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Speakers:

-Mary Gatter, MD, *President, Medical Directors' Council*, *Planned Parenthood Federation of America* and *Medical Director, Planned Parenthood Pasadena & San Gabriel Valley* ("**Gatter**")

-Laurel Felczer, WHCNP, *Senior Director of Medical Services, Planned Parenthood Pasadena & San Gabriel Valley* ("**Laurel**")

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

frame counts are approximate

Buyer: Dr. Gatter, good to see you again.

Gatter: Yea, nice to meet you. Thank God you introduced yourself, I really didn't-

Buyer: We met in October, in Miami.

Gatter: Oh yea, that's right.

Buyer: I was there with one of our procurement techs. Go ahead, yes. [Name] is in the restroom.

Gatter: How are you?

Buyer: Pretty good, it's been really since the holidays, I feel like I've been going on stop. It's been kinda tough to find the time but I'm glad we were able to make it work.

Gatter: Ok, where are you based?

Buyer: We're based in Long Beach.Yea, Norwalk-Long Beach area.

Gatter: Long Beach, ok. The music is loud, what do you think about turning it down?

Buyer: Fortunately it isn't too crowded here, I was surprised. I thought there would be a lot of people.

Gatter: Now, you're in Long Beach, are you associated with an academic institution of any sort or?

Buyer: Myself? Not really, no. I have a relationship with some people at Cal State Long Beach, but it's not very official.

Gatter: Ok, and you're company is called, what, again?

Buyer: [Company Name]. I'm the procurement- Oh, there's my boss.

Gatter: Hi. Mary Gatter.

Buyer: Mary. Nice to meet you. You know what I was just thinking? Is this meeting now supposed to be happening? Sinus headache. Just totally out of it. But,no. I couldn't postpone again, right? Thank you so much.

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Gatter: Keep your eyes peeled.

Buyer: Ok, what does she look like?

Gatter: Mid-fifties. Chunky, my height, blondish hair.

Buyer: Ok, I've got a clear shot. So, how are you?

Gatter: I'm doing well. So, your companion, whose name is?

Buyer: [Name].

Gatter: Ok. I'm getting older, the names-

Buyer: Me too. If we- I have been calling him a different name, and I don't even know, he looked at me, and I was like oh, you'll understand when you get this age. What did I call him. Oh, it was, I said [Name], which is his middle name, but I never call him that. So, I think it's the sinus headache.

Gatter: Plus, this music is loud. Maybe because I put in my hearing aid this morning. Anyway, so [Name] was explaining that your company is in Long Beach. How long have you been around?

Buyer: Well, I'm a start up. We're coming up on our anniversary very soon. One year. So uh-

Gatter: How did you get into this business?

Buyer: Oh, that's a long story. I got into it years and years ago, so eighties. What I was doing, was I was working with women, really doing counseling with them.

The whole stigma, pressure from family, depression. So, that was really where I started. And then, you know, we're about the same age I would guess. How it got babies, very dangerous. So, I was raising my family and that went away. Just still keeping my hands in it. The clinic in this area has closed down since then. Now, I just see such a positive direction I can take.

Gatter: How did you connect that with your-

Buyer: So, my niece was working in research and she knows [Name], and she came to me and she was telling me about the work that she was doing. And that researchers were not able to-

Gatter: Get tissue.

Buyer: Yea. So I just sorta put two and two together, and thought- the main thing at the time. The main thing at the time was this could be positive. If I could work with women saying, no, no, this is not all negative. You don't have to-

Gatter: Well, it's been my experience that people are eager to find some silver lining in the situation, and they're seventy or eighty percent of the people you thought would say yes.

Buyer: Exactly. Really? Is that what you're finding? seventy/eighty-

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Gatter: Years ago, I was involved; I'm stepping back now. For years, I was the medical director of Planned Parenthood Los Angeles. We had fifteen thousand procedures a year. We had a relationship with people out of UCLA, which switched to USC. They would bring their own researcher in- we would get our staff to get informed consent which has to be the federal consent. Then, their staff would get the tissue, what ever tissue they wanted that day. They would come mostly to our main site, where we did procedures to 24 weeks. And they would mostly handle the bigger cases.

Gatter: So it was my experience that maybe 60% to 70%, but a large percent of patients we approached would say yes**.** [inaudible] I don't know how much you know about this. But at Los Angeles we used digoxin- a feticidal agent- once you apply a feticidal agent-

Buyer: It nukes the stem cells.

Gatter: Anyway, about a year and a half ago I retired from PPLA and I had been at Pasadena since '05, so I continued my work at Pasadena, which is a much smaller affiliate, much more suitable for a semi-retired person. I live in San Moreno, much closer to here. Laura who will be joining us, is the lead clinician there. We do about eight hundred abortions a year, and about sixty of them are

between twelve and sixteen weeks. So, I didn't know if that was going to satisfy you, not satisfy you. Or what you were interested in, or what.

Buyer: Well, ok. Whether it would satisfy, maybe it's not the volume I was thinking about, but would it fulfill something else? Yes. I think it would. What do you-

Gatter: So, where we stopped off was with your organization, so you started a year ago as a start up.

Buyer: Yes.

Gatter: And you are for profit?

Buyer: Yes.

Gatter: Your academic connections or researchers are with?

Buyer: I was telling her, Briana coming to me and talking about researcher not being able to get tissue and-

Gatter: It's a perennial problem, thirty years ago when I was working in New Haven and we had people at Yale who were doing research on Parkinson's and stuff like that. I was involved with tissue donation there as well. Not at Planned Parenthood, it was women's health services. They would come, they were very good and they would take whatever I could give them, because they were just desperate to have tissue.

Buyer: So, I might be looking high volume to satisfy needs but, I'm just in a position where I see, this last year, the great strides we made. One problem that I have encountered is saying yes, I can get this for you and then not be able to. So, I don't want to run into that, I don't want to get that reputation. There are some organizations with that reputation.

Gatter: Well, it depends, if you have high enough volume you can get pretty much anything.

Buyer: Right.

Gatter: So, have you thought about FPA or-

Buyer: Yea, FPA is- because we're close with Dr. Nucatola- She was kind of our go between FPA this summer. And FPA doesn't feel like they're in a position to partner with something like that, they feel like it's too research based and-

Gatter: Now that I think about it, you know Rachel Steward, the medical director? I think, this is before Rachel though, they're attitude was they were for profit and they didn't feel like they could partner with another for profit because they'd be accused of selling tissue or convincing people to have procedures [inaudible] it was a PR issue for them. They do fifty thousand abortions a year, they're a huge [inaudible]

Buyer: Yea, I didn't know much about them when we started talking to Deb**,** and it sounded really good but- apparently she reached out to them, I think she's close to Rachel, they said that's not something they wanted to be involved in. You know, what's kind of the most disappointing thing that summer, was we discovered pretty much every affiliate in California was already partnered.

Gatter: Yea.

Buyer: StemExpress has the whole North and ABR has San Diego, and there's Novogenix in LA, and I guess there's a private lab in Orange. So, had assumed that California was saturated, so we're starting to cast our gaze further.

Gatter: You've got one small pocket of people who are not partnered, that's Pasadena because the volume is not big.

Buyer: And so it's literally eight hundred surgical procedures a year. Wow.

Gatter: That's surgical. Our medical is up too, medicine abortion came around in two thousand (inaudible) Who would want to do this? (inaudible) come in for a quick little surgical procedure. It turn out a lot of women would rather do that than come in for any kind of surgical procedure. So our- it might be as many as thirty percent of out total AB volume is not medicine abortion. That's not- it isn't helpful to you.

Buyer: No. So, you found that- that surprised you when-

Gatter: Yea, I was surprised. I've learned from my experience and (inaudible) But I was surprised. Plus there was a lot of fear, back in two thousand that our phone lines would be overwhelmed but you know, if you do proper counseling up front, and what to expect-

Gatter: You know, when we first, we got calls from 12-year-old kids who hadn't told their parents they were coming in, who were horrified, they were now bleeding, cramping, some of them went to the emergency rooms, some of the emergency rooms were Catholic hospitals, so you know, all this kind of stuff goes on, but in general, we now have permission to go to 10 weeks as well, the original FDA was approved up to 7 weeks, and then evidence-based protocols started- I wonder if my- let me just walk out there, she's usually pretty reliable.
Buyer: So, did you want to wait for Laurel or-

Gatter: We can go ahead and start the conversation.

Buyer: So, what have you done in the past as far as providing tissue, how has that worked with the logisitics-

Gatter: Ok. I was involved in New Haven, I was involved in Boston-

Buyer: Dr. Stubblefield?

Gatter: So Novogenix was our partner in PPLA and they would send us- you know, big volume. They would send their staff to the site, and our staff, our medical assistants were used to discussing with the patients, do you want to consent? And they would say yes or no, and a lot of them said yes. Maybe it wasn't entirely sixty, and then once the patients have signed the consent form, the patients did not receive digoxin, and Heather would look at the tissue- that's probably Laura- she would take the pieces that she wanted and it worked out well for everyone. She was unobtrusive, she was helpful, she did all that kind of stuff.

Laurel: Oh, my apologies. Hi.

Gatter: So we just started the conversation.

Gatter: They're a start up, they've have been about a year in business. They are for profit company connecting researchers with people willing to donate tissue. We just started talking- they were a little bit concerned about the fact that they're in Long Beach, but they understand that every California affiliate is paired up in a tissue donation program, except for Pasadena. Volume, that you for getting it to me is eight hundred a year. We were just starting to talk about the process worked with Novogenix down in Los Angeles when I was there. To back up a little bit, PPFA, our parent body, is on board with tissue donation, but we have to ask for a waiver to do it, and we have to lay out for them what our program's gonna be like. And it's absolutely a requirement that we use only the official, federal government form for tissue donation, that we don't modify it in any way. Novogenix was working on a concept that California has slightly different requirements, and so it's different, and so they wanted to very reasonably insert the California requirements into the consent form, the federal form, PPFA said no, you have to have two separate forms, so it just added to the burden of consent issues. But I was also explaining to them, back when I was in Los Angeles maybe sixty to seventy percent of people said yes to tissue donation.

So Heather, a Novogenix person would come to the site, and our staff would sign the patients up, and get consent. Heather would look at the tissue and take what she required, so logistically it was very easy for us, we didn't have to do anything. There was compensation for this, and there was discussion if that was legal, they

have been paying by the case, and there was some discussion about do we, in a different way, or I don't know what you're used to doing, how you're used to doing compensation. Patients don't care what we do, of course, but-

Buyer: I want to go back to the percentage of people that do consent, do you find it makes a difference with who is approaching them? How they're approached?

Gatter: The person approaching them, medical assistants have to be on board with the program. I didn't find any difference who approached. What I found the difference was, they were not consistently approached because of how busy it was. The busier you are, the less likely the staff is going to take the time to say "by the way, there's two more forms for you to sign." Which is such a waste (inaudible) If we need liver today, and there's a seventeen week patient who would be perfect, but she wasn't approached, then you can't do that.

Buyer: Is that- whether you want to use your clinic staff doing consenting, or whether our technician should be don't that, because that's an option as well. It sounds like it has to be a PPFA form?-

Gatter: PPFA uses the Federal form. The federal government put out a form, saying here's the form for tissue donation, aside from PP. PPFA, the form that we use, is a federal form. Now, you can use the California form, or your company specific form but you've got to use at least, that one.

Buyer: But your experience is always your clinic staff doing all the consenting, not the outside technician.

Laurel: I was with the San Diego affiliate, and they were utilizing the same process. It was the staff who was doing the consenting and then there was someone from the company also. You know, it's an education piece, absolutely for the staff. Support staff are well trained and I think it's a small amount of training and it's easy to bring them up to speed. We're participating in a research project, and that's gone well. There was a learning curve, with the education but they took that on and did quite well with it.

Gatter: What Novogenix did, they came in for a half hour session for the staff, before we started the program. They had a power point saying here is where the tissue is going, here's the diseases that are being helped (inaudible) So, yea I think the staff that understand the program is more likely to buy in to it and want to do it.

Buyer: So, logistically, what would that look like if we were to come in, not come in. We're paying to- I was always envisioning that our tech would do everything, so that's less work for you guys. Obviously they're doing the collecting and

shipping and they would also do the consenting. They can also be a clinic float that way, depending on your flow or however that works.

Laurel: Yea, I mean that's not something to turn down. I think that may well help with flow to decrease the amount of time that they have to take with our staff, and then move them to a different room, then we- I'm trying to strategize about that. We have the three rooms, I don't think, spacewise it would be an issue.

Buyer: It wouldn't be a problem.

Gatter: We could move people for one building to another.

Laurel: Well, I think we could-

Buyer: There's multiple buildings?

Laurel: We use- we have a second building in front of the parking lot. Actually, we just moved into a trial that we're working on (inaudible) It's a separate waiting area for patients who come in for in-clinic abortion and they're able to wait with their partners and it's out of the family planning setting. They are splitting it sometimes but for the most part, let me take it back. they intake in the main clinic and they move them for pre-op and everything, the rest of the time out there. We could keep it consistent (inaudible)

Gatter: Here's a side issue, if we use your staff to do the consenting, obviously this is your employee, not our employee. And so far when's she's dealing with out patients, she took all those courses; how to talk about abortion, how to talk about this, how to talk about that.

Laurel: They're probably a couple that it would fall under, that we'd want her to take.

Gatter: Her status wouldn't be independent contractor. It would be-

Laurel: I don't know what-

Buyer: You feel like Planned Parenthood would contract with our tech or?

Gatter: We would have a contract with you guys that would specify some of these things. (inaudible) It would specify that you wear a nametag, all those things.

Buyer: But on top of that there would be a personal contract with the technician.

Gatter: We were just talking about it, probably not.

Laurel: Maybe not, it may fall under- if they're your employee, then probably not. (inaudible)

Gatter: Tissue donation on the cusp of research and something else. I know that for years, well PPLA and northern California, we were kind of the vanguard to have PP doing this kind of stuff. I know that PP national had a hard time trying to figure out where to draw the lines and whether to have us sign—in fact, now it's all coming back to me. If you guys were doing a specific, one research project, we would have to sign it up as a research project. But if you're collecting tissue for multiple research projects, not just one, then it falls into the tissue donation area. It's complicated. The paperwork is a nightmare. But, yeah.

Buyer: Does that track with what Deb was telling us before?

Dr. Gatter: Yeah, they're always changing their mind, they're always doing things different. I'm sorry. The last moment I checked into this, we did not require any research form submission to do tissue donation, providing it wasn't a one-on-one relationship with a researcher who was collecting the tissues in order to use them.

Buyer: Does that track- I think so. We'll be exhibiting at the Medical Directors Council meeting in a few weeks. I don't know if you'll be attending.

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Gatter: I am now the president of that organization. Of course I'll be there.

Buyer: Excellent. So we'll be there, and I guess- I imagine, I mean I've never been but I imagine there would be more dialogue with the national office or something like that. So that might be a good opportunity to hear what the most up to date protocol is.

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Buyer: What would you expect for intact tissue? What sort of compensation?

Gatter: Well why don't you start by telling me what you're used to paying.

Buyer: Okay. I don't think so. I'd like to hear, I would like to know, what would make you happy. What would work for you?

Gatter: Well, you know in negotiations the person who throws out the figure first is at a loss, right? So [laughs]

Buyer: No, I don't look at it that way. I know, you want to play that game, I get it.

Gatter: I don't want to play games, I just don't want to lowball, because I'm used to low things from—

Buyer: You know what? If you lowball, I'll act pleasantly surprised and you'll know it's a lowball. What I want to know is, what would work for you. Don't lowball it, tell me what you really—

Gatter: Okay. $75 a specimen.

Buyer: Oh. That's way too low.

Gatter: Okay.

Buyer: And that's, really, that's way too low. I don't, I want to keep you happy.

Gatter: I was going to say $50, because I know places that did $50, too. But see we don't, we're not in it for the money, and we don't want to be in a position of being accused of selling tissue, and stuff like that. On the other hand, there are costs associated with the use of our space, and that kind of stuff, so what were you thinking about?

Buyer: Exactly. Way higher than that.

Gatter: Mhm.

Buyer: So I'd like to start at around $100.

Gatter: Okay. Now this is for tissue that you actually take, not just tissue that the person volunteers but you can't find anything, right?

Buyer: Exactly. What is, what we can use, what is intact. So that's why I'm saying no, don't lowball, I want you to be happy and—

Gatter: Well, it's complicated by the fact that our volume is so low too. I mean, are you looking at 8 and 9 week specimens or only 2nd trimester specimens?

Buyer: Well, here's kinda the different factors that come in to that. A lot of the research demand, I would say the majority but a plurality would be for second trimester and later trimester. So, there are some good scientific reasons for that, with cell differentiation, how developed it is and all that. But, at the same time it's all somewhat artificial because there's the practical consideration, like what you

said, of whether the tech can actually find what they're looking for, and it happens to be easier in the second trimester. Whereas if you're trying to do first tri, you're waiting for an intact enough specimen to come out to try and find. Even then, you spend an hour playing find the liver. And uh- it wouldn't be microscope assisted.

Gatter: Naked eye? (inaudible)

Buyer: Our techs are most used to- they're most used to adipose tissue and stuff like that from cosmetic surgery centers. That might be a logistical thing we have to look at a little more carefully.

Gatter: The problem is that we're only doing sixty second tri's a year. If she doesn't say yes, then your staff is tied up the whole day. When we first started the program, we had a situation- a policy that she would call the day before and how many ten weekers do you have, she wouldn't come in unless we had a chance for getting tissue that day.

Buyer: So call the day before? So that-

Gatter: For the schedule, say how many second tri's are- and you know second tri's could not show up, there's a lot of slip between plans and the actuality**.** The staff- your staff would call the night before and say "I need a twelve weeker, do you have any?" That kind of thing. Then they could come in or not come in. It would be irregular for you in terms of whether she could do it or not.

Buyer: So coordinating what we need with what is available, the night before?

Laurel: I mean we- the schedule is full almost a week before, we do-

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Buyer: How much does it change? Within a weeks time? Just ballpark it.

Laurel: Usually the schedule is so full they don't' add anymore appointments, so they move to the next weeks schedule. So at least typically the Monday before the Friday, the schedule's set. It's full.

Buyer: And you don't see so much-

Laurel: No. we can certainly check back, but no.

Gatter: For the full schedule on Monday, have them show up on Friday.

Laurel: Well that's I mean, they're having an excellent show rate today. Last week they were at twenty three patients. The demand is higher up because of the holidays, which is what we always see. But, on the average week we see about twenty to twenty four patients every Friday, and it's a combination of first

and second tri's. in those numbers, you know, second tri's are much less than first tri's.

Buyer: So, is Friday your only procedure day?

Laurel: Mm-h. It is.

Gatter: We're thinking of adding more.

Laurel: Yes. We're on the cusp- staffing wise and the need to carry out family planning visits, we're watching how far out our scheduling is, we're not ready to add a second day yet. As I was just going to share, once in a while, there is a change in the schedule, so coming up in the end of March we're going to change Friday to a Tuesday, and send it out a good month in advance, so we know that too.

Buyer: And would you be adding a second procedure day this fiscal year, or no?

Laurel: Not this fiscal year, no. Unless something dramatically changed with the numbers, in the last year, our in-clinic numbers have been very steady if not dropped just a little bit with the switch to medication abortions. But for the most part the numbers have been fairly constant. (inaudible)

Buyer: When you add another procedure day, I guess it's not relevant for this year. Does that mean procedure volume is more spread out over the week or does it increase-

Laurel: No.

Gatter: It actually increases volume. There's no point if you just divide the days up.

Buyer: The intact specimens, I wanted to touch on that. What I was trying to say is if the 10 to 12 week specimens, end of the 1st trimester, if those are pretty intact specimens, that's something we can work with.

Gatter: So that's an interesting concept. Let me explain to you a little bit of a problem, which may not be a big problem, if our usual technique is suction, at 10 to 12 weeks, and we switch to using an IPAS or something with less suction, and increase the odds that it will come out as an intact specimen, then we're kind of violating the protocol that says to the patient,"We're not doing anything different in our care of you." Now to me, that's kind of a specious little argument and I wouldn't object to asking Ian, who's our surgeon who does the cases, to use an IPAS at that gestational age in order to increase the odds that he's going to get an intact specimen, but I do need to throw it out there as a concern. Because the patient is

signing something and we're signing something saying that we're not changing anything with the way we're managing you, just because we agree to give tissue. You've heard that before.

Buyer: Yes. It's touchy. How do you feel about that?

Gatter: I think they're both totally appropriate techniques, there's no difference in pain involved, I don't think the patients would care one iota. So yeah, I'm not making a fuss about that.

Buyer: Mhm. IPAS is the manual suction, right?

Gatter: Yeah, our shorthand for that.

Buyer: So, would you, I could see where it might present some sort of problem for you. So, to, if we could compensate more on something like that, or—

Gatter: Well, now you're shading into the area of you're paying me to do something that's not right. So [laughs] that's not what I want to talk about!

Buyer: No, I don't, I don't see that. What I want to make sure is that you, whatever you have to go through to deliver intact specimen, that that's compensated. Not that I"m paying you to do something shady or—

Gatter: Well I will discuss it with Ian, our surgeon. We'll see what he has to say. Do you have feelings about this?

Laurel: I'm just trying to think of it from his perspective. You know, I don't know what his opinion would be on that.

Buyer: You're not putting the patient at any more risk, right? As you said.

Gatter: No. Just slight variation of the technique.

Buyer: Okay.

Laurel: Which, the consent they're signing is for suction aspiration, it doesn't describe what kind it is.

Gatter: Yes, but I have heard people argue that for the tissue donation, it says we're not doing anything different, so.

Buyer: That's what I need to understand, because what I'm seeing it as, of course, I'm looking for intact specimens. You know from a medical perspective, the patient is receiving just as good of care. So help me understand the problem.

Gatter: Well, there are people who would argue that by using the IPAS instead of the machine, you're slightly increasing the length of the procedure, you're increasing the pain of the procedure, is it local anesthesia or conscious sedation, so they're technical arguments having to do with one technique versus another.

Buyer: So it's technicalities, is what I'm hearing.

Gatter: It's something that I need to discuss with Ian, before we agree to do that.

Buyer: And when you do second tri's- your gestational limits is sixteen weeks? Are you doing D&E's at all when you go up to sixteen weeks?

Laurel: Thirteen to sixteen weeks are D&E's.

Buyer: And Ian? He's the one who does the procedures? And that's a hard cut off, at that point he switches over to D&E's?

Gatter: It's a cut off. Under twelve weeks, it's a D&C, over twelve weeks it's a D&E, whether you do all with suction or dismemberment. I have written documentation from ACOG describing D&E even though you're doing suction. So, it's totally a billing issue. The technique we use at thirteen weeks is the same suction technique we use at eleven weeks. As it gets a little bigger, because we practice in LA, (inaudible)

Buyer: Even at fourteen weeks, he'll do an actual D&E?

Gatter: He might do a suction, I don't know, I haven't seen him in a while.

Buyer: Ah, yea, then it's kind of a different ball game too, when we're talking about D&E's because then it's all about the cervical dilation-

Gatter: We don't use laminaria, we do everything same day.

Buyer: Oh, interesting. Is that just a personal preference?

Gatter: Yea. What do you guys prefer in terms of collecting?

Buyer: Well, the best for us would be, you know, multi-day induction.

Gatter: Yea. That's not going to happen.

Buyer: Right. I don't know enough about the aspiration procedures, I think that's uncharted territory for- well, maybe not completely uncharted, but it's certainly less common for tissue procurement right now. Most people- what we're most familiar with is D&E's and trying to get as intact a specimen as you can with that. Like I said, if we're looking to increase volume by dialing up specimen quality

earlier then it's just a different kind of thing. So cervical dilation isn't going to affect the intactness of a specimen in the first trimester? Right? or is there any difference in the cannula width or anything like that?

Gatter: No. In the first trimester you train to use a cannula at certain gestation (inaudible) If you over dilate, you can put a bigger cannula in and get a more intact specimen, but again, you promise that you wouldn't change up the procedure (inaudible)

Buyer: Are there any other benefits to having a larger cannula?

Gatter: No. The smaller you go, the more likely you are to miss tissue.

Buyer: Right. That's what I ment- this might be too technical but in your procedure volume figures do you have a breakdown at like the end of the second trimester? Ten, eleven, twelve weeks to know what we're looking at there or?

Laurel: Might be-

Gatter: It's something that we can pull up. Most patients are coming in earlier and earlier so we have more seven weekers than nine weekers.

Buyer: What's your feeling about how your staff would feel about us coming in-

Gatter: I think if you present it in a positive light, maybe give a little fifteen minute powerpoint or lecture about who we're doing this for, they would be for it. Especially if you bring in your own staff to consent.

Laurel: It's an extra burden on them to explain it.

Buyer: Is your staff, are they aware of the research-

Laurel: No.

Buyer: So, that's something I think would helpful, for people to know the positives.

Laurel: Yes.

Buyer: Would that be beneficial? For a little educational-

Laurel: Yea. Absolutely.

Buyer: I mean, when we talked to people before, that seemed like going away from it, there was a change in attitude. Just our presence there, and how people can be used to the flow and what they're used to, and to have people coming in.

So I have found it, so far, when people don't understand the research that's going on, they don't understand the positives, once they're told, once it's presented- so, you think they would be-

Buyer: So, you think they would be open to that?

Laurel: yea, we have, just to share with you, each health center has a monthly meeting and we have speakers that come in all the time.

Buyer: Ok.

Laurel: Whether it's a pharmaceutical company, or we do our own end services and updates on items. They're very interested and appreciative of that kind of thing. I think they would react positively to this because of the understanding.

Buyer: Ok, and then, once there's an understanding about why we're looking for what we're looking for, and trying to coordinate patients with providing that- was it Heather? Did you say Heather was looking for something but because of the rush, rush, rush she's not able to-

Gatter: Because of the rush, rush, rush, they couldn't consent the patients and she couldn't get what she needed.

Buyer: That was why I suggested having our techs doing the consenting, so we don't miss-

Gatter: Even if your techs are doing the consenting, our staff has to identify the patients to talk to them. So, I can easily see with the rush, rush, rush, even if you're person is there twiddling their thumbs, patient services is too busy to enter this topic. Not saying it will happen often-

Buyer: Mhmm. So, how many days is that rush, rush, rush?

Laurel: Ha. One of the ways we would go back to this research we're currently involved with the Ellis study. Is we added a special form to the intake paperwork to remind the staff to ask these specific questions, it's like a script and they don't have to remember this stuff, they could check off on the slip, I would envision probably developing something similar, that would say discuss patient declines, patient agrees, and then the patients who read it would be passed on to your staff member.

Gatter: And how long is Ellis going on for?

Laurel: It's going through May.

Gatter: It would be helpful to finish with that, before starting this.

Buyer: So, you're saying this is something what would need to be in place before we could come in? Is that what I'm hearing?

Gatter: No. I was suggesting that if Ellis finished soon, we could transition.

Buyer: I was going to suggest some kind of pre-screening process, which is what I think you're referring to.

Laurel: Yea exactly. To be more easily be able to identify and have a set script that they can just follow and talk about, it makes it much easier.

Buyer: Is that a reason that you would prefer to have your staff doing that part?

Gatter: We have to have our staff do the initial triage, and then your staff could do the consenting.

Buyer: So, your staff has to be the initial contact?

Gatter: Yea. because otherwise it's ridiculous , if you talk to everybody, then the patients who do want to do it-

Buyer: Mhmm.

Gatter: We would have to have a contact in place before we could even start.

Buyer: Because I was even imagining- I've heard of people who have the tech as a floater, in the front. They can kind of pre-screen, they have a little clipboard. "Hi my name is Heather, my name is Briana, I'm from Novogenix, there's an opportunity at this clinic to donate you're- I just think back to the eighties, you know, when you and I are talking about that. Had this been around, I don't think I would have been doing as much work in those days with women who were suffering and-

Gatter: That might be overstating the case, we were talking about people wanting to see something good come out of their thing, they want to see a silver lining but I'm not sure that would change all that much.

Buyer: I'm more hopeful. I think that's just from working with the people.You've got a different perspective but that's what I would be my hope. If people could, if the staff could just be educated to see it, to know about it. What do you think Laurel?

Laurel: No, I think if you look at our staff, the age range, they're young twenty plus years. We now have a process of MA training, and most of them are. Previously we were training our own staff so I don't think with official MA trained

staff they would get that exposure at all. I'm sure they've heard of it, but I think it definitely brings up their level of interest when they understand something and the reasons behind wanting to do it.

Buyer: Do you happen to remember, off the top of your head, maybe use last week or this week as an example, I guess today is a procedure day, it's Friday. Do you know what the breakdown is for gestational ages today?

Gatter: You keep asking the question, we keep telling you we don't know. Stop asking that question.

Laurel: If we look at the schedule itself, it's not broken down by first or second. I know there were some scheduled, a few weeks ago, I think there were two. It also takes looking at documentation on the individual ultrasound, again-

Gatter: Its also on the EPN. It's on the EPN. (inaudible)

Laurel: It's for first and second tri.

Gatter: Yea, (inaudible) can have the gestational age pulled directly from the ultrasound.

Laurel: Yea, the billing may help.

Gatter: Then you just run the EPN report and it was say that we had seven hundred-eighty nine procedures and how many were second trimesters. When I was at LA, I used to be able to do it myself, it's just not as easy now.

Buyer: So, you think there was at least one second tri today?

Laurel: I didn't look at the schedule, so no.

Gatter: The law of averages is one or two every week.

Buyer: So Mary, did I hear you say that you are semi-retired?

Gatter: Yupp. I filled my schedule, I'm busier than I was when I was working in LA. This was a sixty hour a week job, you know. Now, it's like one day a week, but I joined a barbershop chorus on Wednesdays, these women are serious singers, I mean serious singers. We go to retreats and we sing for twelve hours a day and we stretch and there's a contest coming up, and we wear these costumes they would be embarrassed about in Las Vegas, and I belong to a local amatur theater group and I'm on the membership committee and were discussing what it means to be a member and dues and that conversation, I'm just busy. Then I got a call yesterday from PP national, they want to put together a cadre of medical directors to do international reviews, I also do reviews all

around the country, part of the accreditation process. The answer to your question is I am busy. What were you thinking of? Oh, my daughters wedding, that's coming up, mother of the bride dress, ugh. I'd be having that ruben if I didn't have to fit into the dress. So yea, how about yourself, what do you do?

Buyer: Nothing for fun. Nope. Nothing for fun. But it doesn't sound like, well I don't know, you sound busier now.

Gatter: They're activities but yea. I do research, I had a research paper published last week. There was a research paper inspired by Danco. A lot of red states are trying to limit abortion access by passing ridiculous legislation, and one of them is you have to use the FDA regimen for medication abortion, it's from two thousand, it's outdated and we have evidence alternatives now. But the red state legislation says no, no you have to have seventeen million visitors, you have to do this, you have to do that, and you can't to telemedicine either, which is great. So, Danco- people rarely go back to the FDA to change the label, because it's expensive and there's no point to it and doctors are used to using evidence based alternatives that don't have to have a label. But, if the politicians are saying you have to use a label, we go back to the FDA and say we want to change the label. Danco says you need a big volume of patients to say it's safe and effective, because LA had all those cases. Deb and I put together a paper based on fifteen thousand cases with LAMS and alternative methods saying guess what? Its safer, easier, more effective than the regimen that those stupid idiots want us to use. Im interested in political research so.

Buyer: Mhm. Where do you see that going? You're working with Deborah, you said?

Gatter: We just published, it will be out shortly. And I had worked with some researchers out of UCSF, Tracy's (inaudible) who moved to Omaha to be part of the Buffett foundation. So, the doctors and I looked at if it made a difference in abortion if you were forced to have an ultra sound or not. As it happens we have them in our system but when you record that patients decision, do you want to see it or not, because it California it's optional. So, now they give a court ordered decision to see it, and we have a separate thing asking how sure are you about your decision. Very sure, not sure, you know, So we looked at thirty thousand patients to see if looking at the ultrasound made a difference. Guess what? For most patients, it does not. Sixty percent of patients did not want to look at it, forty percent did. They both proceeded to have the abortion the exact same way, with the exception of women who were unsure about their decision. If you were uncertain and you saw the ultrasound, you are one or two percentage points less likely to have the procedure. So, it's kind of a nuance, and our enemies don't do nuance as you know, so we published that last year. What do you do for fun?

Buyer: I think I enjoy blowing off steam the same way anybody else does. There's lots of funs stuff to do in south LA and Orange county area.

Gatter: Mmm. I can tell you're a clubbing person.

Buyer: Yea, that's a polite way of putting it.

Gatter: You're a young man.

Buyer: I'm sure that Dr. Van Handel of Novogenix would say the same thing.

Gatter: Who else is with Novogenix? It's an Asian guy, I'm so bad at names now. I'm sure he would be horrified.

Buyer: So, they've been exclusively contracted with PPLA for quite some time? Interesting, and that's the thing, once someone is in, there isn't much room to share.

Gatter: They've got to do something really bad to get kicked out. Part of the self sustaining, you know.

Gatter: (Inaudible) Heather, when she came in, was pleasant, unintrusive, she didn't get into anything, she didn't get in the way. She was efficient, wrapped up her specimens, sent them out- shipped them out.

Buyer: I'm thinking about the 2nd tris, if we knew were going to be able to get a liver-thymus, even if it's just one, consistently, per week I think that would be a good start. Obviously, that limits how many researchers are being served at once, but at the same time, it gets you started-

Gatter: It's a promise we can keep.

Buyer: It's a promise you can keep, exactly.

Gatter: So, what gestational age are we talking about, liver and thymus?

Buyer: Well, if it's a liver and thymus pair, that's used in the humanized mouse models, I don't know if you're familiar, the way they have immunodeficient rodent and you can engraft human blood products in order to reconstitute a human immune system. That's used for all kinds of applications, and highly dependant on having a liver- thymus set from a fetal cadaver. So, that's always in demand, people always want that, I was just at two or three-

Gatter: How big is the thymus in case I'm looking for something?

Buyer: The thymus is pretty tiny, and liver is similar in coloration and consistency as the vaginal lining so, that can be difficult, that's one of the reasons for second tri, they're just easier to identify I think but in terms of differentiation of the

progenitor cells in those tissues, there is some some kind of a sweet spot, say fourteen and up. Fourteen to twenty-two weeks, most of the protocols call for eighteen to twenty-two weeks, well, no I think that's an older protocol, sixteen to twenty-two weeks. SCID mice have definitely been engrafted with fourteen week liver and thymus tissue. It's just a matter of knowing that if our tech goes there, you know, that Friday, there is going to be one case there that's got that for certain, we can get it and send it off.

Gatter: So, suppose you call in Monday, and there's two 14 weekers, coming in on Friday, we don't know if they're coming in until Friday. So, you could call again in the morning, be asking again if you should come in. We don't really have the volume you need. That's a problem, when developing a relationship. (Inaudible)

Buyer: Yea, if it's a matter of finding out and committing the day before, it's a two hour round trip, or whatever for someone to drive out there, that could be worth it, that could be really worth it. So, it would be good to- the name of your physician again? Dr.-

Gatter: Ian Tilley.

Buyer: Ian Tilley, it would be good to touch base with him-

Gatter: Actually, I'm having lunch with him in two weeks so, I could chat with him then.

Buyer: Oh, excellent.

Gatter: You know, PPFA takes a enormous amount time to get back in terms of contractual issues and stuff.

Buyer: Oh, so you would have to apply for the waiver that you spoke of.

Gatter: Which, I'm willing- it's not that big a deal.

Buyer: Does that go to Deborah? Is she the one that signs off?

Gatter: She's one of the people it goes to, but they change who it goes to so, she's involved in the process.

Buyer: So, that's why I don't want to lowball. Because, I hear this is what you're going to have to go through, frustration, time just paper work.

Gatter: Oh, we will. Where's your company located?

Buyer: Long Beach.

Gatter: When I was at PPFA, they used to have surgical site in Long Beach. (Inaudible) They stopped that Long Beach site too. I don't think I ever went to Long Beach, now that I think about it.

Buyer: Do you know well, the Orange/San Bernardino affiliate?

Gatter: Jennefer Russo.

Buyer: Because we're told they're very high volume, and they're right there, next door to us. The last that I heard was they were working with a private laboratory in Orange, but I guess that would be a research study, a bone-fide research study because they're going right to the researchers who are using it there. But, I don't know, I don't have any more information on what they were after, and what was being done. It sounded to me like it was just one laboratory. There's probably availability-

Gatter: Room for expansion.

Buyer: Room for expansion. Or maybe room for someone else to come in. I don't know, maybe if Dr. Russo will be in Orlando-

Gatter: She will. Absolutely.

Buyer: Maybe we can have that conversation.

Gatter: Come up to me in Orlando and remind me to introduce you.

Buyer: Definitely, yea that would be helpful. So even though you don't have high volume, I see that their are other niches you could fill for us. Don't you think so?

Gatter: Here is my suggestion. Write me a three of four paragraph proposal, which I will then take to Laurel and the organization to see if we want to proceed with this. And then, if we want to pursue this, mutually, I talk to Ian and see how he feels about using a "less crunchy" technique to get more whole specimens. Then, if we agree to move forward, the steps, I would need to apply for a waiver at PPFA, in order to do this, we need to have a contract, do you have a contract?

Buyer: What we've used in the past is a materials transfer agreement. And obviously, that's open to discussion.

Gatter: It needs to say exactly what your staff is going to do. It needs to say exactly what your expectations are. Exactly what the compensations is. That you're agreeing that your person will only use specified the Federal government tissue donation form, you can add extra forms if you want. California-

Buyer: Do you have a copy of your form that you could send us and-

Gatter: Our form?

Buyer: Your form for tissue donation. The standard one.

Gatter: Outline this in the email you send, because I will forget as soon as I walk out.

Buyer: And are we agreed that $100 would keep you happy.

Laurel: I think so—

Dr. Gatter: Well let me agree to find out what other affiliates in California are getting, and if they're getting substantially more, then we can discuss it then.

Buyer: Yes.

Dr. Gatter: I mean, the money is not the important thing, but it has to be big enough that it is worthwhile.

Buyer: No, no, but it is something to talk about. I mean, it was one of the first things you brought up, right? So.

Dr. Gatter: Mhm.

Buyer: Now here's another thought, is we could talk about specimen, per specimen per case, or per procured tissue sample.

Dr. Gatter: Mhm.

Buyer: So if we're able to get a liver/thymus pair, maybe that is $75 per specimen, so that's a liver/thymus pair and that's $150.

Dr. Gatter: Mhm.

Buyer: Versus if we can get liver, thymus, and a brain hemisphere, and all that, then that's—

Dr. Gatter: Okay.

Buyer: So that protects us so that we're not paying for stuff we can't use. And I think it also maybe illustrates things—

Dr. Gatter: It's been years since I talked about compensation, so let me just figure out what others are getting, if this is in the ballpark, it's fine, if it's still low then we can bump it up. I want a Lamborghini. [laughs]

Buyer: [Laughs] What did you say?

Dr. Gatter: I said I want a Lamborghini! [laughs]

Buyer: Don't we all, right?

Dr. Gatter: [laughs] Exactly! I wouldn't know how to drive a Lamborghini. Oh god I was hysterical, three months ago, driving on the wrong side of the road. Thinking oh my god, I'm too close to that side.

Laurel: I couldn't even sit in the front seat in Australia. It was (inaudible) I'll sit in the back.

Gatter: I sat in the front and my sister was driving, and every time she'd stop or get too close, I'd go eek, eek. And finally, my other sister was sitting in the back goes "Stop. Get out of that seat."

Buyer: Do you have family there?

Gatter: My sister did our genealogy and have Irish and half Scott. For the Scotts part we went to Ireland where my great-great grandfather emigrated, he was a sea captain actually. He wrote some very interesting letters about being caught in the south seas, 1870 or so.

Buyer: That was your first time there?

Gatter: Yes. Yes. Actually, it was my second time because I was in Edinburgh when I was a medical student. We did pre med in OB, that was interesting because the midwives in the deliveries at the time weren't allowed (inaudible) any time there was a delivery, eight am the next morning, the medical student would go out and do (inaudible) it was ridiculous. So, that was my second time.

Buyer: And no you have a wedding coming up?

Gatter: My daughter is getting married in New Jersey, Atlantic City. Yes, she's getting married, she's going to law school, so she's moving forward with her life.

Buyer: And how about you Laurel? Do you have children?

Laurel: Two married children. And one- my daughter is pregnant again. Five months.

Gatter: Oh no! That was quick!

Laurel: She wanted to have them thirteen months apart, guess what? She had them thirteen months apart. I said Good for you. She said:
"Are you ready to retire yet?"
I said: "Can you afford for me to retire yet?" So, very good, five month old granddaughter and then older grandchildren, step grandchildren from twenty six to sixteen.

Buyer: My goodness. What made her reasoning for thirteen months apart?

Laurel: She just wanted to have them close together, it looks like it's going to be thirteen months.

Gatter: Yea, my sister and I are thirteen months apart.

Laurel: Yea, my brother and I are too. Very fortunately, she is a stay at home mom, she doesn't need to work.

Gatter: Hey. alright. How about you? You've got the energy. How are your children doing?

Buyer: They're both in college.

Gatter: Where do they go?

Buyer: They go to Cal Poly.

Gatter: Oh. Two of them go to Cal Poly.

Laurel: Very good.

Gatter: We should be moving on here, we're going to stick you with the check.

Buyer: Yes. Yes. Thank you for taking the time, thank you for being flexible.

Laurel: I really apologize for being late.

Buyer: No need.

Laurel: It's been one of those days.

Buyer: I'll draft a four paragraph proposal, I'll send over one of our draft contracts as an example. Excellent. I will see you in Orlando. Thank you so much.

Laurel: I'm not going to shake your hand because of my cold. Nice meeting you.

Buyer: Nice meeting you.

Gatter: Nice meeting you.