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 30, 2016

Via Email

The Honorable Pam Bondi Attorney General Office of Attorney General State of Florida The Capitol PL-01 Tallahassee, FL 32399-1050

Dear Attorney General Bondi:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel (the "Panel") and empowered it to conduct a full and complete investigation regarding the medical practices of abortion businesses and the practices of entities that procure and transfer fetal tissue.

Over the course of our investigation, we have uncovered documents and received information indicating that Presidential Women's Center, Inc. ("PWC"), at least in part through its relationship with StemExpress, LLC ("StemExpress"), a firm that procures fetal tissue from abortion businesses and transfers it to research customers, violated various provisions of federal and state law, including but not limited to 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05, which forbid the transfer of fetal tissue for valuable consideration.

StemExpress's Business Model and Growth Strategy

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Under its business plan, StemExpress recruited and screened businesses that were most likely to perform abortions that could produce saleable tissue to researchers. The company sought information about the number of abortions the businesses performed each week, the gestational age of fetuses scheduled to be aborted, the days the abortions were done, whether

¹ StemExpress Website Recruitment Form for Abortion Clinics, attachment 1.

digoxin² was used (which would taint the tissue and, thus, render the baby useless for obtaining tissue), and, if so, at what age it was used. Researchers ordered tissue using StemExpress's website. The firm initially had a drop-down menu that allowed researchers to obtain various types of tissue.³ It later switched to another web-based system.

In order to harvest the tissue at PWC, a typical work day for PWC staff went as follows:

- At the beginning of the day, PWC staff logged into the StemExpress Daily Task Page website, which included the day's orders for certain baby body parts and the gestation period, letting PWC staff know what they needed to harvest that day.⁴
- Next PWC staff met with the patients waiting to be prepped for their abortions, and convinced them to consent to donate by saying that the donation will help cure diabetes, Parkinson's, and heart disease.⁵
- After an abortion, PWC staff collected the baby's remains and procured the body parts that were ordered.⁶ PWC staff then packed the tissues or body parts, and shipped them directly to the customer via FedEx.⁷
- Throughout the day, PWC staff updated the StemExpress Daily Task Page website, informing both StemExpress and all other participating abortion businesses' staff of certain patient details via their responses to certain requests.⁸
- PWC staff further shared details from patients' private medical files with StemExpress via forms such as the StemExpress form "Patient and Sample Information Form for Research Study," which asks for the following patient information: name or kit ID, mother's date of birth, mother's ethnicity, date collected (i.e., date of abortion), and gestational age at time of blood draw. The form admonishes, "Please fill out and return with the samples to ensure timely compensation!" Other information appearing on StemExpress Researcher Procurement Forms includes patient height, patient weight, patient smoking history, 11 and

² Digoxin is a heart medication that sometimes is injected into the amniotic fluid or fetus to cause fetal demise before surgical or induction abortion. *See* Abortion in California: A Medical-Legal Resource, *available at* http://californiaabortionlaw.com/wp/?page_id=135.

³ StemExpress Drop-Down Ordering Menu, attachment 2.

⁴ PWC00046, PWC00023-PWC00024.

⁵ BioMed IRB Informed Consent to Participate in a Clinical Research Study, Sponsor: StemExpress, LLC, attachment 3; *see also* PWC00023.

⁶ PWC00023-PWC00024, PWC00040-PWC00042, PWC00054-PWC00057.

⁷ PWC00029-PWC00030, PWC00032-PWC00034, PWC00040-PWC00042, PWC00050-PWC00052. FedEx is the primary shipping method for StemExpress samples. FedEx pickups were scheduled every Tuesday and Thursday for Lab #1 specimens, and tissue samples were dropped off directly with FedEx. For each package, the weight was always listed as 4 lbs. *See* PWC00029-PWC00031, PWC00032. One document stated that the declared value should always be \$1,250 per sample, PWC00030, and another form indicated that the declared value of blood specimens should be \$500 and of tissue specimens. \$750, PWC00033.

⁸ PWC00046-PWC00048.

⁹ PWC00026.

¹⁰ PWC00026.

¹¹ PWC00027.

fetal sex. 12 PWC staff further disclosed information from patient data sheets with StemExpress. 13

StemExpress's stunning revenue growth five years after its formation belies the notion that the firm was not operating for profit. In 2010, its revenue was \$156,312; during 2011, that figure more than doubled to \$380,000; a year later, in 2012, StemExpress's revenue nearly tripled to \$910,000; by 2013, its revenue was \$2.20 million; then in 2014, the revenue had once again more than doubled to \$4.50 million. Based on its three-year revenue growth of 1,315.9%, *Inc. Magazine* named StemExpress one of the fastest-growing privately held companies in the U.S.¹⁴

This revenue growth accompanied an aggressive marketing strategy directed toward abortion businesses. StemExpress distributed its brochure at a conference hosted by the National Abortion Federation (NAF). The brochure promised businesses they would be "[f]inancially profitable" if they allowed StemExpress to procure tissue from the businesses. The brochure also said "By partnering with StemExpress" the businesses will not only help research "but [they] will also be contributing to the fiscal growth of [their] own clinic[s]." ¹⁵

When StemExpress was formed, billing records show the firm was procuring fetal tissue from four businesses. By the end of 2014, the firm had "relationships with more than 30 procurement sites across the country." However, many of those procurement sites had multiple locations, making the actual number nearly 100. In 2015, StemExpress tried to execute a contract with NAF that would have given the firm potential access to nearly 200 additional locations. Its overall strategy was to provide on-demand body parts to researchers. In order to do that, the firm needed a ready supply of fetal tissue. The only way to achieve that was to dramatically increase the number of abortion businesses from which it would obtain fetal tissue.

Presidential Women's Center, Inc.'s Contract with StemExpress

On February 14, 2014, PWC signed a contract with StemExpress providing:

Presidential Women's Center will provide, and StemExpress will pay the reasonable costs for, services and facilities . . . associated with . . . the removal of fetal organs from POCs [(products of conception)]; 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.¹⁷

¹² PWC00029.

¹³ See PWC00029.

¹⁴ The 500: Get to know the 500 fastest-growing privately held companies in America, INC., Sept. 2014, at 137.

¹⁵ StemExpress Brochure Distributed at NAF Conference, attachment 6 (key text highlighted).

¹⁶ Complaint at para. 17, StemExpress, LLC v. Center for Medical Progress, No. BC-589145 (L.A. Super. Ct. filed Jul. 27, 2015).

¹⁷ PWC0001.

In return, StemExpress contracted to pay PWC \$50.00 per 60ccs of maternal blood and \$75.00 for the collection of fetal tissue, if the collection was handled solely by PWC staff. If StemExpress staff participated in the collection, these payments were reduced. PWC agreed to invoice StemExpress monthly by number of tissue and number of maternal bloods procured.¹⁸

PWC agreed to allow StemExpress access to patients' charts and identity of donors "as necessary to obtain patients' consent for use of POCs and maternal bloods." ¹⁹

Presidential Women's Center, Inc.'s Profit

PWC billed StemExpress for the following amounts, and indicated that it was paid for the total amount, other than \$300.00 related to the 1/5/2016 invoice. Based on both the invoices and the "Protocol for Stem Express Research," it appears that PWC provided only fetal livers and villi to StemExpress. 21

¹⁸ PWC0001.

¹⁹ PWC0002: "StemExpress will not receive any information concerning identity of donors except as necessary to obtain patients' consent for use of POCs and maternal bloods."

²⁰ PWC00024.

²¹ It may also have provided placenta at some point. See PWC00029.

INVOICE DATE	ITEM	COST PER ITEM	TOTAL INVOICE AMOUNT	
4/25/2014	POC x3 (2 livers and 1 villi) Maternal blood x18	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,125.00	
5/9/2014	POC x3 (3 livers) Maternal blood x16	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,025.00	
5/23/2014	POC x3 (3 livers) Maternal blood x8	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$625.00	
6/12/2014	POC x1 (1 liver) Maternal blood x6	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$375.00	
6/20/2014	Maternal blood x6	Maternal blood @ \$50.00 each	\$300.00	
7/19/2014	Maternal blood x14	Maternal blood @ \$50.00 each	\$700.00	
8/1/2016	POC x2 (2 livers) Maternal blood x10	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$650.00	
8/28/2014	Maternal blood x13	Maternal blood @ \$50.00 each	\$650.00	
9/9/2014	POC x1 (1 liver) Maternal blood x11	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$625.00	
10/31/2014	POC x6 (6 livers) Maternal blood x12	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,050.00	
11/26/2014	POC x1 (1 liver) Maternal blood x14	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$775.00	
1/13/2015	Maternal blood x10	Maternal blood @ \$50.00 each	\$500.00	
1/31/2015	Maternal blood x15	Maternal blood @ \$50.00 each	\$750.00	
3/5/2015	unknown ²²		\$1,450.00	
4/30/2015	POC x12 (4 livers and 8 villi) Maternal blood x18	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,800.00	
7/3/2015	POC x16 (4 livers and 12 villi) Maternal blood x28	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$2,600.00	
8/3/2015	POC 11 (1 liver and 10 villi) Maternal blood x14	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,525.00	
9/2/2015	POC x12 (3 livers and 9 villi, including that from twins) Maternal blood x11	POC @ \$75.00 each Maternal blood @ \$50.00 each	\$1,450.00	
1/5/2016	unknown ²³		\$2,625.00	
TOTAL			\$20,600.00	

PWC did not provide this invoice in response to the Panel's Request No. 2.
 PWC did not provide this invoice in response to the Panel's Request No. 2.

Unsurprisingly, PWC indicated that they "prefer patients consent to both" blood and tissue donation, though they indicate that they would accept consent for blood only.²⁴

StemExpress's Profit and Loss

StemExpress paid \$75.00 for each fetal tissue sample it obtained from abortion businesses, and then transferred them to researchers for \$595 to \$910 per tissue or body part.

Payments from Customers to StemExpress

Customer	Date	Item	Cost	
Redacted by StemExpress	September 25, 2014	Human Fetal Tissue	\$5,950.00	
Redacted by StemExpress	September 25, 2014	Packaging- Gel Pack or Wet Ice	\$150.00	
Redacted by StemExpress	September 25, 2014	Local Delivery Flat Rate	\$2,250.00	
		Estimated Tax	\$730.64	
TOTAL:			\$9,080.64	
Redacted by StemExpress	November 14, 2014	Human Fetal Brains	\$3,340.00	
		Estimated Tax	\$292.25	
TOTAL:			\$3,632.25	
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (upper and lower limbs with hands and feet)	\$890.00	
Redacted by StemExpress	December 16, 2014	Human Fetal Tissue (calvarium matched to upper and lower limbs)	\$595.00	
		Estimated Tax	\$129.95	
TOTAL:			\$1,614.95	
Yale University	January 19, 2012	Fetal Brain Procurement	\$2,860.00	
Yale University	January 19, 2012	FedEx Priority Overnight	\$85.00	
Yale University	January 19, 2012	FedEx Priority Overnight	\$85.00	
Yale University	January 19, 2012	Fetal Brain Procurement	\$2,145.00	
Yale University	January 19, 2012	Credit for samples	-\$2860.00	
Yale University	January 19, 2012	Credit for FedEx	-\$85.00	

²⁴ PWC00023.

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Customer	Date	Item	Cost
TOTAL:			\$2,230.00

Attached is a sample of a StemExpress invoice to a customer.²⁵ A comparison of invoices, attorney-created accounting documents, and productions from multiple StemExpress customers shows that the firm may have made a profit when procuring and transferring fetal tissue, and passed a portion of that profit along to the businesses from which it obtained its tissue and blood specimens. The Panel's cost analysis shows StemExpress overstated some of its labor costs, and claimed as expenses shipping, supplies, and infectious disease screenings. These were costs charged to researchers.

²⁵ Sample StemExpress Invoice to Customer, attachment 7.

COMPARISON OF STEMEXPRESS COST ANALYSIS WITH GENERALLY ACCEPTED INDUSTRY STANDARDS FOR ONE UNIT OF FETAL TISSUE IN 2013

COST ITEMS AND ESTIMATE PRODUCED BY STEMEXPRESS

ADJUSTED BASED ON REASONABLE INDUSTRY STANDARDS

COSTS ALLOCATED TO MATERNAL BLOOD ESTIMATED AT 50%

Cost Item	Description	Estimated Time	Estimated Cost/Expense	Recalculated Time	Recalculated Cost/ Expenses	½ Costs for Maternal Blood
Procurement Management Labor	Receive and evaluate purchase order, enter into Computer system and task board, assign to clinics.	1 hour x \$35	\$25.00	.5 hour x \$35	\$12.50	\$ 6.25
Packaging Supplies Labor	Packaging all supplies needed for procurement.	1 hour x \$10	\$10.00	.5 hour x \$10	\$5.00	\$2.50
Shipping	Supplies to Clinic	N/A	\$15.00		\$15.00	\$7.00
Mileage	Mileage paid to technician (.56/mile)	N/A	\$75.00		\$75.00	\$35.00
Supply cost	Box, conical tube, media, petri dish, labels, biohazard bag, gel packs, etc.	N/A	\$30.00		\$30.00	\$15.00
Technician Base Labor	Patient consent, procurement, paperwork packaging.	8 hour x \$10	\$80.00	1 hour x \$10	\$10.00	\$5.00
Technician Supplemental Compensation	Technician Supplemental Compensation	N/A	\$30.00		\$0.00	\$0.00
Clinic Reimbursement	Technician space, storage of supplies, blood draw chair usage, consent space	N/A	\$55.00		\$55.00	\$27.50
Infectious Disease Draw	Supplies: tubes, labels, needle, biohazard bag, etc.	N/A	\$15.00		\$15.00	\$7.50
Infectious Disease Screening	Screening for HIV, HepB, HepC, LCMV	N/A	\$70.00		\$70.00	\$35.00
Shipping	Average Shipment cost to the Lab (blood and/or tissue)	N/A	\$20.00		\$20.00	\$10.00
Procurement Management Labor	Review paperwork, communications with courier, communications with researcher	1 hour x \$35	\$35.00		\$35.00	\$5.00
Product Receipt	Receipt of product at front desk, check into Sage, check into log	1 hour x \$15	\$15.00	.25 hour x \$15	\$4.00	\$2.00
Inventory & Supply Management	Prorated stores management	1 hour x \$20	\$20.00	.25 hour x \$20	\$5.00	\$2.50
			\$495.00		\$351.50	175.75

Attorneys for StemExpress created several cost estimates (orange numbers) that purport to show that Stem Express loses money each time it procures a fetal tissue sample and ships it to a customer. Shown in orange, the cost estimates produced by the attorneys are inconsistent with accounting records produced by StemExpress itself. For example, StemExpress lists Clinic Reimbursement which the Panel found was **not** an actual payment made by StemExpress. Also, the costs associated with shipping and infectious disease are passed on to the customer and thus are **not** a cost to StemExpress. Finally, management labor costs at one hour per item ordered, which are counted twice, are dramatically inconsistent with the number of orders actually handled by StemExpress. Similarly, StemExpress estimates do **not** allocate any costs (such as mileage) to maternal blood which is harvested at the abortion business at the same time the human fetal tissue is harvested.

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue \$250.00
Disease screening charged to client \$125.00
Shipping charged to client \$85.00
Total Revenue obtained from this sale \$460.00
Estimated cost of Tissue (per above) \$175.75
Excess of revenue over cost \$217.00

Sample review of a sale of fetal tissue to customer Baylor per invoice #1940 of 1/12/2013

Sale price for Tissue \$250.00
Disease screening charged to client \$125.00
Shipping charged to client \$85.00
Total Revenue obtained from this sale \$460.00
Estimated cost of Tissue (per above) \$351.00
Excess of revenue over cost \$108.50

Violation of Applicable Laws

Under 42 U.S.C. § 289g-2, 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." Anyone who violates this law is subject to a fine "not less than twice the amount of the valuable consideration received" and/or imprisonment for up to ten years. ²⁸

Florida state law includes a nearly identical prohibition. Under Fla. Stat. § 873.05, a "person may not knowingly advertise or offer to purchase or sell, or purchase, sell, or otherwise transfer, a human embryo for valuable consideration," and further, "may not advertise or offer to purchase, sell, donate, or transfer, or purchase, sell, donate, or transfer, fetal remains obtained from an abortion."

The Florida statute's definition of "valuable consideration" is virtually identical to that of the federal statute. § 873.05(3) provides that this activity is a felony of the second degree, and is subject to a fine of up to \$10,000 and/or imprisonment for up to 15 years for a first offense. ³⁰

²⁶ 42 U.S.C. § 289g-2(a).

²⁷ 42 U.S.C. § 289g-2(e)(3).

²⁸ 42 U.S.C. § 289g-2(d).

²⁹ Such consideration "does not include the reasonable costs associated with the removal, storage, and transportation of a human embryo." Fla. Stat. § 873.05(1). It may include such costs as associated with a fetus, as well as the other activities for which StemExpress set a flat fee for payment to PWC.

³⁰ Fla. Stat. § 775.082-083; see also Fla. Stat. § 775.084 for sentencing of repeat offenders.

Similarly, Fla. Stat. § 873.01 provides that "no person shall knowingly offer to purchase or sell, or puchase sell, or otherwise transfer, any human organ or tissue for valuable consideration," and further, "no for-profit corporation or any employee thereof shall transfer or arrange for the transfer of any human body part for valuable consideration." The statute lists examples of human body parts that may not be purchased, sold, or transferred in that way, and livers are specifically named. Again, this activity is a felony of the second degree, and is subject to a fine of up to \$10,000 and/or imprisonment for up to 15 years for a first offense.³¹

And Fla. Stat. § 390.0111(6) prohibits using "any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to *or subsequent to any termination of pregnancy procedure*" (emphasis supplied).

The foregoing analysis establishes with a high level of probability that PWC, at least through its contract with StemExpress, routinely violated 42 U.S.C. § 289g-2 and Fla. Stat. § 873.05. This is established by the transactions involving the transfer of fetal tissue to numerous entities for consideration, via its contract with StemExpress, that exceeded statutorily allowable costs.

Finally, it appears that PWC may be in violation of HIPAA protected health information law, 42 U.S.C. § 1320d-6(a)(3), by disclosing individually identifiable health information to another person, which is usually punishable by a fine of up to \$50,000 and/or imprisonment for up to 1 year, but when the personal health information was shared "for commercial advantage," as when PWC transferred protected health information in order to sell fetal tissue, the penalty is a fine of up to \$250,000 and/or imprisonment for up to 10 years. In their contract, PWC and StemExpress agreed that HIPAA guidelines applied to patients' information and that the charts were "privileged" and merited "confidentiality," but based on the information requested on the StemExpress forms, such as "Patient and Sample Information Form for Research Study," described above, it seems that they did not adhere to the law or even to their own internal guidelines. This form admonishes, "Please fill out and return with the samples to ensure timely compensation!," pressuring PWC to improperly share patient information in order to receive their checks. Less specific information than that on the form has been deemed protected health information in at least some states. The province of the protected health information in at least some states.

Based on the facts outlined above and the supporting documentation, I urge your office to conduct a thorough investigation into whether Presidential Women's Center, Inc., violated these statutes and regulations, and, if you agree that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov, or Mary Harned, at (202) 480-7160, Mary.Harned@mail.house.gov.

³¹ Fla. Stat. § 775.082-083; see also Fla. Stat. § 775.084 for sentencing of repeat offenders.

³² PWC0002: "Any information obtained from [PWC] patients' charts shall be privileged, and StemExpress will treat the information in order to preserve the confidentiality of the patients. . . . This will always be done in accordance with HIPAA guidelines."

³³ PWC00026.

³⁴ PWC00026.

³⁵ See, e.g., Planned Parenthood of the Great Northwest v. Bloedow, 350 P.3d 660 (Wash. Ct. App. 2015).

Sincerely yours,

Marsha Blackburn

Chairman

Select Investigative Panel of

the Committee on Energy and Commerce

Attachment(s)

cc: The Honorable Jan Schakowsky

Ranking Member

Select Investigative Panel of

the Committee on Energy and Commerce

The Honorable Vern Pierson

El Dorado County District Attorney