EXHIBIT A

Selections from the Final Report of the Select Investigative Panel of the U.S. House of Representatives Energy & Commerce Committee, December 30, 2016

Final Report

Select Investigative Panel

of the Energy & Commerce Committee
December 30, 2016

federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.

- In response to the Belmont Report, HHS and the FDA significantly revised their human subjects regulations in 1981. The Common Rule applies to research projects that receive funding from federal agencies, requiring three steps to be fulfilled before the research can take place: 1) the human subject must give informed consent; 2) an Institutional Review Board (IRB) must review the proposed research project; and 3) the institution conducting the research must file an assurance of compliance with the federal agency that is providing the funding.

- The Panel's investigation revealed evidence that the IRB process used by some fetal tissue procurement businesses is often grossly insufficient. For instance, on March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of federal regulations, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval. BioMed IRB's executive director informed the Panel on April 4, 2016, that in regards to those records, "there are none." This is an apparent direct violation of federal regulations.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI). PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, provision of health care, or payment for the provision of health care to the individual.

- The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

B. Laws regulating anatomical gifts for transplantation, therapy, research, and education

- Laws regulating anatomical gifts are also heavily centered on the need for informed consent. Additionally, federal and many state laws explicitly prohibit the sale of human body parts.

- The National Organ Transplant Act (NOTA) provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or

The **Advisory Committee on Human Radiation Experiments** (1994-1995), created by President Clinton, investigated human radiation experiments conducted from 1944-1974, while his second commission, the **National Bioethics Advisory Commission**, set out in part to "familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects."[38]

President George W. Bush's **Presidential Council on Bioethics** (PCBE) is perhaps most renowned for the academic seriousness with which it approached bioethics. Guided by the belief that respect for human life and advancing biotechnology were compatible, President Bush appointed a diverse group of scientists and ethicists to the Council to advise him, particularly in regard to embryonic stem cell research. President Bush was especially concerned that research using embryonic stem cells, which he believed ended human lives, was unethical. He relied on policy recommendations from the PCBE to promote bills prohibiting biomedical practices he found morally objectionable. For example, the Fetus Farming Prohibition Act of 2006 was a response to the PCBE's report *Reproduction and Responsibility,* whose policy recommendations attempted to limit questionable practices, particularly by instituting (at least temporarily) moratoriums on those affecting reproduction.[39] The Fetus Farming bill made it a federal crime to be involved in interstate commerce to acquire "human fetal tissue knowing that a human pregnancy was deliberately initiated" to provide the tissue.[40]

The Panel's research found that—even with the material produced by these commissions—answers to many questions were out of date or nonexistent. Of particular concern are current practices in tissue and organ donation; research ethics and the revolution in biotechnology; the ability of the regulatory agencies to address misconduct; and the role of law enforcement. Many of the Panel's questions directed to the Federal Drug Administration and the National Institutes of Health could not be answered at all. The U.S. Department of Justice wrote to the Panel that it had never conducted training on the criminal statute that makes profiting from human fetal tissue sales a felony. The same letter could provide no example of attorney training or convictions under the statute.

4. HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule (Privacy Rule) protects all individually identifiable health information held or transmitted by a covered entity or its business associate and calls this information protected health information (PHI).[41] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual (*e.g.*, name, address, birth date, Social Security number), and includes demographic data relating to an individual's past, present, or future physical or mental health condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.[42]

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[38] *See* Exec. Order No. 12975, "Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission" (1995), https://bioethicsarchive.georgetown.edu/nbac/about/eo12975.htm.
[39] *See* Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics (2004), https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/.
[40] Pub. L. No. 109-242; 42 U.S.C. § 289g-2.
[41] 45 C.F.R. § 160.103.
[42] *Id.*

A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires[43] or as the individual or their representative authorizes in writing. HHS may impose civil penalties on covered entities that fail to comply with the Privacy Rule. Further, both a covered entity that discloses and any person who knowingly obtains PHI in violation of the Privacy Rule can face criminal fines or imprisonment.[44]

The Panel's investigation uncovered a series of business contracts between StemExpress, a tissue procurement business (TPB), and several abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

The Panel's investigation indicates that StemExpress and Planned Parenthood Mar Monte (PPMM), Planned Parenthood Shasta Pacific (PPSP), and Family Planning Specialists Medical Group (FPS) (the abortion clinics) committed systematic violations of the HIPAA Privacy Rule from about 2010 to 2015. These violations occurred when the abortion clinics disclosed patients' individually identifiable health information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

From about 2010 to 2015, the abortion clinics (covered entities under HIPAA) permitted employees of StemExpress (a non-covered entity) to enter their clinics and procure human fetal tissue from aborted infants, obtain PHI about their patients, interact with patients, and seek and obtain patient consent for tissue donation.[45] StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' PHI. Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the clinics.[46]

The abortion clinics and StemExpress violated the HIPAA privacy rule because: (a) the disclosures of patients' PHI made by the abortion clinics and received by StemExpress were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye or tissue transplantation or for research; (b) the consents for fetal tissue donation ostensibly obtained by StemExpress from the abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (c) the disclosures of patients' PHI made by the abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (d) StemExpress is not a "business associate" of the abortion clinics under HIPAA.

The abortion clinics could have directly consented their patients for tissue donation and entered an agreement with StemExpress to provide a limited data set regarding the patients they were seeing on a particular day.[47] Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

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[43] 45 C.F.R. § 164.502(a).
[44] Pub. L. No. 104-191; 42 U.S.C. §§ 1320d-5-1320d-6.
[45] *See* Clinic Procedures & Policies, produced by StemExpress, Exhibit 2.1.
[46] *See* Standard Operating Procedure, produced by StemExpress, Exhibit 2.2.
[47] *See* 45 C.F.R. § 164.514(e).

These disclosures made by the abortion clinics to StemExpress were intentional and purposeful.[48] StemExpress employees were handed a patient's medical chart by her healthcare provider in blatant violation of the HIPAA privacy rule.

B. Laws Regulating Anatomical Gifts for Transplantation, Therapy, Research, and Education

1. National Organ Transplant Act

The National Organ Transplant Act (NOTA)[49] was enacted in 1984, providing for the establishment of the Task Force on Organ Transplantation. The Act also authorized the Secretary of Health and Human Services to make grants for organ procurement organizations, created the Organ Procurement and Transplantation Network (OPTN), created the Scientific Registry of Transplant Recipients, and created an administrative unit within HHS to administer these activities. Importantly, NOTA included a criminal prohibition against the exchange of organs for transplantation for valuable consideration.[50]

NOTA provides that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. . . . Any person who violates [] this section shall be fined not more than $50,000 or imprisoned not more than five years, or both." The term "human organ" is defined to include fetal organs and subparts of organs.[51]

2. Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act (UAGA), a model statute first available in 1968 and most recently amended in 2009, was written to facilitate organ donation for transplantation, therapy, research, and education by ensuring that state laws are consistent across the country.[52] The UAGA, adopted in every state in some form, includes stillborn babies and fetuses in the definition of "decedent" for purposes of obtaining consent from a relative before the deceased infant's body is donated for experimentation or transplantation. In the UAGA's official notes, the drafters explain that the inclusion of stillborn babies and fetuses ensures that they "receive the statutory protections conferred by this [act]; namely that their bodies or parts cannot be used for transplantation, therapy, research, or education without the *same appropriate consents* afforded other prospective donors."[53]

However, the notes also mention that states may choose to treat aborted fetuses

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[48] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[49] 98 P.L. 507; 98 Stat. 2339.
[50] *See* U.S. Dept. of Health & Human Services, Selected Statutory and Regulatory History of Organ Transplantation, http://organdonor.gov/about-dot/laws/history.html.
[51] 42 U.S.C. § 274e.
[52] *See* Revised Uniform Anatomical Gift Act (2006) (Last Revised or Amended in 2009), drafted by the National Conference of Commissioners on Uniform State Laws, http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf.
[53] *Id.*

6. Payments Received by Clinics

Between 2010 and the middle of 2015, StemExpress paid the clinics from which it procured fetal tissue a total of $152,460. Between 2010 and the middle of 2015, StemExpress paid the clinics a total of $366,443 for both blood and fetal tissue.[233] StemExpress produced over a hundred monthly invoices from PP affiliate clinics. Stem refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. StemExpress paid the following amounts for fetal tissue. These numerical sums are calculated by the Panel's forensic accountant from these invoices:

- $123,175 to Planned Parenthood Mar Monte
- $12,705 to Planned Parenthood Shasta Pacific
- $8,130 to Family Planning Services
- $4,875 to Presidential Women's Center
- $2,375 to Cedar River Clinics
- $1,200 to Camelback Family Planning.

Over the same time period (2010 through the middle of 2015), StemExpress paid the clinics a total of $213,983 for blood draws. StemExpress produced over a hundred monthly invoices from Planned Parenthod affiliate clinics. StemExpress refused to produce invoices for other clinics from which it procured fetal tissue. The Panel sought those invoices directly from those clinics. These numerical sums are calculated by the Panel's forensic accountant from these invoices.

StemExpress paid:

- $100,143 to Planned Parenthood Mar Monte
- $88,625 to Cedar River Clinics
- $10,905 to Presidential Women's Center
- $7,750 to Planned Parenthood Shasta Pacific
- $6,415 to Family Planning Services for blood.

[233] Planned Parenthood Mar Monte, Planned Parenthood Shasta Pacific, Planned Parenthood of Santa Barbara, Ventura & San Luis Obisbo Counties, Camelback Family Planning, Cedar Rivers Clinics, Family Planning Specialists Medical Group. Presidential Women's Center, and Women's Health Specialists produced to the Panel documents that reflected payments the entities had received from StemExpress, LLC. Panel staff conducted a forensic accounting analysis of those payments to determine the total amounts to the entities.

The middleman investigation, and in particular the investigation of StemExpress, produced information about several PPFA affiliate clinics.[965] In particular, it became clear that StemExpress was doing all the work to obtain consent for donation from individual patients, that StemExpress was doing the work of harvesting the fetal tissue after an abortion was complete, and that StemExpress was doing the work and passing on its costs of shipping to customers. This raised a profound issue for the Panel: Both the middleman and the PPFA affiliate clinic were claiming the same expenses against their revenue to show a loss on fetal tissue sales.

9. PPFA Affiliates and StemExpress Claim the Same Expenses

Attorneys for StemExpress created several cost estimates that purport to show that StemExpress loses money each time it procures a fetal tissue sample and ships it to a customer. These are graphically summarized in the column with orange numbers in the chart below.

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

[965] *See* Chapter V.A *supra.*

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

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 defined as "Technician space, storage of supplies, blood draw chair usage, consent space" which the Panel found was **not** an actual payment made by StemExpress to the clinics. 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 clinic at the same time the human fetal tissue is harvested.

StemExpress has consistently refused to produce subpoenaed accounting documents that the Panel requires to complete its analysis. In the summary below, StemExpress claimed as expenses various items that were reimbursed by customers. Our forensic accounting analysis revealed that if these reimbursements were accounted for, they would yield a profit to StemExpress.

Sample review of a sale of maternal blood 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

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

StemExpress and other productions reveal that the payments to Planned Parenthood affiliates are for each item of fetal tissue.[966] The graphic below summarizes the known payments to various Planned Parenthood clinics for fetal tissue.

Procurement Business	Planned Parenthood Clinic	2010	2011	2012	2013	2014	2015	Total
ABR	First Avenue	52,075	36,000	20,400	18,600	18,240	-	**145,315**
	Mar Monte	5,390	-	-	-	-	-	**5,390**
	Riverside	16,020	21,660	36,720	33,540	31,740	23,460	**163,140**
	Pacific Southwest	-	-	-	-	-	18,960	**18,960**
	San Diego	-	-	-	-	-	13,080	**13,080**
	San Jose	5,500	-	-	-	-	-	**5,500**
Stem Express	Mar Monte	2,910	48,388	74,625	40,220	40,630	18,955	**225,728**
	Shasta Pacific	-	-	2,520	8,340	8,690	1,375	**20,925**
Novogenix	Los Angeles	-	-	-	-	-	15,750	**15,750**
		81,895	**106,048**	**134,265**	**100,700**	**99,300**	**91,580**	**613,788**

10. Planned Parenthood Production Schedule of their Costs Associated with Fetal Tissue Donation

Deductions from the revenue summarized above were described in Planned Parenthood affiliates' cost estimates produced to the House Committee on Energy and Commerce to each show a net loss resulting from their participation in fetal tissue donation for research. Section 289g-2 makes certain costs associated with fetal tissue allowable as a deduction from and

[966] See StemExpress contracts with PP Mar Monte, PP Shasta Pacific and PP Santa Barbara, [Stem.House.OGR-_000001-6 and 000015-17/Stem.House.Select_0167-172 and 0181-0183], Exhibit 8.25.

12. Comparison of Costs Claimed by Planned Parenthood Affiliates and Expenses Claimed by Fetal Tissue Middleman StemExpress

The Panel took note of both StemExpress and the Planned Parenthood clinics listing the same expenses as costs against their revenue for fetal tissue transfers. In StemExpress' case, they list costs paid by the customer, but both StemExpress and Planned Parenthood list the same costs in their production to the Panel. This comparison is described in the graphic chart below.

StemExpress vs. Planned Parenthood

Cost Deduction Chart[974]

	Claimed By		
Cost Type	**Planned Parenthood**	**StemExpress**	**Comments: PP vs. SE**
Supplies	(Mar Monte) Y	Y	"Supplies/Equipment" for tissue collection and consent vs. "Supplies to clinics" and "supply costs"
Consent	(Mar Monte) Y	Y	"Staff time interpreting... verifying and signing...scanning" consent forms" vs. "patient consent," and "consent space"
Handling supplies	(Mar Monte) Y	Y	"Staff Time cleaning Stem Express Equipment" vs. "Storage of supplies"
Shipping supplies	(Mar Monte) Y	Y	"Shipping labels" vs. "packaging all supplies needed for procurement" and "Shipment to lab"
Work space	(Mar Monte) Y	Y	"Use of Space by StemExpress Representatives" vs. "technician space" and "consent space"

[974] Planned Parenthood Mar Monte and Shasta Pacific Fetal Tissue Costs [PPMM-HOU_E&C-000001-02, PPNC-HOU_E&C-000001-2], Exhibit 8.23.

Planned Parenthood Costs Compared to Allowable Reimbursements Under 42 U.S.C. § 289g-2

Planned Parenthood Affiliates Claimed Costs	Transportation	Implantation	Processing	Preservation	Quality Control	Storage
Planned Parenthood Mar Monte/SE						
Staff Time Coordinating and Managing Patient Flow	NO	NO	NO	NO	NO	NO
Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Interpreting Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Verifying and	NO	NO	NO	NO	NO	NO

Signing Consent Forms						
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Cleaning Stem Express Equipment	NO	NO	NO	NO	NO	NO
Staff Time Invoicing Stem Express	NO	NO	NO	NO	NO	NO
Supplies / Equipment	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Use of Space by Stem Express Representatives	NO	NO	NO	POSSIBLY	NO	NO

Staff Time Supervising / Coordinating with Stem Express Representative	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
Planned Parenthood Shasta Pacific						
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Verifying and Signing Consent Forms	NO	NO	NO	NO	NO	NO
Staff Time Scanning Consent Forms	NO	NO	NO	NO	NO	NO
Operations Costs	NO	NO	NO	NO	NO	NO
General Administrative & Medical Overhead	NO	NO	NO	NO	NO	NO
Staff Time Coordinating Courier Service for Stem	POSSIBLY	NO	NO	NO	NO	NO

14. Job Descriptions of Planned Parenthood Staff ***do not*** Include any Reference to Tasks or Responsibilities Associated with Fetal Tissue

After reviewing the cost schedules of Planned Parenthood affiliates, the Panel requested and obtained job descriptions from the counsel representing the entities. The Panel sought to determine whether job descriptions or job announcements included any reference to tasks related to fetal tissue donation. The Panel similarly sought any information that the affiliates' participation in fetal tissue donation required the hiring of new staff. The Planned Parenthood affiliates produced no evidence to support either job description adjustments or hiring of new employees due to the tasks involved in any aspect of fetal tissue donation. The chart below summarizes the job descriptions of the employees at the affiliates.

Review of Staff Time Claimed by Planned Parenthood as Part of Costs Associated with Collecting and Processing Fetal Tissue as Compared to Job Descriptions of Staff

Staff Title	Includes Fetal Tissue	Does Not Include Fetal Tissue
Planned Parenthood Mar Monte:		
Health Services Specialist: Provides direct service in all health centers, provides clients with accurate info regarding PP services, screens patient history, etc.		☐
Abortion Coordinator: Scheduling, notify patients of follow-ups, provide medical record transfers, serve as liaison between PPMM and outside lab to follow-upon concerns with results interpretation and transmission.		☐
Center Manager: Responsible for the day-to day management of all health center activities.		☐
Chief Medical Officer: Oversee maintenance of medical records, credentialing of staff, hire and supervise senior staff, represent PPMM on managed care plan committees, and local, state, and national task forces, committees and Boards.		☐
Clinician: Review and interpret medical/social history of patients, perform screening procedures/exams, interpret lab		☐

data, provide contraceptive methods, provide non-surgical abortion, act as medical consultant to clinic staff.		
Check-Out Specialist: Posts charges to and ensures accuracy of Electronic Practice Management system, sends CDS to billing department, handles patient check-out, calculates and collects fees, solicits contributions, schedules future appointments.		☐
Assistant Lab Manager: Match specimens to requisitions, prepare specimens for testing, notify clinics of positive results, perform/supervise laboratory testing in compliance with appropriate policies/guidelines.		☐
Accountant: Conduct analysis as needed for the purpose of verifying appropriate allocation of Accounts Payable duties, responsible for completeness and accuracy of Accounts Payable vouchers, review and reconcile vendor statements to include analyzing charges and payments. Verify and maintain all rental, lease, and contract accounts.		☐
Registered Nurse: Provide care for patients under established Medical Protocols, perform various medical procedures, administer medication, assess status of patients.		☐
Center Manager: Ensuring efficient coordination, management of workflow, efficient implementation of new services, and management of health center staff resources for services provided. Assure medical center's compliance with agency's state and federal regulations. Oversight of supervisory responsibilities in accordance with policies and applicable laws.		☐
Medical Assistant: Responsible for all supporting functions in the delivery of reproductive health care services. Assist patients by providing testing, screening,		☐

and education required for the provision of medical productive health care.		
Clinician: Provide quality patient care including exam, diagnosis, treatment, education and counseling for clients in accordance with agency protocols.		☐
Surgical Technician: Member of an operating room team during surgical and endoscopic procedures. Serves as a scrub technician in an operating room and provides direct and indirect care to patients before, during, and after surgery.		☐
Medical Director: Responsible for ensuring provision, coordination and oversight of medical services. Assumes responsibility for training, supervisor and evaluation of all clinicians in concert with medical Management Leadership.		☐
Vice President of Patient Services: Ensures the continuing provision of high quality services to all patients. Oversees laboratory services, research and training program teams and clinical compliance and risk management.		☐
Administrative Assistant for Patient Services: Provides secretarial and administrative support to the Vice President, Patient Services, Medical director, and others in the Patient Services department.		☐
Vice President of Medical Services: Responsible for the overall development, management, and supervision of clinic staff and services. Collaborates with other departments to provide community services. Responsible for center planning and fiscal management.		☐

Center Director: Direct oversight for the overall development, management, and supervision of center staff and services. Monitor client volume, capacity and productivity. Provide direct patient care approx. 10-20% of the time. Plan and implement new programs and services as needed.		☐
Abortion Services Coordinator: Assist with management of abortion services, assist Center Director with compliance to protocols and licensing standards, program management including audits, statistical reports, medical follow-up and maintenance of manuals.		☐
Medical Director: proposes recommendations on medical policies, reviews all medical protocols, serves as the Director of Abortion, Ultrasound, Sedation, and Colposcopy Services.		☐
Medical Services Manager: Works with VP of Medical Services and other staff in development of systems, processes, and forms to enhance efficiency at the centers, manages the proficiency testing program, manages the surgical and medication abortion reporting systems, responsible for the abortion complication reports and colposcopy correlation data systems.		☐
Planned Parenthood Pacific Southwest:		
Front Desk: Responsible for greeting and checking-in clients, preparing, scanning and coordinating paperwork, determining payer source, collecting fees/receipts and donations, collecting IDs, answering phones, scheduling.		☐
Center Manager: Manage and oversee the provision and delivery of efficient center operations and client services in a specialty services (abortion, permanent birth control, colpo/LEEP) setting, as prescribed by the Agency's protocols, policies, and procedures.		☐

[PP Witness #1]: How long, right now, is the average amount of time they spend with a patient?

PP: I would say about ten minutes.

[PP Witness #1]: Per patient.

PP: 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.[1007]

H. StemExpress and Planned Parenthood abortion clinics appear to have committed systematic violations of HIPAA

1. Summary

As discussed above, the Panel's investigation uncovered a series of business contracts between StemExpress[1008] and several Planned Parenthood abortion clinics. These contracts included provisions for the payment of fees by StemExpress to the Planned Parenthood abortion clinics for fetal tissue and maternal blood. StemExpress then resold the fetal tissue and blood to researchers.

StemExpress and at least two of these Planned Parenthood abortion clinics—Planned Parenthood Mar Monte (PPMM) and Planned Parenthood Shasta Pacific (PPSP)—appear to have committed systematic violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule from about 2010 to 2015. These violations occurred when the Planned Parenthood clinics intentionally disclosed patients' individually identifiable health

[1007] *See id.*

[1008] StemExpress and Stem-Ex are the same company.

information to StemExpress to facilitate the TPB's efforts to procure human fetal tissue for resale.

The Panel filed a complaint against each of these entities requesting a swift and full investigation by the Office of Civil Rights in the Department of Health and Human Services on June 1, 2016.

2. Legal Background

As discussed above,[1009] the HIPAA privacy rule (Privacy Rule) protects all "protected health information" (PHI) held or transmitted by a covered entity or its business associate.[1010] PHI identifies an individual, or can reasonably be believed to be useful in identifying an individual, and includes demographic data relating to an individual's health condition, health care, or payments for the provision of health care.[1011] A covered entity may not use or disclose an individual's PHI except as the Privacy Rule permits or requires,[1012] or as the individual or their representative authorizes in writing. Civil monetary penalties may be imposed, and criminal fines or imprisonment can follow violations of the Privacy Rule.[1013]

3. Factual Background

The Planned Parenthood abortion clinics are "covered entities" under HIPAA while StemExpress is not.[1014] StemExpress "procure[s] tissues and isolate[s] cells for researchers' individual needs in its own labs."[1015] From about 2010 to 2015, the Planned Parenthood abortion clinics collaborated with StemExpress by permitting StemExpress employees to: enter their clinics and procure human fetal tissue from aborted infants; obtain individually identifiable health information, or protected health information (PHI) about their patients; interact with patients; and seek and obtain patient consent for tissue donation.[1016] StemExpress embedded tissue procurement technicians inside the Planned Parenthood abortion clinics whose work sequence followed a daily routine:

1) A researcher/customer placed an order for human fetal tissue using an online business portal provided by StemExpress, requesting a particular gestational range for the fetal tissue.[1017]

[1009] *See* Chapter II.A.4 *supra.*
[1010] 45 C.F.R. § 160.103.
[1011] *Id.*
[1012] 45 C.F.R. § 164.502(a).
[1013] Pub. L. 104-191; 42 U.S.C. §§ 1320d-5–1320d-6.
[1014] *See* 45 C.F.R. Part 160.103 (Covered Entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.) *See also* OCR Privacy Brief, Summary of the HIPAA Privacy Rule, http://www.hhs.gov/sites/default/files/privacysummary.pdf (used as reference throughout this section).
[1015] StemExpress, About Us, http://stemexpress.com/about/.
[1016] *See* Clinic Procedures & Policies, Exhibit 8.40.
[1017] *See* Researcher Procurement Record, Exhibit 8.41.

2) The Planned Parenthood abortion clinic faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic.[1018]

3) The day the abortion procedures were scheduled, StemExpress posted the order on a website "task board" (order page) to be accessed by their procurement technician planted in the Planned Parenthood abortion clinic, or communicated the order to the tissue technician via email.[1019]

4) The StemExpress procurement technician informed the Planned Parenthood clinic what they wished to procure (*i.e.*, the type of tissue and gestational range) based on the order page, and the abortion clinic staff member provided the medical files, including PHI, for the patients with abortions scheduled for that day.[1020]

5) The StemExpress procurement technician then sought out particular patients *by name* and obtained their consent to donate fetal tissue while they were awaiting their procedures. The Planned Parenthood abortion clinic also permitted the procurement technician to interview patients and *obtain their PHI.*[1021]

6) StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page.[1022]

7) StemExpress paid the Planned Parenthood abortion clinic for each fetal tissue and each blood sample and then marked up the tissue four to six hundred percent for resale to the researcher.[1023]

The work sequence, when combined with supporting documentation, reveals that StemExpress did not have a medically valid reason to see, and the Planned Parenthood abortion clinics did not have a reason to provide, patients' PHI. Instead, the Planned Parenthood abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefited StemExpress and the Planned Parenthood abortion clinics.[1024]

[1018] *See* Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress (Jan. 10, 2013), Exhibit 8.42.
[1019] *See* Updated Task Assignment: Procurement Schedule Wednesday, 3/20/13 and Navigating the Task Board, Exhibit 8.43.
[1020] *See* StemExpress Emails, Exhibit 8.44.
[1021] *See* Clinic Procedures and Policies, *See* Exhibit 8.40; Consenting Patients, Exhibit 8.45.
[1022] *See* Procurement Technician Compensation Policy for Tissue and Blood Procurement, Exhibit 8.46.
[1023] See StemExpress Services Agreement with Planned Parenthood Shasta Pacific; StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties; Purchase Order No. 60856806; Purchase Order No. 3000014694; Purchase Order No. 60836838; Purchase Order No. 60858758; and StemExpress Invoice # 1439, Exhibit 8.47.
[1024] *See* Standard Operating Procedure, Exhibit 8.48.

4. The Contracts between StemExpress and the Planned Parenthood abortion clinics

Particular language, contained within the four corners of the written contracts between StemExpress and the Planned Parenthood abortion clinics, raises serious concerns that the parties violated the Privacy Rule:

> [a]ny information obtained from [the Planned Parenthood abortion clinics] patients' charts shall be privileged, and [Stem-Ex/StemExpress] will treat the information in order to preserve the confidentiality of the patients. [Stem-Ex/StemExpress] will not receive any information concerning identity of donors *except as necessary* to obtain patients' consent for use of POCs and maternal bloods (emphasis added).[1025]

This admission, on the face of the contracts, that the Planned Parenthood abortion clinics granted StemExpress access to patients' PHI raises the question whether any HIPAA provision permits or requires such disclosure without patients' express authorization. This question is compounded by the contracts' admission that StemExpress reviewed PHI *prior to* obtaining patients' consent to donate fetal tissue *or* patients' authorization to view their PHI.

5. Violations of the HIPAA Privacy Rule by StemExpress and the Planned Parenthood Abortion Clinics

The agreements between StemExpress and the Planned Parenthood abortion clinics, on their face and in practice, appear to be fundamentally flawed. A contractual agreement requiring StemExpress to "treat the information obtained from patients' charts in order to preserve the confidentiality of the patients" cannot trump a law *prohibiting* the Planned Parenthood abortion clinics from permitting these disclosures in the first place. As discussed below, the Planned Parenthood abortion clinics—covered entities under HIPAA—were not permitted to disclose or make available to StemExpress any patient's PHI without the patient's express authorization.

The Planned Parenthood abortion clinics and StemExpress violated the HIPAA privacy rule because: (1) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research; (2) The consents for fetal tissue donation ostensibly obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI; (3) The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants; and (4) StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA.

[1025] *See* Contracts, Exhibit 8.49 (emphasis added).

6. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics, and received by StemExpress, were neither required nor permitted under HIPAA, and in particular did not meet the exceptions for cadaveric organ, eye, or tissue transplantation, or for research

The disclosures of PHI that the Planned Parenthood abortion clinics made to StemExpress are neither required[1026] nor permitted[1027] by law. StemExpress was not involved in the treatment of patients, in the payment for treatment, or in clinic operations.[1028] Rather, StemExpress wanted patients' PHI to facilitate the procurement of human tissue from aborted infants for resale to researchers, and the Planned Parenthood abortion clinics benefited from this arrangement because StemExpress paid them for the tissue.

a) Cadaveric organ, eye, or tissue transplantation

Importantly, Planned Parenthood's disclosures to StemExpress do not fall under the provision in law permitting disclosure of PHI to aid organ transplantation. While the contracts reference the "National Organ Transplant Act,"[1029] the Planned Parenthood abortion clinics were not facilitating the donation and *transplantation* of cadaveric organs, eyes, and tissue. Instead, the clinics were facilitating the donation of human fetal tissue from aborted infants for *research,* which is not covered by the cadaveric organ, eye, or tissue exception.[1030]

b) Research

Further, Planned Parenthood's disclosures to StemExpress do not meet the rigorous requirements applicable to PHI disclosures for research purposes. A covered entity is not permitted to disclose an individual's PHI for research purposes without the individual's authorization unless the covered entity (1) obtains verification of approval from an Institutional Review Board (IRB) for disclosure without authorization; (2) the researcher represents that the use or disclosure of the PHI is solely to prepare research protocol and the PHI will not be removed from the covered entity, and that the PHI is necessary for the research; or (3) the research is on PHI of deceased individuals.[1031]

c) Violations Preceding "Consent"

Because StemExpress employees actually sought consent for tissue donation from patients, the Planned Parenthood abortion clinics permitted the employees to view patients' charts. Medical charts are filled with HIPAA-protected PHI, including names, addresses, past

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[1026] 45 C.F.R. § 164.502(a)(2) (The only "required" disclosures are to (1) an individual or their personal representative when they request access to, or an accounting of disclosures of, their protected health information; and (2) to HHS when it is undertaking compliance investigation or review or enforcement action).
[1027] *See* 45 C.F.R. § 164.502(a)(1).
[1028] *See* 45 C.F.R. § 164.506(c).
[1029] 42 U.S.C. § 274e(c)(1).
[1030] *See* 45 C.F.R. § 164.512(h).
[1031] 45 C.F.R. § 164.512(i).

and present medical treatment, and more. Each time a Planned Parenthood employee shared a medical chart with a StemExpress employee, both violated the HIPAA privacy rule.

No evidence suggests the Planned Parenthood abortion clinics' patients provided authorization for StemExpress staff to view their PHI *prior* to seeking their consent to donate tissue. Therefore, regardless of whether a patient *ultimately* consented to tissue donation and authorized disclosure of her PHI to StemExpress, her privacy was violated.

The Planned Parenthood abortion clinics could have directly consented their patients for tissue donation, and entered an agreement with StemExpress to provide a limited data set[1032] regarding the patients they were seeing on a particular day. Instead, they violated the Privacy Rule by permitting StemExpress to view the most intimate information about their patients.

These disclosures made by the Planned Parenthood abortion clinics to StemExpress were inarguably direct and intentional—not incidental.[1033] StemExpress employees did not merely overhear a patient's name while in the clinic—they were handed her medical chart by her Planned Parenthood healthcare provider in blatant violation of the HIPAA privacy rule.

7. The consent for fetal tissue donation obtained by StemExpress from the Planned Parenthood abortion clinics' patients did not constitute sufficient authorizations for the disclosure of PHI

While StemExpress purportedly obtained consents from patients prior to procuring human fetal tissue from their aborted infants, the forms that they used were insufficient to authorize the disclosure of PHI under the HIPAA privacy rule. The Privacy Rule requires a covered entity to obtain an individual's written authorization for any use or disclosure of PHI that is not permitted or required by law.[1034] Such authorization must be in plain language and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data.[1035]

Neither the consent form provided by StemExpress nor the consent form provided by Planned Parenthood to obtain patient consent for the donation of human fetal tissue of aborted infants met these stringent requirements.[1036] The statement in the StemExpress form that a patient's "health information will be protected at all times" is ironic given that StemExpress' possession of the patient's PHI already placed the Planned Parenthood abortion clinics and StemExpress in violation of the HIPAA privacy rule.

[1032] *See* 45 C.F.R. § 164.514(e).
[1033] *See* 45 C.F.R. § 164.502(a)(1)(iii).
[1034] 45 C.F.R. § 164.508.
[1035] 45 C.F.R. § 164.508(c).
[1036] *See* StemExpress consent form, Exhibit 8.35, and Planned Parenthood consent form, Exhibit 8.34.

The StemExpress form also stated that "[i]n accordance with federal laws (HIPAA), your personal identifying information will be protected . . . health information . . . may be used or disclosed . . . [but] will NOT be connected to your name or any other personal identifier."[1037]

Like the privacy provision in the contracts between StemExpress and the Planned Parenthood abortion clinics, this nod towards HIPAA requirements failed to meet the requirements of the HIPAA privacy rule. The StemExpress form did not describe the specific patient information that will be disclosed or used, but rather provided a generic, nonexclusive list of information that *may* be disclosed. The StemExpress form did not state who will disclose or use the patient's PHI. It also did not state when the patient's authorization will expire, or that the patient can withdraw her authorization for the use of her PHI (it mentioned that the patient cannot withdraw her consent to the tissue donation after she leaves the clinic).

The Planned Parenthood form, purportedly used to obtain patient consent for human fetal tissue donation at Planned Parenthood Mar Monte and Planned Parenthood Shasta Pacific,[1038] was grossly insufficient. The form did not address privacy at all, with no information regarding: PHI that may be disclosed or used; the person(s) disclosing and receiving the PHI; any expiration on the availability of the patient's PHI to researchers or others; or the patient's right to revoke her authorization in writing.

One former StemExpress procurement technician, [Procurement Technician], was embedded at several California Planned Parenthood clinics and told investigative journalists of repeated consent violations she witnessed during her time with Planned Parenthood. In one instance, [Procurement Technician] told a StemExpress coworker that a woman had refused to consent to a blood draw for donation, but the coworker—with full knowledge of the patient's refusal—drew her blood anyway the following day without telling her it was for StemExpress.[1039]

8. The disclosures of patients' PHI made by the Planned Parenthood abortion clinics to StemExpress were not the minimum necessary disclosures to facilitate the procurement of human fetal tissue from aborted infants

The Planned Parenthood abortion clinics and StemExpress violated a central aspect of the Privacy Rule by disclosing/obtaining more than the "minimum necessary" PHI to facilitate the procurement of human fetal tissue from aborted infants.[1040] StemExpress employees did not need to know the names of patients, and they certainly did not need to directly obtain the patients' consent in order to procure fetal tissue. Instead, these deeply private activities could have been performed by Planned Parenthood employees.

[1037] StemExpress Consent Form, Exhibit 8.35.
[1038] Planned Parenthood consent form, Exhibit 8.34.
[1039] Human Capitol-Episode 2: Inside the Planned Parenthood Supply Site (YouTube) https://www.youtube.com/watch?v=ABzFZM73o8M (5 minutes, 30 seconds).
[1040] 45 C.F.R. §§ 164.502(b) and 164.514(d).

As addressed above, the Planned Parenthood abortion clinics could have established a relationship with StemExpress that did not require or result in the disclosure of any PHI. Instead, the Planned Parenthood affiliates permitted StemExpress to use PHI to directly encourage patients to donate human fetal tissue—tissue for which Planned Parenthood would be paid, and that would later be sold by StemExpress to researchers at a huge mark-up.

9. StemExpress is not a *Business Associate* of the Planned Parenthood abortion clinics under HIPAA

A *Business Associate* under HIPAA is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. *Business Associates* are generally involved in claim processing, data analysis, utilization review, and billing. Their services are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services, where the provision of the services involves the disclosure of PHI.[1041]

Clearly, StemExpress did not perform any of these services for the Planned Parenthood abortion clinics, and is therefore not a *Business Associate* permitted to obtain the PHI of the Planned Parenthood abortion clinics' patients.

[1041] 45 C.F.R. § 160.103.