you're thinking of specifically, or?

PPCAPS: Well, there are some in the north east called the Women's Group, Cherry Hill, NJ, Philadelphia, I don't think they're going anywhere, and their state regulations on that side aren't that bad, so there won't be that problem. Are you exhibiting at the National Abortion Federation conference?

Buyer: Yeah, we'll be there again in April. Yeah.

PPCAPS: Good. Yeah, and you then will meet those providers.

Buyer: Yeah, NAF was kind of a grab bag last year. That's where we met Deborah last year.

PPCAPS: Oh, did you go? She was telling me about somebody who was there. I didn't realize it was you.

Buyer: Yeah, definitely. Off the top of your head, as far as Planned Parenthood affiliates, are there, who would you think of is in that range that we're looking at, and has the volume?

PPCAPS: Well, so you want 16 and over?

Buyer: 16 and over, yeah.

PPCAPS: Well, I'm from Seattle and that affiliate, the Great Northwest in the Seattle area, they have one of their health centers provides ABs to 18 weeks, and they're not using dig.

Buyer: Okay.

PPCAPS: So they, that's--

Buyer: And Seattle's probably high-volume, right? Because there's--no it's not?

PPCAPS: No. But four specimens a week? Mmm. Like right there. And that is because that area has a couple of providers that are very high volume.

Buyer: Right.

PPCAPS: But just across the Cascade mountain range is the affiliate called GRNI. Greater Washington and Northern Idaho.

Buyer: Mhm.

PPCAPS: And so that affiliate, they are primarily in Spokane, or central--

Buyer: They're not the ones in Seattle, Seattle is something different?

PPCAPS: No, it's a different affiliate. We actually have four affiliates represented in the state of Washington. But they would likely have 4 or more specimens, though Spokane is not an easy flight.

Buyer: Certainly easier, probably easier than like Trenton, NJ or something like that though.

PPCAPS: Yeah, so that's an affiliate that is--

Buyer: And they're not working with, like, University of Washington or anything like that?

PPCAPS: If GRNI is, um, I don't know the answer to that, that's a good question. And then we have affiliates in Texas, that do it--

Buyer: Yeah, we were just talking to Dr. Fine last night, and earlier today.

PPCAPS: Oh good. What did he say?

Buyer: Because my understanding was that Gulf Coast has been doing this for a very long time.

PPCAPS: Yeah. And they are a very easy affiliate to work with. Their CEO is lovely--

Buyer: And you're getting a higher volume and everything. Yeah, that sounds like it might be a really--and also, Texas is actually, believe it or not, is actually one of the major hubs of regenerative medicine

PPCAPS: Oh yeah. I'm not surprised.

Buyer: Activity and yeah, it's really, California, Texas, North Carolina, research triangle area, and then Wisconsin, those are probably the four biggest hubs of regenerative medicine type research around the country. And so ideally, what we would be great for us, what would really be a competitive advantage for us, is if we could be sourcing from clinical sites that are in each of those areas.

PPCAPS: Oh, and--

Buyer: Because then we're providing to researchers who--

PPCAPS: So Texas, North Carolina--

Buyer: Wisconsin, and--yeah, believe it or not, Wisconsin literally, after California, Wisconsin is the place for stem cells. That's where all of the major--

PPCAPS: Out of the University of Wisconsin-Madison?

Buyer: Madison, yeah. Madison is a big one.

PPCAPS: Do you know Dr. David Estes, long pony-tail, Miami area? He's here. And he's the medical director of one of the affiliates in south Florida, and he's Family Planning Fellowship trained by Dr. Nucatola, and he'd be a very good person to talk to, very progressive.

Buyer: Yeah.

PPCAPS: He's got, like, a sports coat, and--

Buyer: Yeah, I feel like we saw him.

PPCAPS: He's kind of weird, but yeah. And yeah, let's stay in contact about who you've contacted, and who you've approached and--

Buyer: Sure. Do you have a card?

PPCAPS: I do.

Buyer: And this is my card. I'm one of the techs.

PPCAPS: Oh great.

Buyer: And yeah, so.

PPCAPS: So then, when you go to a site, so then, do you consent the woman, or do you just process the tissue, or--?

Buyer: I can do the consenting, just as a floater, or whatever's needed, I also do the processing, just a small section of the path lab, kind of out of the way.

PPCAPS: Yeah, yeah.

Buyer: But we can do whatever to help.

PPCAPS: And are you on site every day that they do procedures, or?

Buyer: We do procedure days, yeah. We work it out on the day that would be best, and then on procedure days.

PPCAPS: Yeah.

Buyer: And some affiliates--sorry.

PPCAPS: And what if, sometimes you do procedures over a couple of days, are you there a couple of days--oh.

Buyer: Mhm. Well, I mean the most important day is the actual procedure day because that's when we'll have the material. And I guess, consenting--there might end up being an issue with states where there's a waiting period, like a day waiting period or multi-visit requirement, because we were talking to some providers in Arizona about that recently, and that is something that, I keep on thinking it might make things easier, because if there's already going to be a whole day devoted to consenting, then we can just do it all in one fell swoop, but apparently that might be an issue as well, so I don't know, that's just one thing--

PPCAPS: Yeah it might be state dependent. I don't know.

Buyer: But that's another thing, depending on what an affiliate wants to do. Some places like to have their own people doing all the consenting work and so we're only collecting, but we're happy to work with whatever's gonna--

PPCAPS: Yeah. Well I witnessed some other organizations in the clinic, so the woman has been consented, you know, they've done patient education, they've determined she's going to go through with the procedure, she's had her ultrasound, blood work, and then she's waiting in sort of a waiting area before she sees the physician, and that's when the procurement agency captured her, and talked to her about donating the tissue and signing the consent. So it was literally moments to, sort of filling in, just a nice way to--

Buyer: Yeah. Yeah, absolutely.

PPCAPS: But that was in a state that doesn't have a 24-hour waiting period, so.

Buyer: Yeah. I think part of it is being very attentive to the practice environment, that you're working with and just--

PPCAPS: Yeah.

Buyer: It's a very unique area, definitely.

PPCAPS: Yeah. So what other types of medical procedures are you collecting tissue?

Buyer: Yeah, so we're actually collecting a lot of adipose tissue right now from lipo--

PPCAPS: Yeah, you said.

Buyer: We actually just got the contract for a major study using that, they're doing with the--what is it, with the telomeres?

Buyer: The translational study?

Buyer: Yeah, they're doing a, something with regenerating the telomeres in aged stem cell populations which is really interesting. But yeah, adipose tissue is great because there's a lot available, we're based in southern California, so we have a relationship with a couple cosmetic surgery facilities. And it's not very complicated, and surprisingly, you get a very good yield of the mesenchymal stem cells that come out of the adipose tissue and apparently it's like 500 times more in that as opposed to bone marrow which is the other source a lot of people use.

PPCAPS: Wow.

Buyer: But, fetal liver is like 5,000 times as much.

PPCAPS: Oh.

Buyer: So, it's, and that's where a lot of the most exciting research action is going on right now. There's stuff actually in FDA clinical trials, for spinal cord injury, and HIV stuff, and--

PPCAPS: So, is it the liver only that you're primarily interested in?

Buyer: Oh it's all kinds of stuff.

PPCAPS: Okay, that's what I would think.

Buyer: Liver is probably easily the most, like the highest in demand right now, because that's used for anything with hematopoiesis, you know blood cells, that whole group. It's used for a lot of the immunology stuff, it's used for the humanized mouse modeling that is done, which is really cool but that's a whole 'nother subject. And neural tissue and neural progenitors is another one, that's very difficult because that's where specimen quality and like the intactness of the specimen is a big concern. Because the brain is really, really fragile. So.

PPCAPS: Yeah. Do you, um--can I ask you about remuneration?

Buyer: Yeah. Compensation. Yeah.

PPCAPS: So, what's your policy and what have you been--

Buyer: We would--I mean, however they want to work it is fine with us. Typically most places are doing per specimen, 'cause it just makes the most sense because that's how they work and that's how we work as well. I'm actually supposed to have a discussion with one of the affiliates possibly later this weekend about that.

PPCAPS: Yeah. Well, one of the things that we advise our affiliates is to really consider that carefully.

Buyer: Yeah, because it has to be very discreet, yeah.

PPCAPS: And if remuneration can be taken off the table at all, that would be great, can we just provide this as sort of a mission-based piece?

Buyer: Yeah. I mean, if they'll do it for free I'm happy to do it! It's just, it's kind of, I know it's a lot to ask to have somebody coming in and using your space and potentially impacting patient revenue.

PPCAPS: Yeah.

Buyer: And so it's, yeah.

PPCAPS: But so the twist then there is how to do sell it not only to the clinic, but

also to the staff, whose day you are interrupting?

Buyer: Right, right.

PPCAPS: And you know maybe you're lucky enough that you're working with a staff that's incredibly interested and just wants to be in there with you, they think this is all fantastic, and then maybe the other staff is where it's like this is just the last thing they need.

Buyer: I know, right? One more thing.

PPCAPS: So then it would be really important in your introduction and your presentation, whatever that ends up looking like is just to sort of explain the value of doing this for research, and how that's very important, and we're already a mission-driven organization, and this is just one more thing that we're doing and we recognize these things. So the more sensitivity you can have to that I think the better you're gonna do that at least with our affiliates. We're non-profit, we're mission-based, that might be kind of a different situation with independents though I have been talking to the executive director of the National Abortion Federation, we're trying to figure this out as an industry about how we're going to manage remuneration. Because the headlines would be a disaster.

Buyer: It has to be very discreet, absolutely. When I go to stem cell meetings, they have whole sessions on, how do we talk about in public what we do? It's not just Frankenstein.

PPCAPS: There is a public education piece.

Buyer: And most of us are nerd scientists who actually don't have our act together anyway, you know, don't really know what to say. And it's been so interesting going to NAF or to Society for Family Planning, and then [Name], my boss, was telling me about some of the other stuff but just the whole issue of stigma, and how do we talk about this, it's just a lot of the same conversations and a lot of the same concerns--

PPCAPS: Oh yeah. Yeah.

Buyer: Yeah. Which makes sense, because part of what we see where you have these two groups, where the family planning community has the supply so to

speak, and the research demand is there, but just there's not enough communication going back and forth.

PPCAPS: Mhm.

Buyer: And so right now the supply is not meeting the demand. And a lot of that is because of this stigma that, you know, so yeah. It's a delicate area, it's a touchy area, and so--

PPCAPS: And so who helps you facilitate those conversations? Who leads those sessions at those conferences?

Buyer: It's just--same as any meeting here. They have a couple of faculty speakers, and a facil--it's nowhere near as extensive as like a values clarification or anything, because these are, you know, everybody is, that's maybe the, it might be a little more, it's certainly not, I don't think the people in the research community are dealing with stigma on the same level as you might be dealing with in the family planning community, it's not as intense.

PPCAPS: Well yeah, I mean you certainly have legislation aimed at you as well, so. Can I ask you a question, were you at last year's NAF presentation when there was a panel on fetal tissue disposal?

Buyer: Yes, yeah, and that was very helpful.

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PPCAPS: So we're going to replicate that our National Conference in a month.

Buyer: Uhuh. We'll be exhibiting there, so.

PPCAPS: And, oh! Good. And we're having one of the attorneys from my team, and then Roger Evans from Litigation & Law, and a CEO from an affiliate in the midwest that's had some problems, and we're going to sort of present some facts on our panel, and then really open it up to the group to ask them what their concerns are.

Buyer: For disposal, or for donation?

PPCAPS: Donation.

Buyer: Specifically.

PPCAPS: Both.

Buyer: So there's an affiliate in the midwest that's done it?

PPCAPS: I mean, we understand that there's a big difference, but we only have a short time frame, we've got to cover it all.

Buyer: Right. Of course. Yeah.

PPCAPS: But do you remember who spoke at last year's NAF meeting? We're trying to identify the woman, and--

Buyer: For donation?

PPCAPS: Yeah.

Buyer: That was the Cedar River Clinics. Because they are actually working with StemExpress. So we can't work with them.

PPCAPS: So was it Connie, or was it Beverly, or?

Buyer: Um, it was one of those names. I don't, I can't remember off the top of my head.

PPCAPS: Okay. And then who else was there?

Buyer: Um--

PPCAPS: And they were talking about donation?

Buyer: They were talking about donation, and I guess they've been doing it for a very, very long time.

PPCAPS: Yeah, they have.

Buyer: And kind of have it down, I think it was Connie.

PPCAPS: Who's as tall as her face is wide?

Buyer: Yeah. And she said, she said, "Well, we might be interested in partnering with multiple organizations, but you have to be able to keep up with us." She said we have the supply, we have it figured out, she says anything you can't use, we give to the University of Washington, they've been doing this for years. Will they be at the Planned Parenthood meeting?

PPCAPS: No, independent providers can't attend, but they will be at the NAF meeting, and they'll have an exhibit this wide, ten times the size of this. And Connie just took over from Beverly, who's the founder--

Buyer: Oh you're in Washington, so you know all these people anyway. And University of Washington, I think for years now, they've been a major source for the academic community, and for a while they were the only source, and now just they're so tapped out, that's why people are looking elsewhere. So there's an affiliate in the midwest you said that has experience with tissue donation?

PPCAPS: She's probably on there because of disposal, now that I think about it.

Buyer: Oh, because of disposal. Okay.

PPCAPS: But do you remember who else was on that panel?

Buyer: There was a woman from Michigan, who ran clinics in Michigan who were having all kinds of disposal issues.

PPCAPS: An independent clinic or?

Buyer: Yeah, it was an independent, it was not--

PPCAPS: Renee Chilian?

Buyer: I don't remember--

PPCAPS: Northland Family Planning?

Buyer: I think that was it, it was kind of a generic name like that.

PPCAPS: Okay. And was there an attorney or somebody who was leading the session.

Buyer: There was an attorney, I don't know if she gave a presentation or led it. But yeah, there was an attorney.

PPCAPS: You don't remember what it was?

Buyer: And whatever she talked about was not really relevant to the other stuff.

PPCAPS: Okay.

Buyer: Yeah I don't know. But that would be, I'm glad to know that that will be at the meeting next month, yeah. Do you know their policy for exhibitors going to meetings?

PPCAPS: At the national meeting. Yeah, I don't know. This will be my first one. I just started in July, and this will be my first meeting, so.

Buyer: We have to email, I'll tell [Name] to email--

PPCAPS: I mean you can ask Deb, she will know--

Buyer: You don't have like a preliminary schedule or anything on you?

PPCAPS: No, because there isn't one yet.

Buyer: Oh, there isn't one yet.

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PPCAPS: I mean they told us what day, it's Wednesday. But I don't know what time.

Buyer: Okay, well that's the day the exhibit opens, so.

PPCAPS: Yeah.

Buyer: Yeah, because that would be really helpful I think, to really get a perspective on how--because what I understand from Deborah is there's not a set PPFA policy right now?

PPCAPS: We are absent a policy and that's relatively intentional, and the policy that we do have suggests that you just really think about what you're doing, vet your procurement service, if there's any way that you can do it mission-based, that's probably better. And that if you do decide that you want to engage in remuneration, that you really need to, like, think that through.

Buyer: Yeah.

PPCAPS: And think, "New York Times headline," when you're creating your policy. And that memo is over a decade old. So one of things that we're going to do is use this meeting that I'm telling you about this panel in a couple weeks to inform a new memo.

Buyer: Yeah, to be brainstorming about it.

PPCAPS: Deb gets requests and I get requests about whether or not people should be working with, well, the requests have been coming, we hear StemExpress.

Buyer: StemExpress is the other one, yeah.

PPCAPS: And should we work with them? Because Shasta-Pacific, now Northern California, they work with them and they're sort of vocal about it. "They're good, we"—yeah.

Buyer: StemExpress has the whole north, yeah. I've heard, they've gotten mixed reviews from some other affiliates. My understanding of them is they sometimes, there's a lot of talk, but they don't always follow through.

PPCAPS: Yeah. I don't know.

Buyer: And they're very ambitious, they're very hooked into the larger biotech world in a real industry sort of way, and so for that reason, I would question how attentive they are just to the practice environment, like I said. That's just something to think about.

PPCAPS: Okay.

Buyer: I won't say anything more about that because I don't want to--

PPCAPS: Well, yeah. And I don't know. And we're not making recommendations, so. But Deb is a big proponent, so, keep talking to her.

Buyer: Yeah, and I wish, unfortunately Novogenix is in really really tight with the Los Angeles affiliate. But actually, I was hoping to meet Dr. Russo.

PPCAPS: Yeah, she's at this meeting.

Buyer: Yeah, because they're in Orange County, and probably geographically the closest to us, and they're working with an actual biotech lab in Irvine or something, but I would guess that there's probably more room, if that's just like one project, there's probably more room there for another group to come in and also do collection, so I would really like to have a chance to find out what that relationship is, and how they like it, and how we can do better.

PPCAPS: Well, I'll--she's got long, black hair with bangs, average height, weight, etc. But yeah, she would be a good person to talk to. She's presenting this afternoon too, so I know she's here.

Buyer: Well thank you so much for stopping by.

PPCAPS: Oh yeah, well Deb told me to stop by.

Buyer: I'm really glad to know about that in March. That will, I think a lot of good will come from that.

PPCAPS: And we're taking notes, so I'll certainly let you know what people are thinking about donations and what their concerns are, and how it would play out in different clinics. But don't hesitate to ever talk to me.

Buyer: Excellent, really good to meet you.

PPCAPS: Goodbye.