

TRANSCRIPT BY THE CENTER FOR MEDICAL PROGRESS

18 March 2015

Speakers:

-Vanessa Russo, *Compliance Program Administrator, Planned Parenthood Keystone (“PP”)*

-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

047000 Vanessa Russo approaches

PP: Hi.

Buyer: Hello. [Name], I'm Procurement Manager.

PP: I'm Vanessa Russo. Nice to meet you.

Buyer: Russo--no relation to Jennefer Russo?

PP: No. Russo's like Smith for Italians. There's so many of us.

Buyer: [laughter] Got it. Which affiliate are you with?

PP: I'm with Keystone.

Buyer: Okay.

PP: Are you familiar with us? We have some key sites--

Buyer: I've heard, you guys were sponsoring the Medical Directors' Council meeting a few weeks ago, right? I saw on the registration forms. What state are you though?

PP: Yeah. Pennsylvania.

Buyer: Pennsylvania. Okay. Interesting. So we, [Company], we're a tissue collection service.

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PP: Right.

Buyer: So we provide all kinds of human biospecimens to medical researchers in different projects.

PP: Can you explain how that works?

Buyer: So for fetal tissue, yeah. Obviously, what the research actually is?

PP: Yeah.

Buyer: It's mainly stem cells. People talk about fetal tissue research, it's really fetal stem cells is what it is, people are familiar with like adult and embryonic, but fetal got kind of lost in the mix, but that's where some of the most interesting translational research is happening and stuff that's actually going to from the laboratory to the clinic soonest. That's where a lot of the FDA clinical trials are. A lot of the disease modeling is done using fetal stem cells and fetal tissue, you have humanized mouse models, which is basically an immunodeficient mouse that has human fetal stem cells implanted into it, it reconstitutes a human immune system in the mouse, so you can do drug testing and--

PP: Right.

Buyer: It's very cool, it's a really exciting field. So anyway, the biggest problem though in that whole area of research right now is supply chain access. The researcher demand for materials is not being met on the supply side because the networking isn't happening. So we're trying to facilitate that.

PP: I understand. I understand.

Buyer: So are you guys a surgical affiliate? Do you do--

PP: We are. Yeah.

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Buyer: How late in gestation do you go?

PP: 16 weeks, 18 weeks. I can't--I forget that.

Buyer: 18 weeks?

PP: Yeah. Are you looking for, do you have a limit, like a low--what's your lower limit?

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Buyer: Yeah. Our lower limit is probably 12 weeks. I mean, depending on the specific researcher, some people are looking for brain specimens at, like, 6 weeks. But that's more the rarity, typically most projects are looking for, like, 2nd trimester specimens. It's easier for our technician to find the material at a later gestation, just because it's not as shredded up and all of that.

PP: Right, right. Okay. Yeah.

Buyer: So, are you a high-volume affiliate? How many procedures per year do you think you do?

PP: Um, I can tell you probably about 5,000.

Buyer: Mhm. Across how many surgical sites?

PP: 5.

Buyer: Oh. And what kind of geographic area is that in Pennsylvania?

PP: We're, if you look at the state of Pennsylvania, we're the eastern half.

Buyer: Okay.

PP: So we cover a lot of territory.

Buyer: Do you cover Pittsburgh?

PP: We don't, no. We're in the eastern half, Pittsburgh's on the western half.

Buyer: Oh.

PP: Yeah, so it's Pittsburgh, Erie on the western half, and we're on the right.

Buyer: Oh, wait! So do you cover Philadelphia then?

PP: Except Philadelphia. We do have Bucks County, which is the county above Philadelphia. So Philadelphia is their own unit at the moment.

Buyer: Yeah.

PP: Yeah.

Buyer: Well Pennsylvania is definitely a big research hub, so if we could start working with a--and actually, really to have any site on the east coast. Because part of our goal is to be sourcing material from locations as close to researchers

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as possible, because that's something that they would want because the material is--

PP: Sensitive.

Buyer: Yeah, sensitive, you're looking for a high cell viability.

PP: Formerly a biochemist, so you don't have to tell me any of that.

Buyer: Oh, yeah. Cell viability, yeah. So the major research hubs, we're talking like California, Wisconsin, Texas, and North Carolina, technically East Coast, but, you get anywhere on the eastern seaboard and you're kind of within courier distance, so it's good.

PP: Right. What's the, how long is it good for in that sense? Because I don't really know much about your area.

Buyer: 24 hours. Really, probably less--

PP: So 24 hours from procedure to delivery.

Buyer: Yeah. Oh yeah, we would literally be like overnighting it or, you know, same-day courier to people. I mean, some researchers can take frozen.

PP: Oh, so okay, now I'm sorry, I'm going to interrupt you a lot, I don't need to but I have impressions, so when the procedure happens we send it directly to you within 24 hours or we send it directly to the researcher--

Buyer: No, we would actually, we would send one of our technicians. Yeah, I'm [Name].

PP: Vanessa. Nice to meet you.

Buyer: I was a little hungry.

PP: That's okay.

Buyer: We would come in, and we would be like a floater, do all the consenting, and then just take a little area of the path lab, and so we would, you know, find the tissues that are there, and then we would box it up and--

PP: Oh, so you would come in and do it.

Buyer: I would, or one of our other techs. Yeah.

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PP: So do you do, that's interesting. So do you do a train the trainer kind of thing, where if someone from my organization were to shadow you, then we can then take up the mantle for you and do that?

Buyer: We could yeah, we're happy to do that. I just think a lot of affiliates probably just given the practice environment would prefer to have their staff doing their stuff, we just want to be as low-impact as possible on you guys.

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PP: Okay, absolutely. So how does that work, money-wise? Let's talk turkey. Like, do we pay you, or you pay us—like obviously, you don't pay us, like—

Buyer: Well, we definitely return a portion of our researcher fees to the clinics and doctors offices that we work with.

PP: Okay, that's interesting.

Buyer: As a thank you for letting us in. Now, if you'll let us do it for free, we don't have to—I mean typically—

PP: Okay. Obviously, right?

Buyer: Typically we're quoting people about \$100 per specimen. And the money is really about two things. It's about number one, securing our place there and kind of our priority, because you know there are other procurement services out there, and once one gets in one place it's very, it's difficult, there's often not room to share.

PP: Right.

Buyer: So we would want to get, to secure our place and priority over any of the other TPOs out there. And then number two, it's just about to compensate for any cost to you, your patient revenue, stuff like that. So.

PP: Okay. So—

Buyer: And what's your position? Are you—

PP: I'm the Compliance Program Administrator for the affiliate, for all of the 16 sites, so I basically deal with the quality management area of medical services. One of the things that I'm looking at is sort of like alternatives. I'm a former researcher myself, I worked in R&D and did a lot of work in advancing ELISA technology for tuberculosis testing and things of that nature. So I come from that world and I love this, and so I'd love to be able to establish something, but you can understand it's delicate for us and so I kind of would need to, I have to—

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Buyer: It has to be discrete.

PP: I'm a little bit more, I kind of don't care what people say, like the work is so valuable that that to me in and of itself is important so just shut up, but I'm not the one that can make that call, so I definitely want to get as much information from you guys and establish an open communication with you guys, because we'll just need a lot of transparency to make the people I work with feel comfortable, but I am all about this. Because I'm a researcher at heart, so I'm really down—

Buyer: Do you have a card on you by any chance?

PP: I do. I heard about you guys in our meeting today—

Buyer: [coughs] Sorry, speaking of tuberculosis. What I need is some stem cells.

PP: [laughter]

Buyer: Oh cool, so it's got the map on here. So you guys are all of that.

PP: Yes, we are all of that.

Buyer: Okay, Vanesaa Russo. So you were in the panel discussion today on tissue procurement. Because Deb VanDerhei told us that that was going to be going on.

PP: It was a topic of discussion in our patient services affinity day meeting. We're starting to get some interesting behaviors from our disposal company, that doesn't necessarily—

Buyer: Stericycle, or—?

PP: Yeah, so it doesn't necessarily want to pick up our materials when there's protestors outside, and that's not something that we can help, so it hasn't really been too much of an issue, but if it progresses, as, I'm trying to project and see how that's gonna go and it doesn't seem like it's going to go well. I would like to start to have discussions and make other arrangements. And this is absolutely the route I would choose to go in a nanosecond. So you know, obviously I want to do what's safest for us, as an organization, and I want to make sure that we maximize the materials we use for research, because I can't tell you, I'm loving this, and I really want to bring this back so do you have like a copy of a contract that I can look at and send to me, that I can disseminate and talk to my people about? I'm real serious about doing this.

Buyer: Yeah, we typically use a Materials Transfer Agreement, I have a redacted version that I could send you, we're in discussions with a couple other affiliates

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right now using that as a prototype. Now you guys have not done tissue procurement before at your affiliate?

PP: Not to my knowledge. Now I've only been with the organization for a year and a half, so I don't know if they did it before and then bowed out because of pressure, like social pressure. I don't know. I'm new. We've just had Stericycle the whole time, so.

Buyer: Was there any guidance from the panel on how to handle contractual issues and stuff like that? Because I know that Deb had said that was something that was going—

PP: It was glossed over. But I think that we have resources to sort of ask those particular questions that sort of affect our affiliate, that was sort of the guidelines of that moment in the meeting. Because there's so much variation state to state to state to state, it becomes very difficult for the Federation to be aware of every single thing, nuance, that each state brings to the table.

Buyer: So they didn't spend a lot of time talking about actual tissue donation.

PP: They did. They spent some time talking about it, it was a combination of talking about that, and talking about disposal, and talking about issues of both. So, obviously, you have to, we have a bigger picture, like if we were any other healthcare facility, it wouldn't be an issue. But because we are who we are, because the material is what it is, it becomes very very tricky.

Buyer: Right.

PP: And so it has to be done very carefully, very thoughtfully. I would like, I would love to, I would want to go ahead right now. Because I feel like we have so much material, you know so much material to offer.

Buyer: Right.

PP: That, it's like a no-brainer for me, but I know that's there's people who've been with the organization 20, 30 years, that have a much bigger social picture than I have, because I'm just the lab nerd. So that isn't a negative, but in this situation I think I kind of have, I want to develop really solid reasoning and have that trust in the people we're gonna be working with.

Buyer: So that when you present it to your people as well, you can very confidently defend it to your people as well.

PP: Exactly, and there has to be trust.

Buyer: Yeah. Yeah.

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PP: So.

Buyer: Do you know, this is kind of a different subject, do you happen to know what your 2nd trimester volume is per year? Of those 5,000.

PP: I don't. So that's the material you're most interested in?

Buyer: Most interested. If you're going up to 16 to 18 weeks, and let's just say, assume that you're tracking with the national average, and 10% of your procedures are 2nd tri, that's at least like 500 a year, which is at least like 10 a week, right?

PP: So you would go, I'm sorry, the bottom end is 12, right? I was told that you want 12 and up.

Buyer: Yes.

PP: Alright.

Buyer: I mean, really most interested in 14 and up, I would say.

PP: Yeah.

Buyer: Just because what they ask us for, what we've been seeing is over 14 and a lot of the emphasis is on the higher gestations.

PP: And what do you do when you come in? Like what, explain that process?

Buyer: Well, I'd come in, kind of just be a floater. I'm mostly just talking to the patients, consenting them, and then on a collection day, I'd be in the path lab, get the specimen, for whatever it is, we have a chart of different people, whatever they're looking for--

PP: Right.

Buyer: And then we collaborate with you guys, and that would be collection day. So collection day, come in, do my thing, and then out of your hair. He's gonna need basically your light dish, for POC examination, like that, we would be using that to do the dissections.

PP: Okay.

Buyer: They could also help out with the float, you know, in the path lab.

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PP: Yeah, I know we have, I would definitely want to be in on that and understand that from like every aspect.

Buyer: And the lower limit for the gestational age, that we can kind of play with too depending on how intact the specimens are coming out. So I don't know, is your Medical Director here at this meeting or any of your providers?

PP: No, no. Actually they were here last year, so it's kind of my turn.

Buyer: Okay. Do you know about their protocols, like how they're doing most of their procedures? For cervical prep? Is it Dilapan or laminaria, or miso?

PP: Laminaria. So, has anybody from PPFA come and talked to you and engaged you on like a national level?

Buyer: Yeah. We're close with Deborah Nucatola.

PP: Okay.

Buyer: She's been really helpful to make a lot of affiliate-level connections and I wish, she's a provider at the Los Angeles affiliate as well, I wish we could be working there, but unfortunately there's already another company that is in very tight with them, and has been for quite some time.

PP: It's hard to break a solid trust-filled relationship.

Buyer: And that's the other thing is the providers are very important, having a lot of communication with the providers and just being able to let them in on what our process is and kind of what we're looking for, because the great thing about you know like Deb or, sometimes they can be very conscientious about trying to facilitate the whole thing and that makes it a little bit better for everybody.

PP: Right. You're servicing one of our affiliates right now, right?

Buyer: We're talking with two right now that I'm not sure I'm supposed to say who they are.

PP: Okay. That's fine.

Buyer: But actually we're scheduled to do a site visit at one of them and we're scheduling the site visit at the other on in just a little bit.

PP: Okay. Okay.

Buyer: Yeah, it's been difficult because we're a start-up, we're very new, we're a year old.

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PP: How many of you are there? Like is it just you two or--?

Buyer: How many TPOs, you mean organizations or--oh no. I'm the Procurement Manager. My boss, who's not at this meeting, but she'll be at NAF, I don't know if you'll be at NAF in April.

PP: Yeah, I will.

Buyer: She's the one who started it, and she used to work in clinics back in like the '80s I think, like a long time ago. And then her assistant is also one of our techs who, [Name], um, and we're pretty small. Just a handful.

PP: That's alright.

Buyer: We operate drop-ship, no, and so, unfortunately, in California, all of the California affiliates are already partnered with existing tissue procurement organizations, so we've been having to cast our gaze a lot farther afield to find, to look in other states to find people to partner with.

PP: So if we all attack you here at this meeting, right?

Buyer: And we can monopolize--

PP: And so, here's my concern, I'm all about small and start-up, and that as well, but like--

Buyer: What kind of capacity do we have?

PP: What kind of growth and expansion capacity do you have?

Buyer: It's pretty scalable. To be honest, this is a pretty simple plug-in solution that's very scalable. Because really all we need, we have a 1099 procurement technician, and we just fly 'em out there for whatever time during the weekend is your highest-volume procedure day, they just set up shop in the back, they bring their fedex boxes, we operate drop ship so they box everything up and ship it off.

PP: We have 5 sites, and they each have a different day, Monday Tuesday Wednesday Thursday Friday. Each has a different day.

Buyer: Each has a different day.

PP: So we'd have to have, you'd have to have the ability to spend the week with us.

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Buyer: Is there one site that has the highest volume though, that's like your biggest surgical center?

PP: They're all pretty high volume.

Buyer: They're pretty evenly distributed.

PP: So it's pretty, it would be high-volume.

Buyer: And is there a procurement, a TPO--Oh there's Deb VanDerhei, she's our other contact on the national level. Are all 5 of those sites, do they all go into the 2nd trimester, or is there only one that goes to 18?

PP: So it would basically be coming to all of our sites. Like, I would want to do that with all of our sites.

Buyer: Do all of your sites do procedures all the way to--

PP: Yes, yes.

Buyer: And you have 5 of them.

PP: So we have--

030800 Deb VanDerhei joins the conversation

PP: She was in the presentation! [Deb to Vanessa]

Buyer: That's what we've been talking about! We've been trying to understand, how much they actually talked about tissue procurement, or—

PPCAPS: No we didn't really talk about procurement, we just talked about if you're going to participate in a donation program, here are some things to think about.

Buyer: Yeah. So we're talking a little about contractual issues and things like that, maybe we shouldn't have this conversation here, I don't know if that's appropriate or—

PP: [shrugs] I just interested in hearing as much as I can [inaudible]

PPCAPS: You asked a great question about, did you ask the question about can you help us with state laws?

PP: Yes. Yea, because I don't know what they are, and I actually [inaudible]

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PPCAPS: But it sounds like Roger's willing to help us.

PP: Okay.

Buyer: Pennsylvania's a big research hub, so I would imagine it's probably a good location.

PP: Yeah.

Buyer: So help us help you. In terms of guidance from Roger and Kristen, what—

PPCAPS: It wasn't any different from what I told you before. It's that we think it's a great idea to participate in research, through tissue donation, that you really need to be careful and follow the rules and think about the headlines if something goes south, and if you're gonna do it, do it right. We're here to help you figure out how to do it right. So understand federal laws and then state laws. And then have air-tight contracts so that somebody can't come back and say, "You're selling tissue for money." You know, that's a bad headline.

Buyer: Right, as far as that goes I feel like failure is not an option. I mean, unless somebody is gonna do some market testing and focus grouping, but otherwise, I don't think, I just don't think it's something you talk about in public, and I mean, it just can't be.

PPCAPS: Well yeah, but I mean, you know, if you're doing it, there's opportunities for people to find out about it.

PP: I sort of, my stance on that is like, I feel like we're sometimes bullied by ridiculous laws and this media that doesn't understand the big picture. And I don't really think that we should participate in that level of discussion. And that we should operate as an organization, the way any other organization would. And I don't feel, and I'm a researcher at heart, and I love the idea of being able to do this and participate in research. I would love to see this happen in some way. I'm probably maybe not so sensitive to like ridiculous, like, let's have a debate on the real issue and truths, that's a discussion I would participate in. I don't feel like we should readily participate in discussions based on crap. I mean, that's my thought process on that. I may be alone, but that's how I feel about that [laughter].

PPCAPS: Are you suggesting that our conversation was too conservative?

PP: I feel like sometimes, like, this is my first time here, I've only been with the organization a year and a half, so I don't know the history like somebody who's been there for a long, long time. But I've always been a supporter, I've been a patient, now I'm working here, and I just feel like we shouldn't participate in ridiculous discussions. We should participate in a valid [way?]. And that we

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should not curtail our business [motions to Buyer table] for ridiculousness. Maybe curtail our business for an actual real discussion.

PPCAPS: I don't anybody was suggesting that you curtail. The message to me, that I heard today, was, "Go for it." We think it's a great idea. Just do it right.

PP: Exactly, and I understand that. But like, a company like this that wants to pay us, that wants to give our organization money for the tissue [Deb VanDerhei nodding yes], I think that that's a valid exchange. And that's okay. [Deb nods emphatically]

PPCAPS: Mhm.

PP: Providing that we are very sensitive to the patient, and the consent, and all of that. I don't see a problem with that. I understand that we have to worry about our rep and everything like that, but—

PPCAPS: Well I think a Congressional hearing from, you know, scared the Bejeezus out of people fifteen years ago and, there was a Congressional hearing, and it turned out to be fraud, but—

Buyer: Really. What was the fraud?

PPCAPS: There was a person, a person that said Planned Parenthood had changed the way it does its procedures so that they can collect tissue so that they can sell tissue. It turned out that was false, but it sparked a Congressional hearing and some federal legislation and that's where that came from. So we just want to not have to repeat that again. And there are a lot of—there are Planned Parenthoods that participate in donation programs that are reimbursed for it. And they—

PP: And that's fine.

PPCAPS: Yeah. It's fine, we're just suggesting that, call us, help us, let us help you walk through some of those steps to make sure—

PP: Okay. Can I give you my card so we can talk about this more?

PPCAPS: Yeah.

PP: I just, I get real passionate about not being bullied.

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PPCAPS: And then there's independent providers that are doing this and we have no control over what they're doing. And that could be the headline. [...] Or it

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could be a very well-recognized hospital that does it. I mean that headline's the headline. I'm just saying that, it wouldn't be Planned Parenthood's headline, but it would be a headline that could potentially create legislation that would make this impossible for anybody. And we don't want to make any missteps. We just want to make sure we do it right and recognize the possibility [inaudible].

PP: I totally understand. And we just have all this valuable material for research.

PPCAPS: Oh I agree.

PP: So I'm just passionate about seeing that happen, and partner with the right people.

PPCAPS: And so are many women. So, as well as people who work in all the health centers. So we're glad you're here. Are you guys the only—

Buyer: We are.

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Buyer: We were talking about the Materials Transfer Agreement that we use for most contracts, and I don't know if they got that specific in the discussion today about what that looks like to be careful about—no?

PPCAPS: We just said if you're going to do it, know that we're here to help you.

Buyer: Don't do it alone! [laughter]

PPCAPS: Well, you know, let us help you review your contracts, or let us help you identify the state laws. We definitely know the federal laws but we don't know all the state laws, because your state hasn't asked.

PP: So Roger is the person to really go to for this.

PPCAPS: Well Roger is the head of Litigation and Law, for many years, he has retired from that position and is now the Senior Advisor for Litigation and Law. Because he was the one who was involved in the Congressional hearings before, 15 years ago, so he has most of the background, so he spoke today in that sense. So he would be somebody who has [inaudible]. But I think he was pretty clear this morning, in what he was saying, go through Kristen. That works for CAPS. And she'll tell him.

PP: Alright.

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PPCAPS: Yeah. I think, go for it. And use us to the extent that you can. And I know Northern California, Mar Monte, LA, they all provide donation for remuneration. So they would also be people to check with about how that goes.

PP: Alright. Thank you. I appreciate it.

Buyer: And then, do you know about the others? So those other 3, there was Shasta Pacific, and then the other 3 that were--

PPCAPS: Shasta-Pacific is now part of Northern California.

Buyer: Oh, oh Shasta-Pacific, I thought it was Southern Pacific, or Pacific Southwest in San Diego.

PPCAPS: Pacific Southwest uses somebody else. Shasta-Pacific is in the northern part of California, now they're called Northern California as of January 1.

Buyer: Okay.

PPCAPS: And then Mar Monte is East Bay and big area.

Buyer: Yeah. The ones in Norcal are all working with StemExpress.

PPCAPS: Yeah. I don't know.

Buyer: But the other 3 out-of-California affiliates, or the non-California affiliates you said, spoke up during the meeting, do you remember--?

PPCAPS: Yeah--no. I don't know where they're from, because I don't know anybody yet. But I asked, when I saw you, I asked my staff to help me figure out who they were. And I see one of my staff, so I'll go ask them. But yeah she [Vanessa] asked more questions than anybody.

Buyer: Oh yeah. She was really getting into it?

PPCAPS: Yeah. I hope that she didn't leave thinking that we were saying don't do it.

Buyer: Were discouraging it.

PPCAPS: Because Roger said, "I'm gonna say a number of things and I only want you to go away with one message: I think this is a good idea. Now, here's what you need to look out for," and at the end of it, he said, "And I just want to reiterate, I think this is a good idea."

Buyer: Good.

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PPCAPS: So.

Buyer: That's good to know. Well you know at least the conversations open, and she's excited, and we're, you know, I think one of her things is just trying to put all the pieces together, and really trying to understand--

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Buyer: And to compare regions, and see what everybody else is doing, so I'm sure there's like a lot of information all at once.

PPCAPS: And I think they--what is their gestational limit, did she say?

Buyer: She said 16 or 18 weeks. I'm hoping 18 weeks, is what it was.

PPCAPS: Oh they're in Allentown. Oh they're Keystone.

Buyer: Which, so Pennsylvania is a big research hub so that would be great to open up that area.

PPCAPS: Yeah. Well and she, our new Executive Vice President was the CEO of her affiliate up until the end of the year. So that's good. That's a good thing.

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Buyer: Yeah. And as far as the specifics of remuneration, is there any guidance from Roger other than how to—because one thing we've talked about with Deb Nucatola before is just to make sure that's kind of back-ended in the right way so that it's a reasonable covering—

PPCAPS: Yes he gave very clear instructions, that the federal law says you cannot be remunerated for tissue, what you can be remunerated for is costs of collection. So if there's admin costs, extra staff time, transport fees, materials or supplies, you just need to really document what those are, and say, you know, "This is \$100 worth of whatever, or \$50 worth of, admin time, materials that it's costing us." So that if somebody comes in and says, "You're collecting money for tissue," we'll say, "No we're not, we're collecting money for administrative costs." So he gave them 4 or 5 things that they should consider. So he was very clear about that.

Buyer: And I guess just to make sure that that language is in there--like how do you put that in a contract? That's just, to frame things in that way.

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PPCAPS: Yeah.

Buyer: On paper.

PPCAPS: I don't know the answer to that. But that would be something that Kristin or Roger, you could talk with. She knows you're here. She's super sick. So don't her. She's got--

Buyer: We just got over--

PPCAPS: You still have it, in here.

Buyer: You think so?

PPCAPS: It seems deeper.

Buyer: He's grown up.

PPCAPS: Yeah.

Buyer: Getting older, you know.

PPCAPS: Okay, well I'll go look for Roger, and I'll find Kristin.

Buyer: Excellent. Thank you so much.