

TRANSCRIPT BY THE CENTER FOR MEDICAL PROGRESS

25 July 2014

Speakers:

-Deborah Nucatola, MD, *Senior Director of Medical Services, Planned Parenthood Federation of America* (“**PP**”)

-Two actors posing as Fetal Tissue Procurement Company (“**Buyer**”)

frame counts are approximate

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Buyer: So, I have a dilemma to ask the doctor.

PP: OK.

Buyer: I really, after this week was looking forward to a glass of wine, maybe a bottle, to share of course. I have such a sinus headache though, I have advil sinus, not over the counter though. Can I mix them?

PP: Uh-huh. Oh yea.

Buyer: Please tell me yes. Ok.

PP: Absolutely. I recommend that you drink as much water as you do wine, or your headache is going to get worse. But yea, no that should be fine. So, where are you guys based?

Buyer: Here we go, Norwalk. Based out of Norwalk.

PP: oh. I was sitting here trying to figure out when we ended up where we are. I was like, are you close you close to here?

Buyer: You're based out of Sherman Oaks right?

PP: Yes, and I'm actually seeing a patient in Calabasas today.

Buyer: So you ok now? Glad to be out of your car?

PP: Oh, I'm so happy to out of my car. Luckily I can take Beverly Glen home, so I'm very happy. I won't have to deal with any freeways after.

Buyer: Well, again we appreciate, I give you time to look over the menu.

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PP: I'm actually going to talk to the waiter and be annoying. But, I pretty much know what I'm going to do.

Buyer: What kind of wines do you like?

PP: I'm generally big red fan, myself.

Buyer: No. All girls are white.

PP: You know, I think what is, I justify the red because it has health benefits. Where the white is purely pleasure. All go for anything, and white's cold and it's ninety degrees outside, so whatever you like.

Buyer: Well, I love red, but I was for sure thinking that-

Waitress: How are you? Iced water ok to start?

PP: I'm well thank you. Iced water fabulous.

Waitress: You need an iced tea or anything?

PP: No, thank you. Do you still have the wine list?

Buyer: They took it. The other folder? They took it.

PP: Good we've finally been able to connect, I know it's been difficult.

Buyer: Was it a good time for you?

PP: Yes, I've been in LA for almost two weeks. I'm leaving again for two weeks on Monday.

Buyer: So, I want to pick your brain and make your time as productive as possible. How much time do you have? I want to make sure we're not-

PP: I have a meeting at 4.

Buyer: At 4. Ok, how long would it take you to get there?

PP: I'm going over Beverly Glen. As long as we're done by three I should be fine. I mean, I don't what you guys have planned, but I think we should have time.

Buyer: Picking your brain. Picking your brain, and having a glass of wine.

PP: What are you guys having?

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Buyer: For food? I like the look of the salmon, with the cherry tomato and the basil.

PP: Oh then it has to be white. It has to be.

Buyer: It does not have to be.

PP: It does. We can do a rosé as well. I'll let them pick, I like to do it based on what we're eating.

Buyer: I am not picky. But, I like you idea about red. You can justify it right?

PP: Of course. It has health benefits.

Buyer: If it's a good red wine, the cheap ones, it's mostly coloring, from what I hear.

PP: Yes, if it's done well and made well, it has health benefits. That's my uh, that's my line.

Buyer: So, the main thing, well, not the main thing that I would like to discuss is, I'd really like to connect with people who feel they don't know we're out there. They don't know there's this opportunity. And that could be a little touchy, for them more for us, and I want to be delicate to any reservations.

PP: Yeah, you know, I don't think it's a reservations issue so much as a perception issue, because I think every provider has had patients who want to donate their tissue, and they absolutely want to accommodate them. They just want to do it in a way that is not perceived as, 'This clinic is selling tissue, this clinic is making money off of this.' I know in the Planned Parenthood world they're very very sensitive to that. And before an affiliate is gonna do that, they need to, obviously, they're not—some might do it for free—but they want to come to a number that doesn't look like they're making money. They want to come to a number that looks like it is a reasonable number for the effort that is allotted on their part. I think with private providers, private clinics, they'll have much less of a problem with that.

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Buyer: Okay, so, when you are, or the affiliate is determining what that monetary—so that it doesn't create, raising a question of this is what it's about, this is the main—what price range, would you—?

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PP: You know, I would throw a number out, I would say it's probably anywhere from \$30 to \$100 [per specimen], depending on the facility and what's involved. It just has to do with space issues, are you sending someone there who's going to be doing everything, is there shipping involved, is somebody gonna have to take it out. You know, I think everybody just wants, it's really just about if anyone were ever to ask them, "What do you do for this \$60? How can you justify that? Or are you basically just doing something completely egregious, that you should be doing for free." So it just needs to be justifiable. And, look, we have 67 affiliates. They all have different practice environments, different staff, and so that number—

Buyer: Did you say 67?

PP: 67.

Buyer: Okay. And so of that number, how much would personality of the personnel in there, would play into it as far as how we're speaking to them—

PP: I think for affiliates, at the end of the day, they're a non-profit, they just don't want to—they want to break even. And if they can do a little better than break even, and do so in a way that seems reasonable, they're happy to do that.

Really their bottom line is, they want to break even. Every penny they save is a just pennies they give to another patient. To provide a service the patient wouldn't get.

Buyer: Because of the losses in that area.

PP: Exactly. So, I don't know your, what you're thinking as far as range. If you're thinking about just California, if you're thinking about just the West Coast, if you're thinking about bigger regions.

Buyer: Right now, we're obviously right here in Norwalk, would love to uh-

Buyer: Get established locally, I think is kinda the primary concern. Uh, to be established with a collection site for fetal tissue locally, and then ultimately, I think, what I would like to see happen, which would be something very different, as far as the different procurement organizations that exist right now, for example, StemExpress, they cater to researchers across the country but they're sourcing material from just Northern California.

PP: Exactly.

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Buyer: But when we're talking about stem cell research, cell viability and the amount of time that we're actually looking at from extraction to you know, getting it to the laboratory is critical. So, ideally if what we can provide is to be able to source as locally as possible to where a given research client is, that would be really, a huge competitive advantage for us. And, also I think that's something that researchers would want, that would facilitate the whole thing a lot better.

PP: And then, what gestational age range were you thinking? When can you start? Because you know, I've worked with people who start at 9 weeks. I've had the ones who wanted the higher gestational ages.

Buyer: There's times depending on the specific project that people want pancreas at 9 weeks, 10 weeks. From my perspective, I think it's not going to be reasonable to be collecting at a site that does not have the capability to go farther up in to the 2nd trimester. It doesn't mean that the facility needs to go all the way up to 24 weeks every time but, to be able to at least say we can go up to 12 and 16, 12 and 18 would probably be better, for the age protocols that require later gestational tissue, 18 weeks is kind of the lowest range, 18 to 20, 24 for certain things. So, if we could get up to 18, that would make it worth it to be operating at that site.

PP: Ok, and we have some affiliates that use digoxin or some other feticide and that would basically limit. So, in general, you're probably going to be able to get to twenty weeks, it's going to be very unusual to get a patient that's above twenty weeks. At the Planned Parenthoods in California. New York, doesn't use digoxin at all-

Buyer: Not at all.

PP: Not at all. There's like a culture war on feticide. People on the west coast seem to prefer feticide, people on the east coast seem to not believe in feticide. Everyone has their own styles.

Buyer: Eleanor Drey was telling me that they do not use it as UCSF.

PP: That's not Planned Parenthood, Eleanor hates misoprostol and digoxin. That's Eleanor.

Buyer: So, that's a personal- ok.

PP: It's a data poor zone, I wouldn't say it's a data free zone because there is some limited data and it is up to interpretation as to what you think of that data. I think it also has to do, again, with model of delivery. Eleanor is in a hospital where they can hold patients all day long, if they need, even overnight. In outpatient clinics I think people are trying to do so in a much more efficient way. So, in general what I'm saying you'll probably get up to twenty and then after

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twenty you' getting feticide. But there are three affiliates right now in California that go up to 20 weeks. The other thing is, have you been speaking with Family Planning Associates at all, in California?

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Buyer: I was told that FPA- FPA is the same thing right? I was told that they start digging at thirteen weeks, once they go into the second trimester.

PP: They're not digging at thirteen weeks.

Buyer: That's not true?

PP: Not at all, I know they're medical director, I can connect you with their medical director, that's not the case.

Buyer: Wow, because I was shocked. When I heard that I thought, wow well- Do you have her name?

PP: Her name is Rachel Steward. I'll connect you all via e-mail.

Buyer: That would be excellent. I know that we had spoken a couple times about the Orange County affiliate, which I think, is literally the closest to us right now.

PP: Yea, and I reached out to their medical director, and they're working with someone, I don't know who it is, but they're just not interested in talking with anyone at the moment. I don't know what's going on with the San Diego and Riverside County affiliates- Orange is Orange and San Bernardino, San Diego is San Diego and Riverside. In L.A. there is the affiliate in Pasadena.

Buyer: And how far do they go?

PP: I think they only go up to 14 weeks.

Buyer: Eh, that's not really-

PP: L.A. is working with a partner-

Buyer: Novogenix

PP: Yea, I guess.

Buyer: You don't know for sure, I guess.

PP: I know the people, I don't know- I know the staff. I've never actually asked, because that's a decision that's not actually made by me. But, it's an established

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relationship, I don't imagine that it's going to change in the short term. Which, is why I think family planning associates is an option because they go from Bakersfield, all the way down to Orange County, so pretty broad range. They definitely go to 18 weeks, and at some sites, a little higher than 18 weeks.

Buyer: When we were talking saying the **\$30-\$100** price range **is per specimen** that were talking about, right?

PP: Per specimen. Yes.

Buyer: And what does per specimen mean for Planned Parenthood? Is that, you guys consider that, a discrete sample.

PP: One case. One patient, and again, there's different steps involved too right? There's who's going to consent the patient to donate. It it's staff, then that's staff time, that gets figured into it, as opposed to if there's someone that's there, then it's just flagging the interested or "eligible" patient and somebody else does the work. It's basically for individual patient. So, if you end up shipping four individual specimens, that's still one patient.

Buyer: Yea, that's what I was going to say. If we take kidney, liver, thymus and say bone marrow-

PP: Yea, to us it's all just one.

Buyer: Because when we charge, that's four different specimens to a researcher but-

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PP: That's basically the way that they do their work. The way they budget is by the amount of time they spend on one patient. That's one bunch of tissue, they handle the tissue, they do what they do, you know, in that way, so. But yea, that's the way- It depends, if you're expecting somebody to process, and package, identify tissue for you, it's going to be at the higher end of the range. In all cases, it's really gonna be about staff time, because that's the only cost to the affiliate. And then, if you want space. For example, it is, it's Novogenix is at PPLA, they have a corner of the lab. And they set up, come in with their coolers and everything, and handle all the tissue, but they're taking up space, so I'm sure the affiliate considers that when they come up with what's reasonable. But I don't think anybody's gonna come up with a crazy number, because they're all very sensitive to this too. And at the end of the day, they want to offer this service because patients ask about it.

Buyer: I think that's what is most important to me is the patient and how can we serve them, and how can we make this- just the whole experience, well maybe

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just my passion for the patient. So can you give me an idea of what that's like for the patient? I get to them after, but doing that, is there a way to do it in a delicate way so that—

PP: Yea, I mean, there are obviously the patients how come in, who are asking about it from the start so it's easy to talk about. **But the others, I mean honestly, there's not going to be one thing that works for every patient. Every patient experiences a whole wide range of emotions about the experience in general, and so you don't know where they're coming at from there. But I think every one of them is happy to know that there's a possibility for them to do "this extra bit of good," in what they do.** And I think patients respond most to knowing the types of outcomes that it might contribute to, so for example Alzheimer's research, Parkinson's research. I think most of these patients have some experience with at least one of these conditions or another. I think the ones that come in asking are the ones who have already had the experience, that's why they come in asking. But um, **I actually think it's an easier conversation to have, than just consenting them for the procedure in general** because at this point, I think it's more important when you have the conversation. I think that a lot of people feel strongly that the conversation shouldn't be had until after they've made their decision to terminate, they know how far along they are, and they know what's going to happen, and when all that is said and done, and they've had time for all of that to sink in, then it's time to basically say, this is how we normally handle the tissue, but if you would be interested here's another opportunity to contribute to research, contribute to science, donate your tissue. Most patients are very motivated. I haven't really seen very many patients that say no. I was in the O.R. yesterday and we had, I'd say, **18 patients, probably half of them were either got digoxin or were under eighteen and the rest of them all donated their tissue.** So, I don't think- I don't think it's a difficult conversation to have because the difficult stuff has already happened, they're kind of prepped for this. **If anything, this is almost a pleasant surprise in a way, you know you've been through the tough stuff, you've made this difficult decision.** Now there is one more opportunity for you to think about. And, I think they appreciate it.

Buyer: And, you're even saying that if you can have the conversation earlier, the earlier the better.

PP: Well, we like- there's always concerns too about kind of coercion. So you always have to make sure they've made their decision, to actually have the procedure, and then before you start adding on other things, any time we do any research. And Planned Parenthood has very strict protocols or grounds, if we're doing a research study in general, when the different points in the consent happen. This doesn't fall into the research bucket because it's not a specific protocol, it's not specific project. So, if there's not consented for a specific project, it's not going to an I.R.B., but yet there's still certain principles we still think it's most ethical to follow. And that is just to make sure they've made their

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decision and they're comfortable with the decision, then to say ok, now that you're past that point in the process, now there's one other opportunity we wanted to let you know about.

Buyer: Well, it can't hurt if I'm in an area that I'm not familiar with, so, I don't even know how to phrase it. If there is a particular organ that we need, would the procedure be any longer?

PP: So, that's a whole 'nother issue, and that's kind of an ethical issue too, ideally you shouldn't do the procedure in any other way. You should always do the procedure the same, and that's what the providers try to do. They're not gonna treat these patients any differently than they would treat any other patients, just the disposition of the tissue at the end of the case is different.

Buyer: So, would that not be something- I'm thinking of specific requests that we have from our researchers, so would, obviously, 20, 21 weeks, I imagine this, but I don't know, I imagine it would take longer. Does the patient know that, are they willing to go through that?

PP: What would take longer?

Buyer: Just the procedure—

Buyer: So, I guess cell viability is a concern right? So, some of the intactness of the specimens is a pretty big deal.

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PP: **Yea, so that's where we kind of get into an ethical situation**, because what I think most providers don't want to have do, they don't want- In terms of the steps and the preparation, and getting them to the actual procedure, you know, if you really want an intact specimen, the more dilation, the better. **Is the clinic gonna you know, put in another set of laminaria to do something different?** I think they'd prefer not to. For example, what I'm dealing with now, **if I know what they're looking for, I'll just keep it in the back of my mind, and try to at least keep that part intact.** But, I generally don't do extra dilation. I won't put in an extra set of laminaria, or add an extra day, **that's going to add significant cost of expense to everybody.** Basically, if you need to add another set of laminaria, and have the patient come back another day, if you provide procedures enough days in a row that you can do that, then you know, that's a whole 'nother consideration. In general, I'd say most people, unless there's a specific research protocol that's been I.R.B. approved, try to avoid that.

Buyer: You're saying, on the researcher side, if their I.R.B. has signed off on what- how they want to do it.

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PP: Yeah, I mean, what I mean is, in general the standard protocol should apply. So, in general, patient was seen the day before, the goal is to get a minimum number of laminaria, and that's it. And once they've reached, if they get what they think is reasonable with laminaria, the patient goes home and comes back the next day for the procedure, they get misoprostol for the same amount of time as everybody else. Some patients are going to respond very well, some patients aren't. I don't think there are a lot of providers who A, have to opportunity to say, well, they're not really that dilated so let bring in another set, their schedules just don't work that way. And, kind of ethically I don't think they want to do that, they basically want to treat the patient as they would any other, and again, it's just the disposition of the tissue. So, you know, every case, every patient that consents and wants to participate, doesn't always yield the tissue that you're looking for. If it were to go beyond that, if there were patients who were treated in a different way, specifically to maintain, you know, it opens a whole new avenue. I think there's a difference consent that's involved.

Buyer: A different consent?

PP: Yeah.

Buyer: So, if the patient was one who was very happy knowing where it was going, would you have more freedom?

PP: You probably would, but they would have to be consented differently right? Because ideally the procedure that they were consented for, they're not going to have the same procedure. The way it's described in their consent form is different. Right now, when they are consenting to tissue donation, they're just consenting to what happens with the tissue after the procedure is done. They would have to have an extra level of consent that would probably say, "I understand that this procedure may take an extra day, or I might be here extra hours. And so it's adds a complexity level for the patient, but also on the staff and the flow of the affiliate to actually accomplish what they're setting out to accomplish.

Buyer: So it sounds like, it's more something if you had in the back of your mind-

PP: Yes. So if I know if somebody's in the clinic, and there's something that's specific they're trying to collect, I'll keep it in the back of my mind, but I'm not going to say no, I'm not going to do this case now, I don't have enough dilation to do that. But we do the best we can with the situation that we have. Like I said, it's just a kind of a consent issue, the idea is they're now not getting the standard of care, like everyone else.

Buyer: But from our end I'm just thinking the consent issue, the staffing, the time, it makes it more complex.

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PP: Yes.

Buyer: Well, that's good to hear.

Buyer: What would you say is the degree of a difference I guess you can make, if you have it in the back of your mind-

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Buyer: We need liver and we prefer, you know, an actual liver, not a bunch of shredded up—

PP: Piece of liver.

Buyer: Yeah. Or especially brain is where it's actually a big issue, hemispheres need to be intact, it's a big deal with neural tissue and the progenitors, because those are particularly fragile. If you've got that in the back of your mind, if you're aware of that, technically, how much of a difference can that actually make if you know kind of what's expected or what we need, versus—

PP: It makes a huge difference. I'd say a lot of people want liver. And for that reason, most providers will do this case under ultrasound guidance, so they'll know where they're putting their forceps. The kind of rate-limiting step of the procedure is the calvarium, the head is basically the biggest part. Most of the other stuff can come out intact. It's very rare to have a patient that doesn't have enough dilation to evacuate all the other parts intact.

Buyer: To bring the body cavity out intact and all that?

PP: Exactly. So then you're just kind of cognizant of where you put your graspers, you try to intentionally go above and below the thorax, so that, you know, we've been very good at getting heart, lung, liver, because we know that, so I'm not gonna crush that part, I'm going to basically crush below, I'm gonna crush above, and I'm gonna see if I can get it all intact. And with the calvarium, in general, some people will actually try to change the presentation so that it's not vertex, because when it's vertex presentation, you never have enough dilation at the beginning of the case, unless you have real, huge amount of dilation to deliver an intact calvarium. So if you do it starting from the breech presentation, there's dilation that happens as the case goes on, and often, the last, you can evacuate an intact calvarium at the end. So I mean there are certainly steps that can be taken to try to ensure—

Buyer: So they can convert to breach, for example, at the start of the—”

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PP: Exactly, exactly. Under ultrasound guidance, they can just change the presentation.

Buyer: Okay.

PP: So the preparation would be exactly the same, it's just the order of the removal of the products is different. And most people see that as not very-

Buyer: Yea, we're not talking about it needs to be a hysterotomy or anything, or something crazy like that, in order to- there's probably an easier solution to this problem.

PP: And, we've been pretty successful with that. I'd say.

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Buyer: So yesterday was a clinic day. So for example, what did you procure?

PP: You know I asked her at the beginning of the day what she wanted, yesterday she wanted, she's been asking, a lot of people want intact hearts these days, they're looking for specific nodes. AV nodes, yesterday I was like wow, I didn't even know, good for them. Yesterday was the first time she said people wanted lungs. And then, like I said, always as many intact livers as possible. People just want—

Buyer: Yeah, liver is huge right now.

PP: Some people want lower extremities too, which, that's simple. That's easy. I don't know what they're doing with it, I guess if they want muscle.

Buyer: Yeah. A dime a dozen.

PP: Mhm.

Buyer: Yeah.

PP: You know, I think it's good to have—so this is another consideration to make, because when you do partner with a clinic, you're probably partnering with the manager, the owner, the director, you're not so much having a relationship with the providers, but I think it helps to have a relationship with the provider, because if you do, you can have this conversation with them, and you can say, this is what we're looking for today, and they're more apt to—

Buyer: Keep it in the back of their mind.

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PP: Absolutely. Of course I want to help. I'd rather this actually get used for something, so I think, as much as the patients, the providers absolutely want to help.

Buyer: And so, if it's something as simple as converting to breech that doesn't require a separate consent? Does that make the procedure take longer? Is that another step for the provider?

PP: No, it's just what you grab versus what comes out. It doesn't make anything any different. The other consideration I think you guys need to make, is who does the training. Because when they do the training, you're basically guaranteed to not get anything.

Buyer: Oh, you mean when it's a provider who's been training.

PP: One who's training, who's basically doing the procedure, it comes out in a thousand- you're not going to get anything intact, so. What we did for a while, and I think it worked pretty well **if there's a trainee, I'd say, any research case, I'll do.** And as you get better, I'll let you do more, but we really need to do this, intact.

Buyer: So, you probably did all the procurement cases yesterday.

PP: I didn't have a trainee yesterday so, it's a lot, they're just starting.

Buyer: When you said training, I thought you meant tissue training, for clinicians. Because that's something that we should talk about, that impacts the contractual relationship with the facility. Is it, does it tend to be more one way, than the other? Are there many affiliates with staff that have tissue training? they know how to handle it, they know what to do with it, they prefer to have their own people doing it. Or because we've been imagining that we would do it, sending techs of our own in. Similar to the Novogenix situation that you have.

PP: I would say, baring some bizarre space issue, because some places have very limited space. Some people would be happy to do as little for you as possible. The more you can do for them, the easier it is. That includes consenting the patients-

Buyer: Right, because I was imagining would be doing consent a well.

PP: That's probably the biggest inconvenience, ugh that's one more thing my staff has to talk about. **They only have so many minutes to talk to the patient.** If you said you're going to do all the consenting, you're going to collect the tissue, I don't know who would really say no. I really don't.

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Buyer: That's really what they want to hear.

PP: That's what they want to hear, they want to hear you basically say, other than taking up a little bit of space, this is going to be as low impact as possible, on you and your flow. You're going to need a room, somewhere to consent the patients, once the patient is ready to be consented. So, you're going to need space in the lab, you're going to need a place to consent. That's it, otherwise, as long as you don't leave anything behind, they're going to be happy. Their affiliates who have been doing this for so long, they have staff that are so good at it, they may just say, that it's something that staff can do. Especially because you know, they know how to identify some stuff. They probably wouldn't know how to identify the stuff you need. They're looking for basically, all of the limbs a thorax a head, to present them, "We've got it all." That's the only concern.

Buyer: How long, right now, is the average amount of time they spend with a patient?

PP: I would say about ten minutes.

Buyer: Per patient.

PP: Per patient. yes. And also contraceptive counseling and all that.

Buyer: That's all pre procedure, pre op.

PP: The layout of the actual Planned Parenthood is counseling rooms and procedure rooms. So, yea those are just counseling rooms with a desk and a chair.

Buyer: Certainly, I'm not an expert in your clinic flow, I don't presume to know where would best fit in. But, I know that what we've done for other practices, for example the cosmetic facilities. We have a clinic float, our tech kind of acts as a float, they have their clipboard, and kind of mark down all the interested patients, you know ahead of time to try to facilitate that. I don't know if that will help or hinder your process.

PP: That's how it works with a lot of the researchers, as well. They kind of just identify who is interested. What did you do at the cosmetic centers?

Buyer: That's where we get a lot of the adipose tissue because that is a very rich source of multipotent and pluripotent stem cells.

PP: There's a private surgical center that I work with in Calabasas, where I was this morning, they have tons of fat. There were six canisters when I get there this morning.

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Buyer: It's not the sexiest thing to work with but-

PP: It works.

Buyer: Yea, and they pay for it, so. It's a good way to start out. As you can imagine, the jokes are not ending.

PP: I bet.

Buyer: So, you spoke with the medical director of the Orange affiliate, and they have an organization already, they're not interested in changing? Do you know anything- what in particular they are really satisfied with from that relationship, that maybe we can emulate?

PP: I didn't probe, I just asked if they were interested, they said they were working with someone. I don't know who it is. I know years ago there was someone they were working with, and they stopped for a little bit, I don't know if they started again.

Buyer: And that situation or the one right now, is that a procurement organization they're working with or is it just a laboratory-

PP: I don't know. That, I don't know. I'm just trying to think of our affiliates up and down the west coast. Like I said, San Diego/Riverside, I didn't ask.

Buyer: From what I understand, ABR is pretty tight with San Diego.

PP: Ok. I'm actually going to be having drinks with their medical director next week so, I can ask.

Buyer: Ok, yea, yea. That would be good. We were talking about it, and we if we were looking farther up field rather than locally around here, then it makes most sense to be looking at that swath or southwestern United States going east. Ideally we could just be going north, but Northern California is kind of dominated by StemExpress. Whether or not that will continue, is an open question. From what I understand of them, but it looks like it's better to go East into kinda more open territory right now. We're looking at Arizona, New Mexico-

PP: Arizona only goes to 20 weeks. There's is a law that says 20 weeks, it was 18, I think it has a stay, but it is definitely a possibility.

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Buyer: But, they do go to 20 in Arizona? Because that's as good as we would be getting in Orange right? Because they start dig'ing at 20 weeks.

PP: I'm sure they would be interested.

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Buyer: In Arizona? Do you know the medical director, or their patient services person? How many surgical locations do they have?

PP: They have two. They used to be two separate affiliates, Northern Arizona and Southern Arizona and they partnered. I think it's Phoenix and Tucson.

Buyer: Those are big cities though, I imagine, if those are the only two clinics they probably have pretty good volume then.

PP: You know, I can't tell you. Off the top of my head, I don't know but they seem to have pretty good volume. But yeah, I think Arizona's good, and they definitely have the gestation—they go as far as the state will allow them to go.

Buyer: Do they have any previous experience with providing, procurement or—?

PP: No and they have a fairly new medical director also, but their CEO is very business savvy and like I said, I can't imagine he wouldn't be interested.

Buyer: You have to talk directly to the CEO as opposed to-

PP: I'll reach out to the CEO, and they have two medical directors, one who handles primary care, and one who handles surgical services. I'll reach out to both of them and ask them who's the best person to connect you with.

Buyer: I did see online that the Gulf Coast affiliate as well already does donation services-

PP: They do a ton of research, so I wouldn't be surprised if-

Buyer: So, I don't know if that's in conjunction with a tissue procurement organization or if they work directly with researchers or if they've already got it covered and there is no need for us but-

PP: I can ask. Of all the affiliates they have the largest research program, they have a multi-million dollar budget. I think they are very well connected. I'll ask.

Buyer: Yea, the research client community in Texas is kind of a hub. Not so much as California or Wisconsin for example. But in terms of the regions of client base we're looking at is basically California, Wisconsin, North Carolina, and Texas are kind of-

PP: North Carolina, they don't have your gestational age-

Buyer: Is there- apart from New York, is there any where else on the east coast- if we could open up the research triangle area in North Carolina, the Raleigh to Chapel Hill area. That's a huge, huge market.

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PP: We have an affiliate in Orlando that goes to 20 weeks right now. I'm pretty sure. We have several affiliates not just in New York city that go to at least 18. I think, I have to see, the southern New England affiliate, Connecticut and Rhode Island and then there's Massachusetts, which is huge, but they also have a very developed research program. I'm sure whatever they are doing, they're doing locally. It's worth reaching out.

Buyer: Washington DC? I met Dr.-

PP: I think they only go to 14 weeks. Genola Perry is their medical director.

Buyer: I didn't meet her, I met the guy who is also the medical director for NAF. Matt Reeves.

PP: Matt Reeves, he's a provider there. Yea, I'm pretty sure they only do 1st tri's there. Not positive.

Buyer: I know that- He and I spoke about second trimester and he indicated he had good volume. It was an interesting conversation because he's friends with someone, I think it was in Pennsylvania, who was actually a researcher and so he's like: "Oh yea, in the '90s we used to collaborate all the time, it was great."

PP: I'm trying to think of the meeting that I had with pretty much all the later 2nd trimester providers.

Buyer: Did people talk about this kind of stuff there, was there a good response to it? What was your impression?

PP: Just causally, the meeting was for several other purposes. I'm just trying to think of who was there. Like I said, the Southern New England affiliate was there along with Connecticut and Rhode Island. Gulf Coast was there, Minnesota, North Dakota and South Dakota go up to 20 weeks. Middle of the country-

Buyer: They're within courier distance though.

PP: Yes they are.

Buyer: Yea, that might be a good one. That's what I mean by sourcing tissue, as locally as possible to a client. Because if we can get it to a point where it's not a matter of FedExing it over night or delivery or something like that, it's just a matter of somebody couriating it a three or four hour drive. That's kind of the critical that makes a huge difference between us and another organization.

PP: Now, is StemExpress just located in Northern California? I don't even know.

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Buyer: That's my understanding, they're located in the Sacramento area. Mar Monte, the big Mar Monte affiliate and I think whatever other Southern California affiliates there are.

PP: Yea, I know that the Shasta Pacific affiliate works with them. I guess Mar Monte works with them. And many, many years ago there was University of Washington, there was a group at University of Washington that reached out to-

Buyer: Yea, University of Washington, that's the NIH they're kind of the official fetal tissue collection service and they- a lot of researchers don't use them- I'm not sure why, I think it's because there's kind of a backlog in their cases. They were the only one around for a long time and the pipeline just doesn't work properly.

PP: So I guess my question is, are you guys planning on exhibiting at a Planned Parenthood meeting?

Buyer: The one that you mentioned earlier, the one in October, Brianna-

PP: Are you going to be in Miami?

Buyer: Yea, we're going to barring unforeseen circumstances.

PP: That would be a good opportunity, all the medical providers are going to be there, some of the CEO's are going to be there. I mean, you want to talk to the surgical services medical director.

Buyer: And the main thing that they're going to want to hear is that we do everything.

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PP: Yes. Basically, like I said- Look, **there is not a provider out there, I can't imagine, who I don't know if you talked to Warren Hern at all**, maybe he doesn't care. **But there is not a provider out there, who doesn't want this.** Everybody just sees this as a way to add another layer of good on top of what they're already doing. They already feel that what they're doing is good. Again, the majority of the providers are non-profit organizations like Planned Parenthood or operating on a razor thin budget. So as low impact that you can be on them, the better. I really do think you have a good opportunity with Family Planning Associates in Southern California. As I said, as soon as I get back to my desk I'll connect you guys with Rachel. They're expanding their services in a lot of ways. To my knowledge networking is even easier in California. So, I think that's a fantastic opportunity there. Right now the laws in Texas are crazy, there's two affiliates- there's only seven clinics. Five of them are independent and two are Planned Parenthood.

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Buyer: So, low volume [inaudible]

PP: High volume, because there isn't anywhere for patients to go. Texas is a huge state and they closed down almost all the clinics. There's a woman named Amy, I'm blanking on her last name. She's from whole woman's health- I'm sure you met her, she got kind of shorter blonde hair, very nice, very outspoken.

Buyer: Yea, we spoke with her.

PP: She's basically got most the clinics in Texas but then, there's Gulf Coast, like I said, I don't know the specifics of what they're doing, but I'll ask. And then there's Greater Texas, which is Dallas and Austin. I don't think they're working with anyone.

Buyer: And, what's their gestational limit?

PP: 20 weeks. So I think that, then again, the affiliates in Texas, I think, even if Gulf Coast is working with someone. I think if you can be creative or come up with another way or a better way, **times are hard in TX right now, anything that you can do to make things a little bit easier for them, or a little bit better for everybody**, I think gets your foot in the door. So, I'd be happy to introduce you to both of their medical directors. Paul Fine is Gulf Coast, and Darryl Johnson is Greater Texas. Both Gulf Coast and Greater Texas have pretty well developed structures and pretty independent surgical services, and people in academic research. One other place I would consider, that you're not thinking about possibly is St. Louis.

Buyer: Right, Missouri, I think we mentioned that.

PP: David Eisenberg is the Medical Director of the St. Louis region. They do 2nd tri's they have a few extensive collaboration with all kinds of research, pretty dynamic medical director, his name is David Eisenberg. I think that's definitely worth your while. And just looking at the map, if there was one place that was untapped, I would say St. Louis.

Buyer: And what's the best way- for you to connect us by email?

PP: Yea, what I'll do, is kinda reach out and see if any of these folks are interested. Like I mentioned, they all be in Miami in October. I guarantee you, even if I didn't connect you, they would come up to your table, because they're all interested in doing this. To my knowledge, everyone has been looking to do this, but they've only been able to find someone who very local or very small opportunity to do this. If there is an organization that someone is working with that they can make an introduction or connection. I think they would be very open to that. So I think that's a possibility, and like I said, you know, like one thing I think is a big pet peeve for many of them- people kinda just don't understand the

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practice environment. They don't understand the way that patients flow, and how it's going to impact them, so if you can show that you're sensitive to that, that's a breath of fresh air. Just say: "We understand that you're time limited, you have your staff, we want to be as low impact as possible. Just flag the patient that is interested, set some space aside some room for us, we can do the rest. We will handle the tissue, we will do everything, all we're asking for, is your space and consideration." And, I think that- I don't know anyone who would say no.

Everyone's been looking to do this for a year and a half, the affiliates in California have been very lucky, because in California there is no shortage of possibilities. That's not the case elsewhere. And definitely saw StemExpress at the NAF meeting but, I don't even know how the connection with Novogenix was made, most affiliates don't even know how to reach out, or who to reach out to, or even how to make this connection.

Buyer: Yea. Has the relationship with Novogenix been for the last year and half?

PP: I don't know how long it's been, I think it's been about a year or two, yea.

Buyer: And what was it about the last year and a half that everybody's talking about? Is StemExpress and the Norcal affiliates?

PP: I think it's a variety of things, I think patients are asking more-

Buyer: Just more, more people are aware, yea.

PP: Patients will call up, make an appointment and say: "I would like to donate my tissue." And the affiliates are really feeling like "Oh wow, I really need to figure out a way to get this done." Because, patients are talking about- you know, in general, in healthcare, a provider is not going to offer a service unless there's demand. And, there is a demand now, I mean, women know that this is something that they can do.

Buyer: So, that would be something for us to think about, just women's, making-

PP: That's going to be the best money that you spend, it's just word of mouth, it's much better than any ad, or anything you could ever do, if you can get women talking, saying "I want to do this", the providers will then say, "Wow, I need to do this, it's what they think about when scheduling appointments."

Buyer: So how many affiliates would you say total, that are actually working with a fetal tissue procurement organization right now?

PP: To my knowledge, right now, I only know the California affiliates. When you mentioned Gulf Coast, I didn't even know that, so I don't believe it's—I don't know what it is they're doing, but the Northern California affiliates, and the Southern California affiliates-

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Buyer: Because it seemed like kind of a trade off to me, whether to try to focus on affiliates who have experience with doing this, either currently or in the past.

PP: Yea.

Buyer: But then, if it's somebody who is already involved, then it becomes an issue of competition. Whereas if it's someone who's never done this before, maybe they're interested but how long it's going to take to get started up.

PP: Yea, you know, I almost feel like I have to say, California is almost done in this regard-

Buyer: Saturated?

PP: And it is, the reason that it's saturated too is, Normally, let's say an affiliate, for example, was looking for a lab to work with, to do their pap-smears or their STD tests. They're going to look for someone who gives the best service for the lowest price. This is a little bit different, because they want to do this, but they want to do it in a way that's not going to impact them, and it's much much less about money. You could call them up and say, "I'll pay you double the money," and they're almost more inclined to say no, because it's going to look bad.

Buyer: Right.

PP: To them, this is not a service they should be making money from, it's something they should be able to offer this to their patients, in a way that doesn't impact them.

Buyer: Offsetting their costs.

PP: Right. No one's going to see this as a money making thing. The other reason affiliates think this is a good thing is, it's less tissue that they need to worry about, it's taken care of. They have to do something with that tissue, it's hard to find somebody that wants to do something with that tissue, so the fact that there's somebody that's looking for that tissue is-

Buyer: And that was a point we were looking into, what if, just taking that from them.

PP: That is such a huge service to them, and I just have to say-

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PP: -time this came up on a national level, is there are issues with disposal of fetal tissue. Probably, the biggest company in the world that does this, is

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Stericycle. Some anti-choice groups got the names of the board of directors for those companies, and started coming to their houses, making them feel uncomfortable, stop picking up tissue. At the houses of the directors, of a waste management company basically, that just handles biological waste. And, I think that's what's started the conversations with affiliates because they're like: "What am I supposed to do with this tissue?"

Buyer: We went to a session on that.

PP: Yea, there was a session on that at NAF, because it is a serious issue. That's a service that affiliates need, so I think some affiliates are looking at it as a way- it's not obviously going to account for everything, not everyone is eligible, not everyone is going to donate, you can't take everything, but that has raised an issue so, I don't know if that is ridiculously far-fetched, we'll handle all of you tissue.

Buyer: Matt Reeves had actually suggested that to us.

PP: Even if you could find a way to do that, can I just tell you? Even if there were people who weren't donating, you'd have huge business just for taking the tissue. People would pay you. They would just say, "Take my tissue!" Then, you could only send off what you wanted to send off, but you would still have to consent the patients though. It's just something to keep in the back of your mind.

Buyer: Yea, I was about to suggest that- I mean if it's the situation of, you know, California, so let's say Novogenix is paying \$50 dollars per specimen, and we say we'll do \$60. "Oh, I don't know, it seems a little sketch."

PP: That makes it look fishy. Exactly.

Buyer: And so, they say, "Alright, well Novogenix is only taking, like, what? They took five samples yesterday-"

PP: Yea, we'll take it all.

Buyer: Yea, what if we could take it all. That is the better way to negotiate about this.

PP: Yea, that's gonna win your business. "We'll take all of your tissue at the end of the day."

Buyer: Right. So we're bartering more about services, than money.

PP: Yes, and again, affiliates don't - affiliates are not looking to make money by doing this. They're looking to serve their patients and just make it not impact their bottom line. If anything, you can make it even better to their bottom line by giving

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them services in kind instead of money. I think a lot of them will take you up on that. That would definitely get people. Say, **“I’ll give it to you for the same price, AND I’ll do that.”**

Buyer: What uh- We only briefly got into it with Matt, what kind of total volume, like, if we’re talking about containers or liters of material, let’s use yesterday as an example, there were 18 cases?

PP: 18 cases.

Buyer: 18 cases, so for those 18 cases, let’s say it was all boxed up and binned up. What kind of volume of material are we talking about here? Quantitatively?

PP: To be on the safe side, let’s say 18 liters.

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Buyer: 18 liters. That’s really not a lot.

Waitress: Any coffee or tea?

PP: No.

Buyer: So, normally how are you guys disposing of it when it’s not being donated? Is it going to Stericycle?

PP: It goes in a labeled box, and it goes to Stericycle, yes. Stericycle, they handle- this is considered pathologic waste, there’s pathologic waste and biological waste. You know, it has to be labeled in a special way, flagged in a special way. Because apparently, I didn’t know this until this whole issue came up, but apparently- a lot of waste is just steam sterilized and then dumped. If it’s biological waste it has to be incinerated, it has to be tagged for incineration, that adds cost. They only have so many sites that do incineration and they charge those for incineration.

Buyer: (inaudible)

PP: For everyone. And then when you have less players who are willing to do it, there’s only one price.

Buyer: Is there a reason an affiliate just doesn’t have it’s own incinerator? Because that, I mean-

PP: I think it’s probably expensive, I think if push came to shove and they had to they probably will. Affiliates are just starting to band together and do certain things, operate labs for example, I wouldn’t be surprised if in the next five or ten

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years, there is somebody who does it, and maybe they take on all of the business- it's still business, they're a non-profit, it's not like they have a lot of money lying around at the start. You have to spend money to do something like that, and they just don't have the money to spend. And, I think they would rather just spend it on helping patients. It's just the right space for it.

Buyer: Yea, I mean obviously we're not medical doctors so this is a little far out of our field with that. I'm surprised that incinerations is so expensive. That's it not a- seems like it's just burning up-

PP: Yea, it's not just that it's so expensive, especially in California, I mean, I don't know there's emission issues-

Buyer: (inaudible)

PP: There's gotta be all kinds of regulations that you can police, because you're probably regulated environmentally, you're regulated by OSHA, you're regulated by the state department of health it's just-

Buyer: It's not easy.

PP: I've said well, can you partner with a hospital across the way- what's the nearest hospital? They have to do something with their waste, they have surgical specimen's and things, what are they supposed to do with everything? Eventually somebody will do it. Eventually it will all make sense. But, no, to take 18 liters of tissue, I mean what do you do at the end of the day? I guess you just ship off your tissue now?

Buyer: Oh, you mean when we have access? We collect what researchers want-

PP: Yea, and that's it.

Buyer: We don't collect- Our tissue procurement really is not based on taking that everything and sorting through it. We're trying to isolate exactly what's needed and move one, Yea. So that was my initial response to Matt Reeves, was like we don't really want to be a disposal service-

PP: Yea, nobody does.

Buyer: We want the stuff that is actually valuable.

PP: Everything just adds another layer of complication to it.

Buyer: Yea, interesting.

PP: But yea, that would be a huge sell, a huge, huge sell.

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Buyer: Yeah. More so than being able to say we'll so \$60 or \$75 per specimen.

PP: Yea. For sure. I'm telling you, Family Planning Associates, they may go for their money. Private providers, they are definitely private clinics, and that's why exhibiting at NAF is great. I don't know how their- it depends on the market. In most markets their volume's not going to compare to Planned Parenthood's volume. We have 40 percent of the market in the whole country.

Buyer: 40 percent?

PP: 40 percent.

Buyer: Wow.

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PP: Yea. Not that we're trying to, we just do. We're looking now- moving forward as access is getting harder, and laws are changing- to figure out how we can partner so that everybody has access, but the way it turns out, if you look at it today, we have 40 percent because we're the largest provider and we're the target-

Waitress: A little more wine, do we split it between the two of you?

PP: We should just pour out what's in the bottle. And if we drink it we drink it, and if we don't we don't.

Waitress: Yeah.

PP: Not gonna throw it away. It'll evaporate. I'm very practical.

Waitress: That's good, it's a good way to live.

PP: But, because of that, we're the target. And because we're the target, we're not looking to make money from this. Our goal is to keep access available. And if we do something that makes a target, that just removes access for everybody.

Buyer: To be sustainable, essentially. Yea, and that's kind of intuitively, I think we've been feeling about the providers we want to partner with, is you know, as far as the Independents, and not to, you know- I think that everyone is doing good work in a really hard situation, not to cast aspersions on that, but a lot of independents don't really seem to have it together, as much as you know, a large center. And-

PP: And a lot of them aren't under the scrutiny that we are under.

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Buyer: And so just in terms of not only in terms of being able to have a workable relationship, but also having a sustainable relationship down the road. You know, if we partner with a clinic that goes out of business in a year, two years, or whatever, you know, that's no good for us.

PP: Well, that's really the fundamentals too, of talking about the cost per specimen. At the end of the day we just want to keep the doors open. And we don't want to let jeopardize keeping the doors open. We just want it to be reasonable for the impact it has on the clinic. This is not a new revenue stream the affiliates are looking at. This is a way to offer the patient the service that they want. Do good for the medical community.

Buyer: Right.

PP: And still have access at the end of the day. That's really where people-

Buyer: And we just want to make sure that we can maintain our access to the stuff and that's why-

PP: Absolutely. I'm sure access is critical to you as well as our patients.

Buyer: But, that's when those specimen fees come in for us. We want to make sure establish a relationship and keep it, um whatever's the best way to.

Buyer: I think just as important though is the volume, knowing that we have it, that we're not making empty promises to people, making sure we have a secure access to a high volume.

PP: Absolutely, you know, PPLA for example, probably about 3,000 2nd tri's, 12,000 total. But what you're going to see, and see more of is, the Planned Parenthood affiliates who do go to 20 weeks, their volume is going to go up, it's not going down. Because what's happening is, the laws, the legal environment, is not shutting us down. They're shutting everyone else down, who just don't have their act together because they're just not under the scrutiny. Um, and there are some groups and some independent providers, but there is only so much independent providers can do to withstand the pressure they're getting. Which is, like I said, why we're trying to partner together, to say, "Look we're not going to be able to go to this community, what can we keep your doors open?" We want everyone to keep their doors open, but we have a little more- I wouldn't even call it a resource, I would call it man power. We have a national office, we have people who are doing work on the advocacy front. We try to do everything we can for, our affiliates still need to do the work on the ground at the end of the day. We try to take as much of the burden off, as we can. The same would extend to you. All the burden we can take off is just one more thing.

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PP: You know, I would love to find a way to frame this, too. And maybe you guys can think about this. You know it's all about framing.

Buyer: To frame if for affiliates or, you mean publicly.

PP: Yes, to frame this publicly, because right now, we're in a position where yes, our patients ask about this, and they feel that this is important, and they feel that they're doing a good thing. But there are a lot of people who think that what we're all doing is bad and they don't want it to happen at all. You know, is there a way to continue to frame this, are there things that we can spotlight, benefits. Because if we can reframe the conversation, it's just a win-win for everybody. More patients will want to do it, more affiliates will want to partner with you, and maybe some of the people who are trying to shut it down on every level will not. I don't know how to do that, if I knew how to do that, I would have done it already.

Buyer: But you're making me think of other things that I do, you know, sometimes it doesn't have to be a public conversations. It can just spread by mouth, as you said.

PP: But, even a public conversation, a few years ago there was someone in the administration, and I'm blanking on who it was, it'll probably come to me, who was just pushing, even when Christopher Reeves was working- there are people who are trying to elevate this and I think we just need to find the right champion.

Buyer: Yea, now that you say that, that's very similar to a conversations that scientists in the stem cell research, the regenerative medicine area have been having for many years now. Ever since it's become a political issue, what ten years ago? However long? I was just at ISSCR, International Society for Stem Cell Research. It's like the major meeting, this is my swag from the meeting. You know, every time they have a session on, "How do we communicate with the public?"

PP: Yes.

Buyer: "About what we know technically and what we're doing." I don't think they're as sophisticated as framing and reframing and discourse and whatever. It's much more techy and kind of nerdy. It's the same kind of problem. I was at an OC business mixer several months ago, and I was talking to someone who does social media about biotech and about tissue procurement. And he says: "Well, if you guys want to increase your client base, you need to be taking pictures of what you do and putting it on Instagram-

PP: No, you don't. He doesn't understand what you do. [laughter]

Buyer: And, I was like wait a sec, get this though, and I say that to him. And he says: "No, people are going to see it, they're going to be grossed out and

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offended, but there's that fifteen year old emo kid who's going to think that liver is the coolest thing ever. He's going to like it, he's not even a scientist, he thinks it's gross, he likes it because he's a fifteen year old emo kid. And then his dad sees it, and his dad is a doctor, or his dad is a researcher, and so he knows to go to you or to donate to you." And I say, well, but what if his dad is a pastor? You know-

PP: Yea, which happens a lot.

Buyer: This guy was very- he doubled down. He said: "Yea, people are going to throw stones-

PP: There's always-

Buyer: "You just have to be proud of what you do, and know that's them, not you. And stand up and-

PP: And, I think-

Buyer: It's a bold vision, but I don't know if, you know-

PP: It is a bold vision, and the conversation needs to continue, but you're right, we all need to figure out a way to talk about what we do. I'm proud of what I do, I know you guys are proud of what you do. But, are there times when I'm sitting on an airplane thinking I don't know if I want to tell this person what I do, because I don't know anything about this person. I have to sit next to this person for the next four hours. It could be the worst four hours of my life. So uh, you don't know, you have to be a little daring, but I do, I do think that we can figure out a way to talk about this. Look we've got to come up with the statistics, four in ten women have had an abortion in their lifetime, you know, by the time they're forty-five- everybody knows somebody who's done this. Wanna know something else? Even more than that I will say, everybody knows somebody who can benefit from stem cells research. We just need to collectively figure out, what the talking points are, but I know that we all want to be strong partners in this for sure. Like I said, I want to see all of this succeed. So, anything that I can do to work for everybody is a good thing.

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Buyer: **Would there be a way, in the future maybe, if there's a way rather than having to deal with all the different affiliates, is there a way to partner with PPFA directly? To get some kind of pre clearance or something, so that we have-**

PP: **So, we tried to do this, and at the national office we have a Litigation and Law Department that just really doesn't want us to be the middle people for this issue, right now. Because we were actually approached by**

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StemExpress to do the same thing. One of the California affiliates said, “We’re working with these people, we love it, we think every affiliate should work with them.” And so we had a conversation, and we said, you know, what if we go out and find everyone who is doing this and present everybody with a menu, and at the end of the day they just decided that right now, it’s just too touchy and issue for us to be an official middleman.

Buyer: But, when they say right now, do they see a future?

PP: Right now, the way the Supreme Court looks, it doesn’t look very good. If you talk to my litigation and law folks they will tell you that anything that goes to the Supreme Court right now, we all lose. There is also the cycle right? There’s the time of the year, anything that’s going to be heard we usually know by April, so after April it’s usually ok to talk because we don’t want to incite anyone to take it to that level. So, we’re at a pretty crappy time right now. We just heard Hobby Lobby and we knew we were going to lose the buffer zone case. **Unless the composition of the Supreme Court changes anytime soon, we don’t want to be raising eyebrows.**

Buyer: Uh-huh

PP: But I will tell you that behind closed doors, these conversations are happening with affiliates. And your presence- yea, in the future sometime, yes. This is something we need to continue the conversation because this is something we are always re-evaluating. And as I mentioned, the patients want to do this, the affiliates want to do this. We just don’t feel like it’s the right decision at the time. The timing is not right. Hopefully we’ll feel better, maybe we’ll feel better after November. Maybe things will look a lot better after November, I’m not so sure, I’m hoping. You know, otherwise I might move up to Canada. I can do my work from Vancouver just as well as I can do it from Los Angeles.

Buyer: I was just there for ISSCR. Beautiful place.

PP: It is a beautiful place. They have wineries, they have farms, very outdoorsy, a lot of snow in the winter but I’ll survive. I’ll come down to Southern California, my house.

Buyer: Ha ha.

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PP: Yea, we’ve asked, and it’s just not something we can’t commit to right now. That doesn’t mean that we’re not continuing to have these conversations, that we are not going to continue to provide opportunities for our affiliates to connect. So, I really do think that you guys being there in Miami is important, not just for Planned Parenthood, but for all the academics. So, the forum- the meeting you guys would be exhibiting at is a partnership between Planned Parenthood and

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the Society for Family Planning. The Society for Family Planning, is essentially every training program that trains abortion providers in the country, is at that meeting. So this means you're going to have people who are going on and doing this in their private practice, or their going to come and do it for Planned Parenthood. So with the exception of some of the more cowboyish independent providers, who we love and we're trying to support. This is where everybody is, this is a win-win. And then look on the flip side, there maybe people who want to partner with you to procure tissue for them.

Buyer: Right. That's what I was thinking when you said academics.

PP: Yea, so there's going to be people from all over the sites, you know, Harvard, name a program the will be there. Wash U, OHSU, University of Maryland. We have twenty-three really strong sites, and many other around the country. So, you will be meeting a lot of academics, who really believe in what you do and good contacts, I mean, you've got Matt. He's got the independent provider side. You've got me who's got the PP side, and hopefully you can make some strong academic contacts. With UCSF? I don't know that their are many academic sites, at the volume and support at UCSF are kind of an anomaly and giant.

Buyer: They are saturated though, that was the word Dr. Drey used. They're volume is saturated with being committed their local-

PP: What about Cook County? Have you connected with Cook County?

Buyer: Where is that? Chicago?

PP: Chicago. The largest family planning provider in the Mid-West. Cook County hospital, Stroger Hospital-

Buyer: And it's a hospital, not an out patient clinic?

PP: Not an out patient, it's a hospital.

Buyer: And what is it called?

PP: Cook county, Ashlesha Patel is the family planning program director. I'll put her on my list.

Buyer: And, what's their limit?

PP: 24. 20, 24.

Buyer: Do they do dig?

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PP: Yea, they dig.

Buyer: How late?

PP: 20, most people do 20.

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Buyer: So that- it's not a PPFA National policy though right?

PP: Not a PPFA National policy.

Buyer: New York is not using it then.

PP: **PPFA National policy is you must comply with the Federal Abortion Act. There are a variety of ways to do that.** In fact, you can't do that before 20 weeks. And there are affiliates who start at 20, there are affiliates that start at 22, and there are affiliates who don't do it at all. New York doesn't do it at all, I don't know if you spoke with them. New York City is- what PPLA is on the west coast, New York City is on the east coast. They don't use dig, so you would have up to 24 weeks, the other thing is, that they're volume is probably as big, if not bigger, they do procedures Tuesday through Saturday.

Buyer: Yea.

PP: This is the type of setting where they check to see if the dilation is enough, if it's not they put another set, and have them come back the next day because they're doing them five days in a row. There you have probably the best opportunity outside of UCSF to get those larger cases. But Cook County is fabulous, it's in the center of Chicago, two airports, plenty of opportunities there.

Buyer: I know that we definitely want to get established somewhere local, and just to have that, it's just more stable. You know? It's kind of a sustainability issue-

PP: I'm just trying to think of a way to get good volume in California.

Buyer: Right. I would love- If we could sit down and have the same conversation with Orange County. I don't know if PP Orange is more tied to their group or PPLA is more tied to Novogenix, you know, who has the stronger-

PP: I don't think anybody is tied to anybody. I think the problem with PPLA right now, is that they're going through a leadership change. So, I don't think anything is going to change anytime soon.

Buyer: You guys don't- aren't in a position to-

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PP: We have an interim medical director, we don't have an ongoing medical director right now, so they're just not in to make any big shifts until a new senior management has kind of settled in. I'll definitely let you know when there's a new medical director on board. You know, Orange I just don't know, I get the feeling that they were like: "We're good." So I didn't push it-

Buyer: Can you find out who the company is that they're working with?

PP: Sure.

Buyer: Because especially if it's not a procurement organization, but just a biotech lab that happens to be in Orange County. So that, I didn't mean to interrupt you. Sorry.

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PP: Oh no. I'll ask them, but I'll also push Jennefer Russo to your table. She's the medical director of Orange County. I'll make sure you guys connect with her.

Buyer: Because that-

PP: You guys can have the conversations with her, she can probably she more than I have any idea. Because I can ask what I can ask her, but I don't know what I'm asking her about.

Buyer: Because that makes a huge difference, if there's only a lab, local that they're working with, I'm sure that lab doesn't have the kind of volume where they need all of their second tri cases. I would be surprised, unless it was UC Irvine.

PP: I don't even know, and like I said, the Novogenix name came about before, they've had three medical directors since the last medical director resigned, she set that up and nothing has been stable enough for them to re-evaluate that situation.

Buyer: (inaudible) That's not normal.

PP: No, that's not normal. The change is in senior management, one medical director retired. And after she retired, they haven't been able to find a good fit yet.

Buyer: So building a relationship with someone and then-

PP: Yea, I just don't feel like there's the opportunity for that right now because everything is so transient that, until I feel we've found something with sticking power, it's not worth your while. I do feel like Family Planning Associates has good possibilities. In fact, I'm going to text her right now to ask the dig question. I can't believe that question.

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Buyer: I was shocked, there goes that opportunity.

PP: I don't think they do dig, I'm going to double check right now. I don't even think they do it at all.

Buyer: They must be really concerned about a sheriff is Bakersfield or something.

PP: I would be shocked, and she's usually pretty quick, she might be with patients, but let's see. Oh, we just got an answer. They don't do dig until 18.6.

Buyer: Oh, 18.6.

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Buyer: Can you ask her if they're working with anyone right now?

PP: Look what says! "Are you working with anyone." In exact, actual words.

Buyer: Read my mind. Is she in the area? Does she want to come and have a drink?

PP: She's downtown. In Koreatown actually, where their headquarters is. I trained her.

Buyer: Oh wow. So you think FPA is a good provider, in your book they're legit. They're not flaky like the independent providers.

PP: Novogenix is very little potatoes, I feel like its'- Doogie Howser basically runs the company, he's a doc. I don't know how he-

PP: You're talking about Novogenix? or FPA?

PP: Novogenix. FPA is totally worth working with, with their medical director, for many years, I was apprehensive about FPA because it was basically just kind of like a for profit organization. They have a medical director there- they offer prenatal care now, they're offering- they're really rounding themselves out. They're going to be become quite a competitor to Planned Parenthood in California. I'm not worried about it-

Buyer: Friendly competition.

PP: They're trying to really build- to strengthen themselves to be a long time player in the community, and I think that's an important collaboration.

Buyer: Almost like Kaiser.

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PP: Oh yea, for sure.

Buyer: If, we can offer to an affiliate that we're going to take care of everything, the consenting, the collection, we don't even need an extra room, we just need three feet of space in the path lab, in the back with a dish so we can do that.

PP: Uh huh. Which we already have set up, you just have to-

Buyer: Right. Is that- are there affiliates, who would just donate the tissue for free?

PP: Probably. I mean really, the guidance is, this is not something you should be making an exorbitant amount of money on.

Buyer: Is that the PPFA guidance or?

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PP: Yes. Our goal, like I said, is to give patients the option without impacting our bottom line. The messaging is this should not be seen as a new revenue stream, because that's not what it is.

Buyer: That seems like it would be, and correct me if I'm wrong. Seems like it would be such an easy thing to not show a profit. No matter how much we compensate, it—

PP: Yeah. Well, but at the end of the day, you still need to have the paperwork to back it up because, we are under a microscope.

Buyer: But your cost, your loss in some areas must be so much that that can be shown to, I don't know-

PP: I understand. If you were to look at it in the big picture, yes. But nobody looks at it in the big picture, they look with the little blinders on.

Buyer: Ok. I'm just trying to brainstorm. Because, I think offering some people, not only, just offsetting their cost in other areas, seeing the potential for that, besides the potential, for the patient, I'm still going down that road, even though I know, I understand what you're saying. This cannot be seen as, "We're doing this for profit."

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PP: No. Nothing, no affiliate should be doing anything that's not like, reasonable and customary. This is not- nobody should be "selling" tissue. That's just not the goal here.

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Buyer: Right. And, I never see that as, I don't look at it that way, we're not selling tissue, we're selling the possibility of what the research can offer.

PP: I think we all would agree with you. That's just not the perception, sadly, for everybody.

Buyer: I mean, researchers are paying for procurement, they're not paying for-

PP: Yea, I know.

Buyer: You're not buying a brain, you're buying a procurement service.

PP: Exactly. Exactly. And, at the end of the day, it is all just sitting there, it's all just going to be wasted otherwise. That's what it is, it's a waste. It's a complete and total waste. I work at a private clinic where, if the patients want to take the remains with them, they can do that. But at the end of the day, it's just being sent off to Stericycle or some other company, I just don't see-

Buyer: It could rot in the ground.

PP: And have an impact. But, I mean I understand, there's so many ethical levels involved, and people have very strong feeling, and they're entitled to their opinions. But at the end of the day, I'm just trying to make the most people happy. And to do the most with it.

Buyer: Right, and do it in a way that's mindful- often times- Lisa Harris was a very interesting presentation, the NAF meeting, how often times stigma masquerades as ethics or conscience, and so again if people are looking at tissue procurement services and looking at it with blinders on, as opposed to seeing the big picture, why are you looking at it with blinders to begin with? That's a manifestation of your own prejudices and judgment.

PP: Yea, Lisa's been doing amazing work, for the last five years so on this. That's another affiliate that goes to 20 weeks.

Buyer: She said she's a quite a bit of experience with it, she's provided materials to Michigan researchers in the past. Although, it's sounds like her volume is not very big.

PP: Oh I don't know her volume- It can't be that big, because they were sending their students to Los Angeles to train.

Buyer: Really? Wow.

PP: She didn't come across on my list. Like I said I think we kinda went through the folks- Like I said, I think your best bet at this point would be FPA. They have

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a ridiculous volume, and Rachel Steward is the person to connect with. Whenever she answers me, I'll follow that up, but I think you've got some good leads.

Buyer: Yea, and if Dr. Russo as well wanted to have a conversation, I think we would both-

PP: I think that she's always willing to talk. It's just- we'll get her on a conversation soon, don't want to be too pushy. And when I'm down in San Diego, I'll just learn a little about what they're doing. I didn't realize that the hostess is in a sling.

Buyer: Her wrist.

PP: Is that what happened? To get surgery or?

Buyer: I asked her and she said it's not very exciting.

PP: She's in this lovely dress and a sling. It's hard not to notice.

Buyer: So, when you're- when you know, in the back of your mind you've got X, Y, and Z organs that need to be procured and we want them to be reasonably intact, and you convert to breech, are you saying that pretty much, I mean there's no guarantees with any of this, but we can pretty much count on having you know, the major areas, torso, thorax, abdomen intact-

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PP: I'll actually collect what you want sometimes, and put it aside.

Buyer: Oh, so you actually do the-

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PP: If I see it. Why not? I'm right there. Oh, for sure, I mean to me, I don't know, it makes the procedure that much better, like I've done something better. Like I said, I think that forming a relationship with the providers, like you did at NAFF because that was a lot of providers. the providers as much as the patients want to do this. I think they would all love to participate in something like this. It just adds another level of interest to what they're doing. **You know, everyone has a different technique, so that's the thing.** There's definitely local variance, like no two people do a C-section the same way, no two people do a hysterectomy the same way. No two people do a D&E the same way. **With that said, if you maintain enough of a dialogue with the person who's actually doing the procedure, so they understand what the end-game is, there are little things, changes they can make in their technique to increase your success.**

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Buyer: Even though they have a set way that they do it, they're open to changing that?

PP: Reasonable, if they're reasonable people, sure. I mean there's always going to be that one person who's like: "This is my thing I've been doing it for one-hundred years-

Buyer: Warren Hern.

PP: Yea. I love Warren Hern, he serves a purpose. I mean, he just lives in an alternate universe. He just lives in Warren's universe. I love him, I use his instruments, I use a lot of his techniques, you know, but he's Warren.

Buyer: If we were to look at it from a different perspective, kind looking across the nation at the providers who are best, or most technically skilled maybe-

PP: Yes.

Buyer: Who we can say, you know, we need two intact brain hemispheres, we need thymus, liver, you know, not shredded liver that's in eight pieces. Does that change the landscape at all? Kind of whoever's better suited to facilitate the process at all.

PP: I'll be honest with you, if you have very specific things you're looking for, you're almost more likely to get that, rather than at a clinic, and a private provider who does exactly what they want, the way they want to do it. So for example, when I worked at PPLA, they were seen by a nurse practitioner going over protocol, you have to get at least six laminaria in, if you get more, great, if you can't, no big deal I'll figure something out. When I see my private patients at the other surgical center where I work, I put in the laminaria myself, I know that this isn't enough, so I'm going to do this, that, different things.

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PP: So, if there are very specific things you are thinking of, sometimes an independent clinic or a private provider, while your volume is going to be lower, your quality is going to be higher. And that's not true for all of them, it's just some of them.

Buyer: But it's possible that they may have more freedom-

PP: Yes.

Buyer: To work the way they want to.

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PP: But, on the flip side, for example, so I had 8 cases yesterday. And I knew exactly what we needed, and I kinda looked at the list and said okay, this 17-weeker has 8 lams, and this one—so I knew which were the cases that were probably more likely to yield what we needed, and I made my decisions according to that too, so it's worth having a huddle at the beginning of the day, and that's what I do. I don't think other providers do that, but I actually like being involved in the process, so I say, 'Okay, what are you looking to supply today?' And then I look at the list, and I say well, all these patients, they only have 3 laminaria, I wouldn't hold your breath for that, I think I might be able to get it for this case, I think I might be able to get it for that case, is there, you know, what else can we do? But it's worth having that conversation, that's why I say that the providers are important. Most of the conversation you're going, I want say- at the NAF meeting there's two different crowds. And I feel like the one's who are going to come to your table, are going to be a lot of the independent clinics, owners of independent clinics, and that's who's going to be coming to your table. But there's also the 2nd trimester providers meeting, that's where you heard Lisa Harris talk, that's where- those are the folks who do just those cases that yield the tissue that you want, you know, there should be a way, maybe Matt and figure this out. But, you guys can establish a relationship with just those providers, to just tap into those practices. There's not a lot of us- that's the conversation to have. In most cases it's going to be the clinic owner or the clinic manager saying: "Yes, we're doing this, this is what we're doing." You're not really going to talk to the provider, they change everyday, they do what they do everyday. If you can establish a relationship with the providers, that would be great. When you work with and affiliate- once or twice a year, they have a providers meeting, maybe you say, I don't know if you have meeting with providers, but we'd love to come in and introduce ourselves, talk about what we do, and that's who those people are in the tissue lab, when they're wondering what that person is in the corner. Maybe you forge that relationship to make your quality a little bit better. It can't hurt, it couldn't hurt.

Buyer: Right. I didn't realize there wasn't a standard number of laminaria for each patient. But it's highly variable?

PP: Every clinic I've been to has an entirely different protocol. Planned Parenthood, New York City, the surgeon that's there that day, takes out the laminaria, does an exam, decides if there's enough for them, if there's not they put more in and come back the next day. PPLA, if they're above 20 weeks, they get at least six in, it's fine. Family Planning Associates in Chicago has what they have. Every- Jerry Edwards has what he has. Warren Hern has what he has.

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PP: As far as medicine goes, this, for a very long time has been a data-free zone. In the last three to five years, we've seen a lot more, because the Society for Family Planning has been publishing guidelines. So, in ten years from now, I think it'll be much more standard, but we're still a long way away from that.

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Buyer: So, that's why it's so important to talk directly with the affiliates because you can't necessarily tell us-

PP: I can't tell you how they're doing it. I can tell you what it says in the standards. I can tell you the protocol as, these are all the things you must do, and it allows for **incredible variability**. Like I said, you don't have to use digoxin, you don't have to use misoprostol. Some people use laminaria, some people use Dilapan, so really all over the map.

Buyer: Would you- because I heard for example from one of the Planned Parenthood providers, in Northern California, who works with StemExpress. She was saying that she uses misoprostol for all her dilations, and that, she thought made a huge difference, in terms of getting out intact specimens. So can we make a request like that- or maybe more realistically. Digoxin. If we were working with somebody who digs at twenty weeks, and somebody really needs twenty two week thymus, can we hold the dig for two weeks.

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PP: So let me tell you an interesting story. So there's not a lot of clear data on digoxin. Providers who use digoxin use it for one of two reasons. There's a group of people who use it so they have no risk of violating the Federal Abortion Ban. Because if you induce a demise before the procedure, nobody's going to say you did a "live"—whatever the federal government calls it. Partial-birth abortion. It's not a medical term, it doesn't exist in reality. So some people use it to avoid providing a "partial-birth abortion." Others use it because they actually think it makes the tissue softer and it makes it safer and easier to do the procedure. Is there data for either of these? No. Because number 1, the Federal Abortion Ban is a law, and laws are up to interpretation. So there are some people who interpret it as intent. So if I say on Day 1 I do not intend to do this, what ultimately happens doesn't matter. Because I didn't intend to do this on Day 1 so I'm complying with the law. There are other people that say well if you induce demise it doesn't matter, you're never gonna do it so you don't have to worry about intent. So that's one side of it. The other side is there are providers who actually feel it makes the procedure easier. I am one of those providers. And so a few years ago, we actually tried to get affiliates to agree together to do a randomized control trial-

Buyer: Oh wow.

PP: -where patients go digoxin and some didn't, but at the end of the day, the affiliates who liked using digoxin, did not want to give that up. And the affiliates who didn't give digoxin didn't want to do it. We couldn't get anyone to agree to randomize, so the likelihood that you're going to go to an affiliate who uses dig and ask them not to do it, and they say yes? Not

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going to happen. Not going to happen, people are not going to give up they're dig. And the dig haters are not going to give in.

Buyer: Wow. Wow.

PP: Even in the face of research. So they say that they work with UCLA and USC but-

Buyer: UCLA is Novogenix, that's where they're based out of.

PP: So, I'm thinking they have Novogenix. Which doesn't surprise me because Dr. Steward sometimes fills in at PPLA who probably works with Novogenix. I asked her if she has a procurement company. So the likelihood that you're going to get someone to not use dig, it's low. You're either going to partner with someone who never uses dig, or you're not going to have a choice.

Buyer: They're really set in their way basically, it's not a-

PP: Until there's more data, I just don't see it changing, like I said, I tried for more than a year to get people to agree, like this is research, this is a randomized control trial, they were willing to randomize everything else. They were not willing to give up digoxin or to give digoxin. Which is- it's amazing how something that has such little data, has such strong feelings.

Buyer: So, it sounds like even with data, the emotions are still going to be there.

PP: Yea, well, I don't know, I don't think we're ever going to get data-

Buyer: Really?

PP: -the data, I would love good data. the problem is, the data that we have right now is wishy-washy. The data is, yes providers can tell, if the dig worked or not, they could tell that there was demise, does it translate to anything at the end of the day? I don't know. Do they subjectively see it was easy, yes. Does it make the procedure any easier? Are we ever going to get the volume to show data? Incidence of complication is so low, you would need tens of thousands of cases to show a difference in complications. So, they're probably never going to show a difference in complications. The third difference is, does the patient experience it differently? and there's only one study that really looked at this well. In a small number of patients it showed supposedly, that nausea was higher in the patients that got dig, but they didn't measure the nausea at different parts, so you don't know what the nausea was really from, was it from the laminaria insertion, was it from the dig injection, was it from just being pregnant? So, the people who are anti dig generally say: "It doesn't give you any benefit, it just increases nausea." I don't see nausea as a negative, I think most of these patients are experiencing nausea already, and I have been able to complete procedures already, that I

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know I would not have been able to complete if it wasn't dig. But again, I don't have a randomized control trial to back that up. I don't know, maybe we'll get there. We've been able to slowly get there with randomized control trials around cervical dilation. So, I don't know if you guys have ever spoken to Alyssa Goldberg? Alisa Goldberg is at Planned Parenthood of Massachusetts, she just got a grant for a very large control trial for what dilation is best? What techniques work? Does adding misoprostol make a difference? And things like that. I think it makes a difference. And so maybe after a few more years of success doing these large randomized control trials on dilation, maybe they'll do it on digoxin again. There's just a lot of people that just want to avoid any problem and if there's some fetal demise, you don't have to worry about intent, you don't have to worry about abortion man or anything else. So, like I said, if you want no dig, your options are UCSF and Planned Parenthood New York City, and that's it. And the reason they for Planned Parenthood New York City is because they all trained at UCSF. So, it's like the UCSF school. They're the only ones to my knowledge that don't use dig before 20, 22 weeks. It's going to be hard to get those later cases. Like I said, New York City is worth going for, and I don't know that they're partnered with anybody. I don't know what the feasibility for that is for you but to me that, other than UCSF is the largest site of 20 to 22 week cases that have not gotten feticide, and I know because I'm a provider there too. So, I mean, I've practiced in both places. My subjective experience, it's easier with dig. The other thing that might interesting for you to learn is that there are some affiliates who are interested, there are,

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PP: so, genetic abnormalities. Do you guys ever collected tissue in patients with genetic abnormalities?

Buyer: Once or twice if there's a specific project going on with that stuff. And even certain genetic mutations are interesting for- not for harmful abnormalities but for HIV, there's a long story we don't have to get involved.

PP: **There are affiliates that will do cases higher than they normally would, because they have genetic abnormalities.** But we don't know if you would accept that tissue.

Buyer: For fetal indications. More than nine times out of ten, more like ninety five times out of one hundred, stem cell researchers want normal healthy tissue, for therapeutic applications.

PP: Well, that's what I figured. You can't develop a cell line if you don't want it to have abnormalities. When I went to medical school I did cell culture for—.

Buyer: Oh, yea, yea yea.

PP: It was just heart and muscle though. I have a little idea.

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Buyer: Oh yea, so you know a little about a certain number of passages, and after a certain number it's no good anymore. You have to source it again.

PP: Well yea, people need to develop cell line, and there was this really interesting story in the news. You must have heard- There was a cell line and they traced it back to the patient and the family is suing.

Buyer: Yea, Henrietta Lacks. The HeLa cells.

PP: Yea, and so I'm reading that and I'm like wow. Take it and do whatever you want with it.

Buyer: Ha ha yea, sometimes there is a specific project that, you know, has to do with Down Syndrome or Sickle Cell Anemia or something very specific and they do want something like that, but that's definitely a rarity, especially when it comes to cell based therapies. Really, the fetal cells are getting the most action right now when it comes to translational research, which is actually taking things from the lab into the clinic, finding therapeutic applications that could go to market. There's some really cool stuff going on with neural progenitor cells going on right now. Human clinical trials going on, stage two and three FDA clinical trials right now.

044142

PP: So, you know there are providers who go beyond 24 weeks. Are you working with any of them?

Buyer: So, you know for example, Susan Robinson-

PP: And Shelley Sella.

Buyer: Over in Albuquerque, they start doing dig at 18 weeks. I had a great conversation with Susan at NAFF, I recognized her from "After Tiller" which I saw about a year ago. And so we had a great conversation and she was saying she had experience working with Planned Parenthood in Fresno maybe?

PP: She works in the Santa Barbara-Ventura, San Luis Obispo clinic and probably Mar Monte and some of those up north.

Buyer: She said a couple years ago, she had been working in the Central Valley clinics. They had been working with StemExpress at the time, and she thought it was so fascinating to watch the tech work, and all the parts. She said it's wonderful, we've done it before, would love to do it but, we start doing dig at 18 weeks in New Mexico, and I think they already working with somebody too, maybe with the university there or something. The really extreme or later cases, that's the- there's a standard that researchers are looking at right now, I would

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say is roughly between 16 and 22 weeks. I think that's kind of where everybody is focused on right now, and maybe some of that is artificial because there just aren't that many places to get 24 and later, so that's why nobody is using higher gestational tissue, I don't know, it's just a result of the supply that's there, not of actually-

PP: So, she's not working with anybody, she's just working in individual studies right now, whenever it happens. I asked if they were interested.

Buyer: And that's?

PP: Family Planning Services. So you might have just hit the jackpot.

Buyer: Ha, another conversation very soon, about that.

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PP: Yea, the reason that I mention that is, there are a few sites that go to 26 or go further and there's a lot of conversation-

Buyer: Those are Planned Parenthood sites?

PP: Not yet- but there's a lot of conversation about who goes to the legal limit in their state, if they don't go to the legal limit in their state why don't they, is there another provider that does? So we're about to start doing some mapping work to say, you know, are there states where nobody's going to the legal limit? And if not, why not, and what can we do about that? So that's just, I'll keep that in the back of my mind, because that's something worth thinking about. You know, another state you should consider, Utah really has just got their service off the ground, but they're are no other providers in Utah. I'm sure they'd be interested in going further.

Buyer: How far are they going now?

PP: I just gave them a waiver. They're probably going to 14 or 16, but I just gave them a waiver to go to 20, and I think they're going to start going to 20 on a regular basis. Utah's got a nice airport, Salt Lake City, right there. It's kind western.

Buyer: It's not too far away.

PP: And uh, they train fellows, but they've got some really motivated providers. I think they would be someone else worth considering. I'll add it to my list.

Buyer: Who's the medical director there? His name is David Turok, he's doing a lot of work right now with emergency contraception and IUDs. Pretty incredible guy, pretty forward thinking, always willing to push the envelope a little further

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than anyone else, that's kinda why he popped in to my mind. I feel that there are about a million introductions that I want to make, you know? Not only to people via email, I want you guys to talk to each other.

Buyer: I mean certainly, the one's who are closer like Dr. Russo, Dr. Patel? Did you say from Family Planning?

PP: No, she's in Chicago. Steward.

Buyer: Steward. I have it here, yea.

PP: Yea, we'll definitely get you-

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Buyer: So, it's easy for us to do the same kind of thing here, and for the ones that are further away, it would be just a little bit more preparation to-

PP: Yea, well, the ones that are further away, it probably makes more sense to chat with them in October and then if something comes of it, follow up from there. October actually is not that far away.

Buyer: October is not too far away, yea. No pun intended right? For Halloween, October.

PP: I'm trying schedule another meeting and looking at the calendar, I'm like we're already in the first two weeks of August, so I'm looking at October for scheduling meetings now. Where has the year gone? It's just wrong, it just gets faster. Can we slow it down a little bit? You know, the work you're doing? Slow down time?

Buyer: Yea, I know. I think that's physics, not biology. (inaudible) Well that's the crazy thing. The biggest thing about R&D time lines, some of them are so shackled to the timeline of availability or unavailability of material to work with and so, if you can really open that up, and get the tissues to researchers when they need them, and the stuff that they need that can literally cut in half. The time that their projecting for what they're working on. You know, if you're doing a study that you're foreseeing to have any kind of clinical application whatsoever, the the biggest thing that you're looking at is being able to reproduce or replicate whatever you're showing, so you need more samples, more trails and again, it's just the volume-

PP: So, I just had a really weird idea. You know I find it very interesting you know, explaining how tissue procurement will affect the projects, and things like that. Have you ever thought about doing a little talk? On it?

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Buyer: Like a little workshop.

PP: Yea, like at the NAF meeting, or just a little something for the local providers or something like that?

Buyer: If they would let us. Yea

PP: You know, where they can hear about and understand where the tissue goes, the impact and things like that?

Buyer: That's a word where going through my mind as you were talking. We need to educate.

PP: Well, I'm sure people are dying to know. And, they're dying to know, here's the thing, if you can do it for providers. In a way, you have backwards word of mouth. They're going to tell it to the patients too, they are able to share that information and everyone's going to get on board. You do a little thirty minute session before the day starts or at the end of the day, about this is what happens once- once the patients donates tissue, this is what really happens. This is how it affects time lines, this is how critical it is to the people, this is the impact that you can have. That's the best marketing you could ever do. Like I said, I think especially in the scientific community would, they would all find it unbelievably interesting. I certainly do.

Buyer: Can we have a wine and cheese evening? We'll get Dr. Steward and Russo and people from Pacific Southwest in a room together.

PP: I think we should. Actually, let me reach out to them and say: Hey you know, do you guys ever wonder about these things? We just have to get together one night, and kinda talk about it and what happens.

Buyer: Then we could brainstorm about messaging afterwards, and all kind of, you know.

PP: Yea.

Buyer: We're going to change the world.

PP: Look, everyday that's what we try to do. Slow work and sometimes you wish things would slow down so you can have an impact but-

Buyer: No, this is the good side of time passing quickly.

PP: There you go. I'm going to start changing the way I think about things.

Buyer: Good. Reframe it.

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PP: I don't consider myself a very political person, but I think it's worth you doing something like that. Let's do kind of a little local thing, and then if it's a hit, you may want to do it for a bigger group.

Buyer: So, when you say local, how many people are you talking about, in what area?

PP: Here's an idea—the southern California medical directors have an LLC meeting quarterly, and they do it somewhere the San Diego, Orange, Pasadena, LA people, and Santa Barbara people all get together. So maybe we can do it like to coincide wherever they're meeting someday, at the end of that day. I could pull in someone who runs the program at USC, I could pull in the person who is at Family Planning Associates, I could figure out if there is anyone locally-

Buyer: What type of venue and how much time?

PP: I would just be interested in hearing about what you were just talking about.

Buyer: So, like thirty minutes.

PP: Yea, so just like a little thirty minutes talk. Just time to chat about it. I think that would be fabulous. You know, you could limit it to medical director people or you could bring in some of the local providers as well. We could pull in the local fellows. You tell me what you think you would want to do. I think that's an amazing idea.

Buyer: You said the meet four times?

PP: They meet every three months, I know they just had one, we may just want to do something as a one off, or we may want to give you guys some time to plan to do something in October.

Buyer: Does that sound like something-

PP: I mean we should talk about this. I feel like-

Buyer: This is exciting to me.

PP: And just, I can't imagine that there's not one of them who wants to understand a little bit better about the other side. We know our side really well, we want to know your side. And it gives you an opportunity to learn our side, and give you ideas as well. But I also think you- you can kinda test it and see what happens, take a shot in the dark, maybe you want to tell them that. You could do a workshop on tissue donation and what it means. We want to do a little reception at the National Medical Conference or Forum or something. I do- I think

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testing it, right here, right now, and seeing what comes of it is probably a good idea.

Buyer: Yea.

PP: UCLA and USC, they both have a fellowship program, so they have OB/GYNs who are training to be providers. So, maybe. No, I think it's worth a little test. I think the conversation would be unbelievably stimulating for both sides. We'd all get a lot of insight. On both sides of the coin.

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Buyer: Yea, speaking of which you don't have, by chance, on you copy of PPFA tissue procurement guidelines or anything like that.

PP: There are no guidelines.

Buyer: Not written.

PP: They're guidelines on research, but there are no guidelines on tissue procurement.

Buyer: Okay.

PP: And there will never be guidelines.

Buyer: Oh. Just to keep it—to keep everything—

PP: There's no guidelines, if something qualifies as research, and an affiliate wants to participate in a particular research study, there are guidelines of how that happens. If they're gonna participate in something like this, you know there are mechanisms by which contracts can be reviewed and things like that, but there are no guidelines. This is something that the national office is not involved in. For the first few years that it happened, it was treated as research, and then we realized that this was kind of overkill because we didn't have a particular IRB approved study, it just didn't fit into our framework. So we just kind of backed off of it.

Buyer: I guess, even in terms of compensation and stuff like that?

PP: Nothing is written. There's nothing in stone.

Buyer: As a security measure, as much as anything else.

PP: You know, it's- if people want to ask for guidance, there is. But do we have a written policy? No. I can't imagine we're going to have one anytime soon.

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Buyer: Yea, I think I would agree, I think these things are kind of best handled- when the atmosphere is the way it is, that kind of thing is best handled at the local level.

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PP: Alright, FPA apparently seems to think that it's research and that it's kinda wishy washy-

Buyer: Wait. Can you explain to me, what did she say?

PP: She said: "Well because we're a for profit-company we can't really get involved in research." I said, well, I'm not sure this is research this is quite different, we actually-

Buyer: If they want to talk profit, I'll talk profit.

PP: Well, it's funny because at Planned Parenthood, we don't consider that research. The FPA apparently they consider it research. I also think that's another interesting conversation, I think there needs to be a meeting so we understand what it is, and how it fits into all our different agendas, whatever, how the environment influences all of us. I think it's worth doing. For sure. So, I think this is definitely to be continued.

Buyer: Definitely. Is there anything you wanted to talk- is there anything else on your agenda?

PP: Any more picking you want to do?

Buyer: No, I think we've got a good pit.

PP: Well, I feel like we've got some good idea's here.

Buyer: I'm excited. Thank you for taking the time.

PP: Yeah, absolutely. Thank you for being persistent and having me here today, and for a fabulous lunch. I have to tell you, I am excited about the prospect of even hearing a little bit about what happens once you leave one of our sites, with your tissue. What it means to the researcher and the bigger picture. It's almost kind of like image building.

Buyer: Yea.

PP: And it's a good thing for everyone. Yea, and who knows, maybe in November we'll feel even better. Something else will happen.

Buyer: There is hope.

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PP: There is always hope, that's why we all do what we do. Yea, so how did you get involved in-

Buyer: I was a bio major in school and I've done graduate research with- my main interest is SCID mouse modeling, which is where you have the humanized mouse model, I don't know how familiar you are with it. So, that's why I say liver and thymus and bone marrow so much, because that's kind of the classic humanized mouse model when you have certain strains of mice that are mutated, they lack a murine immune system.

PP: So, I used to bike, I went to school at the University of Wisconsin, in Madison and I used to bike right past this facility where all these poor mutant mice come from.

Buyer: No, so they're not ugly or-

PP: No, no. They're lacking this gene or they're lacking that gene. What ever mutation they have, they're all have the same-

Buyer: So, if they're lacking a mouse immune system, then you can graft whatever you want into them and they won't reject it. So you can graft human fetal tissue into them, and if it's fresh and the cells still viable, then the thymus will still grow and produce thymus cells and the liver will do it's thing, still have hematopoiesis going on. You can construct a human immune system inside a mouse, and then test different diseases, drugs-

PP: Vaccines.

Buyer: All kinds of stuff on a human immune system, except it's a mouse. It's because of that kind of model that we are on the brink of a cure for HIV. I mean it's right- they're are functional cell based cures, based on bone marrow and things like that. That's when I was talking about the CCR delta-32 mutation, I don't know if that means anything you, it's a mutation that affects the way the actually binds to a cell, and so people- individuals who have the CCR delta-32 mutation in their cells, the virus can't enter the cells.

PP: I know. I know someone who has that.

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Buyer: You know the Berlin patient?

PP: I do, I know the patient. It's funny that you mention it, it's very interesting.

Buyer: I mean so it figuring out- how can we use viral vectors or genetic therapy to take regular stem cell, alter them and put them back in, and producing an

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immune system that it itself immune to HIV truly. And there's other models, there's other ways to go about it. There's a lot of interesting work being done, where it's not the CCR delta-32 mutation. Where the idea is to genetically modify the cells to express the same factors and chemicals as typical HIV anti-virus cocktails, the medicine that people take. There was one study where they combine the three most potent HIV meds and took whatever combination that was and inserted it into the cells, and inserted that into the stem cells, and the stem cells will produce antiviral retro therapy stem cells.

PP: Yeah, we're really excited, we just rolled out PREP through Planned Parenthood-

Buyer: Truvada or something else? Truvada.

PP: It's actually affordable for some patients. Not all of them, but for some. See, that's the thing, if people to hear more about the bigger picture too, that's what you need to tell them about. Everybody, at the end of the day, they need to understand the big picture, the end game. It's very easy to protest when they have their blinders on at they're twenty feet view. They get a ten thousand feet view, and suddenly it all fits together.

Buyer: [inaudible] Where is that person now? Just being sensitive to how much they can hear. How about you? How did you come to do-

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PP: Oh god, you know, it's funny, I train a lot of people, I do a lot of mentoring, I'm probably the worst person ever to tell you how to get where you are. I didn't ever really ever have a plan, I knew what I liked, and knew what I didn't like, and luckily for me opportunities presented themselves every so often and so, I made a decision every few years, but I never looked for a job in my life, I never said I need to do this, I need to do that, it just kind of happened. So, to make a long story as short as possible, I was an athlete and I had a whole bunch of injuries and surgeries, and things like that. I became very interested in orthopedic surgery, and then I said ok, I'm going to be an orthopedic surgeon. And then I went to college and I said, I don't want to be an orthopedic surgeon, maybe I'll just do sports medicine. But, you know I'll be a physical therapist, because that's easier than- Orthopedics are like big old burly guys, and I didn't know if I wanted to be with these people, surrounded, that's just not what I look like, I'm not the orthopedic surgeon type. So I'm going to be a physical therapist, and when I was in college physical therapy became a master's degree instead of a bachelor's degree, and I said, if I'm going to graduate school, I might as well become a doctor. So, I decided to go to graduate school, and then I hung out with all the Ortho people, and I said No, this definitely isn't for me. **But I really liked babies, believe it or not.** And I said ok, I'm going to be a pediatrician. I don't know if you know much about pediatrics, it's really treating moms. It's not really treating kids,

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and the kids you do treat, they're sick, and it's very depressing and I said there's no way I can do this. I could maybe do perinatology, where I deal with like just born babies, and neonatology, and then I said ok, I'm going to be an OBGYN, and then I'm going to become a maternal-fetal medicine specialist. And that was kind where I was going, and I will tell you the date, I was on-call, it was my last day, I was on call, when you're a resident in obstetrics and gynecology you spend a dedicated amount of time in obstetrics and a dedicated amount of time in gynecology. In your senior year, it's four months of each. So, February 28th 1998 was my last day of GYN ever as a resident and then I would be done. July I would graduate and then I would be an OB/GYN. And on that day, there was patient that was transferred to me, from an outside clinic, who had had a D&E, dilation and evacuation, late second trimester abortion, she was bleeding. That patient was transferred to me and she got to the hospital and I met her in the emergency room and I saw her and she was as white as this napkin, and I still remember her name, I remember everything about her, and she looked up at me, and she said, "Don't let me die." And she actually bled to death. We did a hysterectomy in about twelve minutes and she died. It was very distressing and very upsetting. I probably had a very different reaction than most people would, which was **well I do D&Es all the time, and I don't ever have complications.** And I think I'm pretty good at them, I need to keep making sure that there are lots of people doing these D&Es safely so there's not another patient like this. That was the day I said I'm not doing perinatology, which is high-risk OB, I'm going to do family planning, and I'm going to train others to do family planning. So I interviewed for a fellowship in family planning, and Dan Michelle was my program director at the time and he interviewed me and he said: "Why do you want to do this?" And I told him the story, and he said: "What do you see yourself doing in five years?" And I told him all the things I wanted to be doing. He said, "Oh, you want to be the medical director of Planned Parenthood." I said, really? I didn't even know what Planned Parenthood was. I think I went to a Planned Parenthood once when I was in college-

Buyer: What year?

PP: I think it was '90—no, 2001. He said: "You want to be the medical director of a Planned Parenthood." So, I finished my residency in 2002, I did the Fellowship, it was two years, and then about six months after I finished the Fellowship, I was still faculty at USC, I decided to stay, and I was running the family planning program there. Planned Parenthood of Santa Barbara called me and asked if I would interview to be their medical director. I did, the next thing I know, I was there medial director. I did that for three years, but I didn't get the opportunity to do as much research and teaching there, as I did when I was in LA. I left there and became an associate medical director at LA. I ran the research program and I trained all the fellows at USC. I did that for a few years and then I started consulting for PPFA, and they asked me if I would write protocol for this and that, and I did. And they said our Senior Director of Medical Services job is opening up, would you interview for that? I said no, I'm too young and there's a lot of

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things I still want to do. They said: "We understand but we can't guarantee that after you do those things, the job will still be available, we think you should interview." So, I did and I got the job, and that's where I am. That was five years ago and that's where I am now. So, I mean, every few years, I've made a decision based on what I feel I should do. I've been very fortunate, that's just kind of happened.

Buyer: Totally disagree with you about the mentoring thing.

PP: I tell people all the time, I'm just very lucky. I've heard you make your luck. I'm like no, I don't think so.

Buyer: I totally disagree with you, it's fabulous.

PP: Point taken, but yea, how about you?

Buyer: Well, I'm older much than probably both of you combined, it would take too long. What time is it? You need to be out by three? Oh my goodness, my story? I have to go to the bathroom.

[bathroom break]

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Buyer: I'm a terrible not taker, I have kind of a photographic memory so I just like to sit and listen as opposed to-

PP: No, I hear you. I have to write certain things down, just because there are so many, that if I don't have key points then I'll forget it and not do any of it.

Buyer: I'm trying to think if we covered everything. Is there anything that you feel- I think we're good. I don't know, maybe you're clear so maybe we don't need to go over this compensation, how that-

PP: Yea, I feel like you guys-

Buyer: I think I've got- I know that we want to be sensitive when we talk about that obviously, and if it's an issue- it seems like- when we're talking about that- what we're looking at is less a situation of competing with other people or just- it's not so much about competing piles of money. As it is being able to fit the needs of the affiliate, because they're just trying to be a successful non-profit and meet their bottom line. That's ultimately what we're trying to facilitate, does that sound like a good way to summarize it?

PP: Yes, like I said, at the end of the day. What you're trying to do is say, if you were to take money out of the equation, which is what most of the affiliates are

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trying to do. How can we do this for you in the most beneficial way? I think you've totally got it.

Buyer: Yea, what are the cost gaps that an affiliate is typically looking at?

PP: I don't understand what you mean. The way they look at time, is space and staff time. So, you know, it's a matter of- here's how we can help, we're going to take up the least possible space, we're going to do as much as we can, so it's not your staff time, it's our staff time. You know, maybe there is some other, in kind something else that can happen. You know, so that's it's simply not a- they all want to do this. They just don't have to present it to a single patient ever. That would be the ideal situation, obviously that's not going to work. Somebody is going to have to flag somebody or have the conversation and let them know, this is available, and it's probably going to be their staff. The way to do this with leaving the fewest footprints at the health center, it's going to be beneficial for everybody. We can do that.

Buyer: No, I think we started thinking very creatively about way to do that. I do think feedback is good too. Sure, anyone can come get the tissue donation and send it off. I think affiliates would like to know, we send specimens to research who are working on this and this. I think that kind of positive feedback in the end it will just be a better relationship, it just kind of adds a whole human touch.

PP: Yea, and we're talking about people in the non-profit sector, the motivations are a little bit different. This is all- anything you can do to help explain, who's benefitting, the benevolence of what they're doing. I think that holds as much value as any cash prize. You know, I think the affiliates would be proud of this. They would go back to their donors, they would go back to their boards, and say look, we contributed to this, this, this, with just this one service, working with this one partner. You know, I think that this could help you on the back end too, because if there are board members- maybe there are board members somewhere else, that say alright, who else can partner with this organization. How else can we contribute to this? They're are bound to be people that have personal connections, patients, donors, board members.

Buyer: Yea, we have the Berlin patient right over here.

PP: It really, really makes a difference. So, I think, perhaps the difference is, affiliates are looking to benefit in very different ways than just dollars and cents. I mean I get, they're not going to do it in a way that costs them money. They want to break even, they want to be compensated reasonably for the time and space, whatever impact it has. But, I think that they are looking for something bigger.

Buyer: And \$30 to \$100 is what we're going to be looking at in terms of- that's what they'll reasonably think is going to cover-

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PP: I think so. I think, again, you're going to have to do- it's funny we do a lot of training and we've been trying- is there a way to standardize the contract and what the rate looks like, and at the end of the day, the lines be the same, but at the end of the day, it's very different. The staff member that's involved, the amount of time it takes them, the space it's going to be variable. Could we come up with a line item? Sure. This is what we pay for space, this is what I'm going to pay you for your staff time for this- it's almost the way an affiliate comes up with a research budget. Right? I need this level of staff to consent the patient. It's going to take fifteen minutes, this is what they get paid per hour plus twenty percent, that's how much that costs. So, can you come up with a standard way to do it? Probably, but I wouldn't expect it to be the same number.

Buyer: Is that a PPFA project? You're trying to figure out a standard-

PP: A lot of the training programs are funded by the same donors. So, from there they came back to us and they're like: "How come with this affiliate it cost his much to train a resident, how come this affiliate-" I said well this affiliate has five ultrasound machines in two rooms, and this affiliate does one ultrasound in one room and **so they're losing patient revenue**. So, it all has to fit into the bigger picture. So can we come up with a template and line items, and think about this creatively in a way that these are all the things we should consider? Yes. Is the number going to be the same at the end of the day or everybody? No way.

Buyer: Yea.

PP: And that's just the way it is.

Buyer: It's such a tapestry we're looking at.

PP: It's just like when a patient walks into a health center in Nebraska or Los Angeles or Minnesota. It's going to be very different cost, and it's based on the dynamics and the demand and you know, the level of staff that is required by the state medical board and things like that. At the end of the day the number's going to be different. But, all the input should be exactly the same. And yea, hey in the perfect world if you could find a way to help them deal with their biological waste, pathological waste, they would love that.

Buyer: Yea, I'll do some research and see what the details are of getting an incinerator.

PP: And also, some of the people that you supply everybody-

Buyer: Yea because if there's a university that just processes- there's a university hospital they have their own incinerator. There's all kind of networks that this ends up opening up.

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PP: Yea, I know originally, when we did research on it, we looked at- what are all of these labs that we work with, because these labs, we send in the labs tissue and at the end of the day, they do something with it. Turns out they use Stericycle like everybody else.

Buyer: Sounds like Stericycle is able to get the monopoly. They figured out, well everyone has garbage.

PP: That's what ended up happening, they bought up everyone's contracts, they bought up all the smaller vendors, and they're this big multi-national. But no, there has to be another option. Messaging, that's a whole 'nother issue. If you guys could come up with a way to message, it makes it easier for everyone at the end of the day. if there's some kind of one pager that says this is what we offer, this is the service, this is the type of research it contributes to, these are the types of achievements we've been able to work in. This is something you might be interested to ask you doctor or your nurse, if this is something that works for you. It will make it easier for whoever actually does the consenting. **It'll drive demand, it's a win-win.**

Buyer: When- as far as consenting, at your site is it Planned Parenthood counselors who are doing the consenting or is it Novogenix?

PP: It's the same medical assistants who consent for everything else. Once all that's done, they say oh by the way, we also do this.

Buyer: So it's a PPLA consent form.

PP: It is, it's a PPLA consent form for tissue donation. But the interesting thing, I'll tell you is, some people consent, some people don't. The funny thing is, the second day, when that patients actually comes back for their procedure, when they're waiting, what often happens is, Novogenix will talk to people who haven't consented, and they usually do, once someone has the time and energy to sit and have the conversation with them. So, she ends up picking up several more specimens, just from being there and speaking.

Buyer: The seeds have been planted.

PP: The seeds have been planted, they thought about it for twenty four hours, now here's somebody else- they're sitting there, waiting, they've got nothing else to do, it's not like one on top of the next, on top of the next. So, I think it's always beneficial, if you have somebody who that's just what they do, they're going to do it much better than incorporating it in, but it can be, it works both ways.

Buyer: I was just thinking about if we use our own consent form or would we use the Planned Parenthood form.

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PP: You could use the consent form you created, but it would still have to be approved.

Buyer: At the end of the, it's another thing, depending on the affiliate that's gonna-

PP: Yes, one thing I can promise you, it won't have to go through the rigorous role of a research project, because there is precedent for this now, and affiliates know how to deal with it. Like I said before, it was a nightmare, it had to go through an IRB, not just your IRB, it had to be an IRB for the affiliate. It would have to go through the national office, it had to go through contracts and all these other things. We've totally removed ourselves from the equation because, we said look, in reality, is this tissue going to research eventually? Yes. Is this a dedicated product, that adds additional risks, there is no specific protocol, we're not changing the way we care for the patient. It's just a decision between you and the patient, and we're not going to be apart of it.

Buyer: So, is it only the affiliates that have a robust research department like Gulf Coast have IRBs or-

PP: Yea, and most of them use commercial IRBs-

Buyer: I think most people do.

PP: Yea, commercial IRBs, they all know which IRBs to use depending on what they are doing, and how they feel about it so, yea. Most people hate Western IRB now.

Buyer: There's quite a few options out there, Quorum and other.

PP: I get emails from Quorum on a daily basis. But yea, everyone has their own process. With that said, most of the affiliates who go to the higher gestational ages, who also tend to be more developed, there may be a little more process involved. But, I can't speak to everyone's processes. Like I said, I'm going to have a conversation with Rachel, there's misperception on every level. I don't think that misperception exists in Planned Parenthood anymore, because this is a conversation we've been having for years now, where people know it's research and yes, it's an alternative way to help you manage your tissues, but it doesn't account for all tissue, because everybody's not going to be eligible, everybody's not going to consent, you're still going to have someone else manage your tissue, even though it's donated, everything's not donated. At the end of the day, it all goes somewhere.

Buyer: And all that's conversations, like we're having. None of that's written down?

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PP: No.

Buyer: So I mean if we're concerned about messaging, I don't know if- well, you can have messaging be spoken word. You don't have to have things written down.

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PP: Well you can have messaging, **and what happens is, folks will ask the national office questions. We certainly have answers to the questions, but we don't have a policy per se, and that is by choice.**

Buyer: Yea.

PP: So for now, that's the way it will be. And when they ask the questions they're going to get the answer. It's just getting people asking the question. But, I think like I said, people have been talking about this for so long now- California's pretty saturated, I think we have an opportunity with FPA. But most of the other locations, I don't think they are so much, and so it's just a matter of what makes the most sense where you can put some resources and how it can work out. So, between PPFA and FPA in California, I think you have pretty broad reach, I don't know of any other volume providers, and the academic sites will be at the Forum. But, they don't have any particular volume.

Buyer: Yea. Yea.

PP: Cedars is going to have a fellowship program, they're in the process of putting it together. USC has one, UCLA has one. Those are basically the three sites that are training all the providers in the region. So, if everybody who is providing knows you exist, you know, I don't know what your interest is in a small provider, who wants to call you up and offers one case today, do you want to come out and do this? That's kind of a lot of work.

Buyer: Yea, that's really not an ideal situation.

PP: That's why you want to go with someone like PPFA, who does 40 percent of the cases and has a whole schedule for the day. Again, FPA is a possibility we just have to do some education there. On both sides, now you know they don't dig until 18.6, now I just need to let them know, it's not really research.

Buyer: Does FPA do actual research, research where they have IRBs for that or?

PP: Nah, they might participate in a one off study but, like she was just saying, they feel uncomfortable doing research because they are a for-profit. I think it actually looks worse for their research partner.

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Buyer: Oh.

PP: You know for profit companies doing research.

Buyer: I'm sure that the partner can make that determination though- they're talking about people who are partnered with FPA?

PP: She's basically partnered with USC and UCLA to help them recruit for studies, but I guess it looks weird when a for profit partner for a project, because they probably have some- they could be accused of having an outcome in mind, if they stand to gain something. As opposed to just general letting patients donate their tissue, it's a service.

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PP: I see it as a service that is offered to patients, and it just happens to be a service that is offered to researchers on the back side. It's not what's seen on the face of the health centers though. It's if our patients want to do this, we make it available to our patients. And, I think I can have that conversation with Rachel as well. So, it might take a little while, I need to have a few conversation with Rachel before I can make an introduction. We'll see what happens.

Buyer: How much time do you think you need to have that conversation.

PP: Couple weeks. Yea, just because I'm leaving town on Monday. I won't be able to have a real conversation with her until I get back. I'm leaving town for a week, and then I go to New York for half the week, then I get back, so I'm guessing mid-August. It's not too far way, it's July 25.

Buyer: Time goes quickly.

PP: And apparently that's a good thing. I need to just change my perspective. Is there anything else we haven't touched on?

Buyer: I think we're saturated for now.

PP: Haha, like much of southern California.

Buyer: The conversation will continue, I'm sure a million things will come up.

PP: I'm going to have to write a whole bunch of follow-up emails and I'm really- Like, if we can get you guys to the forum, I think that's going to be pretty beneficial. We'll get some people by your table once I know where it is.

Buyer: I'm sure we can commit to that, we've been intending to, I don't know how far Brianna got talking to the organizers but, even- at this point, even if there

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were some other stem cell stem cell meeting that was of conflict of the same weekend, I think this is easily more important so-

PP: It's October 11th or something, it's around October 11th. You know more than I do, I just know I have to go down there on the 9th. Probably then, the 8th.

Buyer: Are you presenting there, or speaking, or anything.

PP: I run a lot of the meetings, and then there's pre-meetings. It's basically three conferences back to back to back, I have to go, I'm having a pre meeting on the 9th. I have to go the meeting on the 10th and 11th, the 12th and the 13th. Then I have to go on the 14th, then I'm hoping to take a few days off to just breathe after like six days of no sleep. But I just go where I'm told. I think I'm giving two talks at the meeting, and part of the panel.

Buyer: So, what can we do? So that you, this part that you're helping us with? In a couple weeks, send a little reminder?

PP: Yea, I'll send a follow up email after, to make sure I've got my follow up thing. I mean, like I said, I'm going to have this conversation with Rachel, I'm going reach out to Arizona, - mean I have to figure out what Gulf Coast is doing, what Orange is doing, figure out what San Diego is doing. To reach out to some people on the East Coast, to reach out to Chicago, and also reach out to Utah. Like I said, I'm going to be at a retreat all next week, so this isn't going to happen until the week of the fourth. Or even the week after the 4th. Why don't we check back in like, mid- August, figure out what's going on with you guys, being at the forum, and me getting some contacts to some people then we can figure out where we are.

Buyer: So, I'm going to say about August 19th.

PP: Wonderful, by then I should have all the emails out. Ok, that's right before I go to the CDC. So, I have a few days to get my act together. Yes, no, and I would like to talk more, just about a little meet and greet. Just even in California to talk about who you're working with, and the work that they're doing, just the whole process. I'm very excited at that. That sounds really good, because everyone talks about tissue donation, but it's kind of a giant brown box. Kinda puts a face on a whole new perspective. Like I said, especially if it's the places where it's our staff that's talking to patients, we know what's going on, they know what's going on. Everyone knows what's going on, it just makes it more genuine. Alright, we will be following up, circling back in a few weeks. This has been pretty beneficial.

Buyer: This has been good. Thank you so much for being able to take the time to-

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PP: Thank you for being persistent. That's what it takes with me because I am busy and have many things going on at one time. Alright, I am going to say my farewell then, so good to see you, thank you.

End of Transcript