

HEARING ON THE *PRICING OF FETAL TISSUE*

Background

Congress Passed H. Res. 461

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Panel on Infant Lives and empowered the panel to investigate issues including “Federal funding and support of abortion providers,” as well as all “relevant matters with respect to fetal tissue procurement.” The Panel Chairman, Congressman Marsha Blackburn, has scheduled a hearing to explore information about the pricing of the tissue and whether abortion clinics and middleman businesses were making a profit from the transfer of fetal tissue.

The release of videos last summer raised the question of whether abortion clinics and middleman tissue procurement businesses were profiting from the sale of baby body parts, organs and tissues. To profit from the acquisition or transfer of fetal tissue violates Title 42 USC §289 g-2, which prohibits the transfer of any fetal tissue for valuable consideration that exceeds the reasonable costs associated with the procurement.

History of the Prohibition of Profiting from Fetal Tissue Sales

On March 10, 1993, the House debated two competing amendments to H. R. 4 the National Institutes of Health Revitalization Act of 1993. Amendments, one offered by Mr. Bliley and one by Mr. Waxman focused on safeguards for the donation of fetal tissue for transplantation and for research. The House passed the Waxman Amendment to H.R. 4, the National Institutes of Health Revitalization Act of 1993. That Amendment includes the provisions codified as 42 USC 289 g-2(a) and (e)3:

42 USC §289 g-2(a) states “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for **valuable consideration if the transfer affects interstate commerce.”**

42 USC §289 g-2(e)(3) “The term **“valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”**

During Floor debate it was repeated over and over by supporters of the Waxman Amendment that fetal “tissue may not be sold.”¹ Mrs. Morella expressed her support for the legislation because “fetal tissue could not be sold.”² Mr. Waxman himself said:

This amendment that I am offering as a substitute would enact the most important safeguards, and those are the safeguards to prevent any sale of fetal tissue for any

¹ 139 Cong. Rec. 1099 (1993) (statement of Rep. John Edward Porter in support of the Waxman Amendment).

² Id. (statement of Rep. Connie Morella in support of HR 4 and the Waxman Amendment).

purpose, just not for the purpose of research. It would be abhorrent to allow for a sale of fetal tissue and a market to be created for that sale.³

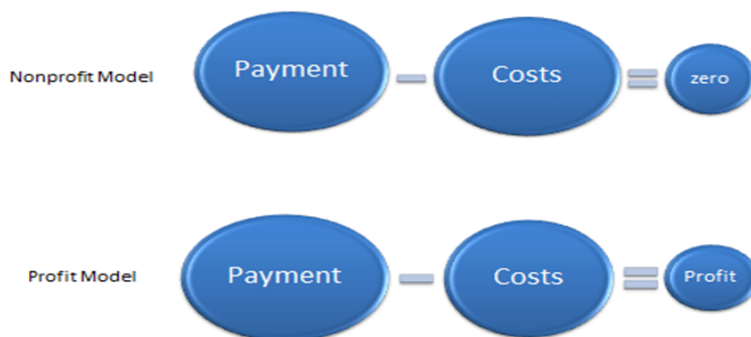
The floor debate corroborates Committee Report language. The Report of the National Institutes of Health Revitalization Act of 1993 from the Committee on Energy and Commerce stated:

Section 498B prohibits the purchase of human fetal tissue as well as the solicitation or acceptance of directed fetal tissue donations.⁴

The Committee prohibition on the sale of fetal tissue is described as making the transfer of fetal tissue parallel with donation of other organs under the Organ Procurement and Transplantation Act.⁵ But the Committee Report adds, “Indeed the Committee has dealt with fetal tissue more restrictively”⁶ The Committee intent is to disallow payment for procurement of any organs.

The intent of the statute is best understood through a simple contrast between two modes of transferring fetal tissue from one entity to another. With the first, an abortion clinic (AC) or middleman Procurement Business (PB) transfers tissue to a researcher, and the researcher may reimburse the AC or PB for its reasonable costs incurred by the transportation, processing, preservation, and quality control of the tissue. With the second, the payment from the researcher exceeds those reasonable costs, enabling the AC or PB to make a profit and thus violates the statute.

This is graphically explained below:



The factual scenario presented by the Select Panel on April 20, 2016, will focus on a particular *Procurement Business* that offers fetal tissue for sale to researchers through a website procurement page or through phone orders. The *Procurement Business* assigns its employees to

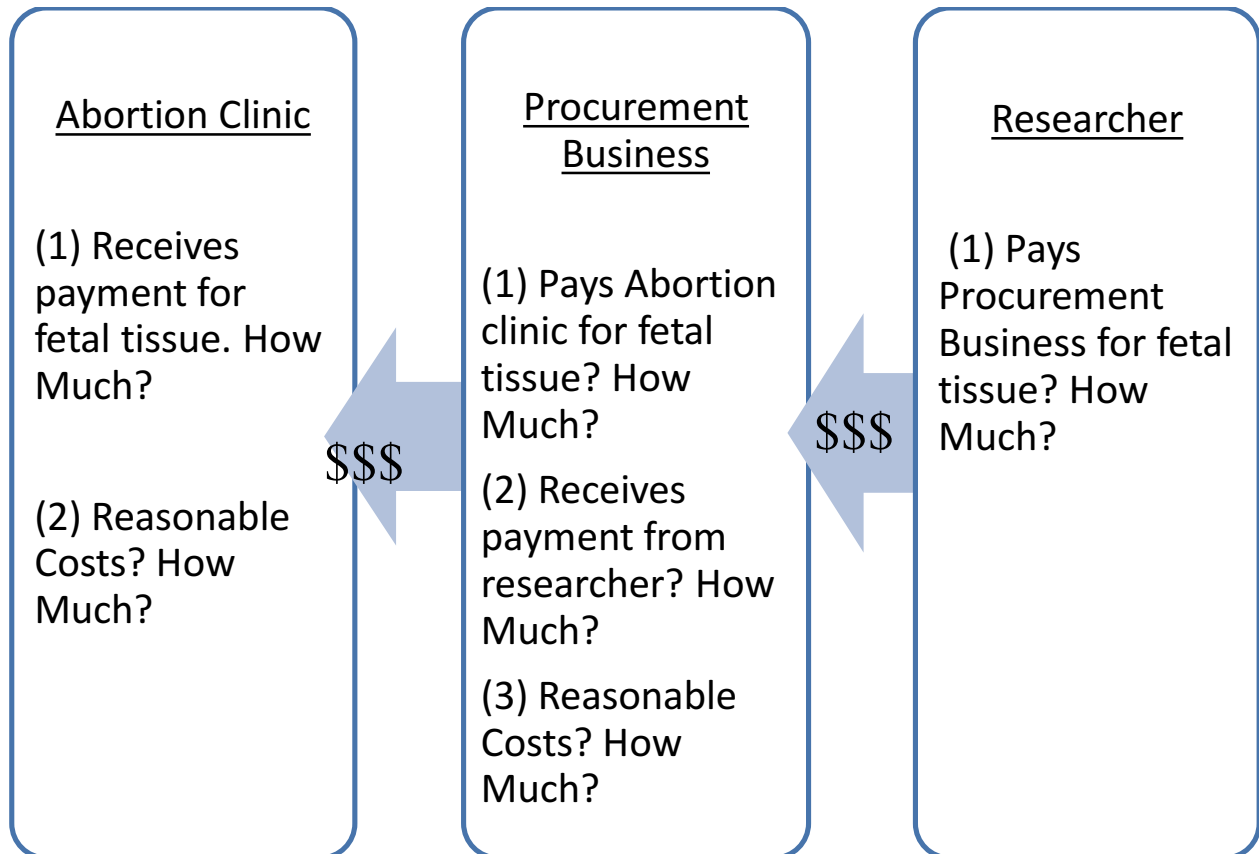
³ Id. (statement of Rep. Henry Waxman).

⁴ H.R. Rep. No. 103-28 at 76 (1993).

⁵ Pub. L. No. 98-507, 98 Stat, 2339 (1984).

⁶ H.R. Rep. No. 103-28 at 76 (1993).

a group of abortion clinics to procure fetal tissue and then ships the tissue to customers. The *Procurement Business* pays the abortion clinics a fee *per item of tissue* that its employees procure. The next graphic shows the transfer of payments and raises the question of, “How much are the reasonable costs that would offset the payments?”



If the payments from the *Procurement Business* to the Abortion Clinic exceed the reasonable costs incurred by the clinic, then the Abortion Clinic has a profit and violates the statute. If the payments from the researcher/customer exceed the reasonable costs incurred by the *Procurement Business*, then the *Procurement Business* has a profit and violates the statute.

How the Procurement Business Markets its Product

Both the *Procurement Business* company brochure and its website marketed itself to abortion clinics as a way to improve the profitability of the abortion clinic. Below are graphic samples of these materials. The company brochure was distributed at a national abortion trade association conference.

Exhibit B3

Partnerships [REDACTED] 6/14/16, 3:11 PM

[REDACTED]

Sign In Register My Account Create Wishlist Order 0 Items - \$0

Select Language [REDACTED]

Enter Product or Catalog Number [REDACTED]

home products & bioservices about [REDACTED]

become a provider get involved news contact

Partnerships

Easy to Implement Program + Financial Profits

[REDACTED] promotes global biomedical research while also providing a financial benefit to your clinic. By partnering with [REDACTED], 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 procedures can, instead, be expedited through [REDACTED] to research laboratories with complete professionalism and source anonymity.

Your Clinic can Advance Biomedical Research

- Financially Profitable
- Easy to Implement Plug-in Solutions
- Medical Director Oversight
- IRB Certified Consents

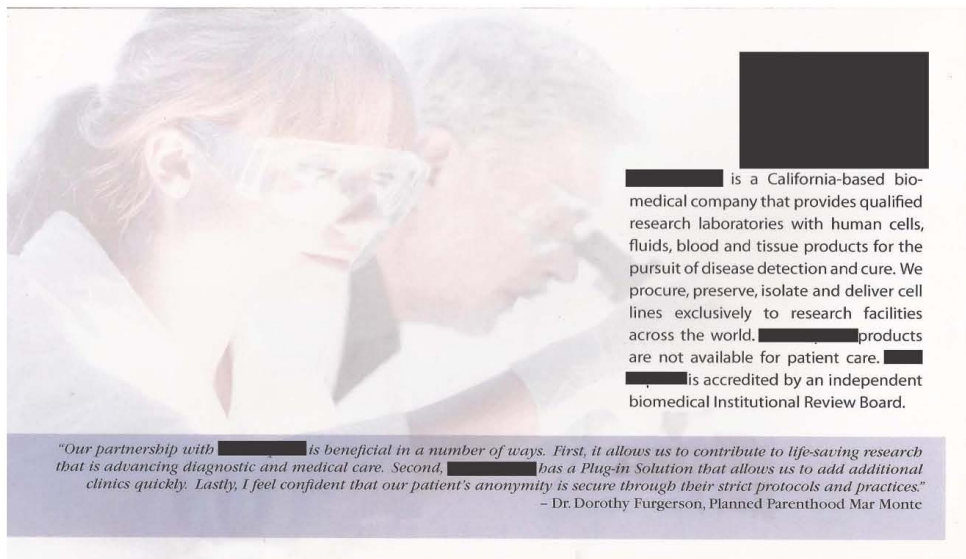
Partnering with Obstetrical-Care Clinics

[REDACTED] Page 1 of 2

Exhibit B2



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



██████████ 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. ██████████ products are not available for patient care. ██████████ is accredited by an independent biomedical Institutional Review Board.

"Our partnership with ██████████ 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, ██████████ 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."
- Dr. Dorothy Furgerson, Planned Parenthood Mar Monte

The Procurement Business Abortion Clinic Acquisition

From its inception in 2010, the *Procurement Business* was very successful at acquiring new abortion clinics from which to procure fetal tissue. In a business magazine article and in sworn legal documents, the *Procurement Business* CEO explained that the business started out in 2010 with three clinics and within two years had 30 clinics. The next milestone was achieved in 2015 when the *Procurement Business* had nearly 100 abortion clinics. During 2014 and 2015 the *Procurement Business* sought a co-marketing relationship with a national abortion clinic trade association. The contract, if ratified, would have given the *Procurement Business* over 250 abortion clinics from which to procure fetal tissue for resale. The contract was never ratified due to several factors, including the public release of the videotapes in 2015. The graph below shows the dramatic growth in the number of abortion clinics.

Exhibit B4



Revenue Growth

Along with the growth in the number of abortion clinics, the *Procurement Business* experienced significant growth in income. The company was featured in several business articles and was listed as one of the fastest growing companies in the nation.

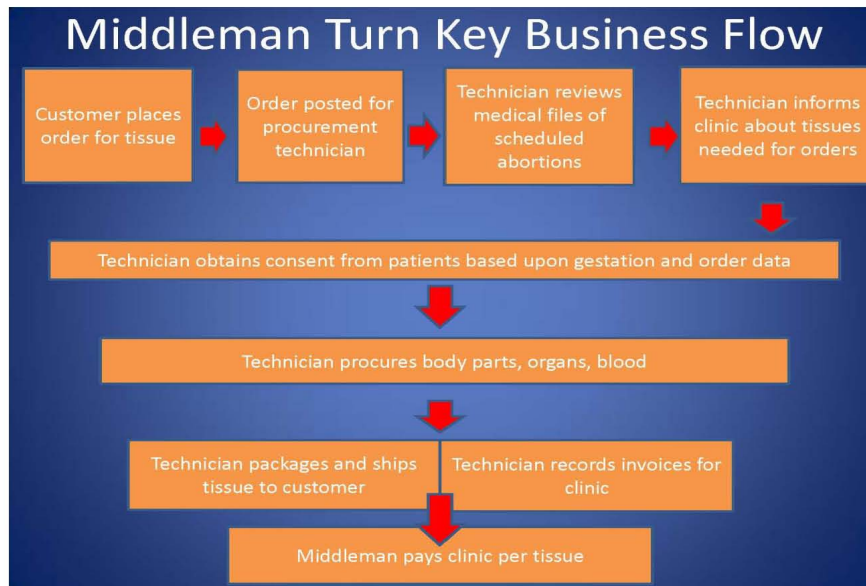
Exhibit B5



The Procurement Business offers a Turnkey or Plug in Service for Abortion Clinics

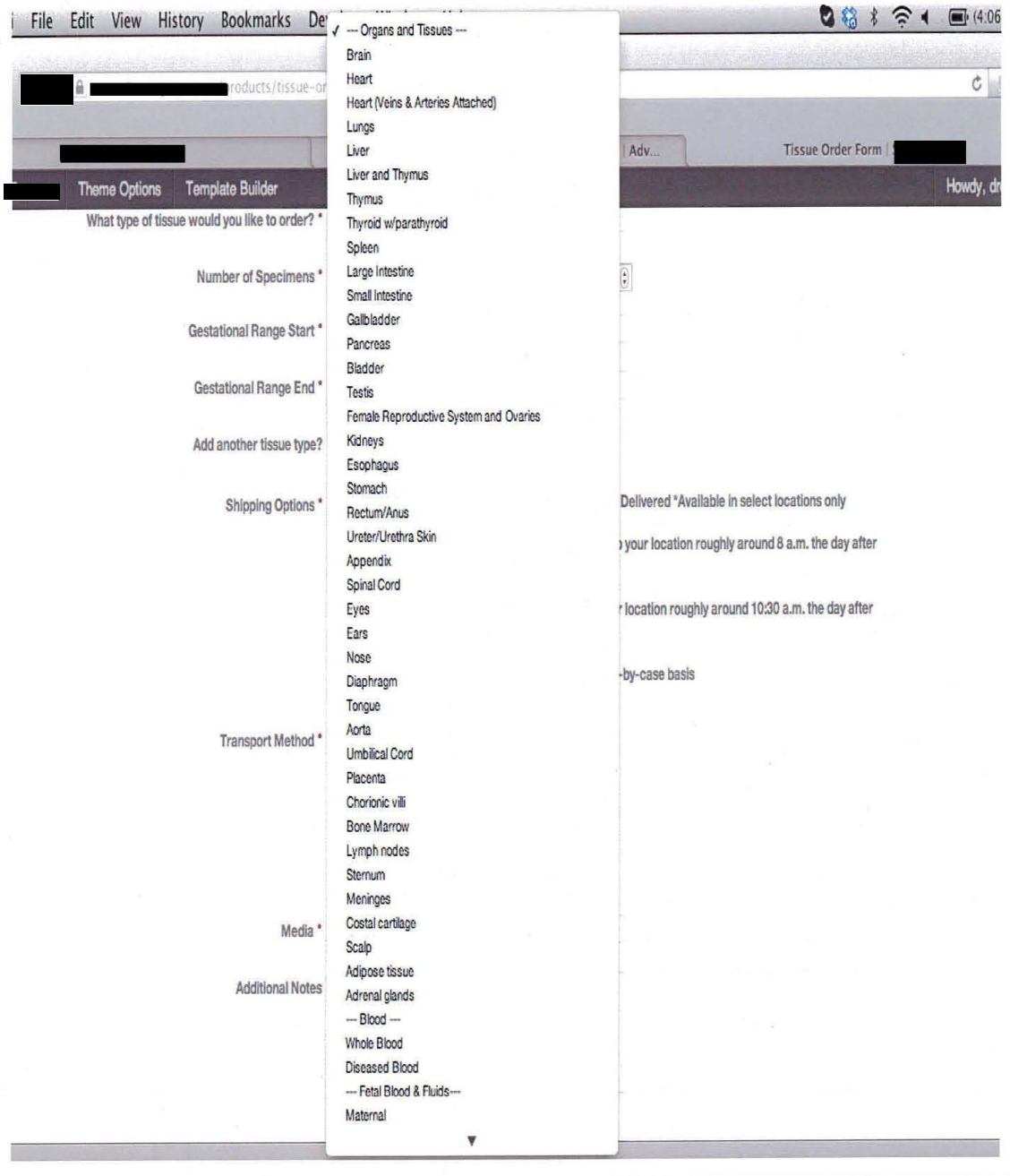
The *Procurement Business* marketed itself as a way for clinics to make additional income by allowing the *Procurement Business* procurement technicians to take fetal tissues and organs from aborted babies immediately after the abortion was completed. The Select Panel investigation reveals that every conceivable task is performed by the Procurement business employees that are assigned to one or more clinics. The first step in the process is for the researcher to make an online order. The screen grab below shows the view that the researcher or customer would have when ordering. After selecting particular baby parts, the next step would be to select the gestational period and finally the method of shipment.

Exhibit C1



The Chart below is a website screen grab of the Procurement Business order form for fetal organs.

Exhibit C3



Daily Tasks Performed by the Procurement Tech

The **work day of the procurement tech** is best understood by a review of the “C” Exhibits in particular C16 (included in the Appendix).

- 1) First thing in the morning the tissue tech gets an email like the one at C4. She reads the orders for certain baby body parts and the gestation period. Now she knows what she needs to harvest that day.
- 2) Then she checks in with the Abortion Clinic Assistant Manager and informs the staff what she will be procuring that day. Described at C9.
- 3) Then the procurement tech reviews the private medical files of the patients for that day to learn their names and the gestation time of their baby. She records the gestations on the gestation tracking log at C5.
- 4) Next the procurement tech approaches the patients waiting to be prepped for their abortion. She doesn't have much time so she must match her orders for the day with patients who are at the right gestation time. She asks for the patients by name. Then she convinces them to consent to donate saying that her donation is all about cures of Diabetes and Parkinson's and Heart Disease. Exhibit C8.
- 5) After the abortion the procurement tech collects the baby's remains and procures the body parts she needs. She carries all of her supplies with her. Described at Exhibit C13. Her shipping supplies are described at Exhibit C12.
- 6) The tissue tech then arranges for delivery: a courier, Fed EX.
- 7) She gets an hourly wage and a bonus for each tissue.

The Exhibit “C” group of documents taken as a whole represents the comprehensive role and tasks undertaken by the *Procurement Business* employee, the procurement technician. Understanding these documents as a group is critical to the analysis of whether the abortion clinics had any responsibility or tasks at all related to the fetal tissue. In fact, it is hard to conceive of the abortion clinics doing anything at all other than being paid per tissue for the work performed by the *Procurement Business*.

The “C” documents show, in great detail, that all possible management guidance, tasks, and responsibilities are undertaken by the PB procurement tech employee and that that no tasks are performed by the abortion clinic. Thus, the costs of tissue acquisition are entirely born by entities other than the abortion clinic.

Exhibit C1 *This is the daily work flow of the PB procurement tech procuring fetal tissue inside Abortion Clinics*

Exhibit C 2 *This is a list of the tasks performed by the PB procurement Tech inside the Abortion Clinics*

Exhibit C 3 *Web site screen grab of how to order any fetal tissue you want*

Exhibit C 4 *Website and phone orders sent to procurement tech via email inside abortion clinics*

Exhibit C 5 *Form the procurement tech uses to check gestation periods so that patients can be matched with orders.*

Exhibit C 6 *Work instructions on procurement given to the procurement tech by the PB for work performed inside the abortion clinic.*

Exhibit C 7 *Procurement Kit provided by the PB*

Exhibit C 8 *PB guidance on obtaining patient consent by procurement tech*

Exhibit C 9 *PB directs tissue tech to tell the abortion clinic manager what is being procured that day.*

Exhibit C 10 *PB Guidance to the procurement tech on keeping track of tissues procured*

Exhibit C 11 *PB Guidance on procurement tech responsibility to obtain disease screening*

Exhibit C 12 *PB Guidance to procurement tech regarding supplies for shipping to customers*

Exhibit C 13 *Supplies inventory that the PB provides for the procurement tech*

Exhibit C 14 *Copy of compensation plan for the procurement tech*

Exhibit C 15 *Copy of the IRB documents provided by the PB for the benefit of the customer*

Payments from Procurement Business to Abortion Clinic (includes blood)

The chart below summarized the flow of payments between the entities described above. The full exhibits are included in the Appendix.

D Exhibits

August 2010	\$11,365
Jan/Feb 2011	\$ 9,060
January 2014	\$ 6,010

Payments from Researcher/Customer to Procurement Business

E Exhibits

Fetal Brains-1 each	\$3,340
Human Fetal Tissue <u>10@595.00</u> each	\$5,950
Upper and Lower Limbs with hands and feet . . .	\$890
Baby Skull matched to upper and lower limbs . . .	\$595
Fetal Brains	\$2,230

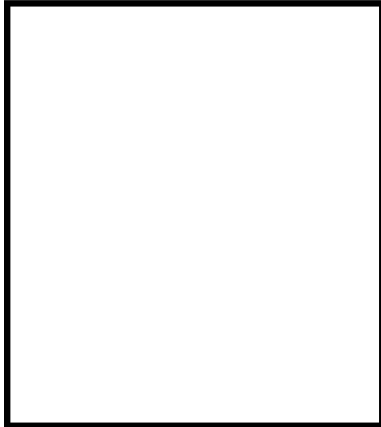
Payments from One Customer to the Procurement Business for one Year

Exhibit F

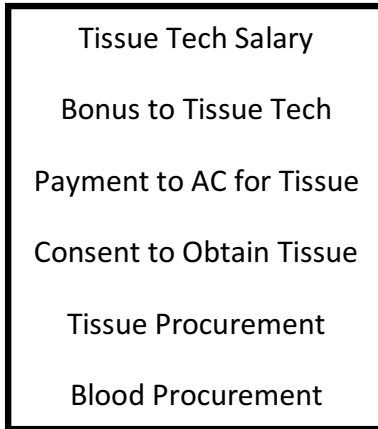
38 Fetal Brains totaling	\$22,610
12 Fetal Hearts totaling	\$7,140
3 Fetal Upper/Lower Limbs totaling	\$2,670
5 Fetal Livers totaling	\$2,975
12 Fetal Pancreases totaling	\$7,140
For an annual total of:	\$42,535

Who Bears the Reasonable Cost of Tissue Procurement?

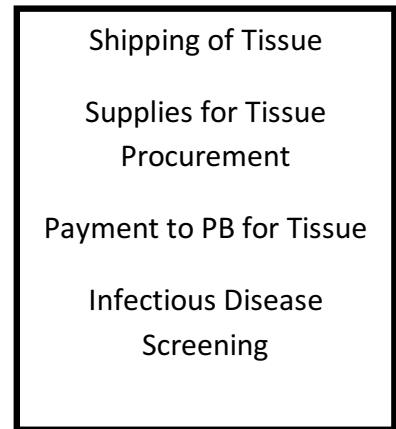
Abortion Clinic



Procurement Business



Customer



If the Abortion Clinic has no reasonable costs to be reimbursed, it raises an inference that it sold the human fetal tissue for a profit.