Exhibit 8.1

U.S. House of Representatives Committee on Energy & Commerce
Subcommittee on Oversight & Investigations
Follow-Up Questions Dated August 20, 2015

Our fact development is ongoing, and therefore our responses are based on the best information that we have gathered to date. We will supplement these responses, if needed, as we receive additional information.

1. **Please identify the affiliates currently facilitating fetal tissue donation.**

   We are aware of two affiliates that presently facilitate fetal tissue donation to a tissue procurement organization ("TPO"), or to organizations using fetal tissue in research. Those affiliates are Planned Parenthood of the Pacific Southwest and Planned Parenthood of Greater Washington and North Idaho. We are not including in this total affiliates that have provided tissue to organizations using only placental tissue, decidua, and/or maternal or cord blood in research.

2. **Please identify which affiliates have facilitated fetal tissue donation in the past ten years, including the following information for each case:**
   - **When did the affiliate initiate such program**
   - **When did the affiliate discontinue such program (if discontinued)**
   - **What was the reason for discontinuing the program (if it has been discontinued)**

   We are aware of six affiliates that have facilitated fetal tissue donation to TPOs, or to organizations using fetal tissue in research, in the past five years. We are not including in this total affiliates that have provided tissue to organizations using only placental tissue, decidua, and/or maternal or cord blood in research.

   Planned Parenthood of Greater Washington and North Idaho entered into a research contract in December 2011 to facilitate fetal tissue donation by its patients. The affiliate did not begin to facilitate tissue donation under this program until 2014. The affiliate's participation in the program is ongoing.

   Planned Parenthood of San Diego and Riverside Counties entered into an agreement with a TPO in June 1999 to facilitate fetal tissue donation by its patients. That affiliate changed its name to Planned Parenthood of the Pacific Southwest, and renewed the tissue donation agreement, in October 2010. The affiliate's participation in the program is ongoing. Planned Parenthood of San Diego and Riverside Counties also received approval for a research program involving fetal tissue donation in October 2008. That program is ongoing through Planned Parenthood of the Pacific Southwest as well.

   Planned Parenthood Los Angeles entered into an agreement in March 2010 to facilitate fetal tissue donation by its patients. The affiliate suspended its participation in the program on July 14, 2015, via telephone notice to the TPO,

and is not presently facilitating tissue donation. The affiliate suspended the program after it received threatening communications following the release of the first Center for Medical Progress video; the affiliate leadership concluded that continued participation in the donation program would raise safety concerns for the affiliate's patients and staff.

Planned Parenthood of Orange and San Bernardino Counties entered into an agreement in September 2008 to facilitate fetal tissue donation by its patients. The affiliate last facilitated tissue donation on June 5, 2015. The program was suspended because the tissue recipient's laboratory was undergoing renovations. The affiliate has not resumed facilitating tissue donation.

Planned Parenthood Northern California entered into an agreement in May 2012 to facilitate fetal tissue donation by its patients. This affiliate last facilitated tissue donation in March 2015. The TPO terminated the program on August 14, 2015.

Planned Parenthood Mar Monte renewed in 2007 an agreement dating back to November 1997 to facilitate fetal tissue donation by its patients. The affiliate subsequently contracted with another TPO in April 2010 and terminated the agreement with the first TPO in July 2010. The second TPO terminated its agreement with the affiliate on August 14, 2015.

5. If a Planned Parenthood affiliate receives any compensation in the course of facilitating tissue donation, is any portion of those funds paid to PPFA?

No. Planned Parenthood affiliates that receive reimbursement for the costs of facilitating tissue donation do not pay any portion of the reimbursement to PPFA.

7. Please explain what services provided by Planned Parenthood affiliates are considered by PPFA to be "core" services.

Planned Parenthood's Core Services are as follows:

- Well Woman Exams, including cervical screening and breast exams.
- Pregnancy Testing and Options Education.
- Contraception, Education, Prescribing/Dispensing for all FDA approved methods.
    - Capability to dispense: Affiliate-selected formulary of both combination and progestin-only oral contraceptives based on affordability, patient and clinician choice; Emergency Contraception; Male Condom.
    - Capability to provide for insertion of: Contraceptive Implant; Copper bearing IUD; Levonorgestrel IUC.
    - Capability to provide for injection of: Depot Medroxyprogesterone Acetate (DMPA).
    - Prescribing or dispensing of other methods: Contraceptive Ring; Contraceptive Patch; FemCap or Diaphragm; Female Condom.

- STI screening, testing, treatment for women and men.
    - STI screening or testing (according to CDC STD treatment guidelines): Chlamydia; Gonorrhea; Trichomonas/Bacterial Vaginosis; HIV; Syphilis; Hepatitis B; Hepatitis C; Genital Herpes Simplex Virus.
    - STI treatment or disease management for: Chlamydia; Gonorrhea; Trichomonas/Bacterial Vaginosis; Genital Herpes Simplex Virus; External Genital Warts; Scabies; Pedioculosis Pubis.
- HIV Point of Service Rapid Testing for Women and Men.
- HPV Vaccine.

Additionally, abortion services must be offered in at least one health center per affiliate, as follows:

- First Trimester medical abortion;
  AND/OR
- First Trimester surgical abortion.

8. Please identify the approximate date at which PPFA converted from a process of requiring PPFA approval of an affiliate's tissue donation program, to a process whereby affiliates were allowed to facilitate fetal tissue donation without prior approval. Please describe why PPFA implemented this change.

As of November 6, 2013, PPFA affiliates have been permitted to elect to facilitate fetal tissue donation without prior approval. PPFA implemented this policy change as part of a broader effort to reduce the administrative burden on affiliates and support affiliate service expansion. This overhaul affected other affiliate services besides facilitation of tissue donation; PPFA no longer requires prior approval for an affiliate to offer certain other non-core services.

10. Please provide background information regarding the PPFA research department, its mission, and the types of research under its purview. Please also describe how PPFA's research agenda implicates the affiliates, for example, are affiliates required to participate in the PPFA research program, or are affiliates permitted to develop their own research programs? If affiliates have their own research programs, please describe what oversight PPFA has of such research programs.

Research Department Mission

Research is an explicit part of the Planned Parenthood mission, one tenet of which is "to promote research and the advancement of technology in reproductive health care and encourage understanding of their inherent bioethical, behavioral, and social implications." *See* http://www.plannedparenthood.org/about-us/who-we-are/mission. As such, PPFA conducts research to answer key clinical

questions, test innovations in clinical care, and conduct health outcomes research and service delivery research to improve patient outcomes.

About the PPFA Research Department

The purpose of the PPFA Research Department is to carry out and support affiliates in clinical and health services research efforts to advance reproductive health. The Research Department has three primary areas of responsibility: technical assistance to affiliates on research related matters and registration of research studies conducted at affiliates; leadership and coordination of multi-center grant-funded and industry-sponsored trials; and development and implementation of PPFA-led studies to improve patient health outcomes. The PPFA Research Department comprises clinical and public health researchers.

The Research Department has a 12-year history of successful implementation and administrative oversight of clinical trials including studies of the safety, efficacy, and acceptability of contraceptive methods; diagnostic and treatment options for sexually transmitted diseases; and other critical areas of reproductive health.

The Research Department has also engaged in investigator-initiated studies and health services research, including a grant-funded study to improve contraceptive use in collaboration with the University of California, San Francisco recently published in the *Lancet*; a randomized controlled trial testing an intervention to increase HPV vaccine completion that was published in *Vaccine*; and an ongoing grant-funded study on contraceptive counseling in collaboration with New York University.

Types of Research Under Research Department Purview

There are three broad categories of research that fall under the purview of the PPFA Research Department: 1) Affiliate-initiated research; 2) PPFA-coordinated research; and 3) PPFA-initiated research.

1) *Affiliate-initiated research* is research that is conducted by or at an affiliate in which Planned Parenthood clients and/or staff are the participants. The research project may be developed by affiliate staff or the affiliate may partner or engage with external researchers. The affiliate is responsible for compiling all appropriate documentation and registering the study with the PPFA Research Department. The affiliate involvement may vary depending on the research project. Studies may include grant-funded or industry-sponsored trials, as well as internal affiliate research projects for which there is no funding.

2) *PPFA-coordinated research* is research that is conducted at multiple affiliates that has been reviewed and coordinated by the PPFA

Research Department. Because PPFA has coordinated the study and reviewed all protocols, contracts, budgets, and regulatory documents in advance, no registration with PPFA by individual affiliates is necessary. Sometimes PPFA is the investigator or co-investigator on such a study. PPFA remains involved in the study conduct through to study close out. These studies may include grant-funded or industry-sponsored trials.

3) *PPFA-initiated research* is research that is conceived and conducted by the PPFA Research Department. This may include research with Planned Parenthood clients or staff or with non-Planned Parenthood clients. PPFA staff are responsible for submitting for external IRB review any research involving human subjects (as governed by the *Code of Federal Regulations*). Studies may include grant-funded or investigator-initiated studies with industry support, as well as internal research projects for which there is no discrete funding source.

All research studies involving fetal tissue have been affiliate-initiated research. PPFA has never initiated or coordinated a research study involving fetal tissue.

Description of How PPFA's Research Agenda Implicates Affiliates

Affiliate participation in research studies is entirely voluntary. The PPFA Research Department makes research study opportunities available to those affiliates that have expressed an interest in research, but participation is not required.

PPFA Research Department Oversight of Affiliates

Affiliates are permitted to develop their own research programs. If affiliates do participate in research, they are required to register that research with PPFA. All research projects conducted at a Planned Parenthood affiliate, those using data generated from or through a Planned Parenthood affiliate, or those conducted by the Planned Parenthood national office must be submitted to and registered by the PPFA Research Department prior to initiation. This includes projects generated within the affiliate and those generated externally, but conducted at the affiliate with Planned Parenthood clients and/or staff.

The PPFA Research Department is not an Institutional Review Board (IRB). All human subjects research studies must be submitted to an external IRB to allow them to make the final determination of exemption or expedited review and must be registered with the PPFA Research Department, whether the research obtains IRB exemption, expedited approval, or full review approval.

To register a research study, affiliates must submit each of the following documents to PPFA:

- a completed research registration form;
- documentation of IRB approval or a letter from the IRB stating that the research is exempt from IRB oversight;
- IRB-approved Informed Consent form (if applicable);
- any contracts or agreements, including data use agreements (if applicable);
- a list of departures or deviations from PPFA or affiliate written standards or protocols (if applicable); and
- the study instrument(s) — survey questionnaire and/or interview guide (if applicable).

Upon receipt of all appropriate study materials and documentation, the PPFA Research Department will process the registration and forward any contract indemnification agreements to Affiliate Risk Management Services (ARMS) for review and approval. Protocol or study instrument modifications may be suggested or required to obtain approval. The affiliate contact person and the affiliate medical director then receive an approval letter. Once the approval letter is received, study activities can begin.

During the conduct of the study activities, affiliates must notify the PPFA Research Department if any of the following occurs:

- a major change in the research design, methods, or planned duration of the project;
- early termination of the research for any reason;
- IRB continuing approval is denied;
- the study site is subjected to FDA audit;
- a change in the Principal Investigator;
- a serious adverse event is experienced by any participant;
- a data breach occurs;
- the study may get media attention prior to completion — affiliates should inform the PPFA Research Department for organizational preparedness.

The PPFA Research Department must be contacted immediately if any serious adverse effects or events occur as part of involvement in a research study.

Non-compliance with any required PPFA standards may affect the affiliate's accreditation status and ultimately result in actions that jeopardize the affiliate's ability to continue to use the Planned Parenthood trademark. Compliance with the mandatory or required standards and/or criteria contained within the PPFA Research Manual is assessed through, but not limited to, the accreditation process which includes Elements of Performance (EOPs) related to research.

13. Please describe whether PPFA is involved in any research involving the use of digoxin in abortion procedures.

To our knowledge, PPFA itself has not been involved in any research studying the use of digoxin in abortion procedures. We are aware of a total of four studies involving digoxin that were conducted at Planned Parenthood affiliates (and registered through the PPFA Research Department), as well as an initial registration request for a qualitative study on women's experiences with digoxin that is still pending additional document submission.

14. Please explain whether PPFA provides any guidance on criteria to affiliates for selecting the direct recipients of fetal tissue donations. If yes, please provide the guidance.

PPFA does not provide any guidance to affiliates on criteria for selecting the recipients who directly receive donated fetal tissue from an affiliate.

16. Please clarify how the affiliates account for costs related to fetal tissue donation. Is any of this information reported to PPFA, either episodically or at regular intervals, such as in quarterly reports or at the time of reaccreditation review?

PPFA policies require that an affiliate that chooses to accept reimbursement for allowable expenses must be able to demonstrate the reimbursement represents its actual costs. PPFA recommends that an affiliate consult with PPFA's Consortium of Abortion Providers ("CAPS") about steps to document and demonstrate actual costs. CAPS works with affiliates to improve access to high-quality abortion services by providing limited clinical training, providing assistance to affiliates operating in restrictive regulatory environments, and administering grants to low-income patients who cannot afford their care.

Individual affiliates decide how to account for their costs related to fetal tissue donation. PPFA expects affiliates to comply with all applicable state and federal laws, but does not require affiliates to report to PPFA on their accounting for the costs related to facilitating fetal tissue donation.

20. Please provide further information on the question of whether doctors performing abortions may know before performing the procedure whether the patient has consented to donate fetal tissue.

Some physicians performing abortions are sometimes aware prior to the abortion that the patient has requested to donate fetal tissue following the abortion. However, whether any particular physician is aware before performing the

procedure varies by affiliate, by physician and, in some instances, by the specific circumstances of each patient.

21. Please explain whether PPFA provides, or has provided, any training on tissue donation or tissue procurement. If so, please provide copies of any materials used in such training.

In the Spring of 2015, PPFA Lawyer, PPFA Senior Counsel, Law and Policy, gave a presentation on PPFA's fetal tissue donation policy at PPFA's Spring 2015 Annual Conference. There were no written materials other than the May 2015 guidance document titled "Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research" (previously produced as PPFA-HOU_E&C-000043-45) used in the presentation. Other than this oral presentation, we are not aware of PPFA providing any other training on tissue donation or tissue procurement.

24. Please explain the reasons why the number of PPFA affiliates has declined from over one hundred to 59. Please explain whether this trend is expected to continue.

Over the years, PPFA has experienced a significant reduction in the number of affiliates due primarily to mergers, and in some cases disaffiliation. Some examples include Texas shifting from ten independent affiliates to three. Pennsylvania has gone from seven to three affiliates, and more recently, Florida has shifted from five to two affiliates in the past year.

Mergers can primarily be attributed to the recognition that better economies of scale would allow for affiliates to reduce duplication in overhead, more effectively invest in patient care and programs, and build stronger leadership. It is anticipated that while mergers will continue, they will not occur at the same pace.

PPFA has provided leadership to affiliates to help guide thoughtful processes for affiliates when they decide to merge with a neighboring affiliate to ensure strong continuity of care, strong leadership and strong programs. In cases of disaffiliation, contributing factors range from compliance with MS&Gs, specifically the adoption of Core Services, and protection of the Trademark to strategic restructuring.

25. Please provide examples of actions PPFA has taken when an employee has failed to adhere to PPFA standards.

PPFA has imposed disciplinary action against PPFA employees for violations of PPFA policies commensurate with the severity of the violation. Discipline options range from conversations and coaching sessions through termination of employment for more severe offenses.

Exhibit 8.2

Harvard Business School

9-598-041
February 13, 1998

Planned Parenthood® Federation of America (C)

Change at the Top

In the months immediately following the April 1995 Chicago meeting, the ambiguity that characterized its end began to manifest in tensions between the PPFA staff and its Board, and between the national organization and its affiliates. Maraldo and her staff, feeling that they had gotten a green light in Chicago, began planning the first steps of implementing the reinvented vision. Board members, in contrast, felt that the staff was moving too fast and not heeding the committee process that had been enacted. The growing tension was heightened by new budget figures, which showed that the reinvention process had been more expensive than anticipated, and a general concern that the financial condition of the national organization had deteriorated. After a special Board meeting in July, Maraldo, feeling that she no longer had the support of the Board, submitted, and the Board accepted, her resignation.

With the departure of Maraldo, several members of her senior staff resigned as well, including key staffers on the reinvention team. In looking for a steadying hand, the Board turned to two trusted Planned Parenthood veterans. Their charge was to calm the waters, deal with the immediate budgetary concerns, and preserve the best parts of the reinvention process. One was Jane Johnson, a long-time PPFA national office manager and most recently the executive vice-president for Maraldo. Ms. Johnson had distanced herself from the reinvention plan focusing her energies on operational matters. She had expressed a desire to retire in a year or two. The other person was Jim LeFevre, a member of the reinvention team and executive director of Planned Parenthood's northern New England affiliate. Jim LeFevre was widely known as one of those voices in the reinvention process that had often counseled caution. He had advocated the need to be tuned to the mission first and foremost and not get totally deflected by the whims of the market forces serendipitously, especially when so many of the reinvention ideas were untested and their feasibility suspect. Jim LeFevre had announced his plans to leave the CEO position at his affiliate in June of 1995 and take up consultancy. He was already in the process of working with PPFA in that role when the phone calls from the Board Chair came. After discussions, Johnson and LeFevre proposed to the Board that they share the presidency during the interim period as the Board mounted a search for a successor president.

Jim LeFevre described his thoughts on taking over as co-president:

> When Jane and I came in, we had to first stop the bleeding. We were about $3 million in the red. One of our first acts was to propose a fiscal austerity package to the Board that let about 25 staffers go. Some senior staffers had already left the organization with Pam Maraldo. We also saw our primary job as one of pulling the affiliates together. Meanwhile, the many task forces constituted in Chicago

Research Associate Elaine V. Backman prepared this case under the supervision of Professor V. Kasturi Rangan as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

(Reinvention II) came back with their conclusions. One by one the news was the same—the proposals were infeasible and based on faulty assumptions.

In April 1996, the PPFA Board announced Gloria Feldt, the executive director of Planned Parenthood's Phoenix affiliate, as its next president. Ms. Feldt, as the past chair of NEDC (National Executive Director's Council), had been instrumental in 1993 in helping Pamela Maraldo take the reins of leadership, which would ultimately lead to her reinvention initiative. But she had also played a key role in the subsequent meetings (especially the one before the tumultuous April 1995 membership meeting in Chicago) where many members had expressed that reinvention had gone overboard. With her vast experience in the Planned Parenthood movement and close up view of the reinvention process, the Board felt that she would be the most appropriate candidate to lead the organization forward.

Sharon Allison, the new chair of the national Board summarized the achievements of PPFA in the past year as follows:

> In 1995-1996, our ability to *continue* serving many of these individuals was subjected to insidious political gamesmanship over Title X, the nation's family planning program. The nation's major effort to provide reproductive health services to low-income women averts unintended pregnancies, reduces the need for abortion, and prevents disease. Yet religious political extremists nearly succeeded in their efforts to eliminate funding for the program.
>
> PPFA's leadership and stunning succession helping to prevent that outcome is emblematic of all our advocacy efforts—undertaken to ensure access to health care information and services by those who urgently need it, and ultimately to secure reproductive rights for all individuals. Among many other activities last year, Planned Parenthood lobbied against restrictions on access to abortion; challenged regulatory obstacles to health care; fought congressional attacks on international family planning; advocated for easier access to emergency postcoital contraception; and worked on behalf of two new nonsurgical methods of abortion.

See **Exhibits 1** and **2** for the operational and financial performance of Planned Parenthood affiliates in 1995-1996.

Gloria Feldt, the new president outlined her vision of PPFA:

> Ultimately, however, Planned Parenthood is much more than a set of health services and advocacy strategies. Planned Parenthood is an idea. It is a moral vision about wanted children, respect and equality for women, healthy families, sexual responsibility, and the individual's right to make reproductive choices without outside interference.

With the appointment of Gloria Feldt as the new president, Jane Johnson retired and Jim LeFevre agreed to stay on and consult several days a week throughout the transition. According to LeFevre:

> The PPFA headquarters was a deserted place at that time. Most of the senior staff that Pam Maraldo had recruited were gone and Jane and I had let these positions remain vacant so the next president could put her own team in place. Gloria needed the company of colleagues and continuity. I was only too pleased to contribute. Both of us had served as executive directors and shared the NEDC forum. Our thinking was quite closely aligned—at least we came at it with a similar set of assumptions.

In October 1996, after six months on the job, Gloria Feldt requested and Jim LeFevre agreed to continue with PPFA, as its full-time chief operations officer (COO). In early 1997, the national Board constituted a subcommittee of seven of its members, including Gloria Feldt and Jim LeFevre, to formulate a strategic plan for the national organization. That task was accomplished in June 1997. Excerpts from that report are provided below:

The Purpose of the National Organization in Achieving Planned Parenthood's Mission

The strategies, goals, and objectives expressed in this plan are created to enable the national organization to advance and protect our mission. A mutually reinforcing partnership between the affiliates and the national organization drives our work toward the accomplishment of Planned Parenthood's mission. However, there is a critical distinction between the role of affiliates and the role of the national organization.

The principal role of the national organization is, in an effective, culturally competent, and fiscally responsible manner, to:

- *enable, develop, and learn from affiliates;*
- *advocate on the national level and serve as a resource in affiliate advocacy efforts;*
- *serve as the national spokesperson for Planned Parenthood;*
- *provide leadership to the reproductive health and rights movement;*
- *develop educational materials that further understanding of reproductive health and sexuality;*
- *promote research and the advancement of technology in reproductive health;*
- *litigate, principally in conjunction with affiliates, against laws and regulations inimical to our mission;*
- *enable and develop reproductive health projects globally;*
- *develop and disseminate to affiliates standards and guidelines for the delivery of reproductive healthcare and ensure compliance against those standards;*
- *protect and enhance the value of the Planned Parenthood service mark.*

With this strategic plan, the national organization recommits itself to its role and fundamental purpose in bringing the reality of its partnership with the affiliates to its fullest manifestation.

Strategic Initiatives

Four major strategic initiatives will drive the national organization forward over the next three years:

1. *To strengthen collaboration with affiliates and to provide them with superlative services.*
2. *To deliver winning, powerful national advocacy and visibility at a level that defines the public debate.*
3. *To provide leadership to the entire field of family planning and reproductive choice.*

4. *To create excellence and achieve diversity in the programs and management of the national organization.*

These are the four organization-wide thrusts that the national organization sets as our highest priorities for the next three years. The goals and objectives under each strategic initiative stake out an ambitious three-year blueprint and timetable for the national organization. By meeting or exceeding these goals by July 1, 2000, PPFA will be a stronger, more vital organization, poised for even greater success as we enter the new millennium.

Exhibit 3 provides a further explanation of the initiatives and their desired outcomes. Each initiative was further broken down into multiple goals and objectives (not shown).

With a sense of accomplishment, Jim LeFevre reflected back on the tumultuous two years of the reinvention process. "Our 150 affiliates and 900 clinics are in better health than they were two years ago. Plus we now have direction and momentum and a sense of continuity. We can finally close the chapter on reinvention, but not on the fundamental axiom that PPFA, on the threshold of the new millennium, will need to constantly change and creatively adapt to a world moving at an accelerated rate. But it must be a change in strategy and tactics, not of purpose."

Exhibit 1 Service Summary, 1994 and 1995

Service	Consumers 1994[a]	Consumers 1995[a]	Percent Change 1994-1995	Referred out 1994	Referred Out 1995
Contraception—female	1,909,362	1,879,604	-1.6	-	-
Contraception—male	18,619	30,258	62.5	-	-
Abortion	133,289	139,899	5.0	93,325	59,682
HIV testing—female	108,381	109,834	1.3	-	-
HIV testing—male	33,284	35,660	7.1	-	-
Vasectomy	2,525	2,407	-4.7	3,239	2,175
Female sterilization	882	726	-17.7	6,236	4,152
Prenatal	11,027	12,172	10.4	108,466	83,116
Infertility	790	686	-13.2	2,212	1,933
Colposcopy	18,099	19,256	6.4	-	-
Cryotherapy	5,867	5,796	-1.2	-	-
Postcoital contraception	13,155	17,082	29.9	-	-
Midlife	9,145	17,223	88.3	-	-
Pregnancy testing	717,001	710,968	-0.8	-	-
Pregnancy testing with pelvic exam	176,172	151,976	-13.7	-	-
Adoption	-	-	-	11,866	5,758
Other Treatment & Health Maintenance[b]					
• Female	108,733	179,317	64.9	153,377	132,388
• Male	45,482	21,339	-53.1	-	-
Total	3,311,813	3,334,203	0.7	383,721	289,204

[a]Consumers are clients who received multiple services and are counted in each service.

[b]Includes all other services not specified above, including well-child services, colposcopy, cyrotherapy, contacted procedures, and other miscellaneous services.

Exhibit 2 Operating and Other Funds, Year Ending June 1996

Combined Statement of Revenue, Expenses, and Changes in Net Assets (all amounts in millions)

	Totals	Affiliates	National Office	Eliminations[a]
Revenue				
1. Clinic income	180.5	180.5		0.0
2. Government grants and contracts	171.9	170.3		1.6
3. Private contributions an bequests	122.7	98.6	26.0	(1.9)
4. Indirect support from affiliates	0.0	0.0	4.8	(4.8)
5. Other operating revenue	21.8	18.4	8.9	(5.5)
6. Alan Guttmacher Institute	6.2	6.4	0.0	(0.2)
7. Planned Parenthood Action Fund	0,9	0.9	0.0	
Total revenue	504.0	475.1	43.1	(12.4)
Expenses				
1. Domestic Programs				
a. Patient services	316.7	317.5		0.8
b. Community services	8.9	8.9		
c Public and professional education & training	26.3	26.3		
d. Public affairs	10.	10.1		
e. Assistance to U.S. family planning	5.9	0.0	5.9	
f. Services to affiliates	12.3	0.0	17.5	(5.2)
Total domestic programs	380.2	2262.8	23.4	(6.0)
2. International Family Planning Programs	5.3	1.4	3.9	
Total program services	385.5	364.2	27.3	(6.0)
3. Supporting Services:				
a Management and general	59.7	55.4	4.3	
b. Fundraising	24.2	18.4	5.8	
Total supporting services	83.9	73.8	10.1	0.0
4. Other Expenses:				
a. payment to related organizations	2.7	7.3	1.8	(6.4)
b. Alan Guttmacher Institute	4.8	4.8	0.0	
c. Planned parenthood Action Fund	0.9	0.9	0.0	
Total other expenses	8.4	13.0	1.8	(6.4)
Total expenses	477.8	451.0	39.2	(12.4)
Excess of Revenue Over Expenses	26.2	24.1	21.	0.0
5. Other changes in net assets	5.4	5.5	(0.1)	
Net assets: Beginning of year	278.4	259.8	18.6	
Net assets: End of year	310.0	289.4	20.6	0.0

[a]Payments and receipts between affiliates and national office have been eliminated.

Exhibit 2 (continued)

Combined Balance Sheet (all amounts in millions)

	Totals	Affiliates	National Office	Eliminations[a]
Assets				
Current assets	228.3	220.4	12.3	(4.4)
Property, equipment, other	156.0	139.4	16.6	1.6
Total assets	384.3	359.8	28.9	(4.4)
Liabilities				
Current liabilities	49.5	46.8	6.8	(4.1)
Mortgages, notes payable, other	24.8	23.6	1.5	(0.3)
Total liabilities	74.3	70.4	8.3	(4.4)
Net Assets				
Unrestricted	128.7	123.8	4.9	
Property & equipment	22.9	21.5	4.9	
Temporarily restricted	121.3	115.3	6.0	
Permanently restricted	37.1	28.8	8.3	
Total net assets	310.0	289.4	20.6	
Total liabilities and net assets	384.3	359.8	28.9	(4.4)

[a]Payments and receipts between affiliates and national office have been eliminated.

Exhibit 3 Strategic Initiatives and Objectives

Strategic Initiative #1:

TO STRENGTHEN COLLABORATION WITH AFFILIATES AND TO PROVIDE THEM WITH SUPERLATIVE SERVICES.

Affiliates and the national organization must elevate our historical practice of working together. Partnerships, joint ventures, and working collaborations must exist in virtually every aspect of our federation. Affiliates are our most important customers and partners. Brutal economic pressures require a new paradigm or our affiliates could suffer, and the patients they serve—the poor, the young, the disenfranchised—could slip through the safety net. For affiliates to flourish, the national organization must provide to them significantly more and improved expertise-based services.

Desired Outcome:

- By 2000, affiliate performance trends in actual results—e.g., number of clients, client visits, rate of new service development, clinical outcomes, and revenue from clinical services—will all be improved over the average of the previous three years.

Strategic Initiative #2:

TO DELIVER WINNING, POWERFUL NATIONAL ADVOCACY AND VISIBILITY AT A LEVEL THAT DEFINES THE PUBLIC DEBATE.

PPFA must constantly assert its role as the premier reproductive health/rights organization. Our national legislative, litigation, grassroots, and media efforts must work in concert, and our public affairs operations—national, statewide, and affiliate—must be better coordinated.

Desired Outcomes:

- Coordinate the development of a nationwide, long-term public policy plan that will be reported out at the 1998 summit and a long-term plan for the Planned Parenthood Action Fund.
- Defeat 90 percent of anti-choice and anti-family planning legislation in Congress.
- Introduce and pass pro-choice and pro-family planning legislation in Congress.

Strategic Initiative #3:

TO PROVIDE LEADERSHIP TO THE ENTIRE FIELD OF FAMILY PLANNING AND REPRODUCTIVE CHOICE.

Because of our history as the world's oldest and largest voluntary family planning organization, we have an enormous responsibility to be strong and to continue to be the pioneer of our movement. Equally, as a member of the choice coalition in the U.S., we hold the unique leadership position of providing advocacy, medical services, and education, combined with a national and local presence spread country-wide—as well as internationally. Thus, we must use our power wisely and well. We must produce results equal to our size and clout. We must continue to create new knowledge, new approaches, and new techniques.

Desired Outcome:

- By the year 2000, opinion leaders will rate PPFA as a primary leader in the field of reproductive health and family planning on a continuous basis.

Strategic Initiative #4:

TO CREATE EXCELLENCE AND ACHIEVE DIVERSITY IN THE PROGRAMS AND MANAGEMENT OF THE NATIONAL ORGANIZATION.

The national organization will manage and govern itself with excellence, in a cost-effective and culturally competent manner, create partnerships with affiliates (focusing on their needs and wants) to make decisions on new priorities, and move resources away from non-strategic objectives.

Desired Outcomes:

- By April 2000, PPFA will submit competitive proposals for the Malcolm Baldrige Award and the Peter Drucker nonprofit competition.
- Based on criteria to be determined, by June 2000, the national organization's structure and operations will reflect the characteristics of a culturally competent organization.
- Each year, a greater percentage of resources will go to program goals and less to overhead.

Exhibit 8.3

Harvard Business School

9-598-002
October 21, 1997

Planned Parenthood® Federation of America (B)

In the closing hours of the Atlanta meeting (October 1994) the PPFA membership voted to create a team to draft a reinvention proposal for Federation-wide consideration. The team was to have nine members selected by the chairs of the National Board, the Affiliate Presidents Council, and the National Executive Directors Council, each selecting three members. The membership further agreed that the national office would provide administrative and research support for the reinvention process.

October 1994-January 1995: Draft One

Shortly after the meeting, members of the reinvention team were announced. Ms. Maraldo was designated by the chair of the national board, Jackie Jackson as a team member. The other eight team members were recognized change-leaders, many of whom had already pioneered new forms of service provision in managed care environments. As one member stated: "The people appointed were generally perceived as doing new and interesting things back home. It was tilted toward the future being a major movement into general health care, primary care, and financing through managed care." Another stated the composition was deliberately structured to facilitate "out-of-the-box" thinking. (See **Exhibit 1** for the composition of the reinvention team.)

To meet the membership's call for timely action, the team targeted mid-January for completion of a first draft. Between November 1st and January 5th, the team met five times in five different cities for two-day meetings. Because of the intense time constraints, the group decided to forego formal voting procedures. Instead, in each meeting the group considered a set of topics, and then left it to Maraldo and her staff to capture the gist of the discussion and translate it into a series of written recommendations for review at subsequent meetings.

As the team rushed through its work, two sets of external events cast the reinvention process in new light. Shortly after the Atlanta retreat, the 1994 Congressional elections swept in a new, conservative Congress with a clear intention of challenging federal funding for abortion clinics. Then, in late January, an anti-abortion activist walked into two women's clinics in Brookline, Massachusetts and opened fire, killing two employees, one a Planned Parenthood staff member. The dramatic change in the political environment and the escalating violence at women's clinics underscored for some members the importance of staying focused on the mission as a way of improving the effectiveness of the Planned Parenthood Federation.

A Planned Parenthood document summarized the situation: Anti-choice groups have built powerful political organizations. The most powerful of these emerging groups—such as the Christian Coalition—have shown a particular talent for candidate recruitment and local policy change. They have been successful at combining articulate national leadership with sophisticated

Research Associate Elaine V. Backman prepared this case under the supervision of Professor V. Kasturi Rangan as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.

communications and fund-raising techniques, as well as aggressive grassroots activity at the local level. They also have built coalitions with other radical groups with powerful ties to political action committees. Anti-choice legislators made significant gains in the 1994 mid-term elections: 53% of the House (up 50 seats) and 45% of the Senate (up 5 seats) are anti-choice; 16 states shifted to anti-choice governors.

In mid-January, the reinvention team distributed the first draft of the reinvention plan. It included a one-page "case for change statement" (see **Exhibit 2**), and detailed statistical analysis on the recent financial performance of affiliates. Some of the conclusions of the statistical analysis were that:

- net margins (total revenue minus total expense) were declining;
- large affiliates, and affiliates providing larger service mixes, were performing better financially;
- private fundraising, which had traditionally provided about 20% of affiliate revenue, was declining.

Based upon these findings, the proposal called for dramatic changes in almost every aspect of the Federation's structure and operations. Some of the more important recommendations included:

- Transformation of Planned Parenthood affiliates from specialty providers focused on reproductive health to general healthcare providers providing a broad range of women-centered health services including primary care, reproductive healthcare, and mental health services;
- Consolidation of affiliates into a smaller number of larger units that, because of the larger scale, would be more attractive to managed care companies. The report suggested that eventually there would be between 30 and 40 affiliates or regional holding companies, each serving 100,000-150,000 clients and revenues of about $30 million, and recommended the use of financial incentives and support for appropriate mergers to be managed by the national office;
- Creation of a PPFA nonprofit subsidiary to provide high-quality management and technology consulting services (MSO), on a fee-for-services basis, for local affiliates entering into managed care agreements or undergoing mergers;
- Creation of a PPFA for-profit subsidiary to pursue commercial revenue through the development and marketing of a broad range of healthcare products bearing the PPFA name and logo, and through aggressive pursuit of licensing agreements. Under consideration were female hygiene products (douches), diapers, and condoms;
- Restructuring the governance structure of the Federation, with membership voting to be weighted by the number of clients served (to increase fairness) , and with a smaller national board composed of members to be chosen by the membership and up to five ex-officio members from the national office and affiliated institutions (to increase flexibility and focus).

The final sections of the first draft laid out a five-year timetable for implementation of the changes, and discussed the costs and proposed financing of the restructuring. The report estimated that the plan would require $311 million dollars over the five-year period, and suggested that the new revenue-generating enterprises proposed in the plan, along with cost savings resulting from affiliate consolidations, would help cover the costs of reinvention. A member of the reinvention team

who was later surprised to see the cost estimates offered this reaction: "I had not seen the basis for those calculations. In fact, many of the team members had not seen it. Perhaps one or two members closest to Maraldo had worked it all out for the report. Many assumptions were questionable. It was a last minute effort."

January 1995-March 1995: From Draft One to Draft Two

Although some affiliates seemed quite pleased with the boldness of the reinvention team's draft proposal, others reacted with dismay. The complaints fell into three general categories.

First, many individuals felt that the plan deviated from the Planned Parenthood mission. In particular, they protested the recommendation that the organization broaden its scope from reproductive healthcare to women's centered healthcare. A confidential letter sent to all of the affiliates lamented that "never has a document seemed so out of touch with our mission," and pointed out that abortion was mentioned only eight times in the entire, 123-page document. It also cautioned that the move toward mainstream, managed care contracts might undermine affiliates' commitment and ability to serve women regardless of ability to pay.

Second, some affiliates, especially those operating in states without a strong managed care presence, felt that a general plan to rush to restructure everywhere was ill-conceived, given local variations and fluctuations in healthcare markets.

Third, some felt that the plan ran counter to the Planned Parenthood strong grassroots values and culture, and its commitment to a decentralized structure. They objected to the proposed changes in the governance structure, and to the idea that the national office could dictate the range of services to be provided by local affiliates. For instance, Alexander Sanger, executive director of the New York City affiliate and grandson of Margaret Sanger, stated:

> This is a grassroots organization, in which every affiliate except ours was founded by a group of prominent women getting together in someone's living room or kitchen. Maybe we could market ourselves better, as some people suggested, if every clinic offered the same services, looked the same, and was open the same hours. It works for McDonald's. But that's not the history of the organization.[1]

These criticisms emerged forcefully in four town meetings held by members of the reinvention team across the country in the weeks following release of the first draft, and were the topic of great concern at a special meeting of the national board held in early February. Some reinvention team members, as well as Maraldo and her senior staff, felt that the team should hold firm, arguing that radical change would be difficult, but that moderate change would not be sufficient to carry Planned Parenthood through to the twenty-first century. However, the majority believed that some of the plan was misconceived, and that change should be more paced, with more voice and control at the affiliate level.

In March, the reinvention team reconvened for a two-day meeting to work on a second draft of the reinvention plan. Because the team recognized that there were serious disagreements within the group, an outside consultant who had previously served as an executive director in a Planned Parenthood affiliate, was brought in to help lead discussions. Even with his help, the meeting was difficult. As one member stated, "It was very painful. I think there was a general feeling that we were cutting the heart out of our best proposals. The trick was to find some kind of middle ground that was responsive to what we'd heard, but that would still have some zip."

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[1] *New York Times*, August 7, 1995.

Several major decisions were made at the March meeting. After much debate, the team decided to back off from its recommendation that all affiliates expand their service mix beyond reproductive health into the full, woman centered healthcare model. Instead, the latter model was identified as a "promising new direction," but the plan reaffirmed the historical reality that affiliates themselves determined their own service mix, with the proviso that all affiliates should provide abortion services. The team also backed off from the recommendation that affiliates merge into 30-40 market groups, calling instead for affiliates to consider a full continuum of collaborative efforts in order to achieve economies of scale and, where appropriate, to compete for managed care contracts. Finally, throughout the report's recommendations, there was a conscious attempt to alleviate affiliate concern that the proposed changes would vastly increase the power of the PPFA national organization vis-à-vis the affiliates.

The structure of the second plan also differed in important ways from the first plan. The text of the new draft began with a full copy of the mission statement, a statement that had not appeared in the first draft. It was followed by an edited statement as to why reinvention was necessary—one which explicitly embraced protecting abortion rights as a key function and which dropped much of the discussion of market pressures forcing change that had appeared in the case for change that was included as an appendix of the first draft. The new document was also streamlined, with only 38 pages, or approximately one-third the length of the first document. Deleted materials included all of the quantitative data and projections on the financial performance of affiliates and on the costs of the reinvention plan. With regard to the latter, the new draft stated explicitly that "(t)he financial projections in the initial draft were premature and speculative."

April 1995: The Chicago Special Membership Meeting

Final action on the reinvention plan was scheduled to take place at a special membership meeting to be held in Chicago in late April. Given the controversy that had surrounded the first draft, members of the reinvention team, as well as members of the PPFA board, its chair Jackie Jackson, and the chairs of the Affiliated Presidents Council (APC) and the National Executive Directors Council (NEDC), were very nervous as the meeting approached. In a brief and tense planning meeting, one shared concern that emerged was that somehow over the course of the reinvention process, the new plan had come to be identified as Maraldo's plan rather than as the Federation's plan. In response to this concern, the group decided to structure the meeting in a way that would ensure active participation and leadership by members of the national board as well as APC and NEDC officers, who had up to this point been more observers than actors in the reinvention process. To accomplish this, it was decided that each component of the reinvention plan would be considered in small, breakout sessions to be led by members of these three governing bodies. There was less agreement on a second question: how to actually vote on the plan. Many of the members of the reinvention team felt strongly that there should be an up or down vote on the plan in its entirety, and that if the process allowed significant modification, the plan would be "watered down to the point where it won't mean anything". The three governing bodies' representatives, however, argued that the plan would not pass an up or down vote, and that the only viable way to proceed was to treat the draft as a "live document," still subject to membership input. After prolonged discussion, the view of the governing bodies prevailed, and it was decided that there would be separate resolutions drafted for each component of the plan integrating proposed modifications that emerged in the breakout sessions.

The actual process in Chicago was far less contentious than almost anyone had anticipated. The breakout sessions were lively but constructive. After they concluded, members of the reinvention team and the governing bodies' leaders worked to draft the resolutions. Although there was some softening of the content of the reinvention's recommendations, the major changes involved the follow-up process. Under the original plan, once the plan was approved, specifying implementation details would be left to the PPFA staff. In contrast, the new resolutions created teams which were to

include affiliate representatives to finalize the details and to make implementation recommendations. One member of the reinvention team made the following observations in reflecting on the Chicago meeting:

> I was really worried that it was going to be a disaster. But some people worked very hard in the last few days creating a structure that honestly said to people "we want your input," and we worked through the night incorporating ideas from the breakouts into the resolution language . . . In the end, everything passed, passed enthusiastically, and the only thing I remember as a lingering frustration was, "let's quit talking about it and just do it."

However, team members noted that although the meeting ended with the passage of all of the draft resolutions (see **Exhibit 3** for examples of some of the resolutions passed), it also ended with a high level of ambiguity. As one said, "It was weird. It was like everybody thought they had won." Another expounded on the point:

> I think the (PPFA) staff and those who shared their vision thought that they had the consensus of the Federation to move forward, to reinvent. And many of the affiliates were saying, "We held them off. At least I don't have to do it. Others can do it, but I don't have to, and I bet that no one is really going to want to. In the end, I think that we still did not have a collective sense of what we wanted to change."

Exhibit 1 Definitions of Core and Reproductive Services

Reinvention Group Members

Walter Burnett, Ph.D.
Faculty Director
Executive Programs Health Systems Management
Tulane University Medical Center

Al Dietsch
PPFA Board Member
Aspen Center for Environmental Studies

Peter Durkin
Executive Director
Planned Parenthood Houston and Southeast Texas

Dian Harrison
Executive Director
Planned Parenthood San Mateo County

Jim LeFevre
Executive Director
Planned Parenthood Northern New England

Pamela Maraldo, Ph.D.
President
Planned Parenthood Federation of America

Sally Perkins
Executive Director
Planned Parenthood Pierce and the Coastal Counties

Gary Stewart, M.D.
Medical Director
Planned Parenthood Sacramento Valley

Don Wineberg
Board President and PPFA Board Member
Planned Parenthood Rhode Island
Cameron & Mittleman

Rita Menitoff
Vice President Health Care Delivery Systems
Planned Parenthood Federation of America

Peter Preziosi
Vice President of Executive Affairs
Planned Parenthood Federation of America

Exhibit 2 Draft One for Change

Case for Change: Why the Federation Chose to Reinvent Itself

We are in the midst of a period when the radically changing political, demographic, and healthcare environments are threatening Planned Parenthood's ability to meet its mission. Planned Parenthood has achieved miraculous victories since Margaret Sanger began her crusade for reproductive freedom, choice, and wanted children. But the need is stronger than ever to create independent and strong economic and political bases if we are to advance our agenda and ensure reproductive and sexual freedoms. Recognizing this reality, participants at the Federation's 1994 annual meeting in Atlanta unanimously voted to reinvent the Federation. Furthermore, while clearly stating its desire to undertake bold change, the membership also overwhelmingly reaffirmed its mission of ensuring reproductive choice and enhancing sexual health through the multiple approaches of education, advocacy, and service delivery.

As the restructuring of the delivery of health services becomes increasingly competitive, affiliates across the nation are at risk. Many are facing increasingly dramatic declines in their margins and financial reserves. If the present trends persist, a growing number of the Planned Parenthood affiliates will face bankruptcy within the next three years. These declines are more acute in affiliates that have not achieved the scope of service and scale of operation that allow them to maintain their positions in the changing marketplace. A review of economic indicators leads to the conclusion that all affiliates are at a considerable competitive disadvantage. Many affiliates are experiencing the reality of clients moving to managed care organizations and changing service providers in managed Medicaid programs. Planned Parenthood's contraceptive price advantage is eroding. Virtually all affiliates are experiencing deterioration in their traditional sources of income. Most are facing continuing reductions in their governmental revenue sources. These factors, in conjunction with the decline of the number of 18-24 year-old women, will inevitably lead to major financial disruptions, closings, and eventual bankruptcies.

To reverse these trends and to position Planned Parenthood as a premier provider of reproductive and women's health services, it is imperative that we transform our current way of doing business. We compete better internally than externally. We are encumbered by our size and geographical reach. We do not exploit our strengths: a commitment to a common mission and delivery of high-quality educational and reproductive health services. We lack the most basic Federation-wide information and communications systems. Our accounting and business information systems are not consistent with the restructuring healthcare marketplace. We are cash poor and undercapitalized. We have virtually no access to new capital for expansion. We lack effective strategies for building on the nation's growing diversity. Our current structure is a barrier to becoming the pre-eminent provider of reproductive health services in the nation. Continuing on this path without a strong economic foundation will mean losing the ability to carry out our mission.

The challenges we face, however, create rich opportunities for rapid growth of the Planned Parenthood movement. We can eliminate the impediments as we move to expand our services to greater and greater numbers at higher and higher levels of quality. There is a window of opportunity, albeit narrow, for firmly repositioning Planned Parenthood in this time of rapid change in healthcare and shifting political attitudes. With our principles, values, and commitment to our mission, and while building on diversity, we can provide society with greatly needed leadership and a positive frame of mind for reproductive freedom and healthy sexuality. If we do this together, we will strengthen and expand our services to the millions of women and men of all walks of life who want our services. We can make a difference.

Source: Draft One, PPFA Reinvention Plan.

Exhibit 3 Examples of Final Resolutions

Reinvented Healthcare

The membership of PPFA:

- Believes reproductive healthcare is the core of Planned Parenthood healthcare services and that our strategic vision should emphasize customer-driven affiliate flexibility in determining a service set;

- Supports affiliates fulfilling the mission by providing at their choice: (a) reproductive health services; (b) general primary care services in addition to reproductive health services; or (c) women's centered healthcare service sets in addition to reproductive health services;

- Refers to a design and review team the tasks of:

  - developing a core set of reproductive healthcare services including abortion, along with disease prevention and health education;

  - the consideration of making these core services mandatory and determining how affiliates will provide these services directly or ensure their provision;

  - developing strategies, monitoring, and timeline mechanisms to ensure the provision of core services;

- And direct the team to report a plan to the membership at its 1995 annual meeting.

Approved by the PPFA Membership, April 22, 1995

Trademark Development and For-Profit Enterprise

The membership of PPFA affirms the November 5, 1993 membership vote establishing the following policy, and amends the policy as follows:

The national organization is permitted to market commercial products bearing the Planned Parenthood name and logo or license others to do so provided that:

- The chair of the PPFA board appoints a review panel, composed of members of the PPFA Board of Directors, NEDC, APC, and the business and marketing community, to approve marketing plans and each grant of a license to use the Planned Parenthood name and logo, and to oversee the program generally and make recommendations to the PPFA board for final approval as needed;

- Each general category of use and the initial licensing agreement as a model for subsequent licensing agreements is approved by the PPFA board of directors;

- The product is of superior quality;

- PPFA shall indemnify and hold affiliates harmless for all related financial and legal risk for products licensed sold by PPFA; and

- all proceeds from such products or licensing are used to fund programs that benefit the entire Federation and that revenue sharing procedures be determined by an ad hoc committee, as discussed below, and approved by the PPFA Board of Directors and the membership at the 1995 membership meeting.

The membership refers to the Trademark Committee the responsibility for recommending how this effort, described in #1, should be organized, and directs the PPFA chairperson to establish an ad hoc committee, composed of Finance and Trademark Committee members with representation from NEDC and APC, to develop a revenue-sharing plan to be presented for approval to the PPFA board at its August 1995 board meeting and to the PPFA membership for its approval at the 1995 membership meeting.

Approved by the PPFA Membership, April 22, 1995

Governance

The membership of PPFA:

- Endorses design and development of a new structure for governance;

- endorses a comprehensive and systematic process for governance structure design based on clear organizing principles and guiding criteria that include:

  - effective and efficient decision-making processes and paths, at all levels, to support the reinvented Federation;

  - board and membership roles and accountabilities to support the governance process; and

  - appropriate structures and reporting mechanisms that increase governance effectiveness and efficiency at all levels of operation;

- and charges an implementation team to immediately begin the process of governance design and directs the team to return to the membership at its 1995 annual meeting with specific recommendations related to governance structure for approval.

Approved by the PPFA Membership, April 22, 1995

Reinvented National Office

The membership of PPFA endorses the reinvention of the national office by the PPFA president to better meet affiliate needs such as:

- better communication between the national office and the Federation;

- mechanisms and strategies for providing input to the national office program development and implementation;

- redefinition of the role and responsibilities of the national organization in light of the challenges ahead and in our commitment to a collaborative culture;

- ways to increase responsiveness to affiliate needs and requests in the most timely fashion.

Approved by the PPFA Membership, April 22, 1995

Design and Review Teams

The membership of PPFA approves that the members of the design and review teams shall be appointed by the chairs of the PPFA board, Affiliate Presidents Council and the National Executive Director Council and shall have strong affiliate representation as well as diverse representation. The number of design and review teams will be determined by the amount of work to be accomplished and the voted-upon timelines.

Approved by the PPFA Membership, April 22, 1995

Exhibit 8.4

HARVARD | BUSINESS | SCHOOL

9-309-104
REV: OCTOBER 29, 2010

ALLEN GROSSMAN
THOMAS STEENBURGH
LAUREN MEHLER
MATT OPPENHEIMER

Planned Parenthood Federation of America in 2008

Introduction

Cecile Richards, president of Planned Parenthood Federation of America (PPFA), put the phone down with a sigh. It was December 2008 and an affiliate from the Southeast had called with an urgent request for help. The affiliate was close to bankruptcy caused by a combination of tough economic times, hostile political environment, and limited ability to raise philanthropic dollars in a resource-constrained area of the country. Richards knew that if this affiliate's clinics closed, it would mean the end of Planned Parenthood services in a part of the country with some of the nation's highest rates of unintended pregnancies and sexually transmitted infections. Richards could not instruct another affiliate to take on this affiliate's programs; instead she would have to *persuade* one or more affiliates with sufficient resources to fill the potential vacuum in services.

Richards was feeling a familiar sense of frustration. She had recently experienced a similar emotion during the launch of Planned Parenthood Online (PPOL). As PPFA's CEO, she was unable to act quickly because she did not have the authority to implement solutions to problems in or among affiliates, regardless of the urgency of a situation. This inability to make rapid decisions emanated from the fact that decision rights were distributed among all of the operating units and was embedded in a decision the organization had made almost 100 years earlier to adopt a multiple 501(c)(3)[a] structure. To this day, Richards knew there were individuals in the organization who could not agree whether this structure helped or hindered Planned Parenthood's ability to effectively and efficiently fulfill its national mission.

Richards began to write a list of affiliates that might be able to help. But her thoughts kept drifting to broader questions: Was the implicit need for consensus in the organization a viable approach? Was restructuring Planned Parenthood the best or only way to enable her to resolve similar issues in the future? Was it instead a matter of trying to further standardize affiliates and equalize resources across

[a] A "multiple 501(c)(3) organization" refers to a nonprofit with tax-exempt status that is organized as numerous separate legal entities with separate boards of directors that have distinct fiduciary and operating responsibilities over their respective entities. Most multiple 501(c)(3) organizations also have a national 501(c)(3) nonprofit organization that requires some level of approval to use their brand and national resources (Planned Parenthood's structure is discussed in more detail later).

Professor Allen Grossman, and Professor Thomas Steenburgh, and Lauren Mehler and Matt Oppenheimer (MBAs 2009) prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

affiliates under the current structure? Or was the answer a combination of these choices or something else entirely?

She did know that to implement any organizational changes she and her team might recommend would require the support of the 99 disparate affiliates around the country.

Planned Parenthood Is Born

Margaret Sanger started the first birth control clinic in 1916 in Brooklyn, New York. When its doors opened, immigrant women lined up for hours to receive birth control information and services. After only a few days of operation, Sanger was arrested under the Comstock Law, which banned the distribution of birth control information. She refused to pay a fine and spent 30 days in the Queens Penitentiary, where she continued her work by teaching fellow inmates about birth control.

At that time, sentiment against birth control was high. It was thought of as "destabilizing" because it "disrupted how society viewed a woman's role as a mother."[1] Sanger felt that she had to convince not only society, but also women that "birth control would not overthrow the family, but would in fact stabilize it."[2]

Sanger founded a national lobbying organization, the American Birth Control League in 1921. In 1923, she opened the Birth Control Clinical Research Bureau, "dedicated to dispensing contraceptives and studying their effectiveness."[3] These two organizations merged in 1939 to form the Birth Control Federation of America, later renamed Planned Parenthood Federation of America.[4] Throughout this time, Sanger became known as a passionate international leader of the birth control movement and a grassroots advocate, community organizer, and visionary who championed the rights of women.

The name "Planned Parenthood" signaled the "institutionalizing of the organization from its radical roots."[5] The organization would not focus solely on "family limitation," but instead on "family planning,"[6] and allowed the national organization to commit to "a broad range of programs related to reproductive health."[7] By the mid-1940s, Planned Parenthood had "emerged as a major national health organization."[8] As expansion continued, PPFA formalized its role as the umbrella administrative organization that supported its affiliates' work on the ground. These affiliates were locally organized and chartered to administratively govern one or more health clinics that operated under the Planned Parenthood banner in cities across the country.

The organization grew from the bottom up, led by hundreds of volunteers and professional medical and social service staff in communities across the country, all working to capitalize on the changing public sentiment toward birth control and family planning. Clinics were built throughout the country, as described by Ellen Chesler, author of *Woman of Valor* and a biographer of Margaret Sanger, "An affiliate started with a cluster of community volunteers, most often galvanized by the passion and vision of Margaret Sanger. As the message caught on, so did the institutions that helped spread it."[9] Chesler stated: "Clinics had been started by individuals from a broad array of political ideologies and social backgrounds, from socialists and radical women to more conservative establishment women who got together behind campaigns against domestic violence and for improved maternal health and welfare. Sanger tried to connect the individuals working on these clinics to gain scale and to enforce uniformly high standards of care."[10]

Even though Sanger strove to unify the efforts of these disparate men and women, at the same time, she granted autonomy over most decisions to the local entities. Sanger focused most of her attention on influencing national policy. As Chesler commented:

> Sanger believed that PPFA needed a structure that was both top-down and bottom-up. Sanger needed people on the ground, on the bottom, to get scale and to provide services locally. But she also knew that to fundamentally change the lives of women, she needed to influence policy and involve the government. That was the responsibility for the "top" of the organization. What she never resolved was how the two would work together. She did not have the time and the temperament to think through the organizational structure. This tension has been there since day one.[11]

According to its website, "By the 1960s, Planned Parenthood was a respected voice in the movement for women's rights, working to increase access to birth control, pushing for the creation and funding of domestic and international family planning programs, and playing a crucial role in birth control research and development."[12] All the while, affiliate expansion continued. By 1960, more than 120,000 men and women were visiting Planned Parenthood clinics every year.[13]

"In 1970, Congress passed and President Nixon signed into law Title X of the Public Health Services Act,"[14] which "designated funding to provide access to contraceptive services, supplies and information to all who want and need them."[15] Later, Congress broadened Title X's mandate to provide community-based sex education programs and preventive services to unmarried teenagers at risk of pregnancy.[16] This funding was essential as affiliates continued to expand and offer an increasing array of services.

PPFA worked diligently throughout the 1980s and 1990s in the face of consistent opposition to family planning and birth control from federal and state governments and agencies, and conservative groups.[17] Compounding the difficulty of the struggle was the evolving complexity of health care. As Bryan Howard, CEO of Planned Parenthood of Arizona, stated: "Business conditions changed during this time at a rapid rate. When I joined the organization in the early '80s, we offered only two formulations of oral birth control and one type of condom. Basically, there was one way to do everything. But starting at the end of the '80s, we saw the introduction of managed care, a more transient clientele, a vast array of family planning options; the list goes on. It became, and is today, a different world."[18]

Planned Parenthood in 2008[b]

By December 2008, PPFA had worked hard to help the organization evolve to better serve its beneficiaries and effectively react to the rapid developments occurring within health care, information, and service delivery.

PPFA's mission was to provide leadership in the following five areas:

- "Ensuring the provision of comprehensive reproductive and complementary health care services in settings that preserve and protect the essential privacy and rights of each individual
- Advocating public policies that guarantee these rights and ensure access to such services
- Providing educational programs that enhance understanding of individual and societal implications of human sexuality

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[b] Some portions of this section are taken directly from V. Kasturi Rangan and Elaine V. Backman, "Planned Parenthood Federation of America (A)," HBS No. 598-001 (Boston: Harvard Business School Publishing, 1997).

- Promoting research and the advancement of technology in reproductive health care
- Encouraging the understanding of their inherent bioethical, behavioral, and social implications"[19]

PPFA had tried to execute its mission throughout its history through health centers and clinics, overseen by local affiliate offices. All local affiliates operated under the Planned Parenthood trademark, which they licensed from PPFA in exchange for following the Standards of Affiliation. While each affiliate committed to adhere to the standards that the PPFA set, each affiliate also had its own mission statement. These mission statements tried to align with the national mission, but were tailored to focus activities on the needs of the specific affiliate area (see **Exhibit 1** for a comparison of affiliates' mission statements).

Local Affiliates

Many believed that by operating in 50 states, the organization's structure as a network of independent affiliates was essential to Planned Parenthood's work and an enabler of growth. In the United States, affiliates oversaw more than 880 health centers that served over 3 million clients per year. The majority of clients were women with incomes below the federal poverty level and to whom the affiliates offered a wide range of reproductive health services. Most of Planned Parenthood's services were related to contraception and preventing sexually transmitted infections, with less than 3% focused on abortion services[20] (see **Exhibit 2** for patient services information).

Affiliates were organized as 99 independent 501(c)(3) nonprofit organizations, each representing specific geographic zones within the United States (see **Exhibit 3** for affiliate and clinic locations). Every local affiliate had a leadership team led by a CEO, who reported to a local board of directors. The board had control over hiring and firing the CEO, had fiduciary responsibility over the affiliate, and was responsible for monitoring performance, approving the mission, and deciding which patient services to offer.[21] Reflecting the federation's tradition of control by volunteers, each affiliate board was composed of local community leaders, none of whom could be Planned Parenthood employees. To operate as a Planned Parenthood organization, the local affiliates had to agree to meet certain mandated standards. In addition, for use of the trademark and support services from the national office, each affiliate paid annual dues of approximately 1.25% of its budget. Affiliates had annual revenues that ranged from under $1 million to over $70 million.[22]

Beyond revenue, affiliates throughout the country were considerably different on a number of other dimensions. Small single-site organizations provided contraceptive services and educational information about reproductive health care within the same facility as the administrative office. There were large, multisite organizations that offered a broad range of reproductive and general health services in clinics throughout an affiliate's zone, all overseen by an affiliate's centralized administrative office. Depending on resources, some affiliates conducted advocacy and educational activities.[23] The number of full-time equivalent employees ranged from under 10 to over 600.[24] The affiliates addressed different issues relating to women's health needs, depending on local conditions. In more politically conservative states, some Planned Parenthood sites worked to maintain a woman's access to basic birth control, while in more liberal states, affiliates had the ability to lobby for increased funding and new programs and services.

An affiliate's revenue came from a number of sources, including private fee-for-service payments, Medicaid payments, government grants, and philanthropic contributions. Funding sources among affiliates varied, at times dramatically, depending on a variety of factors, including the political climate and the health of the economy. Lack of a stable resource base had forced many smaller

affiliates, typically in more politically conservative states, to consolidate administrative functions and resources with other affiliates.[25] The number of affiliates had decreased from 163 in 1994[26] to 99 in December 2008.[27] Consolidation was expected to continue, with approximately 30 affiliates in merger conversations in 2009.

National Office

A 31-member board of directors that was elected by the affiliate membership governed the national organization, PPFA (see **Exhibit 4** for an organizational chart). Like the local affiliates, the national organization was constituted as an independent 501(c)(3) nonprofit corporation.

The national organization's key functions included setting medical standards for reproductive health-care delivery (standards that were mandatory for Planned Parenthood affiliates and voluntarily adopted by many other medical care providers, including the American College of Obstetricians and Gynecologists); advocating for reproductive health nationally; and providing technical, managerial, legal, and advocacy training and support for local affiliates. PPFA also participated in research and policy analysis.

Historically, PPFA did not involve itself with the day-to-day work of the affiliates; instead, it oversaw the broad administrative and policy work that needed to be done to maintain the organization as a whole. Despite the fact that some affiliates had begun to require more financial, leadership, and service delivery assistance, PPFA did not have the capacity to meet these demands.

In 2007, total revenue for PPFA was $104.1 million. Private contributions accounted for roughly 81% of the total, with dues from affiliates and other operating revenue (including some administrative overhead costs associated with selective grants, investment income, and fees for educational courses) accounting for most of the remainder (see **Exhibit 5** for a summary of revenues and expenses for affiliates and the national office in 2007).[28]

Standards of Affiliation and Accreditation Process

One of PPFA's central responsibilities was to evaluate the affiliates to ensure and enforce that their practices aligned with the regulations embodied in the Planned Parenthood trademark. Each affiliate had to meet PPFA's Standards of Affiliation in order to use the Planned Parenthood brand name. The Standards of Affiliation were contained in the bylaws that affiliates had to adopt or modify with membership approval. The Standards of Affiliation were made operational through a list of Accreditation Indicators, which covered areas such as governance, administration, finance, quality and risk management, and medical policies and procedures (see **Exhibit 6** for list of standards). PPFA could intercede if an affiliate was not meeting these standards. The Standards of Affiliation did not include any requirements for performance measurement in areas such as impact, efficiency, or profitability. Nor did they contain directions for marketing and communicating the required services that the affiliates offered, which had been left to the affiliates to manage as directed by their boards.

Once an affiliate was granted accreditation, PPFA reassessed it every four years through a process that included an on-site visit as well as ongoing, but limited, interactions. When PPFA reviewed an affiliate for reaccreditation or renewal, it focused largely on the quality of medical care and ensuring compliance with state and national laws. Four outcomes were possible at the end of the on-site accreditation process: full accreditation (85% of affiliates), accreditation with required actions (7%), one-year accreditation (8%), or revocation (very infrequent). The PPFA board of directors made final accreditation decisions.[29]

Governance Structure[30]

Planned Parenthood's bylaws, which formally governed the organization and set the Standards of Affiliation, were the purview of the Planned Parenthood Membership group. The group consisted of 31 PPFA board members, plus three voting representatives chosen by each affiliate, regardless of the affiliate's size. One of the affiliate's representatives could be its CEO, but the other two had to be volunteers who were not Planned Parenthood employees. In many cases, the chairman of the local affiliate's board and another board member cast the affiliate's second and third votes. Every person serving on the Planned Parenthood Membership group had one vote.

The Membership group elected the 31-member PPFA board of directors, which met four times per year. The PPFA board held ultimate responsibility for Planned Parenthood policymaking, including long-range planning and priorities. Specific responsibilities and rights of the PPFA board included recommending long-range goals and objectives for membership approval; certifying, renewing, and terminating local affiliates; setting the national budget; raising funds for Planned Parenthood activities; and hiring and evaluating the president of PPFA. Members of the PPFA board served three-year staggered terms, which could be renewed for an additional term, followed by a mandatory year off.

While PPFA and its affiliates had worked within this governance structure since the organization's inception, many in the organization acknowledged that the structure made accomplishing Planned Parenthood's goals difficult. Maryana Iskander, chief operating officer of PPFA, stated:

> Planned Parenthood has many layers of stakeholders. There is the national board and PPFA, the affiliates and their boards, and then the clinics that administer a broad range of services. When either an affiliate or the national office wants to get something done on the national level, it is often a complex process that can be time-consuming. This model impacts the organization in countless ways; it shapes how we fund-raise, measure performance and how we operate online.[31]

Planned Parenthood Online (PPOL): A Vivid Example[32]

Richards had heard many stories about Planned Parenthood's attempt to create a cohesive web presence. When the Internet became popular in the 1990s, both affiliates and PPFA agreed that it was an important new way to reach men and women who needed information and services. But they disagreed substantially about the best way to address this opportunity. Each Planned Parenthood affiliate with enough resources had built its own website (see **Exhibit 7** for a collage of affiliate websites). Yet this proved more problematic than beneficial. As Tom Subak, director of online services, stated: "Due to the proliferation of websites, if a client did a search for Planned Parenthood, it would only be through luck that he or she would find any information to meet his or her needs, especially as it pertained to anything geographic. Because services and regulations vary dramatically among states, a client could read information that did not apply to her state and negatively influence her decision making. It made it really hard to find what you were looking for."

The affiliates recognized this problem and realized that they were going to miss out on the Internet opportunity; they raised the issue during interaffiliate conversations. In 2001, a group of more than 30 affiliates came together and formed the E-Enterprise Steering Committee (EESC). The group's objective was to "create one site that better leveraged the strength of the Federation's ability to provide education and service. Also, but to a lesser degree, [the group] wanted to help enable advocacy and fund-raising efforts within committee members service areas."[33]

Initially, PPFA was not involved in EESC because it did not think the project aligned with its objectives. As Subak stated, "The affiliates wanted to centralize health information and services online. The national office saw the Internet as a way to primarily promote advocacy and communication work." But as more affiliates joined the portal and the effort became more widely known, the national office realized that it had to get involved.

Once involved, PPFA added another layer of complexity to the site-creation process. When the committee met, the discussion quickly lapsed into heated debate. The affiliates believed that the central users of the site were their local clients, while the national office saw the site as a platform for influential citizens to gain information about the organization. The different interests of committee members resulted in the committee's inability to effectively govern itself and a lack of clear accountability.

In 2005, after over four years of difficult work and despite the challenges, the site was launched. However, it kept crashing. At this point of crisis, Subak, who had been working on advocacy and fund-raising for Planned Parenthood, was brought in by PPFA to guide the project.

EESC went through a variety of exercises designed to keep the group focused on the true priorities. Subak encouraged the group to align itself around "user-focused design" and go through a detailed process to understand "who the users of Planned Parenthood Online were and how the organization can best meet their needs." This process allowed all parties involved to agree on how the site *should* be designed. But, as Subak passionately stated:

> This is an organization made up of almost 100 unique organizations. They all generally agree on the need for greater standardization to increase the ease with which the public generally, and patients specifically, interact with Planned Parenthood. But it is still very hard to execute federation-wide solutions, because it is not part of our history or culture. We believe online is our best shot at meaningful standardization right now because it just makes sense—but it is easier said than done.

As of 2008, 59 affiliates had paid to join PPOL. Affiliates that joined PPOL received online services that advantageously featured the affiliate. The affiliates involved paid dues totaling $1.75 million annually. PPFA provided $600,000 along with indirect support; the remainder of the budget was funded through national fund-raising efforts.

Subak's online team consisted of 15 PPFA employees who oversaw work on the site and continued to increase standardization and improve its operation. For example, the group found that on the affiliates' job-hiring pages, there were 2,400 different job titles for only 100 to 200 unique types of jobs. The PPFA team had the delicate task of demonstrating to each affiliate that it would not lose the local focus of its website by joining PPOL.

To further the process of Planned Parenthood's standardized online presence, the EESC agreed to allow nonmember affiliates to be included on the site with basic information such as clinic addresses and hours of operation. The committee decided that seeing the message, "We're sorry, your affiliate is not a participant in Planned Parenthood's collaborative online effort. Please click here to leave this site and go to this affiliate's website" was a disservice to those Planned Parenthood was committed to serve.

The affiliates that had not joined PPOL had many reasons for not doing so. Howard observed: "Large affiliates had made significant investments in their own websites, and some of them were more technologically advanced than PPOL. They did not want to give up these advantages. For the smaller affiliates, they did not have the resources available to fund PPOL, so many times they had to do without a site altogether."

Affiliate dynamics was often as important a challenge as dollars. Howard added: "Getting to this point with PPOL has been a bruising process: there have been heated discussions and debates and a lot of compromises. There were a lot of people at both PPFA and in the affiliate network who had not gotten past the process itself and so did not want to get involved. I really think that the thing that prevents the affiliates taking advantage of the online opportunity is the off-line structure."

A Changing Time: Planned Parenthood Looks Within

Richards reflected on the PPOL process as she thought about her current problem with the affiliate in the Southeast that had called for help. It had been a challenge to get all the stakeholders involved to agree on an online presence, and they had *wanted* to create it. How would she be able to convince affiliates to fund on-the-ground services in an affiliate region outside their own?

Richards could not dismiss the cumbersome process to create PPOL and her current problem as isolated; she had seen it too many times in the daily operations of the organization. While this tension had been present throughout Planned Parenthood's history, Richards believed she had to address this fundamental issue in order to best serve the many men and women throughout the country who needed Planned Parenthood's services. Planned Parenthood had what might be a unique opportunity. Internal and external challenges were the impetus for a dialogue about what organizational structure would most effectively help the organization meet its mission. The process was moving forward, and Richards wanted to capitalize on the present momentum in the best way possible.

Internal Changes

Richards became president of Planned Parenthood in February 2006. Prior to PPFA, she had served as deputy chief of staff for House Speaker Nancy Pelosi and was the founder and president of America Votes, a coalition of the largest membership-based progressive groups in the United States. She was the oldest daughter of the late Texas governor, Ann Richards.[34]

Unlike recent PPFA presidents, Richards had never worked for Planned Parenthood before accepting the role as president. This initially caused the affiliates to have a great deal of skepticism about Richards. To earn their trust, she used her first few months as a time to listen and learn from affiliates. She branded this effort the "30-Day Dialogue," which included an online survey that garnered 1,631 responses. She also spoke with 94 affiliate CEOs, board chairs, volunteers, and state public affairs organizations from around the country.[35] Individuals throughout the organization believed that this set a tone of transparency and passionate commitment to the entire organization and opened the door for collaborative work.

The 30-Day Dialogue also identified Planned Parenthood's major objectives going forward. Richards incorporated them into PPFA's strategic plan and included partnering with affiliates, engaging diverse communities, harnessing technology and online activities, and developing the next generation of young leaders. Richards brought in a new team from outside Planned Parenthood with broad nonprofit and for-profit experience to focus on this work. She believed that their emphasis on data, results, and accountability would align with the needs of the affiliates.

She also implemented major governance reform. In March 2008, the Membership group voted to change the PPFA board structure to remove individuals who represented specific groups within Planned Parenthood. Until 2008, various constituent groups within Planned Parenthood, including the National Medical Committee, the Affiliate Chief Executives Council, and groups from specific geographic regions had selected 15 members of the board of directors. This structure ensured diverse

representation, but also created an environment in which the interests of a board member's constituents played a powerful role in influencing board decision making.

Planned Parenthood had also begun reevaluating its fund-raising structure. In the past, direct-mail appeals, donor lists, and donations made online were not coordinated, and each affiliate and PPFA raised money independently. This often resulted in donor confusion, competition for donors among affiliates and the national organization as well as among affiliates, and decreased efficiency. Those within the organization presumed that this led to missed opportunities for raising additional funds. This issue was especially acute because each affiliate could fund-raise only in its geographic area, which significantly contributed to vast resource disparities across areas. No formula existed within the organization for allocating resources more evenly. Affiliates in wealthy areas of the country raised a great deal of money and kept most of it. Affiliates in less resource-rich parts of the country had to make do with much less. Consequently, there was also a disparity in services that could be provided from area to area, which resulted in an uneven delivery of Planned Parenthood's mission. This inequity as well as the conflicts of interest between local and national fund-raising were at the heart of the question before the Financing the Federation task force that the PPFA board had chartered in 2008. How could Planned Parenthood truly meet its national mission with so much resource disparity around the country and an organizational structure that reinforced these differences? As of December 2008, the work of this committee was still in progress, and it had made no formal recommendations.

External Changes

Changes in the external environment created demand for more affiliate support from PPFA. The political environment had reduced government subsidies for affordable birth control at both the federal level and in many states. Furthermore, consolidation in the pharmaceutical industry and the growth of generic contraceptives had radically changed the landscape of providers.[36] The majority of Planned Parenthood clients were significantly below the poverty line, and serving those most in need became increasingly difficult.[37]

The organization was also dealing with the ramifications of an economic recession under way in 2008 that further exacerbated fund-raising challenges at both the local and national levels. This had an impact on all affiliates, with the brunt of it being felt by those affiliates with weaker financial positions and those least able to draw from a strong resource base to weather tough times. Everything from reductions in state family-planning budgets to worsening credit crunches to reduced donations influenced the wave of consolidations that had already been occurring throughout the organization. As reducing costs became a key focus due to continued revenue declines, affiliates were asking themselves if there were more efficient ways of running their operations. Howard soberly summed up the situation:

> There is a growing but not yet universal awareness of the interdependence of the affiliates themselves as well as the affiliates to the national organization. This stems out of interest in common standards and less reliance on developing every system and standard on the local level. However, this growing awareness remains in direct and profound conflict with our independence. Our cultural DNA is maintaining community-level autonomy, but this is butting up against harsh economic realities.[38]

Leaders throughout Planned Parenthood also knew that there were an additional 10 million people in the United States who needed access to the subsidized reproductive health services the organization provided. The lack of these services in the United States contributed to one of the highest teen pregnancy rates and sexually transmitted infection (STI) rates compared to other developed nations. At one point, the Centers for Disease Control (CDC) reported that one in four

teenage girls in the United States had a sexually transmitted infection, with that rate being one in three for Latinos and one in two for African Americans.

All of these factors had become a catalyst for many affiliates to reflect on their own internal operations and subsequently opened deeper lines of communication with PPFA.

Moving Forward: Planned Parenthood Future

Moving forward, Richards knew that the structure of the organization was critical to the success of meeting a national mission. As Richards stated:"At the broadest level, we are trying to meet the mission. This mission is to meet the sexual health needs, care, delivery, and education for the people who need it most in this country. If we see 3 million women and there are 10 million more who need our services, then our question is how do we get to them."[39]

A few options came to mind.

Decentralize and Create a Fee-for-Service Model

Planned Parenthood could continue to develop its fee-for-service model for affiliates. This would extend the model used within PPOL's development and would support further affiliate autonomy. The national office would provide services only to those affiliates that chose to pay for them. As Chris Charbonneau, CEO of Planned Parenthood of the Great Northwest, stated: "Public policy and sexuality education are local issues, and so affiliates need to be able to tailor their programs to meet the needs of their local communities. Therefore, we need a decentralized structure, and the national office should intervene only on issues where it really makes sense to have a national perspective."[40]

Planned Parenthood was currently exploring this decentralized model through other initiatives it was facilitating: a collaborative marketing study for affiliates that chose to participate and technical assistance for affiliates that wished to pay for it.[41] If Planned Parenthood decided to use this approach, PPFA would act more as a consultancy for the affiliates and allow each affiliate to develop its own brand identity, stepping in only when it was necessary (e.g., for brand protection of the provision of medical services, etc.). Richards knew this type of model would benefit the larger affiliates because they could opt in only to programs that benefited the needs of their communities. It would also potentially eliminate internal affiliate debates regarding funding asymmetries, potentially allowing more work to get done faster. She was not sure what would happen to the affiliates with more limited resources that currently relied on PPFA for a wide range of marketing and other services.

Focus on National Collaboration and Consistency

Another approach was to increase collaboration across Planned Parenthood and create programs and structures that encouraged a more direct relationship with the affiliates and PPFA. There were many ways to promote collaboration and consistency, including further standardization of services across affiliates as well as explicit performance measurements that PPFA would enforce. The key would be to balance relationships with the many stakeholders and create programs that would leverage the strengths of each local entity, while acknowledging their autonomy. This was what the group had tried to do during the creation of PPOL, but many believed that focusing on consensus had slowed the organization down considerably. Another example of this work was just beginning with the Financing the Federation task force, and it was too soon to tell if this process was going to be effective. The role of PPFA was to bring the affiliates together on significant issues; to do this, there needed to be internal agreement, and this approach would achieve that. But how much time, energy,

and resources would it take? Richards knew that even Margaret Sanger had had limited success aligning the many constituencies of Planned Parenthood. Could she and her team do it better?

Overhaul the Structure to Meet a National Mission

Was it time to look at whether the structure of the organization prevented it from achieving its mission of providing services to all those in need, not just those who lived in areas where Planned Parenthood had the resources to provide them? Other federated organizations had done everything from consolidating their fund-raising to sharing revenues equally across the country to consolidating organizational structure into a single 501(c)(3). This would be a radical departure for Planned Parenthood, since affiliate boards would evolve into advisory boards and all of the local affiliates would report to a single national entity. As Planned Parenthood neared its 100th birthday, the question was how radical it was willing to be. Could these kinds of ideas significantly jeopardize the day-to-day workings of the organization? Reorganizing Planned Parenthood could potentially create a path for more fully meeting the mission in the areas of greatest need, more clearly present a consistent brand to consumers, and accelerate the decision-making process to maximize timely opportunities. But the costs were potentially significant: by eliminating the positions of many of the current stakeholders, what would happen to their passionate volunteer base? Affiliate board members were critical for fund-raising and community engagement. Would they end their involvement if their positions were to change? Even if the organization decided to dramatically modify its structure, would this fix its problems or simply create new ones? As Laura Philips, board chair of Planned Parenthood of New York City, stated, "Will changing the structure mean anything if we do not change our culture?"[42]

What to Do?

While the current system had imperfections, Planned Parenthood was still able to serve millions of women and men each year. Taking on large organizational structural issues could defer much-needed attention and resources from the day-to-day operations of Planned Parenthood. With a deepening economic recession and more clients who needed Planned Parenthood services, it was critical that the organization remain focused. PPFA had created many channels of communication among the affiliates and with the national organization, and Richards believed they were all working hard to meet the objectives of the mission in local communities across America, but was this enough?

Richards knew that any meaningful changes would be contentious, and that she would need the support of the Membership group to get anything approved. But all of these thoughts would have to wait until after Richards figured out how to ensure that the affiliate in the Southeast did not close its doors.

Exhibit 1 Examples of Planned Parenthood Affiliates' Mission Statements

Planned Parenthood League of Massachusetts:

- "To protect and promote sexual and reproductive health and freedom of choice by providing clinical services, education and advocacy."

Planned Parenthood of Illinois:

- "Provide, or cause to be provided, effective reproductive health services, especially for those who do not have adequate resources in settings which preserve and protect the privacy, dignity and essential rights of the individual.
- Provide, or cause to be provided, education which ensures an understanding of sexuality and its implications for the individual, the family and society.
- Initiate, advocate and cause to be implemented, public and private policies which guarantee reproductive self-determination and the services and resources necessary to ensure it."

Planned Parenthood Mar Monte:

- "To ensure that every individual has the knowledge, opportunity, and freedom to make every child a wanted child, and every family a healthy family."

Planned Parenthood of the Great Northwest

- "The mission of Planned Parenthood of the Great Northwest is to ensure that all people in our communities can make informed choices about reproductive and sexual health; that children will be wanted and loved; and that choice rather than chance will guide the future of humanity.
- We will: advocate to preserve the fundamental right to reproductive self determination, offer high quality, cost effective clinical services, and provide educational services to foster understanding of human sexuality and promote responsible behavior."

Planned Parenthood of the Texas Capital Region

- "Planned Parenthood of the Texas Capital Region, Inc., is dedicated to helping people make informed, private decisions in matters of sexuality, reproduction, and parenthood."

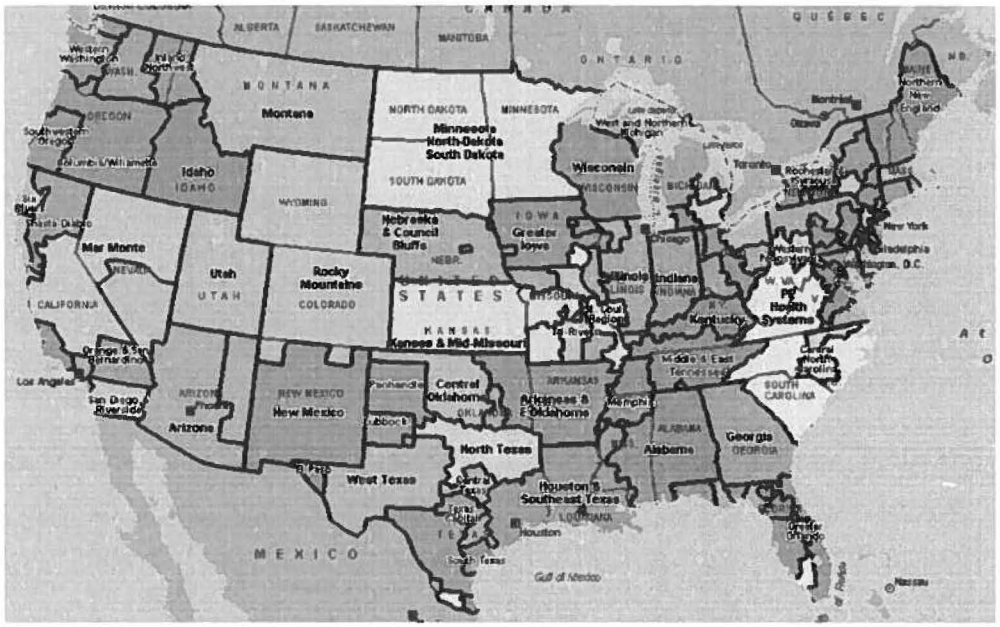
Source: Planned Parenthood websites.

Exhibit 2 Summary of Services Delivered by Planned Parenthood Affiliate Health Centers, 2005 and 2006

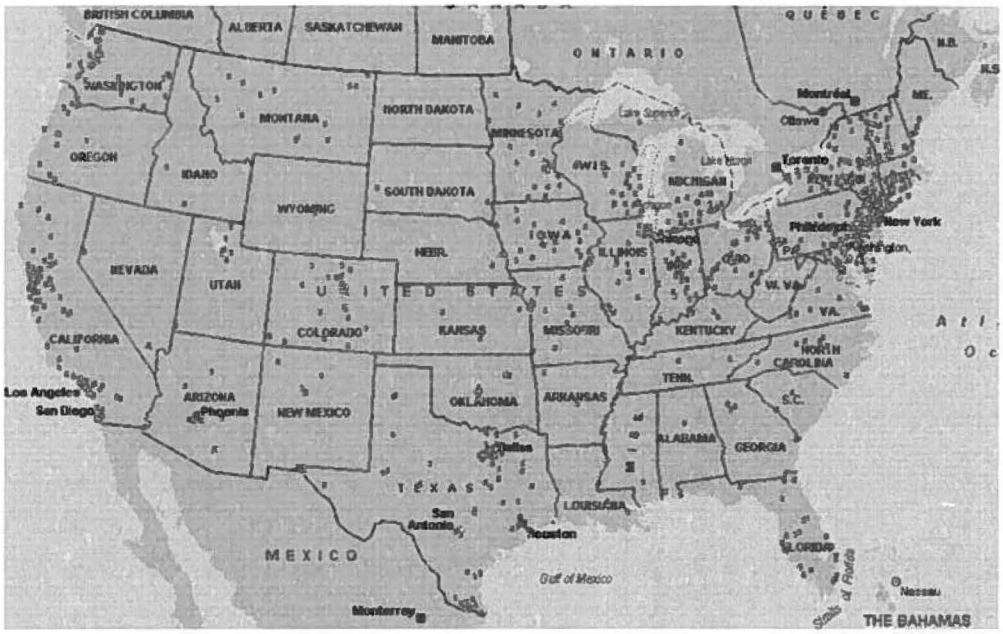
	2005	2006
I. Contraception		
Reversible contraceptive clients, women	2,420,610	2,441,768
Emergency contraceptive kits	1,240,616	1,436,846
Tubal sterilization clients	554	618
Reversible contraceptive clients, men	80,411	95,188
Vasectomy clients	2,407	2,913
Total Contraception Clients (38% of services in 2006)	**3,744,498**	**3,977,333**
II. Sexually Transmitted Infections (STI) Testing and Treatment		
STI testing and treatment, women and men	2,618,477	2,703,917
HIV testing clients, women	188,424	203,478
HIV testing clients, men	62,300	67,795
HIV testing clients, gender not reporting	29,865	42,887
Total STI Testing and Treatment Clients (29% of services in 2006)	**2,899,066**	**3,018,077**
III. Cancer Screening and Prevention		
Pap tests	1,116,681	1,070,449
Breast exams/breast care	842,399	882.961
Colposcopy procedures	44,353	47,557
LEEP procedures	2,836	3,036
Cryotherapy procedures	3,566	3,368
Total Cancer Screening and Prevention Clients (19% of services in 2006)	**2,009,835**	**2,007,371**
IV. Other Women's Health Services		
Pregnancy tests	1,045,892	1,097,397
Prenatal clients	13,261	11,058
Midlife clients	14,163	11,206
Infertility clients	248	316
Total Other Women's Health Services (10% of services in 2006)	**1,073,564**	**1,119,977**
V. Abortion Services (3% of services in 2006)	**264,943**	**289,750**
VI. Other Services (1% of services in 2006)	**150,504**	**162,935**
Total services provided	10,112,642	10,575,443
Total clients served (unduplicated)	3,061,304	3,140,540

Source: Planned Parenthood Federation of America 2006–2007 Annual Report.

Exhibit 3 Map of Affiliate Service Areas and Clinic Locations



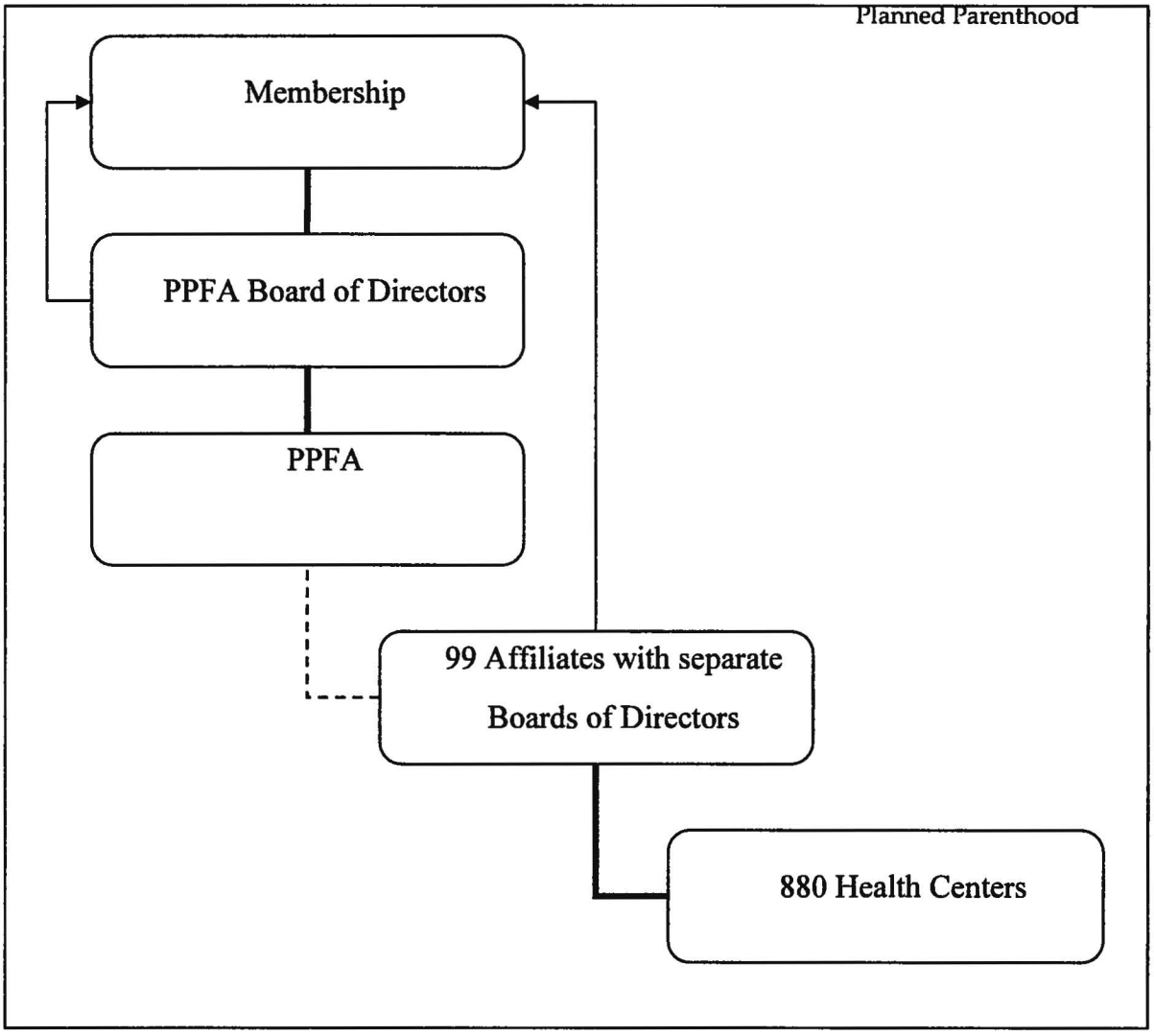
Planned Parenthood Medical Center Locations - 12/09/08



PPFA/ASD/DAG

Source: Planned Parenthood Federation of America.

Exhibit 4 Planned Parenthood Organization Chart



Note: Dashed line represents varying services that PPFA provided to each affiliate and the monitoring of the standards of accreditation (the standards of accreditation are created by the membership).

Source: Planned Parenthood Federation of America.

Exhibit 5 Summary of Financial Activities (year ended June 30, 2007, all amounts in millions of dollars)

	Affiliates	National Office	Eliminations[1]	Total
Revenue				
Health center income	356.9	--	--	356.9
Government grants and contracts	336.7	--	--	336.7
Private contributions and bequests	176.8	84.3	-2.4	258.7
Support from affiliates	--	9.8	-9.8	--
Other operating revenue	56.0	--	-0.4	65.5
Total Revenue	926.4	104.1	-12.6	1,017.9
Expenses				
Programs				
Medical services	588.3	--	--	588.3
Sexuality education	48.0	--	--	48.0
Public policy	53.1	--	--	53.1
Services to the field of family planning	--	16.4	--	16.4
Service to affiliates	--	26.6	-2.8	23.8
International family planning programs	--	7.3	--	7.3
Total Programs	689.4	50.3	-2.8	736.9
Administration and Support				
Management and general	102.6	6.6	--	109.2
Fund-raising	35.9	9.5	--	45.2
Total Administration and Support	138.5	16.1	--	154.6
Total Other Expenses	21.4		-9.8	11.6
Total Expenses	849.3	66.4	-12.6	903.1
Excess of Revenue over Expenses	**77.1**	**37.7**	**--**	**114.8**

Source: Planned Parenthood Federation of America 2006-2007 Annual Report.

[1]Payments and receipts between affiliates and the national organization have been eliminated. These include dues, rebates, and payments to the Guttmacher Institute. Related adjustments have been made to the balance sheet.

Exhibit 6 Example list of Standards of Affiliation

Type of indicator: Board

1. An affiliate policy exists stating neither an employee nor a volunteer of the affiliate uses his/her position with the affiliate to further the manufacture, distribution, promotion, or sale of any materials, products, or services in which he or she has either direct or indirect financial interest.

Type of indicator: Administration

2. The affiliate contributes to the support of the Federation according to the membership-approved National Program Support Plan, but is not required to submit its donor list.

3. The affiliate has positive net expendable assets (unrestricted net assets, excluding plant fund, plus temporarily restricted net assets).

Type of indicator: Finance

4. Net margin is at least 2% (total revenue less total expenses, divided by total revenue. Unrealized gains and losses are excluded).

5. Private fund-raising is at least 10% of total revenue.

Type of indicator: Medical Policy and Procedures

6. For the management of specific conditions for which PPFA protocols do not exist, the affiliate identifies established standards of care that are followed. These protocols or practice guidelines are available at each site where the clinicians practice.

Services/Research Approval

7. All research studies must be approved by PPFA's Research Dept. prior to initiation. All research studies funded by federal monies or subject to FDA restrictions are in compliance with federal guidelines. Applicable state statutes are followed.

Clinical Program Structure

8. Credential verification is done by the affiliate or a credentialing organization for all physicians and midlevel clinicians.

Quality/Risk Management

9. The affiliate has a written, well-defined, organization-wide Quality Management Program that includes process design, data collection/analysis, assessment, and improvement.

Medical Records and Data Collection

10. Medical records are: readily accessible; maintained for every patient encounter; systematically organized; kept on file; part of an internal medical record audit system; as confidential as possible; released only with the written consent of the patient.

Source: Planned Parenthood Federation of America.

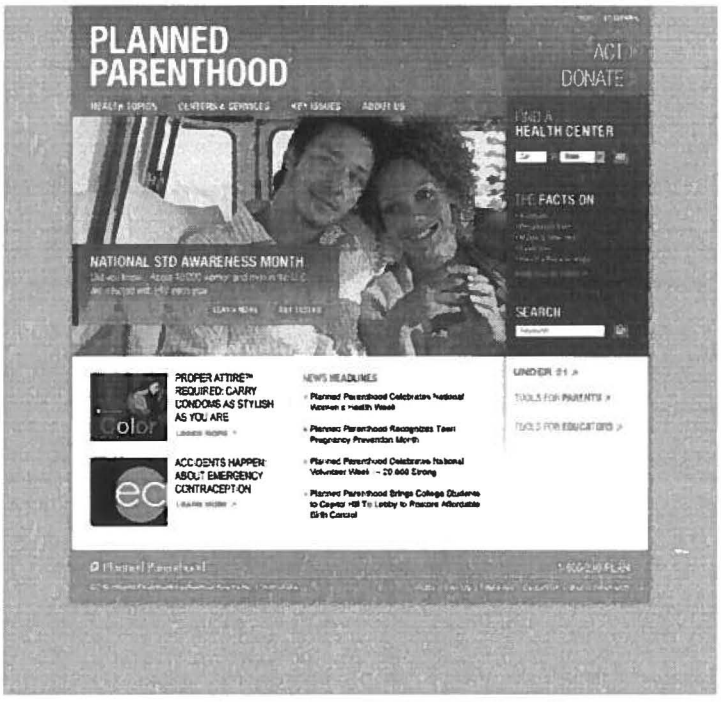
Exhibit 7 Planned Parenthood Websites over Time

Collage of various affiliate websites before PPOL

Exhibit 7 (continued) Planned Parenthood Websites over Time

Plannedparenthood.org in December 2008

Plannedparenthood.org future website (expected launch in March 2009)



Source: Planned Parenthood Federation of America.

Endnotes

[1] Ellen Chesler, interview by casewriters, December 2008.

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[3] Five College Archives & Manuscript Collections, "Planned Parenthood Federation of America Records, 1918–1974 (PPFA I)," Sophia Smith Collection Smith College, http://asteria.fivecolleges.edu/findaids/sophiasmith/mnsss128_bioghist.html, accessed March 2009.

[4] Ibid.

[5] Chesler, interview by casewriters.

[6] Five College Archives & Manuscript Collections, "Planned Parenthood Federation of America Records, 1918-1974 (PPFA I)."

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[8] Ibid.

[9] Chesler, interview by case writers.

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[16] Planned Parenthood Federation of America, "Planned Parenthood: History and Successes."

[17] "Planned Parenthood Federation of America Records, 1918–1974 (PPFA I)."

[18] Bryan Howard, CEO, Planned Parenthood Arizona, interview by casewriters, December 2008.

[19] Planned Parenthood Federation of America, "Mission," Planned Parenthood website, http://www.plannedparenthood.org/about-us/who-we-are/vision-4837.htm, accessed January 2009.

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[21] V. Kasturi Rangan and Elaine V. Backman, "Planned Parenthood Federation of America (A)," HBS No. 598-001 (Boston: Harvard Business School Publishing, 1997).

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[23] Planned Parenthood Annual Affiliate Service Census Report, 2007 Annual Report.

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[25] Rangan and Elaine V. Backman, "Planned Parenthood Federation of America (A)."

[26] Ibid.

[27] Maryana Iskander, COO, Planned Parenthood Federation of America, interview by casewriters, November 2008.

[28] Planned Parenthood, 2006–2007 Annual Report, http://www.plannedparenthood.org/files/AR_2007_vFinal.pdf, accessed January 2009.

[29] Iskander, interview by casewriters.

[30] Ibid.

[31] Ibid.

[32] Tom Subak, director of online support, Planned Parenthood Federation of America, interview by casewriters, November 2008.

[33] Ibid.

[34] "Cecile Richards," Planned Parenthood Federation of America website, http://www.plannedparenthood.org/about-us/national-leadership/cecile-richards-4676.htm, accessed January 2009.

[35] Cecile Richards, "The 30-day Dialogue with PPFA President Cecile Richards," PowerPoint Presentation to Planned Parenthood Membership, Annual Conference, Washington, DC, April 1, 2006.

[36] Ibid.

[37] Ibid.

[38] Howard, interview by casewriters.

[39] Cecile Richards, president, Planned Parenthood Federation of America, interview by casewriters, January 2009.

[40] Chris Charbonneau, CEO, Planned Parenthood of the Great Northwest, interview by casewriters, February 2009.

[41] Iskander, interview by casewriters.

[42] Laura Phillips, board chair, Planned Parenthood of New York City, interview by casewriters, December 2008.

Exhibit 8.5

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 Witness #1 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 Witness #1 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, [redacted]

PP Witness #1 Are you going to be in Miami?

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

PP Witness #1 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.

31

PP Witness #1 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** Abortion Doctor **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 [redacted]. 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.

Exhibit 8.6

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

PP Doctor #1 [redacted] 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 [redacted] was telling us before?

PP Doctor #1 [redacted] 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.

002800

PP Doctor #1 [redacted] 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.

005300

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

PP Doctor #1 [redacted] **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?

PP Doctor #1 [redacted]**: 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.

PP Doctor #1 [redacted]**: 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—

PP Doctor #1 [redacted] **Okay. $75 a specimen.**

Buyer: Oh. That's way too low.

PP Doctor #1 [redacted] **Okay.**

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

PP Doctor #1 [redacted] **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.

PP Doctor #1 [redacted]**: Mhm.**

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

PP Doctor #1 [redacted]**: 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—

PP Doctor #1 [redacted] **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

Exhibit 8.7

POSITION TITLE	**REPRODUCTIVE HEALTH/ABORTION AND/OR PRENATAL PROGRAM COORDINATOR**
DEPARTMENT:	Services
SUPERVISION RECEIVED:	Center Manager/Patient Flow Manager/Site Supervisor
SUPERVISION EXERCISED:	None
FLSA STATUS:	Non-exempt/Hourly
PROTECTED HEALTH INFORMATION (PHI) ACCESS REQUIREMENT:	Yes, access required for patient treatment purpose.
NEXTGEN ACCESS LEVEL:	"ZZ_NGHN_MA_Security" and"EMR" and "5Clinic Staff-Non-Licensed".

DESCRIPTION OF DUTIES: (as appropriate to work site and scope of services)

Essential Duties:

- As directed by a provider, notify patients of needed follow-up for breast abnormalities, colposcopy results, other specified abnormal results, and referrals
- Coordinate and assist in scheduling PPMM and outside referral appointments;
- Assist patient in identifying funding sources for follow-up care;
- Keep clinician apprised of any problems, incidents or potential problems involving patients or staff as relates to above services;
- Provide medical record transfers, as necessary for referrals;
- Maintain necessary logs and documentation to track patient compliance with follow-up and referrals;
- As directed by a provider, send reminders to obtain follow-up care;
- Maintain accurate statistical information and prepare reports, as necessary;
- Serve as liaison between PPMM and outside lab to follow-up on concerns with results interpretation and transmission.
- Perform audits and chart reviews, as necessary**;**
- Contribute to achieving health center productivity goals;
- Demonstrate PPMM customer service standards;

☐ **Abortion Coordination**

- Oversees abortion clinic, coordinates clinic functions, monitors flow to ensure timeliness of patient services, makes recommendations for improvements;
- Has input in the hiring and evaluating of abortion clinic staff, as well as, staff training;
- Assists physician with surgical procedures, as needed;
- Assures that quality care is provided in accordance with PPMM protocols;
- Coordinates medical follow-up, including lab reports and abortion complications;
- Oversees audits and chart reviews, reviews medical records for completeness;
- Ensures maintenance of accurate statistical information;
- Ensures adequate clinic staffing (with clinic manager) including MD scheduling;

☐ **Prenatal Coordination – as required by MediCal a High School Diploma or GED is mandatory for this position.**

- Work with Center Manager and/or Special Services Coordinator/CPSP Program Coordinator in the implementation of prenatal program and CPSP and other related prenatal services such as prenatal outreach;
- Coordinate and assist in scheduling patient visits with clinician and PMD;
- Provide case management and coordination for prenatal patients;
- Maintain patient records and provide records to OB Physicians;
- Follow-up test results with Clinician and notify patient of results;
- Schedule ultrasound appointments and other referrals and transfers.

Non-Essential Duties:

- Oversee inventory; assure appropriate ordering of supplies, equipment, and medication; and maintenance of equipment
- Function as a Health Services Specialist when necessary
- Works with/supervises volunteers/interns as applicable.
- Other duties as assigned

QUALIFICATIONS:

Ability to perform the duties described above. A typical means of acquiring those abilities would be:

- High school graduate or GED
- A minimum of one year program coordination experience within a health care center
- A minimum of one year Health Services Specialist experience

REQUIREMENTS:

- Ability to communicate clearly and interact with the public and staff in a variety of situations
- Ability to maintain composure under stress
- Strong customer service orientation;
- Ability to project a professional manner
- Ability to act in a leadership role with peers
- Experience using a windows based program and mouse and willing to learn new computer skills

PHYSICAL DEMANDS: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions of the position.

PHYSICAL ACTIVITIES	**----------Amount of Time Spent----------**			
	Rarely 0 – 12%	**Occasionally 13 – 33%**	**Frequently 34 – 66%**	**Regularly 67% +**
Seeing: Must be able to see and read with or without corrective lenses.				**X**
Hearing: Must be able to hear adequately to communicate with people in person and via phone systems.				**X**
Sitting				**X**
Standing/Walking			**X**	
Climbing/Stooping/Kneeling/Bending	**X**			
Lifting/carrying up to 25 lbs	**X**			
Lifting/carrying over 25 lbs	**X**			
Pulling/Pushing/Reaching	**X**			
Grasping/Feeling/Finger Use of both hands: Must be able to write, type, use a keyboard and telephone system.				**X**

This job description is subject to change at any time. This is not a contract and duties may be added to meet business needs. By signing below the employee acknowledges that s/he has reviewed and received a copy of this job description and understands the functions of her/his position.

_____ _____

Employee Signature Date

_____

Print Name

Exhibit 8.8

05/09

POSITION TITLE: HEALTH CENTER MANAGER

DEPARTMENT: Clinic Services

SUPERVISION RECEIVED: Area Services Director

SUPERVISION EXERCISED: All clinic staff/Volunteers

FLSA STATUS: Exempt/Salaried

PROTECTED HEALTH INFORMATION (PHI) ACCESS REQUIREMENT:
Yes, access required for patient treatment purposes.

NEXTGEN ACCESS LEVEL: "ZZ_NGHN_MA_Security and "EMR" and "5Clinic Staff-Non-Licensed" and "5Clinic Mgmt & Backups"

DESCRIPTION OF DUTIES: (as appropriate to work site and scope of services)

ESSENTIAL DUTIES

Responsible for the day-to day management of all health center activities. Manages the health center to meet or exceed goals in productivity, financial performance and client visits. Requires development and execution of strategy planning from concept to implementation. Supervises center staff with emphasis on leadership skills, and ability to lead change. Conducts community outreach, networking and education as well as internal and external marketing in order to attract and retain clients.

Responsible for ensuring a client-centered service model by creating an environment that stresses service delivery responsive to client needs. Ensures response to customer requests and complaints in courteous and timely manner.

Monitors and ensures compliance with PPMM medical protocols and administrative procedures, HIPPA, CLIA, OSHA and state pharmacy regulations. Submit audit data when assigned; ensure center meets agency QA requirements.

Responsible for all aspects of employment for health center staff and volunteers. Responsible for staffing center effectively by hiring, coaching and training staff to provide all clinic services per their job descriptions. Monitors and evaluates staff and volunteers in their daily performance. Responsible for discipline of staff.

Responsible for financial management of the health center. Monitors monthly financial statements and client visits. Manages revenue, expenses and staffing to ensure successful operations and

financial stability. Accountable for daily reconciliation and submission of deposits and logs.

Responsible for effective transition to EMR including oversight of staff usage, training and patient flow. Responsible for ensuring performance of various computer tasks. Able to use MS Office programs, including MS Work Excel and Outlook. Able to accurately enter data into PPMM's NextGen system.

Ensures daily, weekly and monthly reports are completed accurately and in a timely manner.

Oversees ordering and accuracy of inventory for medical supplies, contraceptive supplies and office supplies for the health center. Assures appropriate inventory levels are maintained.

Responsible for monitoring and maintaining the physical health center facility

NON – ESSENTIAL DUTIES
Performs all direct clinic services as needed;

Responsible for proper preparation, storage and control of the center's patient health records;

Performs other duties as assigned.

QUALIFICATIONS
Ability to perform the duties described above. A typical means of acquiring those abilities would be:

-B.A. or B.S. degree in a health field or management, preferred;

-two years of successful experience in a performance driven community health care setting.

REQUIREMENTS
-Ability to think and act strategically

-Ability to lead others, especially related to change

-Ability to communicate effectively, make decisions, solve problems and function as a team leader;

-Strong customer services emphasis

-Excellent organizational skills, a sense of responsibility and a high level of motivation;

-Ability to set priorities and maintain composure under stress and provide leadership in a fast-paced

environment.

-Flexibility in working hours, including the ability to work nights and weekends.

_____ _____

Employee Signature Date

_____

Print Name

Exhibit 8.9

Planned Parenthood
Care. No matter what.
Planned Parenthood Los Angeles

JOB DESCRIPTION

Position/Title: Mid Level Clinician I
Department: Patient Services
Salary Grade: N-25

Reports to: Regional Clinician Lead/ Center Manager
Location: Varies
Status: Non-exempt

PURPOSE OF POSITION:

To provide quality patient care including exam, diagnosis, treatment, education and counseling for clients in accordance with agency protocols.

QUALIFICATION REQUIREMENTS:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. The requirements listed below are representative of the knowledge, skill, and/or ability required:

1. Must pass any applicable agency qualifying exam(s).
2. Possess any applicable certifications, as required by the agency.
3. Ability to travel to multiple clinic sites.
4. Ability to work flexible hours, including evenings and Saturdays.
5. A reliable and flexible means of transportation is required.
6. Must have excellent customer service skills and be committed to providing the highest level of customer service.
7. Ability to work independently and as a team member.
8. Ability to diplomatically communicate and interact well with patients, staff and volunteers.
9. Able to demonstrate mature judgment, initiative and critical thinking.
10. Accuracy and attention to detail essential.
11. Ability to read and implement written instructions.
12. Ability to relate to diverse communities.
13. Professional appearance and attitude.
12. Possess a warm and caring manner.

EDUCATION AND/OR EXPERIENCE:

1. A valid and current California license as a Nurse Practitioner, Certified Nurse Midwife, or Physician Assistant
2. Current furnishing license, if applicable.
3. Current CPR certification is required.
4. Current ACLS certification may be required.
5. New graduates or less than one (1) year experience.
6. National Certification within the 1st year is required.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following:

1. Family Planning
2. Gynecologic Exam
3. Male Services

4. Mid-Life Services
5. Post Abortion Exams
6. Phlebotomy
7. Proficiency in EMR

The following are specific responsibilities of Planned Parenthood clinicians as outlined in the Medical Standards and Guidelines:

GENERAL:

1. Secures a complete health history, including gynecologic, contraceptive, medical, surgical, sexual, family health, and psychosocial: document accurately and efficiently into the EMR.
2. Performs physical exams with special emphasis on the reproductive system, including breast examination, pelvic examination, cancer screening tests, diagnosis of sexually transmitted infections, and other types of more specialized procedures as may be indicated by medical policy.
3. Performs, orders, and interprets diagnostic studies as indicated and permitted by affiliate medical protocols.
4. Recognizes and treats minor deviations from the normal, using prescribed protocols and consulting with the physician as needed.
5. Provides relevant health instruction to include family planning, nutrition, sexual counseling, and principles of health promotion and maintenance.
6. Collaborates with the health team and other community agencies and resources through joint planning and coordinating of activities, in providing comprehensive care.
7. Works to insure understanding and acceptance, by colleagues, other professional, consumers, and the community at large, of the role of the clinician.
8. Adhere to affiliate goals and policies on professionalism, wait time in-clinic and on the system for addressing client complaints.
9. Participate in health center efforts to achieve established goals for productivity.
10. Participate in health center/affiliate efforts to achieve established revenue cycle goals.

SPECIFIC:

1. Obtains a general health history, performs a general screening physical examination, and obtains and/or interprets appropriate diagnostic procedures and laboratory tests – Examine two (2) table patients per hour and increase to three (3) table patients per hour within 1st year of employment.
2. Provides general health supervision, health maintenance, education, and counseling to women during the life cycle.
3. Recognizes common non-gynecological medical problems and other deviation from normal and provides management or referrals as appropriate.
4. Obtains a gynecological history, performs a gynecological examination, and obtains diagnostic studies and laboratory tests relevant to gynecology.
5. Recognizes gynecological deviations from normal, formulates a diagnosis in collaboration with a physician (as necessary) and provides education and management, or refers when appropriate.
6. Provides education and appropriate management for women and men in need of reproductive related services, including fertility control, infertility, and sexually transmitted diseases.
7. Obtains history and conducts pre-abortion assessment.
8. Serves as a resource for medical and surgical abortion services in the affiliate or community at large.
9. Conducts post abortion follow-up examination with recognition of normal and abnormal findings and refers or collaborates with physician as appropriate.
10. Interprets scientific studies based on knowledge of basic research principles.

11. Recognizes ethical, legal, and professional issues inherent in providing care to women throughout the life cycle.

QUALITY MANAGEMENT:

1. Perform Quality Management audits, if requested.
2. Adhere to Quality Management policies and procedures.
3. Notify the Center Manager if deficiencies are found.

SAFETY/RISK MANAGEMENT:

1. Adhere to safety/Risk Management policies and procedures.
2. Notify the Center Manager if deficiencies are found.

OTHER DUTIES AND RESPONSIBILITIES:

1. Perform other duties as may be assigned by the Regional Clinician Lead, Center Manager and/or Medical Director.

This Job Description is subject to review and change. Signature of employee indicates solely that this position description has been received, read and understood.

Print Employee Name: _____

_____ _____

Signature of Employee Date

Exhibit 8.10

Planned Parenthood®
Pacific Southwest

JOB DESCRIPTION

Job Title	Medical Assistant III – Speciality Services	
Reports to	Speciality Services Manager*	
Supervises	N/A	
Department/Center	Patient Services	
Salary Grade 12	**Overtime Status** ☐ Exempt (salaried, not eligible for overtime) ☒ Non-exempt (hourly, eligible for overtime)	**Required Driver** (Required drivers must have valid driver's license, current auto insurance with limits of $100,000/$300,000 bodily injury per person/accident and $50,000 in property damage, acceptable driving record to be covered under Agency auto insurance and reliable transportation) ☐ Yes ☒ No

JOB REQUIREMENTS

Minimum Education	High School diploma equivalent.
Minimum Work Experience	Graduate of an accredited medical assistant or surgical technician program and 2 years comparable clinical back office medical assistant experience. -or- 3 years comparable clinical back office medical assistant experience. Experience in ambulatory or outpatient medical-surgical or specialty area preferred. Women's health experience preferred.
Other Requirements	Ability to establish rapport with all clients. Ability to take initiative and to utilize resources effectively. Ability to multi-task and must be detailed orientated. Willingness to maintain relevant knowledge about anatomy and physiology, methods of contraception, STDs, pregnancy, adoption, abortion, early prenatal care, community resources, Agency protocols and referral procedures and all Planned Parenthood programs. Must be able to work independently and as part of a team. Must be able to understand insurance and FPACT contract guidelines. Some positions require bilingual (Spanish/English) skills. Some schedules require Saturday, Sunday and/or evening hours. Willingness to work and travel to other centers as needed based on health center patient demand.
Agency Standards	Ability to communicate effectively with clients and co-workers of all backgrounds. Must have excellent computer skills with knowledge of Microsoft Word, Excel, Outlook, and the Internet. Must have the willingness and ability to adapt to change including advances in technology. Must have excellent customer service and be committed to providing the highest level of customer satisfaction. Lead, guide and model the Planned Parenthood Experience including the Experience Essentials. Supportive of the mission and goals of Planned Parenthood. Commitment to quality healthcare.

GENERAL DESCRIPTION

The Medical Assistant III is responsible for supporting the delivery of abortion care and other reproductive health services under the medical supervision of Clinician and/or Physician. Assist clients by providing testing, screening, and education required for the provision of medical reproductive health care. Assist providers to ensure high quality, efficient delivery of care. Ability to screen clients, prepare exam rooms and cover the front office when necessary. Must provide excellent customer services in a non-judgmental, empathetic manner to clients.

JOB RESPONSIBILITIES

Essential Functions

Essential functions encompass the required tasks, duties, and responsibilities performed as part of the job and the reason the job exists.

- Adhere to affiliate goals and policies on professionalism, wait time in-clinic and on the system for addressing client complaints.
- Participate in health center efforts to achieve established goals for productivity and quality metrics.
- Participate in health center/affiliate efforts to achieve established revenue cycle goals.
- Perform and/or coordinate the following back-office functions:
    - Obtain medical history, interview and educate clients ensuring informed consent
    - Perform options and abortion education; make appointments/referrals for follow-up medical services.
    - Perform POC and recovery room responsibilities.
    - Perform basic lab work (e.g. Hgb, pregnancy test, urine dipsticks) package specimens for outside lab tests, record lab results.
    - Obtain vital signs (blood pressure, height, weight, etc.).
    - Clean and sterilize equipment and stock exam rooms.
    - Assist Providers as needed.
    - Gather information regarding sensitive subjects such as rape, STIs, risks of sexual activity for early teens, and abortions.
    - Monitor center flow and client wait time.
    - Input and update computer client data information. Responsible for the accuracy of client information entered into the Agency's Practice Management system and Electronic Medical Record system.
    - Ensure ongoing communication with Patient Flow Coordinator, Center Manager, and other center staff.
- Perform and/or coordinate the following front-office functions:
    - Greet clients, answer phones, refer calls, and make appointments.
    - Assess client finances, which may include verifying insurance, health plan authorization, Medi-Cal cards with picture ID, collect fees and donations per Agency guidelines, complete appropriate forms and obtain signatures per Agency policy review and reconcile billing on a daily basis.
    - Input and update computer client data information.
- Schedule appointments for family planning including but not limited to contraceptives and abortion services.
- Provide sterilization education..
- Assist and support the clinical staff in the provision of:
    - Contraceptive services.
    - In-center abortion and MAB services including vaginal ultrasound.
    - Colposcopy and LEEP services.
    - Essure and Vasectomy services.
- Participate in Specialty Services Center "on-call" responsibilities to provide after-hours care for clients experiencing complications. Must be able to arrive at specialty center within sixty minutes of physician determining that client must be seen. Core member of specialty services care team that includes on-call physician and Speciality Services RN who provide after-hours care on an as-needed basis. On-call responsibilities may require up to eight days of call coverage on a monthly basis.
- Comply with all safety policies and procedures including infection control.
- Ensure compliance with all regulatory requirements (e.g. annual TB testing, biannual review of emergency policies, procedures and drills, annual OSHA training review, etc.) per Agency policy and

regulatory mandates.

- Attend trainings, staff meetings and in-services to maintain and increase knowledge of protocols and procedures.
- Ensure client satisfaction.
- Prepare center for opening and secure for closing as required.
- Ensure successful completion of required unit.
- In support of PPPSW's Just Culture Philosophy, identify and report errors, near misses, and employee, patient and customer safety concerns in a timely manner.
- To support risk and quality management by proactively communicating identified risks to supervisor in order to minimize risk when possible.
- Comply with PPPSWs Code of Conduct and maintain the highest level of professional and ethical standards and to act in compliance with both the letter and spirit of all applicable laws and regulations.

Non-Essential Functions

- Assist in training of new staff and volunteers by demonstration and observation of techniques and procedures.
- Perform clerical and administrative duties as directed by manager.
- Other duties and responsibilities as assigned.

PHYSICAL REQUIREMENTS

The appropriate physical requirements of this job are determined by the supervisor.
Note: *Reasonable accommodations may be made for individuals with disabilities to perform the essential functions of this position.*

	Rarely (0-12%)	Occasionally (12-33%)	Frequently (34-66%)	Regularly (67-100%)
Seeing: Must be able to read reports and use computer.				X
Hearing: Must be able to hear well enough to communicate with people.				X
Standing/Walking:				X
Climbing/Stooping/ Kneeling/ Bending:			X	
Lifting weight up to 25 lbs.		X		
Pulling/ Pushing/ Reaching:		X		
Fingering/ Grasping/Feeling: Must be able to write, type, manipulate a mouse and use telephone system.				X

* Provision of medical services is conducted under the responsibility of a Lead Clinician and/or MD.

EMPLOYEE SIGNATURE

This job description is subject to review and change. This is not a contract. On this date I have read and understood the position description and job-specific functions of my position:

Employee Signature **Date:**

Employee Name (Printed):

Updated 7/20/12

Exhibit 8.11

manual that needs review by Litigation and Law, someone on my team would go to Roger with questions.

Q Okay. Tell us what the re-accreditation process is.

Mr. Bopp. You're referring to something in the document?

Mr. Bell. Just re-accreditation, I think, is a process that the Planned Parenthood goes through to re-accredit its affiliates from time to time.

PP Witness #1 . Yeah, in my experience it's been referred to as the accreditation process.

Mr. Bell. Okay.

PP Witness #1 . An affiliate undergoes accreditation by the national office and the period of time, the interval at which it happens has changed. I believe it used to be four years. I believe it is now three years, but I am not part of the accreditation team. So I can't 100 percent promise you that that is the correct interval.

BY MR. BELL:

Q Okay. Now, do you supervise that accreditation team?

A I have nothing to do with that accreditation team.

Q Who is in charge of that?

A I -- it depends on where you want me to answer according to the organizational chart. My understanding of the accreditation team, that they report to someone named [redacted], but obviously [redacted] has a supervisor as well.

Q So just so I understand, you have a manual and the manual is the standards to which affiliates are held; is that

correct?

A For clinical care, yes.

Q For clinical care. And that manual, is that manual the sole tester of accreditation for the affiliates?

A It is not.

Q What are the other testers?

A I am not an expert in this. So I --

Q So -- so is the manual part of the accreditation process?

A What I can do is I can briefly summarize my understanding of the process.

Q Okay.

A But I am by no means an expert in the accreditation process.

Q Okay. Why don't you summarize it for us?

A The accreditation team develops a list of accreditation indicators. They draw those indicators from a variety of documents, one of which is the Standards and Guidelines, and then they use that when they do their accreditation visits.

Exhibit 8.12

would report that back to who?

A I don't actually know the answer to that.

Q Don't know. Okay. So the same answer, I assume, for all the documents because the question is basically the same; is that right?

A Which question?

Q That you would -- the accreditation team would report back that somebody was making a lot of money on fetal tissue transfers if these numbers showed a gain instead of a loss.

A If an accreditation team was at an affiliate doing an accreditation visit and noted there was a violation of one of the policies, they would make a notation of it, whatever the policy was.

Q Would you ever see their report of that accreditation team? That come across your desk?

A I don't get those reports, no.

Q Do they come across someone on your staff?

A No, they don't.

Q So that's really not part of what you do.

A That is completely not part of what I do.

Q Okay. I want to ask you a little bit about the conference you were at, and I understand your complaint, by the way, about the videos, but you were at a conference, one of the annual Planned Parenthood conferences, and [redacted]

Exhibit 8.13

Q PP Witness #4 . What does she do?

A PP Witness #4 is the Director of CAPS, which -- which stands for Consortium of Abortion Providers.

Q Is that a consortium that's inside Planned Parenthood or outside?

A No, it -- that is a -- I don’t know if "department" is the right word, but it's an entity inside PPFA.

Q Okay. And what does -- what does CAPS do?

Do they have -- what's their job?

A CAPS advises affiliates and supports affiliates that provide abortion services in doing their job better.

Q Okay. So would that job include surgical procedures, for example?

A Not all affiliates provide surgical abortion procedures, but I believe that those who do provide those services could ask CAPS for advice.

Q So CAPS would be an advice giving entity on abortion procedures to affiliates.

What is the relationship between CAPS' advice and the MS&G manual?

A To me those are separate. MS&Gs are the clinical guidelines that all affiliates follow in terms of core services to provide their care. I believe any work CAPS does would be compatible with everything in the MS&Gs, but CAPS may be advising around logistics or staffing or work flow.

Exhibit 8.14

Ms. Sawyer. And we would like to do so before this proceeds and while they're here to ask questions, so please make that arrangement.

Mr. Bell. All right. I'm going to start the hour now, if that's all right, Counsel. All right, 1 hour. It's 9:15. The hour will end at 10:15.

EXAMINATION

BY MR. BELL:

Q So PP Witness #4 , I want to understand a little bit about your role at CAPS. Can you tell us what CAPS is?

A Certainly. CAPS is a department at the Planned Parenthood Federation of America, and we serve as a resource and clearinghouse for affiliates who provide abortion services at Planned Parenthood.

Q What does it mean when it says you do technical assistance and training?

A So if an affiliate at Planned Parenthood requests technical assistance, whether that be for clinical services or other, we will provide those technical services for them. We will consult with them. We will provide onsite assistance.

Q Okay. And is there a national team or a group of experts that provides that technical assistance?

A Yes.

Q Is that a decentralized team around the Nation or are they located in New York? Where does the team come from?

Exhibit 8.15

And is that the kind of thing that she would get permission for from Planned Parenthood, New York?

A Reviewing research projects at affiliates is -- is one of the tasks of the Research Department in the national office, yes.

Q In the national office, but not part of the -- is it part of the -- would CAPS get those questions or would she go straight to the Research Department?

A If an affiliate is proposing to initiate or become involved in a research project, the affiliate presents information about that project to the National Research Office.

Q Research Office, and does the Research office have its own version of the MS&G, or does the MS&G guide the research office as well, if you know?

A Oh, that's a good question. I wouldn't be able to name any specific document, you know, as an analogy, the MS&G, but there are certainly expectations about explicit expectations about required elements for affiliate participation in research.

Q Yeah. So your capacity is kind of a publisher. Can I call you an expert on contraception?

So I'm going to call you an expert.

A Okay.

Q So if one of these entities was -- Planned

Exhibit 8.16

9/18/15

PP Doctor #1 Briefing

Biographical info [redacted]

b. LA was a full time position (difference is size of affiliate)
    i. While at PPLA
    ii. 19 clinics at the time she left, approx. 20 now – March 2013
    iii. Administrative office downtown and would travel to different sites to perform abortions
    iv. Surgical abortion performed at 6 or 7 sites, medication performed at all sites with exception of express sites that performed non-abortion services
    v. Colposcopy and _____ (pap smear) as it got bigger she trained mid-level physicians to perform, hired urologist to perform and oversee services; oversight of mid-level physicians who were performing birth control, mammogram, non-abortion services
    vi. Over time, oversight increased
    vii. Administrative side as medical director – oversight of other clinicians and services they were performing, interpret and write protocols for mid-level environment, oversee
        1. Medical assistants, RN, Advanced practice clinicians (nurse practitioners, physician assistants; licensed by state), physicians (providing surgical services) [common terminology in CA]
    viii. Budget – income that was generated from clinical services to support clinical services and donations would go to advocacy, etc.
    ix. Senior staff 2013 – configuration changed a lot; board, reporting to board was CEO, chief financial officer, office of counsel, medical director, IT dept., public affairs, _____
c. OBGYN is medical training – practice and perform abortions
    i. Training in Boston learned to perform up to 24 weeks, but at PPLA although supervised up to 24, personally only did up to 16 weeks
    ii. While at PPLA half administrative half clinical position
d. Serving as dual capacity at Pasadena – said she would help them out as medical director until they found someone but ended up becoming medical director
    i. 4 clinics at Pasadena
    ii. Office is at administrative headquarters; roughly same senior staff structure
e. Medical Director Counsel
    i. Affinity group within PP – board of trustees who manage, elected president in Oct. 2014 (around that time) for a 3 year term.

ii. Includes all medical directors of all PP affiliates
iii. 2014 asked to serve as president of
iv. Counsel – advocacy group within PP family for medical directors; liaison for affiliate CEO group ASAC – how they can better support medical directors, how to understand perspective of physicians, liaison was sent to our group to talk about medical care – 1 week, 2x a year – meetings are all across the country
v. Board of trustees meets over telephone as necessary

2. Medical Standards & Guidelines
    a. Responsibility to implement MS&G at affiliate
    b. Clinicians and physicians feel comfortable that medical care is highest standard and criteria – medical committee; clinicians in Oct/Nov get together and sit down and decides what the best treatment is for individual treatments (e.g. breast exams, abortion services, STD treatment)
    c. Medical division makes protocol; that is sent to each affiliate and customize it for local use; when she first started 130 affiliates and were trying to become more standardized but there were still differences in location; each state has different approach to public health
        i. Medical director job is to take state requirements and match them up to MS&G
        ii. Medical director's counsel is off to the side, subside branch, advocacy group, similar to CEO or CFO group
        iii. [redacted] – chairs national committee; not sure of incoming chair; subcommittees; medical division fielded question from field, based on questions they are concerned about – subject matter (surgical questions, infectious disease questions)
3. Experience at PPLA –
    a. Had tissue donation program when she left. Had tissue donation program starting in 2010 (to the best of her knowledge).
    b. Development of program – approached by independent researchers and TPOs to participate. Board said we didn't want to get involved, declined opportunities to get involved. Approached by colleague at UCLA, group organizing TPO and you should talk to them. Spoke to Novagenix – impressed by them and work they were trying to do. Took to CEO and is it time to reopen discussion with board, talked internally, approached board, Novagenix came and gave presentation and decided to move forward with relationship with Novagenix.
        i. Once a year or once every year from 1998 people would knock on our door and approach.
        ii. When some other orgs. Knocked on the door and we approached the board, board not interested until 2010. Was a different board, they were more interested. No direct knowledge for why board was not interested; believe they were interested in focusing on core services at the time (Contraception, STD testing, etc.)

iii. Was Novagenix different? Similar to previous companies, a little more academic, willing to share what they were doing with tissue – plus board had turned over; combination of the two.
    1. PowerPoint,
    2. Came and approached me, sat down and had a conversation, invited them to talk to senior management team, they were impressed; approached CEO, she arranged for them to give PowerPoint to board, board interested, sat down and worked out details. Novagenix came and talked to front line staff.
    3. Man – partner [redacted]
    4. Brought in contract template – clauses that the lawyers want to put in; CEO signed
        a. VP, myself, lead clinician, administrator
        b. Involved PPFA but exact nature I don't recall – would have sent to medical division of PPFA. IF you are affiliate you apply to medical division for permission.
        c. Approval in writing? Usually does come in writing, but no memory of something that came in writing for approval of this.

iv. Board changes over every year – people have term limits.

v. Novagenix proposing to start with 1 health center and if successful go to 2 and then 3. Send their staff person to our center and our staff would identify patients based on last menstrual period who were between 9-16; our staff would get informed consent for procedure, then our staff would say by the way we have program for tissue donation, are you interested? If interested, our staff would explain further and she would sign consent for tissue donation, then the chart would be flagged so surgeon would know she was donating. Procurement Technician would take tissue, wrap it up.
    1. Electronic medical record system, at time some things still needed to be signed, paper would follow patient. On door of procedure room, thin paper chart and notice would be on chart that they were donating tissue
    2. Sheet of paper that was a different color, that said "patient is performing tissue" or something.
    3. Doctor was supposed to know, and in every single instance, process was to flag it.
    4. Novagenix did not obtain consent, PP obtained consent. PP Doctor#1 did not obtain informed consent; she would talk to patient to confirm consent, proceed with termination.
    5. Started at Mark Tapper center.
    6. Cannot remember exactly, place for physician signature on page patient signed or check box I'm EMR system or separate sheet of

paper. Not sure where but there is a requirement for physician signature.

7. Personally not involved in 1 on 1 research projects, only involved in tissue being donated to entity.
8. Novagenix proposed $45 and I had been approached by others before that have more dollars attached to it, spoke to medical directors and they were getting slightly more, did rough calculation of what cost would be and $45 was well within ballpark of expenses and agreed to $45 Novagenix proposal – per specimen for Novagenix to take away. Did not employ anyone to do an audit. Believe language did not specify that you needed to do that.
9. Pinpoint which version of documents you have, make affirmative position to tell you which one we think was enforced in 2010 when she was engaging in process in 2010.

approval of all ft contracts per PP Doctor #1 [redacted]. back of envelope

In 2010 – understanding was she received in and was aware of it floating around in head, with updates; recall consulted protocol in 2010-did not use independent auditor, did informal rough calculation of cost.

   a. Consulted other affiliates; looked at staff time involved in triage, staff time in discussing tissue donation, consent, notification to patients chart, her time negotiating, space against cost of commercial relations, parking spaces; took basic cost and it seemed more than $45.
   b. Asked staff how long they think it would take them to do these things. Speaking to affiliates to see what they were receiving per specimen, felt she was being conservative because $45 was low end, didn't ask them how they calculated. Talked to at least 3 affiliates but don't remember who, mostly in CA.
   c. Specimen – fetal tissue. If I did 12 week abortion, she would take all or part of that – didn't charge by organ. Specimen is product of conception.

11. [redacted] – spoke about Novagneix. Met her when she moved to LA from Boston. Took over position of Director of Society of Planning Family Fellowship at UCLA. Independent provider who provided abortion services at PPLA. Their fellows trained at PPLA. Not involved in tissue donation to my knowledge.
12. Other TPOs that contacted you? Don't think it was StemExpress, but other CA company. Don't think ABR approached us.

4. Memo – PPFA Lawyer [redacted]
   a. Context of setting up tissue donation program in 2010
   b. Attached standard – "standard" memo that came from legal department but not at this time part of standards and guidelines; when I got this memo in 2001, we were

not doing tissue donation at the time. Time it was re-circulated; we used medical standard and guidelines for our program.

5. National Medical Committee
    a. MS&G, in 2010 there was guidance on fetal tissue donation. Speculate that not all matters of medical care come before NMC; sometimes they are totally confident. Matters only come to NMC if there is controversy or multiple ways to do something.
    b. Medical division within PPFA is in charge of NMC.
6. Experience with Fetal Tissue research
    a. Yale
    b. Approached by nuero researchers treatment of Parkinson's 6-9 months involved with procuring fetal tissue for research, received no compensation. Before statues came out in 1993. Did whatever technique was required to get tissue for them. Much different process. At the time there may have been changes in procedure. No other role in research, just providing tissue; no contract, informal.
    c. CAPS – consortium for abortion providers. Interest group for abortion providers to talk to each other and find best way to do things; as time passed, CAPS was absorbed into bigger planned parenthood family.
7. Accreditation and Re-accreditation
    a. Have been involved.
    b. Used to be every 4 years, changed to every 3. Want same standards as outside non-PP. spend 3-4 days, review hundreds of charts, interview employees, 300 items look at clinical services, look at board, look at financial services, look at everything. Turn over a lot of rocks, look at certificates, are licenses up to date. Affiliate can say "class 1 good", class 2, class 3. PPLA and Pasadena always got Class 1 with some corrections, know when they are coming.
    c. PPLA last audit [PP Doctor #1] was involved in – may have been 2011 or 2012.
    d. Can't recall specifically if tissue donation was reviewed but believe it would have been one of the things that was looked at.
    e. Records would be in custody of PPLA. Outcomes provided to affiliate, accreditation would be with PPFA.
    f. Separate affiliate evaluation department; affiliation and accreditation department
8. Records associated with procedure
    a. Start with informed consent; typically also have discussion about what kind of birth control she is going to go on, might sign consent for that; then blood test done; then ultrasound and ultrasound picture as well as result is part of medical record – performed on every patient to determine gestational age; depending on gestational age if over 12 weeks she might take meds to make cervix softer (if under 26 might have STD testing); then go to procedure room and be identified are you sure want to do this; procedure done, tissue go to tissue room next door, surgeon will look to see If complete, if birth control that will be taken care of; will go to recovery room; then sent home with birth control – all documented (some paper, some electronic consent) version of consent will be same, signature unique

to her chart. Informed consent to donate, there will be paper form. In medical record, there is number of check boxes for outcome (disposed, donated, law enforcement, pathology (if anomaly with fetus). 98% routine disposal but if donated.

b. Rate of donation in experience as clinician – at least 50% of patient agree to donate.
c. General as medication abortion is becoming more frequent, only up to 9 weeks, more early gestation and less late gestation.
d. Clinic she was at in PPLA when doing procedure went to 16 weeks, expanded to Bixby (?) site and went to 24 weeks. But use digoxin between 20-24 so only donating up to 20 weeks.
e. Ballpark 3,000-4,000 per year were 17-24 week gestation– maybe 15,000 total abortions per year (of 19 clinics) – at time she was there

9. Expansion of fetal tissue donation
    a. Was doing quite well, wanted to expand to give patients option to donate. Always the plan to start at one and expand to 2 or 3.
    b. PP national standards and guidelines just took it wholesale mostly and put in our standards and guidelines. Recollection ours was the same as national.
    c. Consent form – took wholesale consent form that had all standards and guidelines. 1 page consent form that came out from PPFA and we put in wholesale, they didn't permit us to modify that.
10. Human Transplantation
    a. Not changing timing, method or procedure. Do I know if TPO is in compliance, I have no way of knowing. I think our contract would state that all partners are in compliance.
    b. Mentioned in broad strokes what diseases they were working on treatment for but don't remember specific methods. No expectation that she should know what research was for. Broad stroke answers e.g. management of diabetes
        i. Not aware of patients asking questions about what not to donate for, occasionally ask to donate to specific program and we have to explain we don't have specific contracts with those orgs.
    c. Not involved with specific research program/department. (while she was there)—consulted with her lawyer on this after he specified while she was there, does that indicate they have done this since?
    d. Initial consent obtained by proxy
11. Knowledge of consent – do know that patient has consented before obtaining tissue.
    a. Exhibit 6 – changes in timing/procedure
    b. Item B4 – no changes
    c. Document produced by PPFA – need to consult them.
12. Novagenix agreement
    a. [redacted] could be person from Novagenix

b. Exhibit B – tissue preparation services – not my area but I would understand tissue that was collected would go under processing techniques, but if asking for details, sorry don't know.
c. Any idea what the contract research would be? No.
d. Are they acquiring specimens or is the fee for services? Reimbursement for expenses. IS it for services or specimen? Not selling specimen, charging what costs are with expenses in providing tissue.
e. Look for documentation on use of specimen
f. Her recollection is that it was paid monthly. During her time, program extended to 2 clinics, one day a week at each clinic. Approx. at Mark Taper, guess maybe 20-22 procedures a day (9-10 would be eligible; half would agree so 4-5 per day). Bigger cases at other site (gestational age wise) 2-3 maybe a day. Novagenix was there for full day at both facilities.
g. 7 years required to obtain medical records; different for minor. Contract specified that they had to be 18 years of age or older. In CA you can get an abortion younger, but chose not to include in tissue donation program.

13. Ultrasound
    a. Some patients if question of completion, question of completion may bring in ultra sound machine.
    b. Federal consent form – PPFA consent form was based on federal guidelines so I refer to it as a federal consent form.
14. Experience with fetal tissue donation, clinic in early 90s – no experience with fetal tissue donation.
15. Since video changed has status changed? No
    a. Conversation with PP officials about what was on that video? Pasadena has been
        i. Provided security and emotional support
        ii. In role as president of board of trustees – other conversations with medical directors some of who were also victimized; conversations with Cecile or people of that nature – no.
    b. supportive, no conversation with PPFA about video (apart from discussion with lawyers)
    c. Not considering establishing fetal tissue donation at Pasadena
    d. Was it appropriate to discuss reimbursement in your role as medical director? Did not believe she was negotiation, preliminary discussion, CEO of PP Pasadena was aware – she understood it was preliminary, her issue was to make sure whatever number we were talking about covered cost.
16. Professional relationship with PP Witness #1? Already medical director at PPLA, trained USC fellows (contract), came over to train as part of fellowship, medical director at Santa Barbara facilitated by me, when she left I hired her to be contract provider and director of research program; then hired away by PPFA and I report to her in that role.
17. Fetal tissue donation was part of medical discussion
    a. Discussed in medical directors council meeting? Not in that context but discussion with other directors outside

b. NMC? Don't recall specific conversations. May have come up but don't recall.
c. Roles and responsibilities as medical director – was part of medical discussion? Within purview of medical director? Yes – part of responsibilities in terms of compliance with those requirements, tissue donation falls under medical staff (not legal); after I have initial conversation would talk to finance, legal, etc.

18. More interest in recent years? Constant – steady, is my impression. Haven't noticed uptick or decline in past 20 years.
19. Nothing prior to 2001 about tissue donation guidance. Was there anything that preceded this? Don't know if there was anything in 1998; if there is a new program it bubbles up and takes a while to get guidance.
20. [redacted]: Novagenix contract viewed by counsel? Yes, also had process where we sent to PPFA.
21. [redacted]: reason to believe it happened? From personal experience when doing cases, when she looked and saw that patient chart was flagged, also looked at consent – from personal experience, never aware of cases where tissue was taken away without consent.
    a. Never audited compliance, good suggestion though.
22. Guidance in effect in 2010 when fetal tissue donation program was created.

Exhibit 8.17

helps support the quality of care in all the clinics by, you know, letting everybody know what is expected and making sure that everybody who works for the organization knows what national standards are.

My main job as Senior Medical Advisor was the creation of and guidance of a national quality improvement department. All the affiliates already have their own quality improvement departments or sorts of departments like that, but we did not have a unified national effort, and we now like everybody else use electronic medical records.

One of the problems with electronic medical records is the data goes in and nothing of greater benefit might come out, and so we've made an effort to figure out how to use our databases to measure quality in our health centers, and we provide quarterly reports to all of our affiliates on their outcomes with regard to measures, such as chlamydia screening, PAP screening, smoking cessation advice, basically the range of HEDIS measures that apply to women's health in the age group that we care for.

So I'm very proud that we're able to do that, and there are also other analyses that will compare Planned Parenthood to other providers showing that we do a good job in these arenas, something that's been part of my job there now as medical Advisor on the quality side, is that we've convened a national work group of other organizations that are

Exhibit 8.18

and within its affiliates conduct research by itself or with a partner?

I'd be interested in any of the goals that it sets for itself, and by that I'm not referring to situations where you're donating specimen that leads to external research, but more sort of in-house type of work.

A Thank you.

Planned Parenthood has actually always done research. At the time it was founded there was a branch of the federation 100 years ago called the Planned Parenthood Research Bureau that worked on developing new contraceptives, and so there's a long history of research at Planned Parenthood, but most recently we've made a concerted effort to think about as an organization where we can contribute.

You know, we're not a laboratory organization. We don't do laboratory based research. So a big area is what you call health services research, trying to figure out how to provide care better, and we look at the actual care we provide for patients in our own health centers, and where there are problems, we devise often randomized trials to test some new intervention against our current approach and see if we can achieve better quality care for our patients.

I mean, one example of that is in patient education and counseling where everybody wants to do it, but we don't know what the best approach is, and so sometimes we will, in fact,

Exhibit 8.19

care, but it also provides a broad range of other health care services. Can you speak to those types of services provided by Planned Parenthood?

A Yes. In looking back to when I was chair of the National Medical Committee is when Planned Parenthood instituted the concept of core medical services for the first time, and surveys showed that most affiliates back then did provide most services, but this was really a way to codify that women's preventive screening, care for sexually transmitted infections, all contraceptive services and abortion services were tied together in the core mission and needed to be available to all of our patients.

Q I'd like to explore what you just mentioned in terms of contraception services. I understand that you're --

A Un-huh.

Q -- you have particular expertise in the field of contraception. Can you explain the significance of contraception as part of women's overall health care?

A Contraception is actually the single most important thing we can do for maternal safety in terms of woman's life course overall. We do know that most women are capable of becoming pregnant for 30 years and more. Most women wish in the United States, in particular, in this era, wish to be -- actually be pregnant for only a short period of those 30-plus years. So -- and most women are at risk of pregnancy the

Exhibit 8.20

From: ClinicalServices
Subject: Aborted Pregnancy Tissue Donation Programs
Date: Wednesday, January 26, 2011 11:19:11 AM
Attachments: Aborted Tissue Programs MEMO 040401.doc

To: Affiliate CEOs, Medical Directors, Patient Services Directors

Cc: Affiliate Services Division

From: [redacted], Senior Director, Clinical Services

[redacted] Director, Clinical Services

Date: January 26, 2011

Re: Aborted Pregnancy Tissue Donation Programs

Recently we have been in communication with several affiliates about the Client Information for Informed Consent (CIIC) — Donation of Aborted Pregnancy Tissue for Medical Research, Education, or Treatment used in their aborted pregnancy tissue donation programs (Section VII-E-1). We want to remind everyone that changes to the CIIC require approval from Clinical Services. Requests should be sent through Affiliate 411.

We would also like to take this opportunity to remind affiliates about the federal law relating to payment for participation in such programs. The attached memo was sent almost exactly 10 years ago (yikes!). Given the time that has elapsed and that there has likely been staff turnover, we thought it would be helpful to resend it to assure continuing compliance with the statutes.

If you have any questions related to the law please contact [redacted] at [redacted].

MEMORANDUM

TO: AFFILIATE CHIEF EXECUTIVES
AFFILIATE MEDICAL DIRECTORS
PATIENT SERVICE DIRECTORS

FROM: PP Lawyer Senior Director, Public Policy Litigation and Law
PPFA Medical Officer #1 Acting Vice President for Medical Affairs
PPFA Medical Officer #2, Vice President For Medical Services

RE: Federal Regulations for Aborted Pregnancy Tissue Donation Programs

DATE: April 4, 2001

Among the enclosed standards is a new standard for "Aborted Pregnancy Tissue Donation Programs. This Memorandum is to supplement the standard by advising affiliates of the federal law relating to payment for participation in such programs, and to provide affiliates with two alternative approaches to assuring compliance with these laws.

A. An Overview of the Federal Law

Fetal tissue donation programs are governed by two federal laws, the National Organ Transplant Act (42 U.S.C. 274e) (NOTA) and the NIH Revitalization Act of 1993 (42 U.S.C. 289g-1 and 2) (NIHRA). These laws, particularly NIHRA, govern many aspects of fetal tissue donation programs, and the attached Standard addresses all of these issues that affect medical practice and clinical functions.

These laws also forbid the payment or receipt of valuable consideration for fetal tissue. However, they permit "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage" of fetal tissue. In addition, NOTA permits reasonable payments for the "removal" of fetal tissue when the research is supported by federal funds. (These laws do not affect a provider's ability to charge its normal and customary fee for the abortion.)

B. Assuring Compliance With Federal Law

Affiliates can choose one of two methods to comply with these laws.

1. One method would be to recover *no costs* associated with any aspect of participation in a fetal tissue donation program. This would mean that all staff time, clinic space, supplies, etc., would be donated by the affiliate, and the affiliate would receive no payments or in-kind services from the entity to whom the tissue is being donated.

2. The second method would be to employ an independent auditor to conduct a credible and good-faith analysis of the actual costs incurred *by the affiliate* in the transportation, implantation, processing, preservation, quality control, or storage of the fetal tissue and, if the research is supported by federal funds, for the removal of the fetal tissue. Under this method, affiliates must maintain careful records of actual tissue donations and of payments received from the researcher or the tissue-gathering entity. Affiliates must be able to demonstrate that the payments do not exceed the actual costs of the actual tissue donations.

Sometimes tissue-gathering entities offer to pay rent for space occupied by one of their employees who would be on-site at a clinic on a regular basis. If an affiliate determines to enter into such an arrangement, then the independent auditor would also conduct a credible and good-faith computation of the actual cost of the space occupied by the tissue-gathering entity employee, in order to determine the amount of rent to be paid by that entity.

PPFA accreditation reviews will confirm, in the same way as for any other Medical Standard, that one of these two methods has been employed by any affiliate that chooses to participate in an aborted pregnancy tissue donation program.

C. Compliance With State Laws

We remind affiliates that, in addition to the federal laws outlined above, there are laws in many states governing fetal tissue donation programs. Affiliates must take great care to assure compliance with those laws as well.

If you have questions about the federal statutes, feel free to call PPFA Lawer at: [redacted].

Exhibit 8.21

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6115

Majority (202) 225–2927

Minority (202) 225–3641

VIA EMAIL

September 8, 2016

K. Lee Blalack II, Esq.

[redacted]

Dear Mr. Blalack:

Thank you for your recent correspondence regarding Planned Parenthood Federation of America and its affiliates' willingness to voluntarily comply with the Select Investigative Panel's document requests. Planned Parenthood has previously produced a number of documents to various Congressional Committees, and, in particular, the Energy and Commerce Committee of the House of Representatives. As we discussed on the telephone, the Panel has reviewed those materials and has narrowed its scope as much as possible. The Panel seeks to work with your client to narrow document requests to the pertinent information necessary to the Panel's responsibilities to the House of Representatives.

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered the Panel to investigate issues related to fetal tissue research. This document request is made pursuant to the scope of investigative responsibility of the Panel. Under the authority of H. Res. 461, we are seeking the following documents and information regarding the cost and payments related to the transfer of fetal tissue.

Pursuant to the authority delegated to it under H. Res. 461, the Panel is investigating whether entities, such as middleman companies that procure fetal tissue, are using loopholes in federal law or engaging in business practices that have the effect of undermining the purpose of laws prohibiting the interstate transfer of any fetal tissue for valuable consideration. As part of that investigation, the Panel is examining whether 42 U.S.C. § 289g-2 is effective, or needs to be amended to better achieve the legislative goals of the statute. Under Title 42 U.S.C. § 289g-2, which is, at its heart, an accounting statute, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any fetal tissue for valuable consideration if the transfer affects interstate commerce. The term "valuable consideration" does not include reasonable payments

associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

Planned Parenthood has already produced documents pertinent to the costs and consideration related to fetal tissue – in particular PPLA-HOU_E&C-000018-000019; PPMM-HOU_E&C-000001-000002; PPNC-HOU_E&C-000001-000002; and PPPSW-HOU_E&C-000001-000002. These four documents referred to below as the Planned Parenthood Cost Documents are very helpful but also raise questions critical to our analysis of statutory sufficiency. As a result, we are requesting the following:

1) The working calculation papers relied upon to produce cost estimates for each item listed in the Planned Parenthood Cost Documents.

2) The accounting basis and records that were relied upon for each cost item in the Planned Parenthood Cost Documents.

3) Any documents that show an adjustment for annual costs based upon 2015 as a partial year of providing fetal tissue (Planned Parenthood announced a discontinuance of participation sometime after mid-year 2015).

4) Any accounting documents that show acost adjustment in Planned Parenthood's Cost Documents when an employee of an outside company participates in obtaining consent, or obtains the consent.

5) For particular line items in the Planned Parenthood Cost Documents, where an employee has partial responsibility for work related to fetal tissue donation, provide (name redacted) documents sufficient to show that position's work plan, job description, or any other document that describes the responsibility of the position to participate in fetal tissue donation.

6) For the item "Attending Morning Meetings Discussion of Donation Program" provide information about the subject matter(s) of the meeting other than fetal tissue donation.

7) Any job or position announcements that show the need to hire additional personnel to complete the tasks of fetal tissue donation.

8) Any accounting or audit reports similar to the four documents referenced in this request that show the costs allocated to any services provided by Planned Parenthood for surgical services, testing, exams, birth control or any other services.

It is our hope that by providing the above referenced materials we can come to closure on the Panel's examination of the consideration for fetal tissue and offsetting costs. Please do not hesitate to contact me if you have questions.

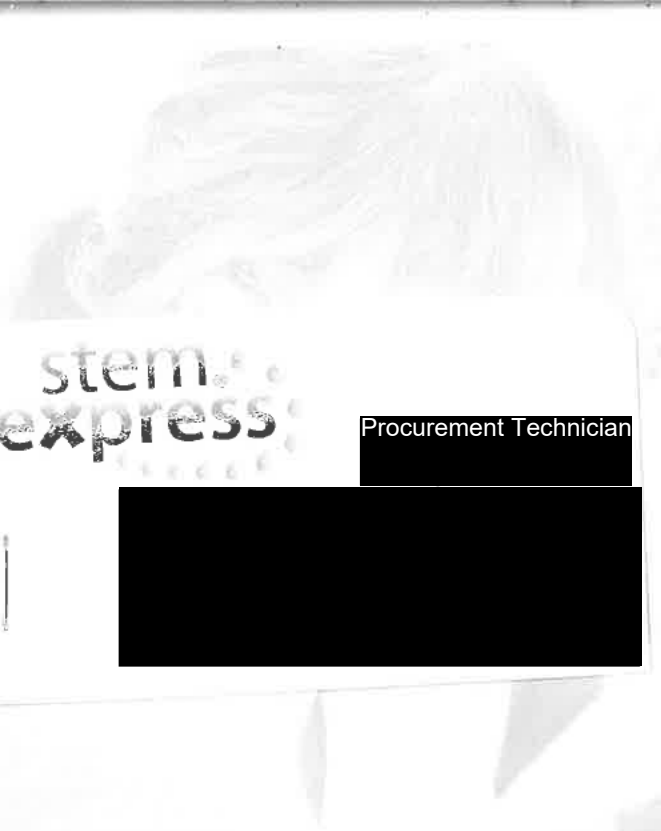
Sincerely yours,

T. March Bell
Chief Counsel and Staff Director
Select Investigative Panel of
the Committee on Energy and Commerce

cc: Heather Sawyer
Democratic Staff Director
Select Investigative Panel

Exhibit 8.22


Your clinic can advance biomedical research.
Financially Profitable • Easy to Implement Plug-in Solution • Medical Director Oversight • IRB Certified Consents
NAF-000001



stem
express

About StemExpress

StemExpress is a California-based biomedical company that provides qualified research laboratories with human cells, fluids, blood and tissue products for the pursuit of disease detection and cure. We procure, preserve, isolate and deliver cell lines exclusively to research facilities across the world. StemExpress products are not available for patient care. Stem Express is accredited by an independent biomedical Institutional Review Board.

"Our partnership with StemExpress is beneficial in a number of ways. First, it allows us to contribute to life-saving research that is advancing diagnostic and medical care. Second, StemExpress has a Plug-in Solution that allows us to add additional clinics quickly. Lastly, I feel confident that our patient's anonymity is secure through their strict protocols and practices."

Abortion Doctor [redacted], Planned Parenthood Mar Monte

Advancing BioMedical Research Together

Join the StemExpress partner program that fiscally rewards clinics for contributing to the advancement of life-saving research — with a solution that is easy to incorporate into your clinic practices. StemExpress is a California-based biomedical company that provides human tissue products ranging from fetal to adult tissues and healthy to diseased samples to many of the leading research institutions in the world. Our IRB approved protocols and consents protect you as well as donor's privacy in accordance with HIPAA guidelines.

Partnering with Obstetrical-Care Clinics

Cell-free fetal DNA circulates in maternal blood throughout pregnancy. Noninvasive, stem cell free methods to obtain fetal DNA are being used for earlier detection of genetic diseases as well as reproductive decision-making. Research pioneers who develop noninvasive diagnostic technologies rely on the blood samples that are collected from hospitals and clinics throughout the United States.

Easy to Implement Program + Financial Profits

StemExpress promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with StemExpress, not only are you offering a way for your clients to participate in the unique opportunity to facilitate life-saving research, but you will also be contributing to the fiscal growth of your own clinic. The stem cell rich blood and raw materials that are usually discarded during obstetrical procedures can, instead, be expedited through StemExpress to research laboratories with complete professionalism and source anonymity.

stem® express

SUSTAINING QUALITY OF LIFE
THROUGH RESEARCH™

StemExpress, LLC • [redacted]

Contact us at [redacted]

Exhibit 8.23

Planned Parenthood of Los Angeles (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Preparing Surgical List and Internal Coordination		
Front Desk	$	59.28
Registered Nurse	$	141.96
Staff Time Coordinating with Novogenix Representative		
Center Manager	$	390.00
Front Desk	$	79.04
Medical Assistant	$	265.20
Staff Time Attending Morning Meetings' Discussion of Donation Program		
Center Manager	$	93.60
Clinician	$	532.48
Front Desk	$	76.96
Licensed Vocational Nurse	$	97.76
Medical Assistant	$	332.80
Registered Nurse	$	567.84
Surgical Technician	$	91.52
Staff Time Managing and Overseeing Tissue Donation Program		
Medical Director	$	1,476.90
Vice President of Patient Services	$	660.00
Supplies / Equipment		
Disposable Gloves	$	129.28
Disposable Masks	$	22.88
Laundry	$	62.40
Shoe Covers	$	37.44
Underpads	$	80.08
Management & General Overhead[2]	$	638.76
Subtotal	**$**	**5,836.18**

Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Discussing Program with Patients, Obtaining Consent or Declination		
Clinician	$	4,333.56
Medical Assistant	$	1,835.36
Registered Nurse	$	1,061.97
Staff Time Preparing, Processing, and Photocopying Consent Forms		
Front Desk	$	492.11
Registered Nurse	$	189.28
Supplies / Equipment		
Photocopies	$	4.87

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.

[2] Management & General Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

Printing	$	218.40
Slipsheets	$	10.74
Management & General Overhead	$	1,001.18
Subtotal	**$**	**9,147.47**

Costs Associated with Transportation, Preservation, Quality Control, and Storage

Staff Time Transferring Tissue to Novogenix Representative		
Surgical Technician	$	158.90
Staff Time Disposing of Unused Tissue		
Surgical Technician	$	158.90
Staff Time Coordinating with Novogenix Representative		
Surgical Technician	$	246.48
Staff Time Invoicing Novogenix Reimbursement		
Administrative Assistant for Patient Services	$	84.42
Staff Time Revising Electronic Health Records		
Nurse Informatics	$	57.30
Management & General Overhead	$	86.77
Subtotal	**$**	**792.77**

Costs Associated with Use of Facility Space

Use of Space by Novogenix Representatives		
Dedicated Work Areas[3]	$	282.51
Shared Common Areas[4]	$	642.97
Management & General Overhead	$	113.74
Subtotal	**$**	**1,039.22**
TOTAL COSTS	**$**	**16,815.65**

Reimbursements

Reimbursement		
$45.00 Service Fee for 350 Donations	$	15,750.00
TOTAL REIMBURSEMENTS	**$**	**15,750.00**
NET GAIN/LOSS	**$**	**(1,065.65)**
PERCENT GAIN/LOSS		**(6.77%)**

[3] Represents the portion of facilities costs for space dedicated for the Novogenix representative on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[4] Represents the portion of common-area space utilized by Novogenix representative on days present.

Planned Parenthood Mar Monte (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Coordinating and Managing Patient Flow		
Health Services Specialist	$	831.14
Abortion Coordinator	$	5,017.20
Staff Time Supervising / Coordinating with Stem Express Representative		
Center Manager	$	579.62
Chief Medical Officer	$	347.78
Supplies / Equipment		
Disposable Gloves	$	104.55
Flush Solutions	$	90.34
Gauze	$	5.89
Band-Aids	$	4.32
Operations Costs[2]	$	853.42
General Administrative & Medical Overhead[3]	$	1,880.22
Subtotal	**$**	**9,714.48**
Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Interpreting Consent Forms		
Health Services Specialist	$	1,170.44
Staff Time Verifying and Signing Consent Forms		
Clinician	$	1,813.33
Staff Time Scanning Consent Forms		
Check-Out Specialist	$	183.85
Supplies / Equipment		
Photocopies	$	130.98
Operations Costs	$	378.92
General Administrative & Medical Overhead	$	882.60
Subtotal	**$**	**4,560.12**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Staff Time Cleaning Stem Express Equipment		
Health Services Specialist	$	260.61
Staff Time Invoicing Stem Express Reimbursement		
Assistant Lab Manager	$	704.33
Accountant	$	237.43

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.

[2] Operations Costs represent additional direct costs allowed per 2 C.F.R. § 200, including telephone usage, postage, office supplies, and other direct costs.

[3] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

Supplies / Equipment		
Shipping Labels	$	8.79
Operations Costs	$	142.62
General Administrative & Medical Overhead	$	324.91
Subtotal	**$**	**1,678.69**
Costs Associated with Use of Facility Space		
Use of Space by Stem Express Representatives		
Dedicated Work Areas[4]	$	4,286.55
Storage Areas[5]	$	1,005.47
Subtotal	**$**	**5,292.02**
TOTAL COSTS	**$**	**21,245.32**
Reimbursements		
Reimbursement		
$55.00 Service Fee for 176 Donations	$	9,680.00
$35.00 Service Fee for 265 Donations	$	9,275.00
TOTAL REIMBURSEMENTS	**$**	**18,955.00**
NET GAIN/LOSS	**$**	**(2,209.32)**
PERCENT GAIN/LOSS		**(12.08%)**

[4] Represents the portion of facilities costs used by Stem Express representatives on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[5] Represents the portion of facilities costs used by Stem Express representatives for storage of materials and supplies.

Planned Parenthood: Shasta-Diablo, Inc. DBA Planned Parenthood Northern California (FY 2015)[1]

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[2] Supervising / Coordinating with Stem Express Representative		
Vice President of Medical Services	$	359.32
Center Director	$	168.86
Abortion Services Coordinator	$	397.62
Operations Costs[3]	$	154.89
General Administrative & Medical Overhead[4]	$	194.52
Subtotal	**$**	**1,275.21**
Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Verifying and Signing Consent Forms		
Medical Director	$	87.35
Staff Time Scanning Consent Forms		
Flow Coordinator	$	12.74
Operations Costs	$	21.02
General Administrative & Medical Overhead	$	21.80
Subtotal	**$**	**142.91**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Staff Time Coordinating Courier Service for Stem Express Representative		
Flow Coordinator	$	12.74
Staff Time Screening Donated Tissue		
Medical Director	$	16.91
Staff Time Invoicing Stem Express Reimbursement and Coordinating Program		
Medical Services Manager	$	301.95
Supplies / Equipment		
Autoclave Sterilization Indicator Tape	$	0.78
Chemical Sterilization Indicator Strip	$	1.22

[1] This analysis reflects costs and reimbursements for the Concord health center only. The Walnut Creek health center also made five donations, one of which resulted in no reimbursement and has been written off as non-collectible, totaling $220.00 in reimbursements. Costs and reimbursements from the Walnut Creek center have been excluded from this analysis due to their small size.

[2] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.

[3] Operations Costs represent additional direct costs allowed per 2 C.F.R. § 200, including telephone usage, postage, office supplies, and other direct costs.

[4] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

Tubing for Sterile Instrument Transportation	$	4.72
Operations Costs	$	36.42
General Administrative & Medical Overhead	$	67.45
Subtotal	**$**	**442.19**
Costs Associated with Use of Facility Space		
Use of Space by Stem Express Representatives		
Dedicated Work Areas[5]	$	166.89
Storage Areas[6]	$	125.76
General Administrative & Medical Overhead	$	52.68
Subtotal	**$**	**345.33**
TOTAL COSTS	**$**	**2,205.64**
Reimbursements		
Reimbursement		
$55.00 Service Fee for 25 Donations[7]	$	1,375.00
TOTAL REIMBURSEMENTS	**$**	**1,375.00**
NET GAIN/LOSS	**$**	**(830.64)**
PERCENT GAIN/LOSS		**(60.41%)**

[5] Represents the portion of facilities costs used by Stem Express representatives on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[6] Represents the portion of facilities costs used by Stem Express representatives for storage of materials and supplies.
[7] The Concord health center made a total of 31 donations, six of which resulted in no reimbursements and have since been written off as non-collectible.

Planned Parenthood of the Pacific Southwest (FY 2015)

Costs Associated with Coordinating Tissue Collection and Processing		
Staff Time[1] Communicating with ABR Representative Prior to Collection		
Front Desk	$	154.56
Center Manager	$	534.49
Flow Coordinator	$	325.62
Medical Assistant	$	112.28
Staff Time Supervising / Coordinating with ABR Representative		
Center Manager	$	3,008.40
Flow Coordinator	$	4,808.84
Medical Assistant	$	1,017.52
Supplies / Equipment		
Chucks	$	23.42
Disposable Gloves	$	95.82
Ziploc Bags	$	21.54
General Administrative & Medical Overhead[2]	$	2,501.38
Subtotal	**$**	**12,603.87**
Costs Associated with Obtaining Patient Consent for Donation		
Staff Time Discussing Program with Patients, Obtaining Consent or Declination		
Medical Assistant	$	5,789.94
Staff Time Preparing Consent Forms, Whiteboard, and Anonymized Consent List		
Front Desk	$	907.44
Medical Assistant	$	1,651.51
Manager	$	585.48
Flow Coordinator	$	825.21
Staff Time Sending Consent Forms to Administrative Office		
Front Desk	$	131.00
Supplies / Equipment		
Photocopies	$	184.00
General Administrative & Medical Overhead	$	2,494.47
Subtotal	**$**	**12,569.05**
Costs Associated with Transportation, Preservation, Quality Control, and Storage		
Extra Tissue Examination Time[3]		
Medical Assistant	$	1,194.97

[1] Staff costs are calculated by multiplying the employee's wage and benefits by the amount of time spent on tasks associated with the fetal tissue donation program.

[2] General Administrative & Medical Overhead represents the portion of costs for overall function and management associated with maintaining the tissue donation program, exclusive of the costs directly allocated.

[3] These figures represent additional time required to examine products of conception because the tissue was either not washed or washed in cold water, as required for donation.

Flow Coordinator	$	52.80
Staff Time Transferring Tissue to ABR Representative		
Medical Assistant	$	235.52
Flow Coordinator	$	195.04
Staff Time Managing Deliveries, Moving Boxes, and Discarding Documents for ABR Representative		
Center Manager	$	447.12
Medical Assistant	$	253.00
Front Desk	$	220.80
Staff Time Coordinating Courier Service for ABR Representative		
Front Desk	$	1,015.68
Medical Assistant	$	9.75
Center Manager	$	149.04
Staff Time Invoicing ABR Reimbursement		
Center Manager	$	35.64
Staff Time Installing Shelf for ABR Representative		
Maintenance	$	25.92
Supplies / Equipment		
Shelf for ABR Representative	$	279.21
General Administrative & Medical Overhead	$	1,018.75
Subtotal	**$**	**5,133.24**
Costs Associated with Use of Facility Space		
Use of Space by ABR Representatives		
Dedicated Work Areas[4]	$	124.60
Storage Areas	$	1,588.51
Shared Common Areas[5]	$	4,157.91
General Administrative & Medical Overhead	$	1,453.66
Subtotal	**$**	**7,324.68**
TOTAL COSTS	**$**	**37,630.84**
Reimbursements		
Reimbursement		
$60.00 Service Fee for 316 Donations	$	18,960.00
TOTAL REIMBURSEMENTS	**$**	**18,960.00**
NET GAIN/LOSS	**$**	**(18,670.84)**
PERCENT GAIN/LOSS		**(98.47%)**

[4] Represents the portion of facilities costs used by ABR representative on days present, including the costs of utilities, taxes, depreciation, and repairs & maintenance.
[5] Represents the portion of common-area space utilized by ABR representative on days present.

Exhibit 8.24

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

November 14, 2016

DELIVERED VIA EMAIL

Mr. K. Lee Blalack II
[redacted]

Dear Mr. Blalack:

As you know from our meetings, telephonic conferences, and correspondence, the Select Investigative Panel ("the Panel") is charged by the House to study and report upon the fetal tissue industry, and make recommendations. The key statute that covers fetal tissue is Title 18 U.S.C. §289-g, which makes it illegal to acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration. Under that law, valuable consideration does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

In order to determine whether Planned Parenthood Federation of America ("PPFA") and its affiliates' compliance with 18 U.S.C. §289-g, the Panel requested, and your clients agreed to produce, documents that provide the cost accounting basis for PPFA's contention that its affiliates did not receive valuable consideration as defined in the statute.

On November 11, 2016, we received the production from Planned Parenthood Mar Monte ("PPMA") that reflects PPMM's costs associated with the procurement of fetal tissue. The Panel requested the same documents from Planned Parenthood Los Angeles, Planned Parenthood Shasta-Diablo ("Northern California"), and Planned Parenthood Pacific Southwest.

Our forensic accounting review of the PPMM production finds that the production appears to be an accounting policy document reflecting how the entity records and reports revenues and expenditure and how it treats common costs or allocate indirect costs. This production does not appear to be responsive to any of the 8 items requested in our September 8, 2016, letter. The items requested in our letter were very specific. Please have PPMM specifically state to which of the requested items in the September 8, 2016, letter the production is responsive.

Please produce the requested PPMM documents, as well as the same documents from Planned Parenthood Los Angeles, Planned Parenthood Shasta-Diablo ("Northern California"), and Planned Parenthood Pacific Southwest, no later than the close of business on November 28, 2016.

Sincerely,

T. March Bell
Staff Director & Chief Counsel
Select Investigative Panel

cc: Ms. Heather Sawyer
Minority Staff Director & Chief Counsel
Select Investigative Panel

Exhibit 8.25

STEM-EX, LLC

Services Agreement

This agreement is made as of April 1st, 2010 between Stem-Ex, LLC, a limited liability company, and Planned Parenthood Mar Monte, a professional corporation.

WHEREAS, Stem-Ex is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Mar Monte provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Mar Monte will provide, and Stem-Ex will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which Stem-Ex representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Mar Monte will invoice Stem-Ex monthly for the number of POC's and number of maternal bloods procured by Stem-Ex. Stem-Ex will pay Planned Parenthood Mar Monte within two weeks of receipt of the invoice.

6. Any information obtained from Planned Parenthood Mar Monte patients' charts shall be privileged, and Stem-Ex will treat the information in order to preserve the confidentiality of the patients. Stem-Ex will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Mar Monte
[redacted]

Stem-Ex
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Mar Monte is not obligated to provide any minimum number of POCs or maternal bloods. Stem-Ex is not obligated to take any minimum number of POCs or maternal bloods, nor is Stem-Ex obligated to take all the POCs or maternal bloods made available by Planned Parenthood Mar Monte.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Mar Monte

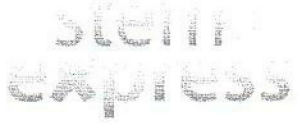
By: Abortion Doctor

Title: Medical Director

Stem-Ex, LLC

By: StemExpress Founder and CEO

Title: President



Services Agreement

This agreement is made as of 5/15/2012 between StemExpress, LLC, a limited liability company, and Planned Parenthood Shasta Pacific, a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Shasta Pacific provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Shasta Pacific will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Shasta Pacific will invoice StemExpress monthly for the number of POC's and number of maternal bloods procured by StemExpress. StemExpress will pay Planned Parenthood Shasta Pacific within thirty days of receipt of the invoice.

[redacted] Shipping & Receiving
[redacted]
[redacted] www.stemexpress.com

6. Any information obtained from Planned Parenthood Shasta Pacific patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Shasta Pacific
[redacted]

_____

StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Shasta Pacific is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by Planned Parenthood Shasta Pacific.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the

[redacted]Shipping & Receiving
[redacted]
[redacted]www.stemexpress.com

performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Shasta Pacific

By: [redacted] 5/16/12

Title: President/CEO

StemExpress, LLC

By: [redacted]

Title: CEO 5/16/12

[redacted] Shipping & Receiving

[redacted]

[redacted] www.stemexpress.com

Services Agreement

This agreement is made as of October 23, 2103 between StemExpress, a limited liability company, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties, Inc. (PPSBVSLO) a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, PPSBVSLO provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. PPSBVSLO will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal blood; seeking consent for donation of fetal organs and maternal blood from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty dollars ($50.00) per 60cc's of maternal blood, and seventy five dollars ($75.00) for the collection of fetal tissue, if collected solely by PPSBVSLO staff. If StemExpress staff is onsite to physically collect the sample, then there would be a cost adjustment for the collection of the sample. PPSBVSLO will invoice StemExpress monthly for the number of POC's and number of maternal bloods

[redacted]

procured by StemExpress. StemExpress will pay PPSBVSLO within thirty days of receipt of the invoice.

6. Any information obtained from PSBVSLO patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods. This will always be done in accordance with HIPAA guidelines.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and can be renegotiated for successive years there after. Parties may, at any time, give each other a ninety days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate ninety days after the receipt of such notice. .

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Abortion Doctor Medical Director
[redacted]

StemExpress Founder and CEO
StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. PPSBVSLO is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by PPSBVSLO.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

[redacted]

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

StemExpress, LLC

By: [redacted] StemExpress Founder and CEO

Name: [redacted] StemExpress Founder and CEO

Title: **CEO**

Planned Parenthood Santa Barbara, Ventura & San Luis Obispo Inc.

By: [redacted]

Name [redacted]

Title: President / CEO

[redacted]

www.stemexpress.com

Exhibit 8.26

O'MELVENY & MYERS LLP

BEIJING
BRUSSELS
CENTURY CITY
HONG KONG
LONDON
LOS ANGELES
NEWPORT BEACH

[redacted]

NEW YORK
SAN FRANCISCO
SEOUL
SHANGHAI
SILICON VALLEY
SINGAPORE
TOKYO

[redacted]

November 10, 2015

VIA ELECTRONIC MAIL & HAND DELIVERY

The Honorable Fred Upton, Chairman
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Timothy F. Murphy, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
2332 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joseph R. Pitts, Chairman
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: ***Planned Parenthood: Reasonable Payments Associated With Fetal Tissue Donation***

Dear Chairman Upton, Chairman Murphy & Chairman Pitts:

Please accept this letter in further response to your letters to the Chief Executive Officers of Planned Parenthood Los Angeles, Planned Parenthood Mar Monte, Planned Parenthood Northern California, and Planned Parenthood of the Pacific Southwest, dated September 30,

2015 (the "September 30 Letters"), requesting that the affiliates provide documents and information used to determine "appropriate reimbursement costs" for donating fetal tissue.[1]

As a threshold matter, it is important to restate what PPFA has already communicated publicly and to your staff. At Planned Parenthood—the nation's leading provider of reproductive health care—facilitating patients' donation of fetal tissue has always been an incidental service offered to patients by a small number of affiliates across the country. Today, only two of 59 affiliates—one in Washington and one in California—facilitate their patients' donation of fetal tissue for medical research. During the last five years, four Planned Parenthood affiliates facilitated their patients' donation of fetal tissue for research, and accepted reasonable payments associated with the costs incurred to facilitate such donations. Two others also facilitated these donations but did so while foregoing any reimbursement for their expenses. Enclosed please find accountings of payments and costs responsive to the Committee's request that were prepared by the four relevant affiliates.

The enclosed accountings confirm that the four affiliates complied with federal law governing payments associated with the donation of fetal tissue. The relevant statute expressly permits "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[2] As you can see from the cost accountings the affiliates have produced, the reasonable payments each received were less than the allowable costs associated with their fetal tissue donation programs—in some cases, by significant margins.

The affiliates' accountings assign their costs of facilitating fetal tissue donation to four general categories of costs for which it is permissible to receive reasonable payments under federal law. Some or all of these four affiliates have incurred, and recovered, costs associated with coordinating tissue collection and processing; costs associated with obtaining patient consent for donation; costs associated with transportation, preservation, quality control, and storage of tissue; and costs associated with the use of health center facility space by organizations that procure donated tissue.[3] As the statutory language, relevant legislative

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[1] Federal law defines "human fetal tissue" as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. §§ 289g-2(e)(1), 289g-1(g). That definition does not encompass the donation of tissue from other products of conception, such as placental tissue or decidua, for which certain affiliates have also facilitated patient donations for medical research.

[2] 42 U.S.C. § 289g-2(e)(3).

[3] The history of the federal law governing fetal tissue donation makes plain that clinics are permitted to recover the reasonable costs of obtaining consent from patients prior to donation. *See* Report of the Human Fetal Tissue Transplantation Research Panel 37 (1988) [hereinafter Reagan Panel Report] (affirming that "a tissue retrieval agency may reimburse the abortion clinic for using its space and staff to obtain consent for tissue donations"). Indeed, a review conducted in 2000 by the then-titled U.S. General Accounting Office found that clinics donating fetal tissue are commonly reimbursed for the costs associated with obtaining the necessary consent of patients. *See* U.S. Gen. Accounting Office, GAO-01-65R, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (2000) [hereinafter GAO, Human Fetal Tissue]. Similarly, a clinic facilitating the donation of fetal tissue may recover the reasonable costs of allowing a tissue procurer to use facility space. *See* Reagan Panel Report at 11 (explaining that reasonable payments for tissue donation are sometimes intended to cover, among other things, "use of the clinic space by employees of the procurement agency"). And in practice, tissue procurers have regularly and

history, and subsequent government reviews make abundantly clear, recovery of each of these types of reasonable costs is both legally permissible and common practice in the medical research community.[4]

Furthermore, the affiliates' cost accountings are based on a conservative interpretation of the law, as they reflect actual costs incurred. The law provides that a donor of fetal tissue may receive "reasonable payments" associated with general categories of activities relating to fetal tissue donation. The affiliates have applied a conservative approach to this language by reading the word "costs" into the statute, but there may be other, more permissive—and legitimate—interpretations of the law that would yield legally proper payments in higher amounts.

The affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation, and have demonstrated conclusively that those costs exceeded the payments they received. Your September 30 Letters separately request that the affiliates provide to the Committee all audits conducted of the fetal tissue donation programs, along with documents, such as calculation sheets and budgets, relating to the reimbursements they received. We have determined that these four affiliates either did not conduct or cannot locate contemporaneous cost analyses, or secure independent audit opinions as articulated by PPFA's then-existing guidance. To state the obvious, the absence of contemporaneous documentation or audits does not implicate compliance with federal or state laws. PPFA's guidance exceeded the requirements of the law. Federal law does *not* require a contemporaneous cost analysis or an independent audit opinion *before* facilitating a patient's donation of fetal tissue for medical research. Indeed, the relevant federal statute does not even refer to documentation requirements. Federal law requires only that payments accepted for donating fetal tissue be "reasonable" and "associated with" several broad categories of tissue procurement activities, and the enclosed accountings confirm that these four affiliates complied with this legal requirement. Moreover, in order to end any unfounded accusations in the future that its affiliates were "profiting" by facilitating their patients' donation of tissue for medical research, PPFA recently announced a policy that affiliates may no longer recover even legally permissible costs.

Over the past several months, partisans have seized on the heavily edited videos recorded by anti-choice extremists to allege that Planned Parenthood affiliates "profited" from facilitating

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properly reimbursed clinics facilitating tissue donation for the costs of using facility space. *See id.* (explaining that tissue procurement organizations, in practice, pay clinics "a small fee for each fetal tissue retrieved to cover the costs of retrieval, including time of staff and rental of space"); David H. Smith et al., Using Human Fetal Tissue for Transplantation and Research: Selected Issues (1988), *reprinted in* Reagan Panel Report app. at F15 (quoting a tissue procurement organization spokesperson as saying they pay clinics "a rental payment for the use of their equipment and facilities, which may range from $300 to $1,000 per month, depending on the amount of time the technicians are in the clinic").

[4] Consistent with accepted accounting practices, several of these permissible cost categories include allocations for the affiliates' indirect costs that make tissue donations possible for Planned Parenthood patients. The failure to account for indirect costs would yield a cost analysis that did not capture the actual costs associated with facilitating fetal tissue donation. *See* Fed. Accounting Standards Advisory Bd., Handbook of Federal Accounting Standards and Other Pronouncements, at SFFAS 1-46 (as amended June 30, 2014) ("Full assignment of all costs of a period, including general and administrative expenses and all other indirect costs, is an important basis for measuring cost of service.").

fetal tissue donations for medical research. Putting aside the misleading and unreliable nature of those videos, the allegation is absurd on its face. First of all, Planned Parenthood and its affiliates are all nonprofit organizations, and therefore generate no profits from any revenues they receive to reimburse them for their work providing medical and other services. But even more importantly, the payments these affiliates received for facilitating their patients' fetal tissue donations amounted to a miniscule portion of their overall revenues and budgets:

- At Planned Parenthood Los Angeles, cost reimbursements to facilitate patients' tissue donation amounted to $15,750 for the relevant year, as compared to total revenues of $59,717,927. These payments represented less than 0.027% of PPLA's total revenue.
- At Planned Parenthood Mar Monte, cost reimbursements to facilitate patients' tissue donation amounted to $18,955 for the relevant year, as compared to total revenues of $94,422,729. These payments represented less than 0.021% of PPMM's total revenue.
- At Planned Parenthood Northern California, cost reimbursements to facilitate patients' tissue donation amounted to $1,375 for the relevant year, as compared to total revenues of $47,268,637. These payments represented less than 0.003% of PPNorCal's total revenue.
- At Planned Parenthood of the Pacific Southwest, cost reimbursements to facilitate patients' tissue donation amounted to $18,960 for the relevant year, as compared to total revenues of $57,357,352. These payments represented less than 0.034% of PPPSW's total revenue.

In other words, for each of the four affiliates, their total payments were no more than a fraction of one percent of the affiliate's operating revenues. It defies logic—and common sense—to assert that these very modest reimbursements motivated affiliates to facilitate tissue donation out of a desire to "profit" from fetal tissue donation.

Moreover, the payments these affiliates received, which ranged from $35 to $60 for all tissue collected from a single patient, are well within the ranges cited in the public record as reasonable reimbursement amounts. The Human Fetal Tissue Transplantation Research Panel convened by President Ronald Reagan (the "Reagan Panel") in 1988—which recommended restoring federal funding to fetal tissue research—included in the appendices to its report anecdotal evidence of fees charged for fetal tissue procurement, including a letter from a biologics company representing that it paid a tissue procurement organization ("TPO") $50 per tissue donation,[5] and a report from the Poynter Center citing another TPO as paying $300 to $1,000 per month in rent to a clinic that facilitated tissue donation.[6] Similarly, a report issued in 2000 by the U.S. Government Accountability Office ("GAO") described a survey of what NIH-funded researchers paid to procure fetal tissue. GAO reported an average fee of $80 per sample, well above the payment amounts the four Planned Parenthood affiliates received here. And these

[5] Letter from H. Fred Voss, Vice President, Research & Dev., Hana Biologics, Inc., to Hon. Arlin M. Adams, Chairman, Human Fetal Tissue Transplantation Research Panel (Sept. 15, 1988), *reprinted in* Reagan Panel Report app. at D266.

[6] Smith, *supra* note 3, at F15.

amounts do not even account for the impact of inflation over the last fifteen years; the $50 payment discussed by the 1988 Reagan Panel would be approximately $100 in 2015 dollars, and the $80 payment referenced by the GAO report in 2000 would be approximately $110 in 2015 dollars.[7] Recent press reports about this issue are consistent with these earlier government reports, with researchers and TPO personnel citing reimbursements of up to $100 per sample as reasonable charges to reimburse costs associated with fetal tissue procurement.[8]

In sum, the payments received by these Planned Parenthood affiliates were associated with their costs of facilitating fetal tissue donation and those payments were consistent with well-documented evidence regarding what is considered "reasonable." That the affiliates have now demonstrated that their costs were more than these payments only underscores what has been clear from the beginning of this inquiry: the very few Planned Parenthood affiliates that received reimbursements for facilitating their patients' fetal tissue donations have not profited, and never sought to profit, from this service.

We hope that providing these materials today definitively resolves any concerns the Committee may have had regarding this issue and demonstrates the misleading nature of the allegations that have been leveled against our clients by extremists who are opposed to abortion and other legally protected services that Planned Parenthood provides. Should you have any questions, please contact me at your earliest convenience.

Very truly yours,

K. Lee Blalack II / AMS

K. Lee Blalack II
of O'MELVENY & MYERS LLP

Enclosures

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[7] *See* CPI Inflation Calculator, Bureau of Labor Statistics, http://www.bls.gov/data/inflation_calculator.htm.

[8] *See, e.g.*, Denise Grady & Nicholas St. Fleur, Fetal Tissue From Abortions for Research Is Traded in a Gray Zone, N.Y. Times, July 27, 2015, http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html (stating tissue procurement organizations "pay small fees, usually $100 or less a specimen, to abortion providers" in exchange for procurement services); Dave Levitan, Unspinning the Planned Parenthood Video, FactCheck.org, July 21, 2015, http://www.factcheck.org/2015/07/unspinning-the-planned-parenthood-video/ ("Four experts in the field of human tissue procurement told us the price range discussed in the [Center for Medical Progress] video — $30 to $100 per patient — represents a reasonable fee.").

cc: The Honorable Frank Pallone, Jr.
Ranking Minority Member
Committee on Energy and Commerce
United States House of Representatives

The Honorable Diana L. DeGette
Ranking Minority Member
Subcommittee on Oversight and Investigations
United States House of Representatives

The Honorable Gene Green
Ranking Minority Member
Subcommittee on Health
United States House of Representatives

Charles Ingebretson, Esq.
Chief Counsel
Subcommittee on Oversight and Investigations
United States House of Representatives

Alan M. Slobodin, Esq.
Chief Investigative Counsel
Committee on Energy and Commerce
United States House of Representatives

Una Lee, Esq.
Counsel to the Minority
Subcommittee on Oversight and Investigations
United States House of Representatives

Christopher Knauer
Staff Director for the Minority
Subcommittee on Oversight and Investigations
United States House of Representatives

David J. Leviss, Esq.
O'Melveny & Myers LLP

Exhibit 8.27

out of here by 5.

All right.

Mr. Bopp. Yes.

BY MR. BELL:

Q So, PP Witness #2, as I understand this agreement, whether it was consummated or not, I don't know, but it will help us understand, I think, the way some entities work with universities. So under payment on the first page highlighted is: "Planned Parenthood will consent up to 500 patients." And then on the next page it has staff time involving informed consent and sterile procedure room setup, and then the total of those, 150; the annual administrative fee; and then the CITI training fee.

So the administrative fee, it says down below, is for oversight, storage, and supplies, supply storage. And then the CITI training fee is some training, I understand, that Planned Parenthood staff goes through so that they can participate in certain types of studies.

Have you seen this agreement ever before?

A I have.

Q And is this the type of thing that you would participate in the development of?

A I have.

Q Okay. So the question -- one of the questions that we have is, when you decided staff time for consent 50, sterile 100,

did you do -- how did you come up with those numbers?

A They were basically back-of-the-envelope-type calculations involving the time it takes staff to conduct those procedures relative to the study.

Q Okay. And have you ever multiplied, in your analysis, did you ever multiply 500 times 150?

A I have not.

Q Well, it's $75,000. What's the life of an agreement like this? Is this a year, 18 months?

A Typically in a contract, the term and termination would be the life, but this is not a valid contract.

Q And it's not valid because?

A It does not have both signatures.

Q Well, I understand this copy is not. Did PP Gulf Coast ever ratify this contract?

A This contract was never signed by [redacted].

Q Okay. Was one like this signed?

A To the best of my recollection, because this one says amendment 2, there were predecessors to this agreement.

Q Right. So that's a yes or a no. Was an agreement like this -- did Planned Parenthood Gulf Coast and University of Texas Medical Branch ever reach an agreement to provide reimbursements under these terms or similar terms for tissue?

A Under similar terms, yes.

Q You don't happen to remember those terms, do you?

A Oh, no.

Q And just to make sure I understand, it's unclear from your

Exhibit 8.28

BY MR. BELL:

Q Do you see the price on there?

A Are you referring to the total?

Q Yeah, the price per unit.

A Oh, so unit price.

Q Thirty-one and some change?

A Thirty-three, forty.

Q Three thousand three hundred and forty. Now, that -- that particular brain is shipped -- is shipped out of the clinic.

Now, here's the scenario, and we'll be done. Tissue tech learns who's available for contributing. She goes -- I'm using "she" because they all happen to be female. I'm not using a pejorative sense that some might use it. She goes and gets the consent. She gets paid a bonus. The Planned Parenthood clinic, I believe, gets $55, but it's in the range of 30 to 100, and StemExpress resells that brain for over $3,000.

And you'll notice -- you may notice on there that the shipping and maybe some other things are paid for by the customer.

Now, does that bother you?

A No.

Q Okay. So if StemExpress made a profit by marking up what they paid for the tissue 2,800 percent, would that bother you?

A I don't know that they're making it up. I have no

idea what their costs are.

Q Well, if they -- if it was a profit would it bother you?

A It's really none of my business, no.

Q It's not your business what StemExpress does, but how is not your business when StemExpress does this work inside of Planned Parenthood Federation clinic?

They offer a profitable situation of the clinic. They get the consent. They get the tissue, and they resell it, and you're in a contractual relationship with them. They're a vendor of Planned Parenthood. If it was a profit of 2,800 percent, would that raise a red flag for you as an organization?

Mr. Bopp. Is your supposition that they're breaking the law? Is that what you're telling me?

Mr. Bell. My supposition is if they were profiting, would that bother the host organization that's hosting this company.

Mr. Bopp. But you're asking for her to decide whether what they're doing is breaking the law or not?

Mr. Bell. No.

Mr. Bopp. I mean you're giving us what you're saying is not a hypothetical.

Mr. Bell. No, it's not. It's not. We wouldn't ask her to reach a legal conclusion.

Mr. Bopp. Okay.

Mr. Bell. What I'm trying to understand, counsel, is the management mindset of a senior manager at Planned Parenthood who

may or may not have seen this error before today and may or may not have known how the consent works or how the tissue tech is paid or what StemExpress marks up the tissue for.

I'm saying as the senior manager of Planned Parenthood that oversees her scope of work, is it a concern -- so when they're in a contractual relationship -- is making what looks like a huge profit on selling fetal tissue.

PP Witness #1[redacted]. So the first thing that I want to just correct is you said that they were offering a profitable service or something to our affiliates, which they're not. Our affiliates don't make a profit on tissue donation.

Mr. Bell. But I just --

PP Witness #1[redacted]. I just wanted to correct that statement.

Mr. Bell. I think you're right to correct that. My concern, my question to you, Doctor, is not to reach a factual conclusion. You're one of the top people in this organization. What I want to learn is are you concerned when an organization comes to your organization and offers a profit to them, which seems to violate the guidance in the legal memo that we read earlier.

BY MR. BELL:

Q Is that a concern to you?

They come in and say, "I know you're not supposed to make a profit, but partner with us because it'll be profitable."

Mr. Bopp. So we're back to the past, the last exhibit.

Mr. Bell. I'm trying to explain the nature of the

question.

Mr. Bopp. Right. I get it.

Mr. Bell. And here's a more granular example. It looks like StemExpress, who for several years only did abortion clinics, now they do lots of stuff, lots of other stuff. But for several years of their life they only got tissue from Mar Monte, Shasta Pacific, and resold it at prices like this.

And I just want to know what's sort of the global management perspective of a Planned Parenthood senior leader like you if that's a 2,800 percent profit.

BY MR. BELL:

Q Would that bother you?

A So just so that I'm clear on the question you're asking me if it bothers me that StemExpress makes money reselling the tissue?

Q Yeah.

A It's none of my concern. It doesn't bother me.

Exhibit 8.29

PP Witness #4 So.

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

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

PP Witness #4 And I think they--what is their gestational limit, did she say?

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

PP Witness #4 Oh they're in Allentown. Oh they're Keystone.

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

PP Witness #4 Yeah. Well and she, our new Executive Vice President was the CEO of her affiliate up until the end of the year. So that's good. That's a good thing.

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Buyer: Yeah. And as far as the specifics of remuneration, is there any guidance [redacted]ger other than how to—because one thing we've talked about with PP Witness #1 before is just to make sure that's kind of back-ended in the right way so that it's a reasonable covering—

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

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

Exhibit 8.30

PP Witness #1 [redacted]: 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 Witness #1 **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 Witness #1 **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 Witness #1 **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—"

PP Witness #1 **Exactly, exactly. Under ultrasound guidance, they can just change the presentation.**

Buyer: Okay.

PP Witness #1 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 Witness #1: And, we've been pretty successful with that. I'd say.

004600

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

PP Witness #1 **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 Witness #1**: 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 Witness #1 **Mhm.**

Buyer: Yeah.

PP Witness #1 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.

PP Witness #1 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 Witness #1 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 Witness #1 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 Witness #1 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 Witness #1 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 Witness #1 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.

Exhibit 8.31

Mr. Bell. Okay. Thanks.

BY MR. BELL:

Q Now, do you think that doctors in your position should huddle in the morning?

You say, "I like to do that." It's sort of an ongoing tense.

Do you think the doctors should huddle with a tissue tech to see what they're procuring, is on their list that day?

A I don't really have a feeling as to whether other doctors did. I like to be helpful.

Q And so you found it helpful that at least on this one day to huddle with the tissue tech and learn what Procurement Technician was searching for, what orders she had; is that right?

A I would ask her what tissue she was looking for, yes.

Q All right. Do you think that's a good idea for the whole fetal tissue donation program, that doctors and the tissue techs huddle each morning to discuss what they're going to try and procure that day?

A I think it could be helpful.

Mr. Bell. Okay. Thank you.

I want to direct you to one of the middle men that we wanted to get your opinion about. First of all, this is 17 through 19. This is a StemExpress brochure.

Exhibit 8.32

level of interest to their procedure.

Q Okay.

A But I don't know how they would feel.

Q Let's skip down just a couple lines. "You say, you know, everyone had a different technique. So that's the thing. There's definitely local variance like, you know, 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."

And this is the part I'm interested in getting your opinion on. "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."

What did you mean by that sentence?

A I mean exactly what it said, which is their -- providers can change their technique to increase success.

Q What would that -- what would be that change in technique?

A I can't speak for every provider. If -- every procedure is different. Providers make changes in technique as they're doing a procedure the whole time for a variety of reasons. There are probably a myriad of changes that can be made.

Q Okay. Which ones could be made to increase the success of a fetal tissue donation?

A That's a very broad question and I think unless we

were talking about a specific procedure I couldn't answer it for you.

Q "There are little things they can make in their technique to increase your success." What are those little things?

A Again, as I mentioned, a change in instruments, a change in where they're grasping the tissue. These are changes in technique that a provider can make for a variety of reasons. I --

Q But it could be made to increase the success of fetal tissue donation.

A Yes, that's what I'm saying.

Q Okay. Now, so those little techniques that you just described, if there was no fetal tissue donation to increase the likelihood of success, they wouldn't -- they wouldn't make those little changes, would they?

A Well, providers make changes in technique for a variety of reasons.

Q Right. They would making them for other reasons, other than likelihood of success; isn't that right?

A [Pause.]

Mr. Bopp. Why don't you ask her the question directly, if she ever changes technique in order to --

Mr. Bell. Well, you suggest that providers may include -- there are little things they can make in their technique to increase their success. You said what those were.

BY MR. BELL:

Q Now, the question is: if there was no fetal tissue donation, those little things, changes that would be made to increase their likelihood of success, those wouldn't be made, would they?

A Well, I can't say across the board they wouldn't be made because there's probably other reasons that a provider during a procedure --

Q They wouldn't be made for the purpose of getting fetal tissue, would they?

A No, they wouldn't.

Q So they would be made for other reasons.

A Yes.

Q So one set of little changes is chosen for other medical reasons, and one set of little changes could be chosen to increase the likelihood of success.

A Yes.

Q Thank you.

Now, I want to refer you back to this PPFA Manual for Medical Standards and Guidelines. I think this is the one

that says revised June 2011 on top of it.

Mr. Bopp. Is this 15?

Mr. Bell. Fifteen or 16? Oh, it's email. So it's number --

Mr. Bopp. This one here?

Mr. Bell. Yes, that's the one.

PP Witness #1. I don't think I have it.

Mr. Bell. Let's look at the second page of that if you would please under Roman numeral three, documentation, three, Arabic numeral two.

"Documentation must include a notation signed by the clinician performing the abortion that blood and/or aborted tissue is donated, consent was obtained prior to requesting, and no substantive alteration, the timing of terminating or the method used was made for the purpose of obtaining blood or tissue."

BY MR. BELL:

Q Do you sign those documents after every abortion you've participated in where there was a donation of blood or tissue?

A Are you asking me if I have personally signed a -- a statement to this effect?

Q Yes.

A I have never signed a statement to this effect.

Q Have you ever been a clinician performing an abortion?

A I think we know I have.

Q But this is in the manual, and it says that someone is supposed to sign this document noting these three square bullets. Am I misunderstanding something?

A No, I don't think you are.

Q So to your knowledge do other clinicians sign this piece of paper?

A Other clinicians where?

Q Anywhere in Planned Parenthood.

A I can only answer based on the Mar Monte form that you showed me earlier, which I believe is -- it's only one page -- Number 31 has a statement to that effect on page 2. So I am assuming -- and this is purely an assumption -- that the clinicians at Mar Monte sign that document.

Q But you've never actually signed one.

A I've never worked at Mar Monte.

Q Well, you never signed on at any PP where you worked.

A That's correct.

Q Okay. I want to talk a little more about the famous StemExpress brochure about which you have no personal knowledge. If we can just turn to page 1 of that, there's two people looking like they're lab people in it, right?

The last bullet says "IRB certified consents." You know

Exhibit 8.33

PROGRAMS FOR DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

I. GENERAL INFORMATION

Aborted pregnancy tissue donation and research are humanitarian undertakings that hold the potential to cure disease, save lives, and ameliorate suffering. Affiliate participation in donation programs is entirely voluntary.

Affiliates that choose to participate in such programs **must** recognize that there are federal, and frequently, state laws that govern these activities, as well as ethical considerations. Great care **must** be taken to assure that these programs are above reproach in all respects.

Provision of Services

1. Affiliate **must** submit a written request to initiate an aborted tissue and/or blood donation program to PPFA for review and approval. Submit request to Affiliate 411 Request Form. (See Section I-A-1 Clinical Program Structure for requirements.)
2. If the affiliate is a partner in a specific research study or project that includes the provision of donated aborted tissue and/or blood and also involves the participation and consent of the client as a research subject, this research project **must** be registered with the PPFA Research Department and **must** meet all the documentation requirements. (See Section I-D-1 Research). The required registration form can be accessed at Affiliate Study Submission Site.
3. Affiliate protocols **must** include provisions to ensure compliance with any federal, state, and local laws regarding
   - minors' consent and participation in aborted pregnancy tissue donation
   - documentation
   - retention of records
   - storage and transfer of aborted pregnancy tissue
4. The timing, method, or procedure of abortion **must** not be substantively altered for the purpose of obtaining the tissue and/or blood.

II. CLIENT EDUCATION AND INFORMED CONSENT

The following **must** be in any protocol and **must** be stated in mandatory language:

1. The option of donating aborted tissue **must** not be offered to a client until
   - after she has decided to have an abortion
   - she has completed the process of signing an informed voluntary consent to the abortion
2. If the client is interested in donating blood and/or aborted pregnancy tissue, she **must** provide a separate informed and voluntary consent and sign the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2). The informed consent process **must** instruct, and the consent form reflect, that

- The donation is made without any restriction regarding who might receive the donated tissue or for what purpose it might be used.
- There is no financial remuneration or consideration provided to the client for her consent to donate tissue.

3. The wording in the consent for donation of blood and/or abortal tissue for research has been adopted from federal statute. The affiliate **must** seek approval from PPFA Medical Services to alter the consent form language other than to add the affiliate name, address, and phone number or other demographic information. Submit request to Affiliate 411 Request Form.
4. If, in addition to donating blood and/or aborted tissue, the client is participating in a research project involving the donated blood and/or aborted tissue, any consent form required by the IRB-approved protocol **must** be signed in addition to the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment (Section VII-E-2).

III. DOCUMENTATION

To preserve the anonymity of the donor, documentation may be kept separate from the client's medical record. A system **must** be maintained in the affiliate from which documentation of aborted tissue donation can be retrieved and cross-referenced with the client's medical record. The documentation **must** be kept on file in accordance with state laws governing the retention of medical records.

Documentation **must** include

1. all applicable consents signed by the client, including, at a minimum, the [PPFA] Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment form (Section VII-E-2).
2. notation signed by the clinician performing the abortion that
   - Blood and/or aborted tissue was donated.
   - Consent for the abortion was obtained prior to requesting or obtaining consent for the blood and/or tissue donation.
   - No substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the blood and/or tissue.

Exhibit 8.34

Planned Parenthood
Mar Monte

Client Information for Informed Consent

DONATION OF BLOOD AND/OR ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson's disease, Alzheimer's disease, cancer, and AIDS.

You can donate your blood and/or pregnancy tissue after an abortion. Before you give your consent, read each of the following statements and initial the line to the right. We will be happy to answer any questions you have.

Before I was shown this consent, I had already decided to have an abortion and signed a consent form for it. _____

I agree to give my blood and/or the tissue from the abortion as a gift to be used for education, research, or treatment. _____

I understand I have no control over who will get the donated blood and/or tissue or what it will be used for. _____

I have not been told the name of any person who might get my donation. _____

I understand there will be no changes to how or when my abortion is done in order to get my blood or the tissue. _____

I understand I will not be paid. _____

I understand that I don't have to give my blood or pregnancy tissue, and this will not affect my current or future care at Planned Parenthood Mar Monte. _____

Signature:_____ Date:_____

Witness:_____ Date:_____

PATIENT NAME: _____
DOB: _____
DATE: _____

___ Aborted tissue was donated.

___ Consent for the abortion was obtained prior to requesting or obtaining consent for the tissue donation.

___ No substantive alteration in the timing of terminating the pregnancy or of the method used was made for the purpose of obtaining the tissue.

_____
Physician's Signature

Exhibit 8.35

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: Stem Express, LLC

Protocol Number: 101-01

Protocol Date: January 24, 2011

Principal Investigator: StemExpress Founder and CEO

24-Hour Phone Number: 877-900-7836

Client Information for Informed Consent

DONATION OF ABORTED PREGNANCY TISSUE FOR MEDICAL RESEARCH, EDUCATION, OR TREATMENT

Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and many more. Tissue can be obtained as a result of donation of pregnancy tissue after an abortion. Before you give your consent to donate pregnancy tissue and/or a blood sample, read each of the following statements. If there is any statement you do not understand, or if you have any questions, someone will discuss them with you. Your participation is entirely voluntary.

Before this consent was ever offered to me, I had previously decided to have an abortion and signed an informed consent document.

I agree to donate the tissue from the abortion and/or miscarriage, and a blood sample if needed, as a bodily gift to be used for the advancement of medical science. I also agree that a sample of my blood may be taken after the abortion and that it may be used for research and routine testing for AIDS, hepatitis, or other infectious agents. I understand that, if there is testing, the results will be confidential unless the law requires that they be disclosed. The benefits of consenting to donation today include furthering medical research in finding cures for diseases like diabetes, leukemia, lymphoma, Parkinson's disease and more. The risks to this donation are minimal in that your abortion procedure will not change in any way; your health information will be protected at all times; and most blood donors have only minor discomfort from the needle stick, although some people may have a light-headed feeling, an upset stomach, bruising, or pain where the needle stick was. The alternative to this donation is to refuse consent.

I understand the donation is made without any restriction regarding who might receive the donated tissue or for what research purpose it might be used. I have not been informed of the identity of any individual who will receive the tissue that I am donating, and I understand that cells derived from the donation may be stored for years.

If you choose to participate, you will have your blood drawn by a trained phlebotomist or nurse. The amount is small, usually 10-60ml which is about 1-3 tablespoons. You will have no responsibilities once you leave the clinic.

In accordance with federal laws (HIPAA), your personal identifying information will be protected and not connected with your donation once the procedure is completed. Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your age, ethnicity, medical history, and number of previous pregnancies or abortions. All of this information will NOT be connected to your name or any other personal identifier.

CONSENT

You have the right to withdraw your donation at any time while in the clinic. Since your donation is completely ANONYMOUS, you cannot withdraw your donation once you leave the clinic as it will no longer be possible to know which donation was yours.

I understand there will be no payment to me for the donated tissue or for any product, process or service that may result from this donation.

I understand the method, timing or procedure of abortion cannot and will not be substantively altered for the purpose of obtaining the tissue. I understand that I may refuse to donate pregnancy tissue, and this will not affect my current medical care or my ability to get any future medical services at this clinic.

I understand that, if I have any questions about my donation, I can contact StemExpress at [redacted].

By signing below, I agree to donate tissue and/or blood as described above.

Signature:_____ Date:_____

Witness:_____ Date:_____

FOR CALIFORNIA RESIDENTS ONLY
EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Witness	Signature of Witness	Date

Exhibit 8.36

UNIVERSITY OF WASHINGTON
BIRTH DEFECTS RESEARCH LABORATORY

H-

Consent Form for the Donation of Embryonic or Fetal Tissue

Investigators:

[redacted]

Professor, Pediatrics
Associate Professor, Pediatrics
Research Scientist, Pediatrics
Research Scientist, Pediatrics
Research Scientist, Pediatrics

[redacted]

Researcher's Statement:

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you to decide whether to be in this study. Please read the form carefully. You may ask questions about what we will ask you to do, the risks, the benefits, your rights as a volunteer, or anything else about the research on this form that is not clear. When all your questions have been answered you can decide if you want to be in this study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of our research is to study birth defects and other diseases. We use tissues from fetuses and embryos in this research. With these donated tissues, we can study the causes of birth defects and how organs and tissues develop normally. We can look at the causes and treatment of cancer and understand more about certain brain disorders such as Alzheimer's and Parkinson's disease. We can also study the effects of drugs on the growing brain, what may cause blindness, and study HIV infection. Research using donated tissues can take place in many areas of science.

STUDY PROCEDURES

You are being asked to participate in this study since you have made the decision on your own to have clinical care related to fetal loss, miscarriage or decided to have an abortion. The timing or procedures for your medical care will not be changed to allow us to collect this tissue. If your doctor or hospital needs to look at the tissue they will be able to. We will only take tissue that your doctor or hospital does not need for your care or treatment. If you give your permission we may want to talk to your doctor about your medical history and about anything we learn that is important for your healthcare. Your doctor may put this information on your medical record.

Sometimes the fetal tissue will be collected from an intact fetus. Incisions like those used in autopsy will be made to collect the tissue or organs for research. Then the incisions will be closed. If you and your doctor have discussed having an autopsy performed, please know that donating to research will not effect this decision. We will collect tissue only after the Pathologist has completed their exam and taken enough tissue to make a diagnosis.

We send tissue to scientists at other hospitals and schools. Examples of tissue collected and sent to scientists for study are: brain, liver, kidney, ovary or testis, eyes, and skin. Please note this is not the complete list of tissue or organs collected and sent to researchers. The tissue may be used in research and/or for education purposes. Tissue is **never** used for commercial purposes. The Birth Defects Research Lab will be unable to return any remains unless you choose to make private arrangements.

RISKS, STRESS, OR DISCOMFORT

There is no known risk in participating in this study. However, you may experience emotional distress while you are trying to decide if you want to donate tissue for research.

BENEFITS

If you donate tissue it will not directly benefit you, but we hope the information gained by researchers will help future generations.

SOURCE OF FUNDING

[redacted] and the study team is receiving payment from the study sponsor the National Institute of Child Health and Human Development for the time spent completing study-related duties.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have a Certificate of Confidentiality from the National Institute of Health of Child and Human Development. Having the certificate means we do not have to give out your personal information, even if we are asked to by a court of law. You may still share information about yourself or your part in this research as you see fit. There are some limits to this protection.

- Some federal agencies can review our **identifiable** research records.
- The Certificate doesn't protect information kept in other places, like your medical record.
- The University of Washington, the funding agency, **and other groups involved in the research** can look at our records to make sure the research is being done well.
- **If someone who is accused of a crime believes that our research records could be used for defense, we might be forced to provide the records.**

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that someone might discover that you are in this study, or might obtain information about you. University and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk or harm.

We will identify the tissue and information about you with a study code. The link between the study code and the consent form with your name is kept in a separate secure area accessible only to the researchers involved in this study. This link will be kept for six years. Written and electronic records of work will be kept indefinitely, but it will not be possible to learn who you are from these records. If we send your tissue to researchers who are not part of the Birth Defects Research Laboratory we will not send them your name.

OTHER INFORMATION

We will not pay you to be in this study. We will not pay you for donating the tissue. You don't have to donate tissue if you don't want to. You will have the same medical care you would have if you choose to donate tissue or not donate. Donated tissue cannot be returned. We will not tell you which researchers might use this tissue or what the donated tissue will be used for.

If you have questions about the research you can call [redacted] or Laboratory staff at [redacted]

Printed Name of person obtaining consent Signature of person obtaining consent Date

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research I can ask one of the researchers listed above. If I have questions about my rights as a research subject I can call the Human Subjects Division at [redacted] I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed Name of Subject Signature Date

Age: _____

Date of **last** menstrual period _____

Age at first menstrual period _____

Is it regular? ___YES or ____ NO

# of Pregnancies (including this pregnancy) _____

# of Terminations (including this pregnancy) _____

# of Miscarriages (including this pregnancy) _____

Medications (name/dosage/frequency):
(please include prescription and over-the counter)

_____

_____

_____

Recreational Drug Use:
during this pregnancy only
Last use / How Often?

- □ Alcohol _____
- □ Tobacco/Cigarettes _____
- □ Marijuana _____
- □ Methamphetamine _____
- □ Cocaine _____
- □ Heroin _____
- □ Other (specify) _____

Ethnicity/Race: _____

Health History: *(please indicate by circling)*

- □ Heart Disease Self or Family
  - □ congenital
  - □ other
- □ High Blood Pressure Self or Family
  - □ medication-regulated
  - □ with pregnancy only
- □ Diabetes Self or Family
  - □ insulin-dependent
  - □ gestational diabetes
  - Age at diagnosis _____
- □ Epilepsy Self or Family
  - □ medication-regulated
- □ Cancer Self or Family

_____

_____

- □ Birth Defect and/or Genetic Disorder Self or Family ***including this pregnancy***

_____

_____

- □ Other Self or Family

_____

_____

Copies to: Subject and Investigator's files

Provider to complete this section:

Fetal Anomalies
Yes _____ No _____ Specify: _____ _____ Referring Physician _____

Ultrasound Measurements			Procedure	Fetal Tissue Measurement	
Date			Procedure Date: _____	▫ FF	_____mm
_____	▫ CRL	_____mm/cm	Procedure End Time: _____	▫ Other	_____
_____	▫ BPD	_____mm/cm			
_____	▫ Gest. Sac	_____mm/cm			
_____	▫ FL	_____mm/cm			

Dissection Date: _____

Dissection Time: _____

Exhibit 8.37

Mr. Bopp. Have we established that she had anything to do with this form?

Mr. Flint. I'm just asking her a question.

Mr. Bopp. And I'm asking you back. I don't think we have established --

Mr. Flint. Established?

Mr. Bopp. -- that she has anything to do with this form. It's not her form. She didn't write it.

Mr. Flint. I'm not saying that it is. I'm asking her to simply evaluate the form. That's it.

PP Witness #1[redacted]. If I'm evaluating the form now, you are correct. To my knowledge there is no cure for AIDS. So that is probably an inaccurate statement.

BY MR. FLINT:

Q Would that be an unethical statement?

A I'm making a supposition here. I told you I am not an ethicist, but a consent form should not have an incorrect statement.

Q Thank you.

Is that a statement that could be viewed as coercive or likely, more likely to induce somebody to want to donate fetal tissue, in your opinion?

A As someone who has never donated fetal tissue, I can't tell you what motivates people to donate fetal issue. I can understand your concern that perhaps this may make someone think about donating fetal tissue because of this potential.

Q Do you think that it would make somebody think about that?

A As I told you, I can understand that it might. I don't know if it does or doesn't. I haven't ever been in that situation.

Q So it might be more coercive?

A I don't think -- I don't know. You have to define "coercive." If it's something that someone would take into consideration when they were making their decision, yes. "Coercive" to me implies someone is being forced to do something, and I don't think it forces anyone to do anything.

Q Would it make them more likely to want to donate, in your opinion?

A Maybe.

Mr. Flint. Thank you.

Exhibit 8.38

BY MR. BELL:

Q Because you would agree this is inadequate?

A I would agree that that is insufficient for obtaining informed consent, correct.

Q Okay. Thank you. And you would prefer maybe something more like what Wisconsin or University of Washington does, something more in depth and more involved?

A We use an IRB-approved informed consent form, and that is required, based on my understanding and training, by the regulations. We use this supplement because it is required by Planned Parenthood. And using both keep us in compliance with our Federal and State regulations, the IRB that oversees the research, and the requirements of Planned Parenthood Federation.

Q Great. Now --

Mr. DeBopp. To the best of your knowledge?

BY MR. BELL:

Q To the best of your knowledge.

A To the best of my knowledge, based on my understanding and training.

Q All right. Well, that's our understanding too how it's supposed to happen. So who is the IRB for Gulf Coast?

A We do not have a specific IRB for Planned Parenthood Gulf Coast.

Q You don't?

Exhibit 8.39

PP Witness #1 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 Witness #1**:** 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 Witness #1**:** 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 Witness #1**:** 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 Witness #1 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 Witness #1 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.

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

PP Witness #1**:** 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 are 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 Witness #1 I would say about ten minutes.

Buyer: Per patient.

PP Witness #1 Per patient. yes. And also contraceptive counseling and all that.

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

PP Witness #1 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 Witness #1 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 Witness #1**:** There's a private surgical center that I work with in Calabasas, where I was this morning, they have tons of far. There were six canisters when I get there this morning.

Exhibit 8.40

Clinic Procedures and Policies

As a representative of StemExpress you are required to act in a professional manner and follow all clinic policies. Please take note the following procedures and policies are **extremely important** regarding our presence in the clinics:

1. **Communication with the Assistant Manager and HSS's** – Upon arrival, inform the staff clearly what you are procuring for the day. Just as important, **you must inform the Assistant Manager and HSS's when you have completed your work.** This will insure they do not continue to consent and draw unnecessary blood samples. In addition, please **notify the Assistant Manager upon departure** of the clinic and remember to thank them for their assistance.

2. **Cell Phone Use** – It is essential we follow clinic rules with respect to cell phone use. **Please DO NOT pull your cell phones out in the hallways for ANY reason.** While we realize our cell phones are critical to our internal communication, we need to follow the etiquette set by the clinic. If you receive a text or call, step to an appropriate private area or into the nearest unoccupied room to read the text or answer your phone. Phones should always be on vibrate while in the clinics.

3. **Perfume Free Policy** – All clinics have a Perfume Free Policy, Please refrain from applying perfume or any fragrance prior to or when you are in the clinic.

4. **General Clinic Etiquette:**
   - Calm demeanor
   - Sensitive to Patients' Privacy and Situation
   - Professional at all Times
   - Respectful to Patients and Clinic Staff
   - Maintain Confidentially for Patient Information

I have read and understand the above Clinic Procedures and Policies

Print Name [redacted] Signature [redacted] Date [redacted]

Exhibit 8.41

RESEARCHER PROCUREMENT RECORD

APPROVALS

All approvals are maintained and controlled in the [redacted] e system.

Please refer to the [redacted] e system for the current controlled revision and approval records.

REVISION HISTORY

AUTHOR	*REVISED SECTION/PARAGRAPH*	*REV*	*RELEASED*
[redacted]	**Initial Release**		01/10/2014

Draft and Archived/Obsolete revisions are not to be used.
Access [redacted] system to verify revision.

TABLE OF CONTENTS

1. PURPOSE

All procurement of tissue and/or blood must have a form of documentation for the client, laboratory, procurement technician, and billing. StemExpress refers to this documentation as an Researcher Procurement Record (RPR). Each RPR is unique to every client and may even be unique to specific researchers under the same client. Identifying information regarding the donor is not included on the RPR and donor anonymity is maintained at all times. This document will cover the correct method for completing an RPR.

2. SCOPE

The *Researcher Procurement Record Standard Operating Procedure* covers the general process for all RPRs. The information used to complete this form is specific to each client's needs and therefore varies from client to client. Subsequent Standard Operating Procedures will cover specific researcher needs.

3. DEFINITIONS

- Gestation- the process of carrying or being carried in the womb between conception and birth. On the RPR, the gestation is listed as the number of weeks the woman has been pregnant.
- RPR- Researcher Procurement Record.
- SOP- Standard Operating Procedure.
- IDS – Infectious Disease Sample

4. RESPONSIBILITIES

- Training Officer – Shall ensure that all personnel are properly trained and oriented to the SOP by providing initial instruction, reviewing the material, and any further instruction or correction at a later time. Shall also maintain training log for the SOP.
- Procurement Technician – Shall follow the SOP to properly perform all aspects of tissue and/or blood procurement.
- Regional Procurement Manager – Shall ensure that the above personnel are correctly performing their job duties.

5. POLICY

5.1 Overview

After the procurement of a specific tissue or blood sample the RPR must be completed for the researcher and for StemExpress records. An IDS sample is usually required for tissue specimens and the information for the IDS test will be included on the RPR. Please refer to *Infectious Disease Screening (IDS) Sample Standard Operating Procedure* for instructions

on filling out IDS forms and sending IDS samples. Each RPR will include specific tissue and patient/donor information.

5.2 Details

5.2.1 Blood and Tissue RPR Details

5.2.1.1 Select the RPR from the database on the StemExpress WebOffice website [redacted]. More information about the database can be found in *Understanding the Database Standard Operating Procedure.*

5.2.1.2 Start at the top of the document and work down.

5.2.1.3 **DATE:** Using the drop down menu put in the date of the procurement.

5.2.1.4 **SHIP TO**: The name, address, email, and phone contacts will be pre-filled out.

5.2.1.5 **FEDEX ACCOUNT** and **TRACKING #**: The FedEx number will be pre-populated with the client's FedEx account number if the client has requested that their FedEx account be billed. The tracking number is from the FedEx website after the shipping form is prepared. The *FedEx Shipments Standard Operating Procedure* focuses on how to prepare the shipment using the FedEx website.

5.2.1.6 **REF #**: The reference number is usually the Purchase Order # but can also be the Quote #. This information is obtained from the Daily Task Page database under the column heading PO #.

5.2.1.7 **DELIVER BY**: is only used for local delivery. The courier name, or company name should be included here. If FedEx is used to ship the sample, this section is to remain blank.

5.2.1.8 **PROCUREMENT TECH**: the technician ID number who procured the sample.. If more than one technician participated with the procurement of the sample, the second technician ID should be placed in the 'Additional Techs' field. Please see the Training Officer if you do not know or have not been assigned a procurement technician ID number.

5.2.1.9 **LOCATION**: is identified by a number. Each clinic or site has a specific number assigned to it. Please ask the Training Officer for your specific clinic or location ID number.

5.2.1.10 **ID#**: this is a drop down menu and is based on the order the blood/tissue is procured, regardless of the researcher. All ID#s for blood end in the letter 'B'. The numbers without the letter B (01, 02, etc) refer to tissue procurement. The ID# is based on the time the sample is procured, and does not reset for each researcher. One RPR could have ID# 01B, 03B, 04B, and a second RPR for a different researcher would have 02B, 05B, etc. If two blood requests from different clients are filled using a draw from the same patient, the ID number remains the same. For example if 8 tubes are procured on the first draw of the day from one patient, and 4 are going to Researcher A and 4 going to Researcher B, they would both be labeled ID 01B on the separate RPRs.

5.2.1.11 **TIME**: is the time that the blood or tissue specimen is procured. The drop down menu is in 15-minute increments. Round to the nearest time increment when selecting the time of draw..

5.2.1.12 **PATIENT #**: is automatically generated once the date, procurement tech number, and ID number are entered into the RPR.

5.2.1.13 **SPEC #**: is the specimen number that is either placed on the blood tube or tissue specimen tube, or the label that is already on the blood tube, depending on the researcher. If the tubes are not already labeled, StemExpress labels are to be put on the tubes. StemExpress blood labels end with the letter B, and the tissue specimen labels are numbers only. Please refer to *Labeling Tubes Standard Operating Procedure.*

5.2.1.14 **GEST**: is the gestation of how many weeks pregnant the woman was at the time of the blood draw or tissue collection.

5.2.1.15 **SPECIMEN**: is a drop down menu and is the type of specimen procured.

5.2.1.16 **SEX**: is based on the blood or tissue specimen from whom the blood or tissue was procured. For example: for maternal blood the sex is female, for tissue procurement, the sex would be based on the actual sex of the product of conception (POC). M for male, F for female, or UNK if the sex is not known.

5.2.1.17 **COMMENTS**: this section varies depending on the client/researcher. There are a number of different items that may be referenced here and the items requested will already be generated on the form and must be filled in based on the patient information.

5.2.2 Tissue Sample with IDS

Some tissue samples will require a blood test (IDS) to go with them. From the Daily Task Page under the column heading IDS Testing check to see if the client/researcher has requested any IDS. If so, they will be listed here.

5.2.2.1 Fill out the RPR as described in 5.2.1.

5.2.2.2 Add the IDS test directly underneath the row for the tissue sample.

5.2.2.3 The **ID#** for the blood test is the exact same as the ID# for the tissue. By selecting the same ID# this generates a **patient #** that is the same.

5.2.2.3.1 Although most blood draws have an ID# that ends with the letter 'B', the IDS sample does not.

5.2.2.4 The **Time** is the same time listed for the tissue procurement and must be in military time.

5.2.2.5 The **specimen number** is the number on the label that was affixed on the blood sample tube. This number will be a StemExpress blood label and will end with the letter 'B'.

5.2.2.6 The **gestation** is the same as the tissue gestation.

5.2.2.7 The **specimen** is 'Maternal Blood Test'.

5.2.2.8 The **sex** is always female for IDS testing because it is a maternal blood sample.

5.2.2.9 Under **comments**, the blood tests required are specified. For example HIV, HBSAG, HCV. This information is taken directly from the IDS Testing column from the Daily Task Page.

5.2.2.10 A second form must be sent with the tissue RPR when there is an IDS sample. More information on how to fill this out can be found in the *Infectious Disease Screening (IDS) Sample Standard Operating Procedure*.

6. APPLICABLE REFERENCES

- See attached RPR

Exhibit 8.42

CMP19 DD

stem express

SUSTAINING QUALITY OF LIFE
THROUGH RESEARCH™

Main Address
[redacted]
Shipping and Receiving
[redacted]

Send To: StemExpress
From / Clinic: THE ALAMEDA, SAN JOSE
Recipients Fax Number: [redacted]
From: [redacted]
Date: 01/10/13
Total Pages: (Includes Cover) 14

Fax

Urgent ☐ Reply ASAP ☐ Please Comment ☒ Please Review ☐ For Your Information ☐

Comments:

Next Days Schedule: Potential Patients: US/MAB 10 PT _____ ROB _____ AB _____
Time of First Appt: 0830

Exhibit 8.43

From [redacted]@stemexpress.com
Subject: Updated Task Assignment: Procurement Schedule Wednesday 3/20/13
Date: March 20, 2013 at 9:00 AM
To: [redacted]@stemexpress.com

The following task has been updated on the "StemExpress" web office site.

TASK NAME: Procurement Schedule Wednesday 3/20/13
ASSIGNED BY: [redacted]
PROJECT: Procurement Schedule
CATEGORY: Procurement Schedule
PRIORITY: 2-Normal
STATUS: 1-Not Started
ASSIGNED TO [redacted]
VISIBLE TO: Everyone

DETAILS:
Liver & Thymus (same donor)/16-20wks/RPMI/Wet Ice/HIV,HBSAG,HCV,CMV/FedEx Priority Overnight/Mass General Hospital Researcher FT
1 SPEC=
IMPORTANT: Please document PO#0005446200 in the reference section

Liver & Thymus (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/UMASS Researcher FT
1 SPEC=
IMPORTANT: Please document PO#0006147108 in the reference section.

Liver/18-22wks/RPMI/Wet Ice/FedEx Priority Overnight/ UCLA Researcher FT
IMPORTANT: Please document PO#1559NQA55800 in the reference section.
2 SPEC=
**This used to be researcher- UCLA: Researcher FT

Liver, Thymus & Skin (Same donor)/16-20wks/RPMI /Wet Ice/ HIV,HBsAG,HCV/FedEx Priority Overnight/HARVARD Researcher FT
1 SPEC=
IMPORTANT: Use FedEx account #431793989. Note: THE LIVER AND THYMUS SHIP TO Researcher FT AT UMASS AND THE SKIN SHIPS TO Researcher FT AT HARVARD. SHIP ALL TISSUE UNDER HARVARD'S FEDEX NUMBER.
Researcher FT PhD, Research Specialist Melton Group, HHMI/Harvard Dept of Stem Cell and Regenerative Biology, [redacted]

PROCURE ON WEDNESDAY ONLY- Pancreas/14wks/HEPES with antibiotic/Gel Pack/HIV, HBSAG, HCV/FedEx Priority Overnight/UMASS Researcher FT
2 SPEC=
IMPORTANT: Use gel packs that are NOT frozen but just chilled.
IMPORTANT: Please document PO#0006147108 in the reference section.

Brain /16-18wks/Complete but can be in piecest/Use Client Supplied Media/Wet Ice/HIV,HBsAG,HCV/Use Clients FedEx Priority Overnight/Temple Univ Researcher FT

1 SPEC=
Note: Media contains anti-fungal/anti-mycotic and antibiotics
Researcher: Researcher FT [redacted]

Mid Brain/10+wks/RPMI/Wet Ice//HIV, HBSAG/FedEx Priority Overnight/University of Illinois at Chicago Researcher FT
1 SPEC=
Researcher: Researcher FT [redacted]

Brain/14+wks (2cm in width)/Whole brain In-tact or one whole Hemis intact/Dry

Brain/14+wks (2cm in width)/Whole Brain In-tact or one whole Hemis Intact/Dry Ice on aluminum foil protocol/FedEx Priority Overnight/HIV,HCV,HbC,HBSAG,RPR/Yale (Franjic)
IMPORTANT: Please document PO#SNP5725137 in the reference section. Donor information required: Sex of fetus if identifiable,Age,Ethnicity,Past drug use if known.
3 SPEC=
Researcher:[redacted]

Same Day, Pick Up

PROCURE ON THURSDAY ONLY Fetal kidney (In-tact: Renal vein/artery, ureter, inferior vena cava(descending aorta); without Digoxin applied)/18-20 wks/RPMI/Wet Ice/Same day pick-up/ Ganogen, Inc. [redacted]
1 Spec=
Call co-founder [redacted] Personal pick-up on site near clinic location to reduce ishemia time

PROCURE ON THURSDAY ONLY- Brain/17+ gestation/Both Hemis In-tact -or- call for approval of hemis, forebrain, hindbrain, brainstem(semi-intact(70%)approved)/RPMI/Wet Ice/Stanford [redacted]
1 SPEC=
Note: Please call [redacted] with a best guess delivery time window (Ex: eta- 11am to 1pm) [redacted]

Brain 8+wks/Inact Calvarium -or- <7wks/Whole Embryo/RPMI(1-2hrs;ASAP)/Wet Ice+barrier/The Rockefeller University [redacted]
1 Spec=
Ships to StemExpress Lab for procedure
IMPORTANT: Please document PO#419428 in the reference section.

Same Day, Local Delivery

To access the task in the web office, click the link below:
[redacted]

NAVIGATING THE TASK BOARD

APPROVALS

All approvals are maintained and controlled in the X3 ERP system.

Please refer to the EX ERP system for the current controlled revision and approval records.

REVISION HISTORY

AUTHOR	*REVISED SECTION/PARAGRAPH*	*REV*	*RELEASED*
[redacted]	**Initial Release**		11/23/2014

Draft and Archived/Obsolete revisions are not to be used.
Access X3 ERP system to verify revision.

Table of Contents

1. PURPOSE

StemExpress has a wide variety of requests for tissue and blood that change on a daily basis. There are many clinics operating daily. It is necessary for multiple users in remote locations to be able to: access and update information that identifies each researcher or clients specific requests: provides pertinent information and necessary documentation for packaging and shipping of the sample(s): and keeps track of what is being procured by each technician and each clinic daily.

2. SCOPE

Navigating the Task Board Standard Operating Procedure explains how to interpret the information on the Task Board, which can be found at http://[redacted] and will describe all functions and menus within the Task Board. The Task Board is essential for knowing what samples to procure, how to ship the samples, what media is used, along with specific researcher requirements.

3. DEFINITIONS

- Gestation – the process of carrying or being carried in the womb between conception and birth.
- IDS – Infectious Disease Screening
- POC – The product of conception
- Procurement – The act of obtaining a sample
- Researcher Procurement Record – or packing slip. A document that displays the specimen information requested by the researcher. It is shipped with the samples to the client.
- SOP –Standard Operating Procedure
- Task Board - Online system used by StemExpress to share information within the company, as well as remote sites, and obtain information necessary for procurement and billing.

4. RESPONSIBILITIES

- Procurement Technician – Shall follow the SOP to properly perform all aspects of tissue and/or blood procurement.
- Training Officer – Shall ensure that all personnel are properly trained and oriented to the SOP by providing initial instruction, reviewing the material, and any further instruction or correction at a later time. Shall also maintain training log for the SOP.
- Supervisory Personnel – Shall ensure that the above personnel are correctly performing their job duties in a safe and effective manner.

5. POLICY

5.1 Overview

Navigating the Daily Task Page Standard Operating Procedure explains what information is in each section of the Task Board and how the Procurement Technician uses that

information. The content of the Task Board is updated daily by a supervisor. It also changes in real time as samples are procured in the field and the technician's update what samples have been fulfilled. The specific details for procurement, number of specimen procured by each technician, and the packing slip (Researcher Procurement Record) can all be found on this database.

5.2 Details

5.2.1 Navigating the Task Board

5.2.1.1 From the Internet browser, navigate to http://[redacted]
Enter your ***Username*** and ***Password***, and then click ***Log In.***

5.2.1.2 At the top of the page is a drop down menu labeled *Clinic*. Click on the drop down arrow and choose the clinic that you are assigned to that day.. If the user that is signed in only procures from one clinic, there will not be a drop down menu and the clinic will be automatically listed.

5.2.1.3 Up at the top right hand side of the screen there is a ***Logout*** option that can be clicked on at any time to log out of the open session.

5.2.1.4 On the left side of the screen there are 4 items: ***Dashboard, Procurement, Orders,*** and ***Printing***.

5.2.2 Dashboard

5.2.2.1 The Dashboard is not currently being used by procurement technicians and if clicked will display a blank screen.

5.2.3 Procurement

The Procurement section lists the client orders that are open that the procurement technician can procure against. Instructions on how to use the Procurement page once a sample has been collected is located in **5.2.4 Filling Out a Procurement Form**. There are eight columns on the Procurement screen that are described below.

5.2.3.1 **Order**: The order column shows the order numbers associated with the items requested from the client and are system generated automatically.

5.2.3.2 **Customer**: The customer column reflects the client that requested the samples.

5.2.3.3 **Item**: The item number is the catalog product code for the type of sample being requested.

5.2.3.4 **Description**: brief description of the sample requested by the researcher.

5.2.3.5 **Gest Range**: The gestational range that the client will accept for the specimen procured. If the sample is not maternal or fetal this line will be blank.

5.2.2.7 **Type**: The type of sample requested, such as whole blood or maternal blood.

5.2.2.8 **Progress**: This item shows how many samples have been procured against the total number of samples requested. If 2 samples have been procured towards an order of 100 samples it will be displayed as 2/100. This means there are 98 more samples to be procured within the clinics.

5.2.2.9 **Due Date**: The due date is the date that the samples must be collected by.

5.2.4 Filling Out a Procurement Form

Click on the ***Procurement*** option on the left hand side of the screen. A list of orders that are open to procure against for the clinic the tech is signed in under will be displayed here. This is where a technician can go to find out what samples can be collected for the day. Once a sample has been procured the steps below need to be taken to create a packing slip (Researcher Procurement Form) to accompany the sample.

5.2.4.1 Click on the order that the sample was collected for and the browser will open to a screen that has the same information that was shown on the Procurement screen, as well as blank boxes that need to be filled in by the technician. All of the blank boxes are information that is required by the researcher and cannot be left blank.

5.2.4.2 ***Order***, ***Customer***, ***Item***, ***Item Type***, ***Description***, and ***Gestational Range*** will be filled in already. Descriptions for each of those items are in **5.2.3**.

5.2.4.3 **Notes**: Any notes from the researcher or management will be located here. This includes, but is not limited to, volume requirements, shipping temperature, special instructions, and client specifications for a particular order.

5.2.4.4 If a red field is displayed with notification that an IDS specimen is required for the sample, the technician must procure the IDS blood sample with the tissue sample. More information on how to procure and label an IDS sample can be found in the *Infectious Disease Screening SOP SEC-FP-0001* of the Training Manual.

5.2.4.5 The technician must fill out all open fields that are located below the Notes section. The fields displayed in the Notes section only include the specific information that was requested by the researcher. These fields will differ for each project and must be filled in by the technician. They may include all or some of the following:

- **Age**: The age of the patient donating
- **Ethnicity: of the donor.**
- **Gestation**: The length of pregnancy measured in weeks and days. This is determined by an ultrasound or estimated from the first day of the woman's last menstrual period. For example, the value would be written as 12.3 weeks for 12 weeks and 3 days.
- **Smoking history**: Should be indicated as smoker or non-smoker.
- **Date of Birth**: Patient's date of birth.
- **Height**: in feet and inches. For example 5' 7".
- **Donor Number**: The number assigned to donors donating in the StemExpress Donation Center.
- **Fetal Abnormality**: Classifies any physical or genetic abnormalities of the fetus.
- **Drug Use**: indicate any drugs the patient is taking.
- **Weight**: in pounds. For example 145 lbs.
- **P.O.C.**- Product of conception. If two specimens were taken from one P.O.C. they would both have the same P.O.C. number. For example if a liver specimen and kidney specimen are taken

from the first P.O.C. collected by the technician, they would both have a value of 01.

- **Sex of Fetus: Male, Female, Unknown.**
- **Diseases**: Any diseases that the patient is known to have.
- **IDS Specimen Number**: If the sample requires an infectious disease screening (IDS), the specimen number from the StemExpress blood label should be placed in this field. Instructions for procuring an IDS sample are in the *Infectious Disease Screening SOP SEC-FP-0001.*
- **Comments**: Any comments relating to the sample procured can be typed here. This may include, but it not limited to, volumes, abnormalities in a blood draw, or any relevant patient information. This section can also be left blank.

5.2.4.6 Any forms that are necessary for the procurement of the sample are identified in the bottom section of the screen under **File Name**. A brief description of the file will be visible. The technician must review all documents in this section. They will vary depending on the researcher and the order.

5.2.4.7 Once all information is filled in, click the **Submit** button at the bottom right hand corner of the screen. If the sample cannot be shipped or the information is incorrect, click **Cancel** in the bottom left corner.

5.2.4.8 After clicking submit, a new screen will pop up which shows all of the information that the technician entered on the procurement screen. This is the last chance to review the information for errors and make edits. If everything is correct, click **Submit**. Once Submit is clicked on this screen the order cannot be edited. It is extremely important that all information be reviewed for accuracy before clicking **Submit**.

5.2.5 Orders

The Orders section of the Task Board is a place to view all open orders for the clinic the technician is signed in under. This menu is available for technicians to view but will not be used during procurement.

5.2.5.1 Click on **Orders** on the left hand menu. A screen titled Orders will appear with a list of all open orders for the clinic specified in the top menu bar. The list will have the following items:

- **Order**: The number assigned to the order by the system.
- **Customer**: The name of the client.
- **Due Date**: Date that the order was entered into the system.
- **Status**: The status of the order. The order will remain open and visible to the technician until the samples have been billed for.

5.2.5.2 Click on the line of the order of interest.

5.2.5.3 The order number and name of the client will be at the top of the screen. The **Status**, **Assigned to**, and **Order date** will be automatically generated.

5.2.5.4 The first tab listed is **Lines**. The catalog number for the product is in the column **Item**. **Description** is a brief description of the item requested by the client.

Filled is how many samples in the order have been procured. **Ordered** indicates how many samples were ordered in total. **Delivery Date** is the day that the samples need to be filled by.

5.2.5.5 The second tab is labeled **Attachments.** Any attachments that are relevant to the order will be attached here. They can also be accessed when viewing an order in the ***Procurement*** section of the Task Board.

5.2.6 Packing Lists

Packing lists, or Researcher Procurement Forms, are documents that need to be printed out for each order and included with the samples as well as faxed to the Procurement Manager. The forms contain all relevant information pertaining to the samples and the client including shipping address, type of sample, specimen number, and specific patient information that was entered in the ***Procurement*** section of the Task Board. All information on the form is auto populated.

5.2.6.1 Click ***Packing Lists*** on the left hand side of the screen. There will be a list of orders that have been procured in the clinic selected at the top of the screen within the Clinics drop down menu. The Order, Customer, and Due Date are identified.

5.2.6.2 Click on the order that a packing slip needs to be printed for. Each sample for that order will be listed. The first column is the auto generated **Lot Number**. The lot number is created from the sample procurement number, date, location number, and technician ID number. The **Item** is the catalog number for the samples procured. **Item Description is** the brief description of the sample procured.

5.2.6.3 Check each box to the left of the Lot Number that should be included on the packing list and click **Submit**.

5.2.6.4 Review the packing slip to make sure that all items that are being shipped are on the form and that all information is accurate. Review the client name, address, and all sample information for errors. The client name and address listed on the packing slip are to be used to create a FedEx shipping label to ship the samples. Instructions on how to create the shipping label using FedEx.com can be found in the *FedEx Shipments Standard Operating Procedure* SEC-FP0006.

5.2.6.5 Two copies of the Packing Slip should be printed. One copy will go with the samples and the second should be faxed at the end of the day to the Procurement Manager. More information on how to package samples and the Packing Slip can be found in the *Packaging Blood and Tissue Samples Standard Operating Procedure* SEC-FP-00005.

6. APPLICABLE REFERENCES

- FedEx Shipments SOP
- Infectious Disease Screening (IDS) Sample SOP
- Packaging Blood and Tissue Samples SOP

Exhibit 8.44

Subject: Re: Procurement update
Date: Wednesday, January 7, 2015 at 10:13:36 AM Pacific Standard Time
From:
To: Redacted

Ok.

Actually, if you have a good sample from any gestational week today, I would like you to please send it.

Best,
Redacted

On Tue, Jan 6, 2015 at 1:53 PM, Redacted wrote:
Hello,

There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation. Thank you,

Redacted

StemExpress
Redacted
[redacted]
Redacted
stemexpress.com

Subject: FW: Procurement update
Date: Wednesday, January 14, 2015 at 8:02:34 PM Pacific Standard Time
From:
To: Redacted

just fyi

From: Redacted
Sent: Wednesday, January 14, 2015 4:03 PM
To: Redacted
Subject: Re: Procurement update

Hi,

Yes, please, put me on the schedule for tomorrow. Can you also change the gestational requirements, to allow any gestational stage (I have changed some things in the protocol, and so need to redo the middle stages).

I am aiming for an even coverage of gestational stages, to get a full view of pancreas development. As I get samples that cover different stages the requirements change.

Best,
Redacted

On Wed, Jan 14, 2015 at 12:40 PM, Redacted wrote:

Hello,

Unfortunately there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?

Thank you,

Redacted

From: Redacted
Sent: Wednesday, January 14, 2015 12:27 PM
To: Redacted
Subject: Re: Procurement update

Hi Redacted

How is the pancreas forecast today - any possible procurements?

Best,
Redacted

Sent from my iPhone

Exhibit 8.45

Consenting the Patient

All patients who donate tissue and blood must sign the IRB approved StemExpress Informed to Participate in a Clinical Research Study.

The consent allows the donation of the fetal tissue and blood for research. It clarifies that the patient decided to have an abortion *before* the consent was offered and that all patient identifying information will not be connected to the donation. The patient can change their mind and choose not to donate while in the clinic but once they leave the clinic the donation cannot be cancelled because the donation is anonymous. There would not be any way to link the sample to the patient. Clinic staff is expected to understand all aspects of the consenting process before asking the patient to consent.

The patient must initial in the bottom right hand corner of each page of the consent. Page 3 must be signed and dated by the patient as well as the trained staff member that is consenting. The areas to be initialed or signed have been highlighted on Page 3 of this work instruction. Page 4 of the consent is to be completed only if the patient is a resident of California.

The completed consent, signed by the patient and the clinic staff, is kept at the clinic for their records. StemExpress will not receive or store any documents that identify the patient.

Exhibit 8.46

Procurement Technician Compensation Policy for Tissue and Blood Procurement Effective 01/01/2013

Procurement Fees

- Procurement Technicians are compensated at a rate of $10.00 per hour plus a per tissue or blood bonus as outlined in the table below:

Tissue Bonus Structure			
# Specimens	Category A*	Category B*	Category C
1-10 Specimens	$35/Tissue	$15/Tissue	$10/Blood
11-20 Specimens	$45/Tissue	$20/Tissue	$15/Blood
21-30 Specimens	$55/Tissue	$25/Tissue	$20/Blood
31-40 Specimens	$65/Tissue	$30/Tissue	$25/Blood
41-50 Specimens	$75/Tissue	$35/Tissue	$30/Blood

*Blood Samples may be obtained with these specimens in which case Category C bonus does not apply.

Please refer to the Procurable Specimens by Category dated 01/01/2013 for a detailed listing of Tissues.

Two or More Procurement Technicians working in Unison

- Procurement Technicians often work in unison so procurements are split equality between the technicians.

For example, if two technicians are working together at the same clinic, and two maternal bloods are procured, each technician would receive $5 for the Blood Procurement.

Procurable Specimens by Category
Effective 01/01/2013

Category A*
Brain
Heart
Lungs
Liver
Thymus
Thyroid w/parathyroid
Liver
Spleen
Large Intestine
Small Intestine
Gallbladder
Pancreas
Bladder
Testis
Ovaries
Esophagus
Stomach
Rectum/Anus
Ureter/Urethra
Appendix
Spinal Cord
Spinal Column
Eyes
Diaphragm
Lymph nodes
Sternum
Adipose tissue
Lymph nodes
All Muscle tissue
All Bone structures

Category B*
Kidneys
Adrenal glands
Ear
Decidua
Chorionic Villi
Umbilical Cord
Placenta
Amniotic Fluid
Large Intestine
Small Intestine
Skin
Nose
Tongue
Scalp

Category C
Maternal Blood
Post Surgery Blood
Umbilical Cord Blood
Trisomy Blood

*Note: Blood Samples may be obtained with these specimens in which case Category C bonus does not apply

[redacted]
www.stemexpress.com

Procurement Technician Compensation Policy for Mileage and Other Expenses Effective 01/01/2013

Mileage Reimbursement

- Each StemExpress contractor is assigned a worksite location, which generally is the primary assigned clinic. Any mileage driven on behalf of StemExpress exceeding the mileage to and from their resident and their current assigned worksite location will be reimbursed at $.55 per mile based on the Federal Mileage Rate. This rate is subject to change via the federal government and will be changed accordingly.

Expenses

- On occasion, StemExpress Contractor's will need to purchase supplies, i.e. ice for shipping. StemExpress Contractor's will be reimbursed for these necessary items. Receipts are required for reimbursement.

Exhibit 8.47

Services Agreement

This agreement is made as of 5/15/2012 between StemExpress, LLC, a limited liability company, and Planned Parenthood Shasta Pacific, a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Shasta Pacific provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Shasta Pacific will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Shasta Pacific will invoice StemExpress monthly for the number of POC's and number of maternal bloods procured by StemExpress. StemExpress will pay Planned Parenthood Shasta Pacific within thirty days of receipt of the invoice.

[redacted] Shipping & Receiving
[redacted]
[redacted] www.stemexpress.com

6. Any information obtained from Planned Parenthood Shasta Pacific patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Shasta Pacific
[redacted]

StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Shasta Pacific is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by Planned Parenthood Shasta Pacific.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the

performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Shasta Pacific

By: [redacted] 5/16/12

Title: President/CEO

StemExpress, LLC

StemExpress Founder and CEO

By: [redacted]

Title: CEO 5/16/12

[redacted] Shipping & Receiving

[redacted] www.stemexpress.com

Services Agreement

This agreement is made as of October 23, 2103 between StemExpress, a limited liability company, and Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties, Inc. (PPSBVSLO) a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, PPSBVSLO provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. PPSBVSLO will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal blood; seeking consent for donation of fetal organs and maternal blood from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty dollars ($50.00) per 60cc's of maternal blood, and seventy five dollars ($75.00) for the collection of fetal tissue, if collected solely by PPSBVSLO staff. If StemExpress staff is onsite to physically collect the sample, then there would be a cost adjustment for the collection of the sample. PPSBVSLO will invoice StemExpress monthly for the number of POC's and number of maternal bloods

[redacted]

procured by StemExpress. StemExpress will pay PPSBVSLO within thirty days of receipt of the invoice.

6. Any information obtained from PSBVSLO patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods. This will always be done in accordance with HIPAA guidelines.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and can be renegotiated for successive years there after. Parties may, at any time, give each other a ninety days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate ninety days after the receipt of such notice. .

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Abortion Doctor Medical Director
Planned Parenthood of Santa Barbara, Ventura
& San Luis Obispo Counties, Inc.
[redacted]

Attn: StemExpress Founder and CEO
StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. PPSBVSLO is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by PPSBVSLO.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

[redacted]

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

StemExpress, LLC

By: StemExpress Founder and CEO [redacted]

Name: StemExpress Founder and CEO [redacted]

Title: CEO

Planned Parenthood Santa Barbara, Ventura & San Luis Obispo Inc.

By: [redacted]

Name: [redacted]

Title: President / CEO

Redacted

PURCHASE ORDER

Winter Closure Warning: Redacted will be closed for Winter Break from Monday, December 22, 2014 through January 4, 2015. Redacted Redacted will reopen on Monday, January 5, 2015. No staff will be here to receive deliveries during this closure unless they have made special arrangements with you to be here to receive this shipment. If you cannot deliver by Friday, December 19, 2014 please schedule your shipment to arrive as soon as possible on or after, Monday January 5, 2015.

DATE	PURCHASE ORDER NO.
12-DEC-2014	60856806
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: STEMEXPRESS LLC
[redacted]
United States
ATTN : Redacted

Ship To:
Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			17-DEC-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	5263 Stemexpress invoice 5263 for trisomy and normal Fetal calvarium	1	EACH	2,130.00	2,130.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted ☐

Exempt as purchase on behalf of U.S. Government ☐

Exempt because use is exempted. ☐

Authorized Signature

Redacted

Chief Procurement Officer

Direct questions to Redacted

ESTIMATED TAX: 186.38

TOTAL: 2,316.38

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/12_1017.pdf.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Redacted

Purchase Order

3000014694

Purchase Order	Date	Revision	Page
3000014694	2014-10-04		1 of 2
Payment Terms	**Freight Terms**	**Ship Via**	
Due Now	FOB DEST	BEST WAY	
Buyer	**Phone**		**Currency**
Redacted	Redacted		USD

Vendor: Redacted
STEMEXPRESS LLC
[redacted]
United States

Ship To:
Redacted

Bill To:
Redacted

Purchase Order Comments

Redacted

Attached are the quote and meditract documents.
PLEASE ATTN: 3000014694
PLEASE CONTACT Redacted FOR QUESTIONS: Redacted OR Redacted
IF SHIPPING CHARGES ARE APPLIED PLEASE USE FED EX COLLECT Redacted (FOR COLD ITEMS PLEASE SHIP USING "STANDARD OVERNIGHT"
FOR NON COLD ITEMS PLEASE SHIP 2ND DAY.
PLEASE SEND CONFIRMATION/ETA/TRACKING INFO TO: Redacted

PLEASE ATTN: 3000014694
PLEASE CONTACT Redacted FOR QUESTIONS: Redacted OR Redacted
IF SHIPPING CHARGES ARE APPLIED PLEASE USE FED EX COLLECT Redacted (FOR COLD ITEMS PLEASE SHIP USING "STANDARD OVERNIGHT"
FOR NON COLD ITEMS PLEASE SHIP 2ND DAY.
PLEASE SEND CONFIRMATION/ETA/TRACKING INFO TO: Redacted

Line-Sch	Item #/Description	Vendor Item ID	Quantity	UOM	Unit Price	Extended Amt	Due Date	Tax Y/N
1 - 1	Human Fetal Tissue-Pancreas; Infectious Disease Screening: HIV, HBsAg, HCV; Packaging-Gel Pack or Wet Ice	1144	1.00	EA	760.00	760.00	10/07/2014	Y
					SUT Code: LA (9%)	68.40		
					Schedule Total	828.40		

Contract ID: Redacted Version: 1 Contract Line: 0 Category Line: 0 Release: 3
For Redacted Reference Only

Authorized Signature
Redacted

Redacted

PURCHASE ORDER

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DATE	PURCHASE ORDER NO.
14-NOV-2014	60836838
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: STEMEXPRESS LLC
[redacted]
United States
ATTN : Redacted

Ship To:

Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			19-NOV-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	5231 4 Human Fetal Brains As described in Invoice # 5231	1	EACH	3,340.00	3,340.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted ☐

Exempt as purchase on behalf of U.S. Government ☐

Exempt because use is exempted. ☐

Authorized Signature

Redacted

Chief Procurement Officer

Direct questions to Redacted

ESTIMATED TAX: 292.25

TOTAL: 3,632.25

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/12_1017.pdf.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Redacted

PURCHASE ORDER

Winter Closure Warning: Redacted will be closed for Winter Break from Monday, December 22, 2014 through January 4, 2015. Redacted Redacted will reopen on Monday, January 5, 2015. No staff will be here to receive deliveries during this closure unless they have made special arrangements with you to be here to receive this shipment. If you cannot deliver by Friday, December 19, 2014 please schedule your shipment to arrive as soon as possible on or after, Monday January 5, 2015.

DATE	PURCHASE ORDER NO.
16-DEC-2014	60858758
PAGE NO.	REVISION NO.
Page 1 of 1	0

To: STEMEXPRESS LLC
[redacted]
United States
ATTN : Redacted

Ship To:
Redacted

ORDER PLACED WITH	FOB	FREIGHT	VENDOR: If freight not included in price, prepay and add	DELIVERY DATE	TERMS
	Destination			17-DEC-2014	N30

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	EXTENDED PRICE
1	FT0101F Human Fetal Tissue (Estimate 5251) - Gestation requirements: 17-18 weeks - - upper and lower limbs with hands and feet	1	EACH	890.00	890.00
2	FT0101F Human Fetal Tissue (Estimate 5251) - Calvarium - Matched to upper and lower limbs	1	EACH	595.00	595.00

TAXABILITY

Exempt because items are for resale. California Sellers Permit: Redacted ☐

Exempt as purchase on behalf of U.S. Government ☐

Exempt because use is exempted. ☐

Authorized Signature: Redacted
Chief Procurement Officer

Direct questions to: Redacted

ESTIMATED TAX: 129.95

TOTAL: 1,614.95

Unless specifically stated otherwise, Redacted is subject to Sales Tax. Suppliers should invoice for taxable items. If a Supplier does not have the authority to collect California Sales Tax, Redacted will accrue the tax and remit to the State Board of Equalization in the form of Use Tax.

California Revenue and Taxation Code, Section 18662, require withholding for payments made to nonresidents of California for income earned in California related to independent contractor services, rent, and royalty distributions. For more information on this requirement reference https://www.ftb.ca.gov/forms/2012/12_1017.pdf.

This Purchase Contract may be accepted only on the terms set forth herein. The complete Terms and Conditions can be found at: Link. Terms in any acceptance by Seller which are in addition hereto or not identical with the terms hereof will not become a part of any Purchase Contract unless Buyer specifically and expressly agrees in writing that such other terms are accepted. By accepting this Purchase Contract or any part hereon, Seller agrees to and accepts all the provisions of the Purchase Contract.

INSTRUCTIONS

Applicable unless otherwise stated

A. **Invoices** - Separate invoices for each purchase order. Show purchase order number on all documents. Mail invoices to Accounts Payable at:

Redacted

If this order involves services and you have not advised Redacted of your tax status, please contact the Financial Support Center at Redacted Failure to provide tax information may result in delayed payment. For more information, email Redacted

B. **Correspondence** - Redacted Redacted

C. **Transportation** - If freight is not included in price, prepay and state separately on invoice. **Do not ship collect.** Include a packing list with each shipment, and attach to outside (not inside) of container. Show purchase order number on outside of each container

D. **Late Shipment** - Advise at once if order will not reach destination on time.

E. **Terms and Conditions** - Link.

Okay to Pay Invoice 1047732.00.0061AM.833695.733001

Initiator = [redacted]

IMG74120201-EML001_0

stem express

STEMEXPRESS, LLC

[redacted]

stemexpress.com

Invoice

Date	Invoice #
01/19/2012	1439
Terms	Due Date
Due on receipt	01/19/2012

Bill To

Yale University
School of Medicine, Neurobiology
[redacted]
New Haven, CT 06510 USA

Purpose: the tissues are used for RNA extraction to perform genome-wide gene expression of brains exposed to environmental stressors

Ship Via	Researcher	Shipping
FedEx	[redacted]	StemExpress Acct

Description	Qty	Price	Amount Due
01/14/2012			
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	4:00	715.00	2,860.00
• Fedex Priority Overnight	1:00	85.00	85.00
Subtotal: 01/14/2012 = $2,945.00			
01/17/2012			
• Fedex Priority Overnight	1:00	85.00	85.00
• Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 03	3:00	715.00	2,145.00
Subtotal: 01/17/2012 = $2,230.00			
01/19/2012			
• Credit for 1/14/12 Samples - Fetal Brain Procurement Project: 5-24 wks - exposed to environmental factors, e.g. seizure, infection, hypoxia, alcohol, smoking, drug abuse. HIV Testing, Snap Freezing, Shipped on Dry Ice. Sample to be provided intact or in 4 parts/tube (anterior, middle, posterior cortex, and brain stem) POC #01, 02, 04, 05	-4	715.00	-2,860.00
• Credit for 1/14/12 - Fedex Priority Overnight	-1	85.00	-85.00
Subtotal: 01/19/2012 = $ -2,945.00			
		Total	$2,230.00

Thank you for your business. If you have any questions, contact [redacted] Procurement Technician or by email at [redacted]@stemexpress.com.

X [redacted] [redacted]

Administrator 5-4325 01/27/2012

Exhibit 8.48

January 3, 2011

Protocol Number: 101-01

Protocol Date: January 24, 2011

Study Title: Tissue Procurement for Non-therapeutic Research

Sponsor: StemExpress, LLC.

Primary Investigator: Redacted
StemExpress, LLC
[redacted]
Redacted

Standard Operating Procedure

1. Purpose

This SOP covers Tissue Procurement for Non-therapeutic Research.

This protocol describes the set up, equipment and procedures for procuring cadaverous tissue to use in non-therapeutic research.

2. Scope

This applies to all procurements for non-therapeutic research.

3. Prerequisites

The day before surgery:
Check WebOffice for researcher requests;
Determine your location for the next day;
Call the clinic to verify how many surgeries are scheduled.

4. Responsibilities

It is the procurement technician's responsibility to bring the general and medical supplies listed in this SOP to each clinic. The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.

5. Equipment

General supplies:
Current blank RPR (Researcher Procurement Record)
logs Pre-printed FedEx forms

General supplies:
Current blank RPR (Researcher Procurement Record) logs
Pre-printed FedEx forms

Medical supplies:
Scrubs
RPMI
Hepes Solution with antibiotic added
Petri dishes
Shipping boxes
Personal instruments to procure
Conical tubes
Mini urine specimen cups
Cold packs

6. *Procedure*

On the day of surgery, the following steps are taken to procure tissue from POC: Arrive at the clinic and change into scrubs.
Inform the consenting staff of which gestations to consent. Place chucks down.
Set up the light box, instruments, RPMI, Hepes, petri dishes and tubes or cups. Set up enough blood draw bags for the day.
Get out the sequential numbering labels.
Print a copy of the day's Procurement Schedule.
Follow along with the chart flow so you know what gestations to expect.
If required, initiate blood draw from clinic staff. We do NOT want a patient label on the blood tube. Give the clinic staff the blood bags and correct blood tubes for the given researcher. If these are blood samples to accompany the tissue sample, number them in order as soon as complete. See the SOP "Maternal Blood Samples for Infectious Disease Testing" for specific guidance on those blood samples.
Once a consenting donor has undergone surgery, procure the specimen(s) on the petri dish and light box.
With minimal manipulation after isolating the specimen(s), move the petri dish to the packaging room and carefully transfer the specimen(s) to the appropriate container (conical tube or mini urine specimen cup). Add the researchers media of choice and seal with parafilm.
Keep track of time, gestation, fetal foot size or sono report and date.
Package the specimens and blood tubing for shipment once all specimens have a number. Be sure to place them on ice or cold packs.
Note the specimen numbers on the RPR log. For delivery:
If the specimen is local courier, be sure to call the courier once you know you have obtained an appropriate specimen.
If the specimen is going by FedEx, be sure to know the local cut-off times for your closest FedEx office. Each FedEx location is listed under "contacts" in WebOffice. Always know which FedEx you will be dropping off at and consider traffic. Log on to www.fedex.com with your assigned log on and password. Print shipping label and affix to box.
All instruments must be sterilized once you are done for the day.
Clean the area(s) thoroughly and discard all unused POC in the appropriate receptacle. Gather your supplies to leave and change out of your scrubs.

7. *Cautions*

Health and Safety Warnings

All blood and tissue should be handled with standard Biohazard care. Gloves and other personal protective equipment should be worn at all times when handling blood or tissue. Meticulous care should be taken while using sharp dissecting instruments. Immediately report any injury to StemExpress.

Interferences

Care should be taken to preserve the longevity of the equipment. This includes dissecting tools, light boxes, packaging supplies and media. Gentle handling of specimens is essential to quality control. Do not move or manipulate the tissue any more than is absolutely necessary. Ensure proper printer functioning first thing in the day, and contact StemExpress immediately if there are printer problems.

If you have an excellent sample with no researcher listed on today's schedule, please contact [redacted] immediately, and they will work to call researchers who may be interested even though they are not currently scheduled.

8. *References*

Researcher Procurement Record
MSDS for RPMI
MSDS for Hepes
MSDS for Antibiotic
SOP "Blood Samples for Infectious Disease"
HIPAA
Biohazard
Presentation

I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol; deviations from the protocol are acceptable only with a mutually agreed upon protocol amendment with the IRB approval. I also agree to report all information or data in accordance with the protocol, and in particular I agree to report serious adverse experiences as defined in this protocol.

Redacted

3/17/2011

Signature of Principal Investigator

Date

Redacted

Printed Name of Principal Investigator

Exhibit 8.49

STEM-EX, LLC

Services Agreement

This agreement is made as of April 1st, 2010 between Stem-Ex, LLC, a limited liability company, and Planned Parenthood Mar Monte, a professional corporation.

WHEREAS, Stem-Ex is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Mar Monte provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Mar Monte will provide, and Stem-Ex will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which Stem-Ex representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Mar Monte will invoice Stem-Ex monthly for the number of POC's and number of maternal bloods procured by Stem-Ex. Stem-Ex will pay Planned Parenthood Mar Monte within two weeks of receipt of the invoice.

6. Any information obtained from Planned Parenthood Mar Monte patients' charts shall be privileged, and Stem-Ex will treat the information in order to preserve the confidentiality of the patients. Stem-Ex will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Mar Monte
[redacted]

Stem-Ex
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Mar Monte is not obligated to provide any minimum number of POCs or maternal bloods. Stem-Ex is not obligated to take any minimum number of POCs or maternal bloods, nor is Stem-Ex obligated to take all the POCs or maternal bloods made available by Planned Parenthood Mar Monte.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Mar Monte

By: Abortion Doctor

Title: Medical Director

Stem-Ex, LLC

By: StemExpress Founder and CEO

Title: President

Stem Express

Services Agreement

This agreement is made as of 5/15/2012 between StemExpress, LLC, a limited liability company, and Planned Parenthood Shasta Pacific, a professional corporation.

WHEREAS, StemExpress is a company devoted to providing services related to the procurement of human organs, tissues, and blood for medical research in order to facilitate medical research utilizing those tissues; and

WHEREAS, Planned Parenthood Shasta Pacific provides medical services, education programs, and advocacy initiatives in order to improve people's lives;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained in this Agreement, and in order to further their mutual goals, the parties agree as follows:

1. The term "fetal organ" has the same meaning as the term defined in the National Organ Transplant Act (42 U.S.C.A. 274e(c)(1)) and means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ or any subpart thereof, as from a fetus.

2. The term "product of conception" ("POC") means any fetal organ or other fetal or placental material taken from the human uterus during an abortion.

3. The term "maternal bloods" means blood samples taken from a pregnant woman.

4. Planned Parenthood Shasta Pacific will provide, and StemExpress will pay the reasonable costs for, services and facilities at mutually agreed upon health centers (hereinafter collectively referred to as "services") associated with the following: the removal of fetal organs from POCs; the processing, preservation, quality control, and transportation of the fetal organs; appropriate space in which StemExpress representatives and employees may work; disposal services for non-used portions of cadaveric materials; obtaining maternal bloods; seeking consent for donation of fetal organs and maternal bloods from appropriate donors, and; maintaining records of such consents so that verification of consent can be supported.

5. The reasonable costs associated with the services specified in this Agreement shall be fifty-five dollars ($55.00) per POC determined in the clinic to be usable, and ten dollars ($10.00) per maternal blood. Planned Parenthood Shasta Pacific will invoice StemExpress monthly for the number of POC's and number of maternal bloods procured by StemExpress. StemExpress will pay Planned Parenthood Shasta Pacific within thirty days of receipt of the invoice.

[redacted] Shipping & Receiving
[redacted]
[redacted] www.stemexpress.com

6. Any information obtained from Planned Parenthood Shasta Pacific patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods.

7. The term of this Agreement shall be for one year, beginning from the date hereof, and terminating one year thereafter. Parties may, at any time, give each other thirty days written notice of the intention to terminate this Agreement, whereupon the Agreement shall terminate thirty days after the receipt of such notice. In the absence of such termination, this Agreement shall continue for further successive terms of one year thereafter.

8. Written notices pursuant to this Agreement shall be sent to the following:

Attn: Medical Director
Planned Parenthood Shasta Pacific
[redacted]

_____

StemExpress
[redacted]

9. The parties do not know how many patients will consent to donate POCs or maternal bloods for research, and thus do not know how many POCs or maternal bloods will be obtained pursuant to this Agreement. Planned Parenthood Shasta Pacific is not obligated to provide any minimum number of POCs or maternal bloods. StemExpress is not obligated to take any minimum number of POCs or maternal bloods, nor is StemExpress obligated to take all the POCs or maternal bloods made available by Planned Parenthood Shasta Pacific.

10. The parties mutually agree to defend, protect, and hold harmless each other's officers, directors, agents, employees, and consultants from and against any and all expenses, liabilities, demands or claims for loss or damage to property, or for personal injury or death suffered as a result of any actions by the parties in the

[redacted]Shipping & Receiving
[redacted]
[redacted]www.stemexpress.com

performance of the Agreement and attributable to the fault or negligence of the parties or their respective officers, directors, agents, employees, or consultants.

11. No modification to this Agreement, nor any waiver of any rights, shall be effective unless agreed to in writing by the party charged with such waiver or modification. Waiver of any breach or default shall not constitute a waiver of any other right hereunder, or any subsequent breach or default.

12. This Agreement constitutes the entire and exclusive agreement between the parties.

13. This Agreement shall be governed by and interpreted under the laws of the State of California, and venue for any dispute arising hereunder shall be in the County of Sacramento.

14. The prevailing party in any action to enforce the terms of the Agreement shall be entitled to reimbursement by the other party for all costs, including the reasonable attorney fees and professional fees, incurred in connection with such proceeding.

15. This Agreement may be executed in counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this agreement by their duly authorized representatives as of the date written above.

Planned Parenthood Shasta Pacific

By: [redacted] 5/10/12

Title: President/CEO

StemExpress, LLC

By: [redacted] StemExpress Founder and CEO

Title: CEO 5/10/12

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