

EXHIBIT B

Selections from the Majority Staff Report for
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**HUMAN FETAL TISSUE RESEARCH:
CONTEXT AND CONTROVERSY**

MAJORITY STAFF REPORT

PREPARED FOR THE USE OF THE

**COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

**ONE HUNDRED FOURTEENTH CONGRESS
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logs, procurement technician compensation policies, estimates of costs, and other information. Because of the technical aspects of manufactured isolated cells, the Committee's inquiry regarding StemExpress focused on its business in transferring unaltered fetal tissue.

1. Contracts with Planned Parenthood Affiliates

StemExpress's contracts with the Planned Parenthood affiliates set forth the basic framework for its acquisition of fetal tissue from them.²⁴⁶ The company's contracts with both PPMM and PPNC defined "product of conception" as "any fetal organ or other fetal or placental material taken from the human uterus during an abortion."²⁴⁷ The contracts stated:

Planned Parenthood Mar Monte [or PPNC, as applicable] 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. . . . 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.²⁴⁸

As with ABR's contracts with Planned Parenthood, the definition of "POC" and the terms of the contract seem to imply that StemExpress might pay \$55 per fetal organ specimen to the clinics. However, StemExpress's attorneys represented to the Committee: "StemExpress was not invoiced by PPSM [sic] and PPMM per specimen. Rather, the PP clinics invoiced StemExpress per POC, which includes placental, cord, or fetal tissue, that are procured for use in medical research."²⁴⁹ Accordingly, similar to ABR, StemExpress would purportedly pay \$55 for a single "useable" aborted fetus regardless of the number of specimens it obtained from the fetus and transferred to its customers. StemExpress reported to the Committee that its payments to Planned Parenthood pursuant to these contracts as of July 2015 were as follows:²⁵⁰

StemExpress Payments to Planned Parenthood Mar Monte Affiliate Clinics For Blood and Tissue Collection Costs (2013 - 2015 YTD)			
	2013	2014	2015 YTD
Annual Payments for Blood	\$ 13,105.00	\$ 14,000.00	\$ 2,600.00
Annual Payments for Tissue	\$ 20,175.00	\$ 24,425.00	\$ 12,370.00
Annual Payments Total	\$ 33,280.00	\$ 38,425.00	\$ 14,970.00

StemExpress Payments to Planned Parenthood Shasta Pacific Affiliate Clinics For Blood and Tissue Collection Costs (2013 - 2015 YTD)			
	2013	2014	2015 YTD
Annual Payments for Blood	\$3,820.00	\$2,550.00	\$30.00
Annual Payments for Tissue	\$2,420.00	\$4,290.00	\$715.00
Annual Payments Total	\$6,240.00	\$6,840.00	\$745.00

After the CMP videos were released, StemExpress ended its business relationship with Planned Parenthood.²⁵¹

2. StemExpress's Payments to Its Technicians

As with ABR's technicians, StemExpress's technicians working at Planned Parenthood were located onsite to obtain fetal tissue specimens from procured fetuses.²⁵² Unaltered fetal tissues were packaged and shipped on the same day they were collected.²⁵³ At the clinics, "StemExpress personnel were typically provided with access to (1) an office and/or work room to perform their administrative functions, including paperwork related to procurement and shipping; and (2) a counter space made available in the clinic laboratory to procure POCs after termination procedures."²⁵⁴

StemExpress paid its technicians \$15 an hour.²⁵⁵ Unlike ABR, StemExpress also provided technicians "\$50 for the first tissue procured from any given POC" and \$25 per tissue for any additional ones from the same fetus.²⁵⁶ Prior to September 1, 2012, they received \$50 per tissue specimen obtained.²⁵⁷ These bonus payments appear to be valuable consideration paid to the technician for acquiring the fetal tissue and do not appear to be tied to any additional expenses accrued in the process.

3. Example of a StemExpress Fetal Tissue Transaction

Evaluating a sample StemExpress fetal tissue transfer process helps demonstrate StemExpress's business operation. In addition to providing its contracts with Planned Parenthood affiliates and information about its technicians' pay, StemExpress provided the Committee with procurement logs and invoices sent to its customers for sample periods. Unlike ABR, StemExpress's procurement logs do not document the length of time the technician spent obtaining the specimens. However, cross referencing the procurement logs, the customer invoices, and the underlying contracts with Planned Parenthood still provides key information.

For example, in August of 2012, a StemExpress technician obtained a 19-week-old fetus at a PPMM clinic.²⁵⁸ From that one fetus, StemExpress sold its brain for \$250 to one customer,²⁵⁹ its liver for \$250, its thymus for \$250, and its torso skin for \$250 to a second customer.²⁶⁰ Those fees are merely the service fees for the specimens themselves; StemExpress separately charged each of its customers for shipping/delivery, disease screening, cleaning, and freezing, as applicable.²⁶¹ So, from that single fetus, for which StemExpress paid PPMM \$55, StemExpress charged its customers a total of \$1,000 for tissue specimens. The procuring technician was presumably paid \$15 an hour, plus \$200 in bonuses for the four specimens obtained.²⁶² Indeed, within the sample range of procurement logs and invoices the Committee obtained, StemExpress's fee per fetal tissue ranged from \$250 to \$595.²⁶³ But StemExpress reportedly now charges \$595 per sample,²⁶⁴ so at today's prices the total for the specimens obtained from the sample fetus would be \$2,380.

Fetal Tissue Specimens StemExpress Transferred From PPMM 19-Week Fetus (No. 0807120602)		
Invoice Number	Specimen	Specimen Service Fee
1710	Brain	\$250
1701	Liver	\$250
	Thymus	\$250
	Torso Skin	\$250
TOTAL:		\$1,000

4. StemExpress's Purported Cost Justification

As with ABR, the example fetal tissue transfers seem to show StemExpress charging specimen fees far in excess of its actual direct costs. While StemExpress similarly claimed that its payments were only allowable reimbursements for its incurred costs, it also had apparently

not conducted any contemporaneous cost analysis when setting its fee structure. In response to the Committee's request that StemExpress provide a detailed accounting of the costs it incurred in transferring unaltered fetal tissue, StemExpress responded, stating:

StemExpress's modest accounting system does not allow for immediate reporting of revenue or line-item expenses associated with particular types of tissues. . . . StemExpress had manually reviewed records for 2014 and determined that unaltered fetal tissue procured from Planned Parenthood affiliates generated approximately \$50,000 in gross (pre-tax) revenue against expenses in excess of \$75,000. StemExpress charges researchers a fee of roughly \$500 to \$600 for unaltered tissues, but incurs directly associated expenses of approximately \$750 to \$1000 for each procurement. Part of those expenses include the roughly \$30,000 paid to two Planned Parenthood clinics for reasonable costs and expenses Other expenses include compensation paid to StemExpress's tissue procurement personnel and costs associated with training, packaging and ordering supplies, overnight shipping charges, infectious disease screening, and general overhead²⁶⁵

There are several problems with this purported explanation. First, StemExpress's purported breakdown of expenses for each individual transfer is cursory; StemExpress has provided the Committee no evidence to support these conclusory claims. Second, StemExpress stated that fetal tissue transfers constitute 10% of its business, and that unaltered fetal tissue transfers constitute only 1%.²⁶⁶ Yet in subtracting costs from the revenue it gained from transfers of unaltered fetal tissue, it attempts to subtract the entire \$30,000 it paid to Planned Parenthood – an amount that presumably covers costs for both unaltered fetal tissue transferred and fetal tissue used for manufactured isolated cells. If the breakdown of fetal tissue obtained from Planned Parenthood mirrors that of the company's obtained fetal tissue in general – 10% fetal tissue transferred unaltered and 90% used for manufacturing isolated cells – then StemExpress should only count ten percent of the \$30,000 in fees paid to Planned Parenthood, \$3,000, against its income. Third, StemExpress claims that the fees it charges for fetal tissue specimens cover expenses for "overnight shipping [and] infectious disease screening."²⁶⁷ Yet, the invoices provided clearly show that StemExpress separately charged customers for overnight shipping and infectious disease screening; those were not part of the specimen fee.²⁶⁸ Lastly, StemExpress's attempted aggregation to its entire unaltered fetal tissue transfer business is subject to the same problems as the aggregation approach used by ABR.

D. Novogenix Laboratories, LLC

Novogenix Laboratories, LLC was incorporated in February 2010.²⁶⁹ The company's attorney informed the Committee that from its creation until 2015, it had contracts with 102 clients, all but three of which were labs and academic institutions.²⁷⁰ Beginning in March 2010,

by PPFA's then-existing guidance."³⁰⁸ Indeed, the attorneys stated that the affiliates had only actually tried to determine their costs at the insistence of the Committee: "In response to your October 26 letter . . . the affiliates have each performed a good-faith accounting of their costs associated with facilitating fetal tissue donation."³⁰⁹ A little over a week after Chairman Grassley sent his October 2, 2015 letter, and well before Planned Parenthood substantively responded to it, Planned Parenthood announced it would no longer accept any payments in connection with its fetal tissue transfer programs.³¹⁰

5. Planned Parenthood's Post Hoc Cost Calculations Created in Response to the Committee's Inquiry

Unsurprisingly, those affiliates' *post hoc* accounting of their costs associated with facilitating fetal tissue argued that they had done nothing improper.³¹¹ They include a laundry list of purported expenses. While § 289g-2 only allows for reasonable payments associated with "the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue," Planned Parenthood has sought to invoke that narrow exception to cover the following universe of purported costs:³¹²

NIH Panel's Recommended Exception to the Ban on Fetal Tissue Payments	289g-2's Statutory Exception to the Ban on Fetal Tissue Payments
"payment for reasonable expenses occasioned by actual retrieval, storage, preparation, and transportation of the tissues"	"reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue"
Planned Parenthood's Purported Costs Invoked to Justify the Fetal Tissue Payments it Received	
<p>PPLA: staff time preparing surgical list and internal coordination - front desk, registered nurse; staff time coordinating with Novogenix representative - center manager, front desk, medical assistant; staff time attending morning meetings' discussion of donation program - center manager, clinician, front desk, licensed vocational nurse, medical assistant, registered nurse, surgical technician; staff time managing and overseeing tissue donation program - medical director, vice president of patient services; supplies/equipment - disposable gloves, disposable masks, laundry, shoe covers, underpads coordination tissue collection and processing - management and general overhead; staff time discussing program with patients, obtaining consent or declination - clinician, medical assistant, registered nurse; staff time preparing, processing, and photocopying consent forms - front desk; registered nurse; supplies and equipment - photocopies, printing, slipsheets; obtaining patient consent for donation - management and general overhead; staff time transferring tissue to Novogenix representative - surgical technician; staff time disposing of unused tissue - surgical technician; staff time invoicing company - administrative assistant for patient services; staff time revising electronic health records - nurse informatics; transportation, preservation, quality control and storage - management and general overhead; use of space by company representative - dedicated work areas, utilities, taxes, depreciation, repairs and maintenance; shared common areas; use of facility space - management and general overhead.³¹³</p>	

PPMM: staff time coordinating and managing patient flow – health services specialist, abortion coordinator; staff time supervising/coordinating with StemExpress Representative – center manager, chief medical office; tissue collection and processing supplies/equipment – disposable gloves, flush solutions, gauze, band-aids; tissue collection and processing operations costs – telephone usage, postage, office supplies, other direct costs; **general administrative and medical overhead**; staff time interpreting consent forms – health services specialist; staff time verifying and signing consent forms – clinician; staff time scanning consent forms – check-out specialist; obtaining patient consent supplies and equipment – photocopies; obtaining patient consent – operations costs; obtaining patient consent - **general administrative and medical overhead**; transportation, staff time cleaning StemExpress equipment – health services specialist; staff time invoicing StemExpress – assistant lab manager, accountant; transportation, preservation, quality control, and storage - shipping labels; operations costs, **general administrative and medical overhead**; use of space by StemExpress representative – dedicated work areas, utilities, taxes, depreciation, repairs and maintenance; storage areas.³¹⁴

PPNC: staff time supervising/coordinating with StemExpress Representative – vice president of medical services, center director, abortions services coordinator; coordinating tissue collection and processing operations costs – telephone usage, postage, office supplies, other direct costs; coordinating tissue collection – **general administrative and medical overhead**; staff time verifying and signing consent forms – **general administrative and medical overhead**; staff time scanning consent forms – flow coordinator; obtaining patient consent – **general administrative and medical overhead**; staff time coordinating courier service for StemExpress representative – flow coordinator; staff time screening donated tissue – medical director; staff time invoicing StemExpress – medical services manager; transportation, supplies and equipment – autoclave sterilization indicator tape, autoclave sterilization indicator strip, tubing for sterile instrument transportation; transportation, preservation, quality control, and storage – operation costs, general administrative and medical overhead; use of space by StemExpress representative – dedication work areas, utilities, taxes, depreciation, repairs and maintenance; storage areas; **general administrative and medical overhead**.³¹⁵

PPPSW: staff time communicating with ABR representative prior to collection – front desk, center manager, flow coordinator, medical assistant; staff time supervising/coordinating with ABR representative – center manager, flow coordinator, medical assistant, supplies/equipment for coordinating tissue collection and processing – chucks, disposable gloves, Ziploc bags; **general administrative and medical overhead**; staff time discussing programs with patients, obtaining consent – medical assistant; staff time preparing consent forms, whiteboard, and anonymized consent list – front desk, medical assistant, manager, flow coordinator; staff time sending consent forms to administrative office – front desk; supplies and equipment for obtaining patient consent – photocopies; obtaining patient consent, **general administrative and medical overhead**; extra tissue examination time – medical assistant, flow coordinator; staff time transferring tissue to ABR representative – medical assistant, flow coordinator; staff time managing deliveries, moving boxes, and discarding documents for ABR representative – center manager, medical assistant, front desk; staff time coordinating courier service for ABR representative – front desk, medical assistant, center manager; staff time installing shelf for ABR representative – maintenance; shelf for ABR representative; transportation, preservation, quality control, and storage – **general administrative and medical overhead**; use of space by ABR representatives – dedicated work areas, utilities, taxes, depreciation, repairs, and maintenance; shared common areas; use of facility space – general administrative and medical overhead.³¹⁶

In short, Planned Parenthood has attempted to shoehorn a vast array of indirect or tenuously related costs into § 289g-2's exception, including attributing several thousands of dollars in costs to amorphous "General Administrative & Medical Overhead." As noted above, interpreting § 289g-2's exception this broadly would clearly be at odds with the primary purpose of the law, which is apparent from the legislative history. Any company could simply shift

unrelated costs into such categories to hide actual profits obtained from the transactions - the very scenario Senator Smith described when trying to resolve the issue in 1999.

Accordingly, there is reason to question whether Planned Parenthood fully complied with federal requirements relating to fetal tissue transfer payments. As noted above, when PPFA learned that its affiliates had failed to comply with the policies it had in place to prevent breaking the law, PPFA reportedly contacted the affiliates and then modified PPFA accreditation reviews in a manner that facilitated the continuation of those fetal tissue payments. PPFA's and the affiliates' actions may implicate the federal criminal conspiracy statute, 18 U.S.C. § 371.

F. Continued Lack of Oversight and Enforcement

In 2000, Congressman Bliley referenced the fetal tissue laws within NIH Revitalization Act of 1993, lamenting:

[O]ver the last 7 years, since this bill became the law of the land, there has been no government oversight of any type concerning whether this important law is being followed. We contacted the National Institutes of Health, and it informed us that since the law was passed the agency has not reviewed at all whether the law is being complied with. We contacted the Department of Justice, and their representatives told us the same thing, even though the 1993 law is a criminal statute with criminal enforcement provisions.³¹⁷

Unfortunately, the situation has not changed much since then. While the GAO did nominally conduct reviews in 1997 and 2000, they were cursory and fundamentally too limited to be meaningful evaluations.³¹⁸

Moreover, 42 U.S.C. § 289g-1 required substantial documentation in order to implement the NIH Panel's recommended safeguards for fetal tissue transplantation research. That documentation was to be kept available for audit by the HHS Secretary. As part of this investigation, Chairman Grassley asked HHS how many times the HHS Secretary had exercised his or her authority to conduct audits.³¹⁹ In response, HHS informed the Committee that from the time the law was passed in 1993 through 2007—the last year it applied to any ongoing HHS research—the Secretary *never* conducted a *single* audit.³²⁰

Chairman Grassley also contacted the Department of Justice and FBI to ask how many investigations of possible violations of 42 U.S.C. §§ 289g-1 and g-2 they had undertaken since the laws' enactments, how many of those investigations led to prosecutions, and how many of those prosecutions led to convictions.³²¹ In response, the Justice Department wrote that, since their enactments in 1993, there have been no prosecutions brought under either law.³²² As best as the Department could tell, there had only ever been two investigations for violations of § 289g-2.³²³ Those investigations were related to the companies at issue in the undercover 20/20 video in 2000: one was of the Anatomic Gift Foundation and the other was of Dr. Jones, the