

III. THE SELECT PANEL FOUND NO EVIDENCE OF WRONGDOING



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THE SELECT PANEL FOUND NO EVIDENCE OF WRONGDOING

Congress modeled the federal law governing fetal tissue donation on the National Organ Transplant Act, which prohibits the transfer of human organs for “valuable consideration” but allows “reasonable payments” associated with the costs of donation, which can be considerable.¹ The federal law regarding restrictions on the “purchase” of human fetal tissue – 42 USC 289g-2(a) – similarly forbids valuable consideration but allows “reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”²

These reasonable payments are not unlawful, nor do they represent “profit” from the sale of fetal tissue. And contrary to the continued inflammatory claims from Panel Republicans, the Select Panel has no evidence that amounts paid in connection with fetal tissue donation were not reasonable in light of the time, expertise, facilities, supplies, quality control, storage, and transportation involved with facilitating fetal tissue donation.

In fact, the more than 34,000 pages of documents and additional evidence submitted to the Panel demonstrates that many clinics do not accept any payments for facilitating tissue donation; others receive relatively minimal reimbursement – generally ranging from \$35 to \$75 per donation of the tissue from an abortion, depending on the particulars of the clinic’s fetal tissue donation program. As one expert in the use of fetal tissue research publicly stated in July 2015, “[in] reality, \$30-\$100 probably constitutes a loss for [Planned Parenthood]. The costs associated with collection, processing, storage, and inventory and records management for specimens are very high.”³

Tissue procurement organizations and research universities also consistently explained that their costs related to fetal tissue procurement exceed amounts charged and received for these services.

The Panel similarly uncovered no evidence to support various other Republican allegations related to consent, unlawful alteration of procedures, infants allegedly “born alive” following abortion procedures, or patient privacy rights.

A. No Evidence of Unlawful Profit From Fetal Tissue Donation

By the time the Select Panel was established in October 2015, three House Committees had already investigated the fraudulent Daleiden/CMP video allegations and uncovered no wrongdoing.

Over the course of these investigations, Planned Parenthood Federation of America (PPFA) produced approximately 25,000 pages of material. PPFA-affiliated physicians and other staff – many of whom had been featured in the deceptively-edited videos – briefed the Energy

and Commerce Committee; and the organization's President, Cecile Richards, testified before the Oversight and Government Reform Committee for nearly five hours. At the close of that Committee's investigation, that Committee's Chairman Jason Chaffetz admitted: "Was there any wrongdoing? I didn't find any."⁴

Evidence obtained by the Select Panel – consisting largely of testimony from witnesses, some of whom had already briefed Congress – confirmed what Congress already knew: PPFA's affiliates do not profit and actually lose money when they facilitate fetal tissue donation for their patients.

1. Planned Parenthood Had Already Demonstrated No Wrongdoing

Immediately following public release of the Daleiden/CMP videos, PPFA explained to Congress how its guidelines address fetal tissue donation and provided details about the small number – only six of its fifty-nine affiliates – that have participated in such programs since 2010.⁵

As PPFA explained, four of these six affiliates were no longer facilitating fetal tissue donation as of August 2015 – and three of them had stopped because of the Daleiden videos.⁶ Before these four stopped their donation programs, one had never accepted any reimbursements for costs while the other three affiliates had been receiving from \$35 to \$60 per donation.⁷

For the two affiliates that still had fetal tissue donation programs as of August 2015, one was receiving \$45 to \$60 per donation, and the other affiliate received no reimbursement for its costs.⁸

Documents produced to Congress confirmed these amounts and outlined the various services and costs that these payments reimbursed. For example, the agreement between one tissue procurement organization (Novogenix) and a PPFA affiliate showed that the affiliate would receive \$45 per donation for its services, which were identified as including "reasonable administrative costs associated with the identification of potential donors, as well as the obtaining of informed consent."⁹ Agreements with Advanced Bioscience Resources, Inc. ("ABR") and StemExpress reflected payment for "services and facilities" associated with donation, including seeking consent from donors, creating and maintaining donation records, and "processing, preservation, quality control, transportation, and storage."¹⁰ Affiliates were reimbursed between \$35 to \$55 per donation by StemExpress and up to \$60 per donation by ABR.

However, PPFA announced that, as of October 2015 – "in order to completely debunk the disingenuous argument that our opponents have been using" – none of its affiliates would accept reimbursement for the costs of donation going forward.¹¹

As PPFA explained, all affiliates are required to provide "core services," including well-women visits, and education and prescriptions for all FDA-approved methods of contraception. Fetal tissue donation is not a core service and affiliates may elect to participate, or not, without

prior approval from PPFAs.¹² For those affiliates that elect to participate, PPFAs have recommended guidelines and forms that “exceed the legal requirements” imposed by the federal prohibitions regarding fetal tissue contained in 42 U.S.C. 289g-2.¹³ Among other things, and before the organization announced that its affiliates would no longer accept reimbursement for their costs, those guidelines recommended audits to analyze and demonstrate an affiliate’s donation-related costs even though federal law has no accounting or documentation requirements.¹⁴ Planned Parenthood acknowledged in November 2015 that the participating affiliates had not conducted or could not locate the recommended audits, but that they performed a “good-faith accounting of their costs,” which were provided to Congress.¹⁵

Those reports provide estimated costs for space occupied and supplies utilized as well as various tasks performed by clinic staff, including, coordination with tissue procurement organizations; consenting patients; preparing, processing, and copying consent forms; and processing, storing, and transferring tissue.¹⁶ The Government Accountability Office (“GAO”) recognized these types of expenses as reimbursable costs sixteen years ago, in its 2000 report on “Human Fetal Tissue: Acquisition for Federally-Funded Biomedical Research.”¹⁷

Planned Parenthood also explained to Congress in November 2015 that, for the few affiliates that facilitate fetal tissue donation and without accounting for costs, amounts received from these programs represented from 0.003% to 0.021% of their total revenue. As the organization explained: “It defies logic – and common sense – to assert that these very modest reimbursements motivated affiliates to facilitate tissue donation out of a desire to ‘profit’ from fetal tissue donation.”¹⁸

2. Select Panel Confirmed No Wrongdoing by Planned Parenthood

Congress had all of this information when Panel Republicans issued their interim update in July but they did not mention it. They also did not interview a single witness associated with Planned Parenthood until October 2016. When they did, these witnesses confirmed what Planned Parenthood explained to Congress more than a year ago, and before this Panel even started its work.

For example, one witness (PP Witness #1) – who had also previously briefed the Energy and Commerce Committee – told the Panel that that she had “no reason to believe” that the Planned Parenthood affiliate where she had been working when Daleiden/CMP released their videos “was ever compensated for more than its cost related to tissue donation.”¹⁹ PP Witness #1 explained that, as a physician who facilitated fetal tissue donation, she understood the costs involved in the donation process, and that “[t]his is not something with any revenue stream that affiliates are looking at. This is a way to offer patients a service that they want and to do good for the medical community.”²⁰

This witness had been secretly recorded without consent by David Daleiden, who misrepresented himself as “Robert Sarkis” and claimed to work for a fake company (“BioMax Procurement Services”). PP Witness #1 explained why she agreed to meet with Daleiden:

In my experience, women frequently desire to donate their tissue to medical research. In my view, they should have the opportunity to do so, provided, of course, that all applicable laws are followed. I attended this lunch [with Daleiden] because I believe that fetal tissue research is a good thing, and I wanted to help this small company in its stated goal of facilitating legal tissue donation.²¹

PP Witness #1 further explained that – posing as “Robert Sarkis” – David Daleiden “went on and on about all of the fabulous, you know, potential research that was being done” with fetal tissue, and that – while she personally had no role in establishing agreements for donation on Planned Parenthood’s behalf—she wanted to help “Robert Sarkis” in his stated goal of furthering fetal tissue research. As PP Witness #1 made clear to the Panel, she was never interested in profiting from fetal tissue donation:

Minority counsel: And were you interested in profiting from the unlawful sale of fetal tissue?

Witness: Never.

Minority counsel: Did you agree at any time to engage in the unlawful sale of fetal tissue?

Witness: I did not.

Minority counsel: Did you agree at any time to otherwise break any laws?

Witness: I did not.²²

Panel Republicans nonetheless questioned the witness using select portions from unsourced “transcripts” of the Daleiden/CMP videos. As the PP Witness #1 explained:

If you review the entire two hour and 42 minute video, you will see me repeat ten times that Planned Parenthood does not make a profit from fetal tissue donations. Over and over again, I explained that Planned Parenthood offers tissue donation as a service to its patients.²³

The Panel also interviewed the research coordinator for another Planned Parenthood affiliate (PP Witness #2) who similarly confirmed that “to my knowledge, there’s never been any profit” from fetal tissue donation.²⁴ She explained that “during my time [with the affiliate] we have never partnered with a tissue procurement organization and have never engaged in research involving fetal tissue obtained from second-trimester abortions.”²⁵

As the PP Witness #2 further explained, that affiliate had only participated in a limited number of donation programs for nearby university researchers, with the last of those ending in

2011. For that program, the affiliate facilitated donation for researchers who were studying “a molecule called dystroglycan on placentas in an effort to prevent miscarriages.”²⁶ PP witness #2 explained the additional work required of clinic staff, including the back-and-forth process of obtaining patient consent for donation, and the need to “keep and maintain study-related documents” and files.²⁷

She also outlined the logistics that would accompany specimen collection:

That is a much higher level of preparation that has to happen in the procedure room with specialized equipment that has to be swapped out prior to the procedure, very time intensive activity, in addition to collecting a blood specimen, which, again, that is not our clinical standard of care to collect a blood specimen at that point in the visit, so that also had to be incorporated into the clinic’s activities and ensure that it’s properly labeled and it’s properly paired with the correct specimen.²⁸

As the PP Witness #2 explained, her “back-of-the-envelope” assessment of costs for these various tasks reflected her:

General understanding of what the staff that would be reviewing and obtaining the informed consent and the staff that are working in the procedure room that would do the work of setting it up, a general understanding of what their salary base would be and approximately how much time, of course on the narrow end, because, of course, we can’t have valuable consideration. So, you know, again, it was just cost basis.²⁹

PP Witness #2 also explained that, for this project, she “was getting feedback from the clinic that it was taking longer than my back-of-the-envelope original projection. I was grossly undercalculating, and so we had to revise it” to more accurately reflect the staff time and costs involved.³⁰

Panel Republicans acknowledged that “you set these prices based on, you know, a thoughtful—just because you said back of the envelope doesn’t mean it’s not thoughtful – thoughtful estimate of what the staff time, the sterile procedure costs.”³¹ And, as PP Witness #2 confirmed, “there’s never been any profit” in the limited instances where her affiliate participated in fetal tissue donation for university research.³² She also explained, “I love the work that I do, and I appreciate that our work contributes to advances in medical science.”³³

PP Witness #2 also met with and was secretly recorded by David Daleiden, who similarly misrepresented himself to her as “Robert Sarkis” and posed as an employee of the fake procurement company “BioMax.” She agreed to arrange a site visit for Daleiden because he “came recommended to me by several trusted colleagues and had attended various industry conferences in which security is extremely tight.”³⁴ This type of site visit is “typical practice”

and “not out of the norm” for clinics and potential research partners seeking to “assess the feasibility of conducting a proposed study.”³⁵

As PP Witness #2 told the Panel, her “trust was misplaced,” as she later learned that Daleiden and his associate had deceived “me and others into believing that they were people that they were not.”³⁶ During their visit:

[Daleiden and his associate] repeatedly implied they would pay significant amounts of money for fetal tissue. I repeatedly refused to engage in their attempts to discuss payments that could be in violation of PPFA guidelines and applicable laws and instead made it clear for fetal tissue research, we only seek to recover costs.³⁷

Panel Republicans also questioned PP Witness #2 using select portions of an unsourced “transcript” of the Daleiden/CMP videos.

With regard to one exchange in the transcript reflecting the witness as saying “I go to great efforts to demonstrate what the cost, actual cost is to us – to whomever asks – and then, this is what is budgeted. So they know, okay, you’re covering costs, there’s margin, that’s covering overhead, or whatever we need, just to make sure everything is covered,” PP Witness #2 explained:

I think you can see from the context of that entire paragraph that if you take away my intent – and, again, I used that paragraph in my opening statement to reflect that our intent is to recoup costs. And however I spoke, misspoke, bumbled through it, that was my intent was to just demonstrate that we recover costs.

She further acknowledged that “it didn’t come across as clear as I had intended, but the intent was to make sure that it was clear that we do not make a profit off of our fetal tissue studies.”³⁸

As PP Witness #2 also made clear, “while watching the [CMP/Daleiden] videos, it was clear that my words had repeatedly been taken out of context in an attempt to make it seem like [the affiliate] is engaging in illegal activity.”³⁹

Like others, PP Witness #2 made clear that she was not seeking profit:

Minority counsel: So Merriam Webster dictionary defines entrapment as, quote, “The illegal act of tricking someone into committing a crime so that the person you have tricked can be arrested.”

From your perspective, do you believe that Mr. Daleiden wanted to trick you into committing or agreeing to commit a crime?

Witness: It sure seems like it.

Minority counsel: And were you interested at any time in profiting off the sale of fetal tissue?

Witness: No.

Minority counsel: And did you agree to otherwise break any laws?

Witness: No, I did not.

This is also the conclusion of federal judge William H. Orrick who determined that:

Having reviewed the records or transcripts in full and in context, I find that no NAF [National Abortion Federation] attendee admitted to engaging in, agreed to engage in, or expressed interest in engaging in potentially illegal sale of fetal tissue for profit.⁴⁰

B. No Wrongdoing by University of New Mexico and Southwestern Women's Options

Panel Republicans have repeatedly criticized the relationship between the University of New Mexico (“UNM”) and Southwestern Women’s Options (“SWO”), a nearby reproductive health care clinic, but the Panel has no evidence of wrongdoing by either entity. With regard to fetal tissue donation, the Panel has known since January 2016 that SWO receives no money for tissue donated by its patients to UNM researchers. While Panel Republicans also express displeasure that UNM provides reproductive health care and takes steps to ensure that medical residents and fellows obtain training that is mandated by various accrediting institutions, these activities do not implicate a single criminal law.

The Select Panel has known since January 2016 that “tissue is donated at no cost” when SWO facilitates donation by its patients to UNM researchers.⁴¹ Chair Blackburn nonetheless issued unilateral subpoenas for depositions of university and clinic doctors, claiming these were “necessary” because “some abortion supporters seem to be clearly rattled with the basic facts coming to light.”⁴² The Chair never asked if these doctors would appear voluntarily and refused to pay their expenses for appearing, though Republicans reimbursed some of their own witnesses at public hearings.⁴³

After interviewing these witnesses, Panel Republicans sent a “criminal referral” letter to the New Mexico Attorney General.⁴⁴ Though acknowledging that SWO receives no money for services related to fetal tissue donation, Chair Blackburn alleged that SWO received other unlawful “benefits” because three SWO doctors serve as volunteer faculty for UNM and helped train their fellows and residents. In so doing, Chair Blackburn failed to mention evidence

obtained by the Panel rebutting her numerous allegations and the contrary legal opinion of the United States Justice Department’s Office of Legal Counsel (“OLC”).⁴⁵

OLC concluded in 2007 that the federal prohibition on “valuable consideration” does not reach non-monetary benefits exchanged in connection with organ donation programs.⁴⁶ Providing that opinion in the context of the National Organ Transplant Act, the OLC noted that use of that same language in 42 U.S.C. § 289g-2 demonstrated Congress’s intent for “that text to have the same meaning in both statutes” and concluded that that “‘valuable consideration’ is monetary or at least has a readily measurable pecuniary value.”⁴⁷ But even if the law somehow reached non-pecuniary benefits, UNM and SWO demonstrated that there are no “benefits” provided by UNM to SWO in exchange for fetal tissue donated by SWO patients to UNM researchers.

As UNM explained to the Panel, volunteer faculty positions held by three SWO physicians “are not only uncompensated, they are not unique at UNM. Indeed, there are approximately 1000 Volunteer Clinical Faculty throughout UNMHSC [University of New Mexico Health Sciences Center], of which the Ob-Gyn department has 58.”⁴⁸ Thus, the alleged unlawful “benefits” identified by Chair Blackburn (e.g., use of the campus library and gym) are available to all volunteer faculty and “are not material inducements to provide fetal tissue.”⁴⁹

Likewise, both entities explained that SWO physicians did not receive medical malpractice insurance coverage from UNM in exchange for fetal tissue donation. Instead, SWO “had to obtain and pay for its own insurance coverage” independent of any coverage that may have been provided under the New Mexico Tort Claims Act, which applies to malpractice claims arising from care provided by “UNM medical students, residents, fellows and faculty.”⁵⁰ Moreover, SWO has never made a claim for coverage under UNM’s state-issued insurance.⁵¹

Finally, SWO’s supervision of medical residents and fellows benefitted UNM, not the clinic. “Teaching residents and fellows created more work for SWO doctors. It slowed down the procedures and required SWO preceptors to take more time and effort to teach and train.”⁵² This training, which is mandated by various accrediting institutions, is critical to women’s health care and ensuring that the care women receive remains safe.

The effort by Panel Republicans to criminalize a common educational practice and demonize valuable community-university partnerships – at least when it comes to training the next generation of reproductive health care providers – has no basis in law or in fact.⁵³

C. Independent Clinics Do Not Profit From Fetal Tissue Donation

Republicans also sought and obtained information from independent (i.e., not affiliated with Planned Parenthood) clinics. Documents and materials produced by these clinics and tissue procurement organizations show that many – six out of the twenty-two of those identified to the

Panel – receive no money for services provided when they facilitate fetal tissue donation, not even the “reasonable payments” expressly permitted by law.

Other clinics produced documents showing minimal “reasonable payments” that varied based on how these clinics elected to partner with tissue procurement organizations. In situations where tissue procurement organizations had staff on-site in the clinic to fulfill certain responsibilities, providers generally received approximately \$50 to \$75 per donation. When tissue procurement organizations had no staff on-site, providers generally received \$50 to \$250 per donation, a higher amount presumably since they were responsible for all aspects of fetal tissue donation.

The costs identified by clinics in agreements with tissue procurement organizations included processing, preservation, quality control, transportation, obtaining informed consent, and maintenance of records. As is true for the few Planned Parenthood affiliates that participate in donation programs, the types of costs identified and amounts received by these independent clinics on a per-donation basis are similar to those identified by the Government Accountability Office (“GAO”) sixteen years ago.⁵⁴

D. No Evidence of Unlawful Profit by Tissue Procurement Organizations

Over the course of this investigation, four tissue procurement companies – StemExpress, ABR, DV Biologics, and Novogenix – produced more than 8,000 pages of documents, including email correspondence, purchase orders, invoices, accounting records, and other documentation related to fetal tissue transactions.

These companies consistently explained that costs related to fetal tissue procurement outweigh revenue that they receive for this service. Some also explained that, in addition to transferring unaltered fetal tissue to researchers, they also work with human blood, adult tissue products, bone marrow, adult primary cells, and other manufactured isolated cells that researchers need to perform their research. Unlike unaltered fetal tissue, these products are not subject to the federal ban on “valuable consideration” and it is not against the law for companies to profit from these services.⁵⁵

These companies also offered witnesses to explain their business practices and answer the Panel’s questions. Panel Republicans refused these offers, electing instead to levy allegations based on their own interpretation of documents and staff-created exhibits and questioned witnesses with no personal knowledge of the facts in an apparent effort to confirm their preferred partisan narratives. But, as outlined below, the Select Panel uncovered no actual evidence of wrongdoing by these tissue procurement companies.

1. StemExpress

Panel Republicans aggressively targeted the same company – StemExpress – that received the most attention in the Daleiden videos and alleged throughout the investigation that they had uncovered “evidence” of criminal misconduct by the company.⁵⁶ In reality, the approximately 1,700 pages of documents and accompanying explanations provided to the Panel by StemExpress do not show unlawful profit or other misconduct.

StemExpress is a “small life sciences company that supports leading research institutions” by providing “stem cells and other human tissue critical to medical research.”⁵⁷ The “overwhelming majority” of its work involves “isolating and purifying cells derived from donated adult tissue and blood” – not fetal tissue.⁵⁸ These products are not subject to the ban on “valuable consideration” and it is not against the law for StemExpress to profit from their sale. With regard to fetal tissue, “StemExpress does not provide fetal tissue to its customers to make money; rather, it is offered to support the needs of the world’s best researchers in their efforts to treat and cure diseases.”⁵⁹

Fetal tissue procurement “has constituted roughly 1% of the company’s total revenue before accounting for costs and expenses.”⁶⁰ The other approximately 99% of StemExpress’s business relates to human blood, adult tissue products, bone marrow, adult primary cells, and other manufactured isolated cells that researchers need to perform their research. As the company made clear:

“[F]etal tissue revenue is an exceedingly small fraction of StemExpress’s total revenue in any given year. Any revenue derived from fetal tissue must be offset by reasonable costs and expenses related to the processing, preservation, quality control, transportation, and storage of fetal tissue.”⁶¹

Once these costs are factored in, the company lost money on its services related to fetal tissue donation. As the company explained:

From 2014 to 2015, StemExpress collected \$74,955 in gross revenue from providing fetal tissue but incurred an estimated \$95,160 in costs and expenses related to the processing, preservation, quality control, transportation, and storage of fetal tissue. The financial impact of these substantial costs is a two-year loss estimated at \$20,205 on providing fetal tissue to clients.⁶²

StemExpress explained to the Panel that it generally charged researchers “roughly \$500 to \$600 for unaltered tissues” but the costs related to each transfer were “approximately \$750 to \$1,000.”⁶³ The hundreds of invoices and purchase orders produced by StemExpress to the Panel are consistent with the company’s explanation, with amounts differing depending on the type of tissue because costs incurred are “not uniform across all procurement of fetal tissues.”⁶⁴ In limited circumstances, invoices and accounting records indicate that StemExpress charged higher

amounts for certain types of tissue. For example, StemExpress explained that it charged one researcher \$890 for a specimen given that it involved “procurement of four separate and distinct tissues,”⁶⁵ and another researcher \$950 for a disease-specific request given the long time such requests remained on the schedule and the need to establish “specific procurement partnerships.”⁶⁶

To demonstrate costs, the company provided an estimated breakdown for employee labor, supplies, shipping, clinic reimbursement, and screening of tissue for infectious disease.⁶⁷ By agreement with the Majority, StemExpress also created accounting reports that detailed estimated costs and expenses and confirmed that the company lost money on fetal tissue procurement.⁶⁸

Characterizing these agreed-upon documents as self-serving accounts, Chair Blackburn demanded additional records from the company’s bank and accountant.⁶⁹ But these documents, provided to the Panel by the company’s bank, shed no light on the company’s fetal tissue services because they do not distinguish what amounts, if any, relate to the approximately 1% of the company’s business related to fetal tissue procurement – as opposed to the 99% of its business involving other services. Chair Blackburn nonetheless elected to pursue criminal contempt against StemExpress in September for alleged failure to produce even more banking and accounting records – and did so without ever responding to the explanation of compliance sent by the company four months earlier.⁷⁰

While Panel Republicans have pointed to what they describe as unjustified estimated expenses by StemExpress, such as overstating shipping and infectious disease screening costs that are passed on to researcher customers,⁷¹ the documents produced by the company have already addressed some of these claims. For example, documents produced by StemExpress explain that shipping expenses included costs for shipping supplies from StemExpress’s headquarters to clinics as well as costs for shipping specimen to an outside laboratory or to the StemExpress headquarters laboratory for infectious disease screening.⁷² These costs were separate from shipping costs associated with sending tissue directly to a researcher.

With regard to any remaining allegations of unjustifiable costs or unlawful profit, Panel Republicans steadfastly refused to interview witnesses offered by the company to explain its business practices and answer the Panel’s questions. This included the company’s Procurement Director, who had previously served as a Procurement Manager, and another witness who had performed accounting work for the company.⁷³ Nor did they ask to re-interview the company’s Chief Executive Officer, who had already appeared voluntarily for a bipartisan briefing with staff of the Energy and Commerce committee during its investigation.⁷⁴ As the company noted, “[r]ather than depose any of these individuals, the Select Panel appears intent on driving a predetermined narrative that suits its ends.”⁷⁵

2. Advanced Bioscience Resources, Inc.

Advanced Bioscience Resources, Inc. (“ABR”) is “a small, non-profit operation” that was “established to help lifesaving medical research.”⁷⁶

In documents first produced to the Energy and Commerce Committee in October 2015 and then reproduced to the Select Panel, ABR included thousands of pages of invoices showing that the company charged researchers between \$200 and \$550 per specimen to cover their costs. ABR also produced a breakdown of total income, income from fetal tissue, and total expenses for 2009 through 2013⁷⁷ demonstrating that ABR did not profit but, instead, “operated at a significant loss almost every year for the past five years.”⁷⁸

In their “interim update,” Panel Republicans asserted that “materials produced to the Panel by ABR created an unclear picture of their conduct and income.”⁷⁹ They nonetheless created their own narrative about the company’s purported business practices, including an unsourced recitation of how ABR receives and processes researcher requests.⁸⁰

Panel Republicans did not interview a single witness from ABR who could have explained the company’s business practices and answered the Panel’s questions. Nor did they re-interview ABR’s President, who had previously briefed the Energy & Commerce Committee during its prior investigation into the fraudulent Daleiden/CMP video allegations.

3. Novogenix

Novogenix was a small company established to help “propel regenerative medicine to the forefront of available treatment options for patients.”⁸¹ The company also was a target of the Daleiden/CMP videos and cooperated with previous congressional investigations. When initially contacted by the Select Panel in December 2015, the company informed us that “[d]ue in large part to the costs born from having to respond to these congressional inquiries, our client is no longer doing business.”⁸²

As the company explained in a September 2015 letter to the Energy and Commerce Committee:

“In each fiscal year, from Fiscal Years 2011 through the present, Novogenix has yielded a loss for its work related to fetal tissue and stem cells therefrom...”⁸³

Documents provided to the Energy & Commerce Committee are consistent with this explanation, including a detailed accounting for fiscal years 2011 through 2015 based on contemporaneous data and documentation. In briefings and follow-up with that Committee, Novogenix explained that it received between \$200 and \$250 per specimen from researchers as reimbursement for their costs, which included preparation, processing, and transport of fetal tissue.⁸⁴ Novogenix invoices and purchase orders produced by universities conducting fetal tissue research that received their tissue from Novogenix confirmed the company’s explanation.

Panel Republicans did not interview a single witness from Novogenix who could have explained the company’s business practices and answered the Panel’s questions.

4. DV Biologics

DV Biologics is a small biotech company whose mission is to “provide biological tools needed to advance the innovation of technology that will ultimately be used to treat or prevent multiple human degenerative disorders and diseases.”⁸⁵ The company explained to the Panel in January 2016 that in regards to itself and its parent company, DaVinci Biosciences, the “overwhelming majority of the companies’ activities involved adult tissue.”⁸⁶ Unlike fetal tissue, these products are not subject to the ban on “valuable consideration” and may be profitable. And, in a subsequent letter to the Panel, DV Biologics explained that they do not presently transfer “any materials derived from fetal tissue” for research purposes.⁸⁷

DV Biologics’ and DaVinci Biosciences’ prior work with fetal tissue consisted of isolation, incubation, and culturing cells in the appropriate medium.⁸⁸ As explained to the Panel, the sole source for this tissue was Planned Parenthood of Orange and San Bernardino Counties, and DV Biologics “did not pay any money to Planned Parenthood for the donated fetal tissue” it received.⁸⁹

As it explained to the Panel, the company “operated at a loss. Therefore, it did not receive more than ‘reasonable payment’” in connection with fetal tissue.⁹⁰ In support of this explanation, DV Biologics produced hundreds of invoices – reflecting charges to researchers between approximately \$175 and \$604 for fetal tissue specimens – and detailed spreadsheets tracking, for each specimen type, expenses related to processing, preservation, storage, quality control, and other administrative expenses along with a formula describing their costs related to fetal tissue procurement.

Panel Republicans did not interview anyone from DV Biologics and, in their July interim update, represented that the company had “fully complied” with its requests for information and did not raise any concerns about the company’s practices.⁹¹

In October 2016, the Orange County, California, District Attorney filed a civil complaint in state court against DV Biologics for unlawful, unfair, and fraudulent business practices related to the company’s fetal tissue procurement services. The complaint references the company’s work with fetal and adult tissue, and the cause of action alleges unlawful practice in connection with fetal tissue and derivative products. It is not clear what, if any, of these products and services are subject to the federal ban on “valuable consideration” for unaltered fetal tissue.

Chair Blackburn nonetheless issued a press release about the complaint but, in stark contrast to the District Attorney who brought the case – and whose office made clear that Planned Parenthood was not part of their investigation or complaint – the Chair accused Planned Parenthood of wrongdoing.⁹²

After seeing this release – which claimed that “evidence uncovered during the Panel’s investigation” supported the Chair’s claim – Panel Democrats asked Republicans for that evidence.⁹³ When Panel Republicans ignored this request, Democrats contacted DV Biologics and learned that the company had provided documents and information to Panel Republicans

pursuant to congressional subpoena five months earlier. Panel Republicans never shared that information, which – as counsel for DV Biologics subsequently explained – reflects charitable contributions of \$3,600 over an eight year period (from 2008 to the present)⁹⁴ that were not related to fetal tissue donation.

E. No Evidence to Support Other Republican Allegations

While the federal prohibition on the transfer of fetal tissue for “valuable consideration” applies to all transfers involving interstate commerce, certain additional requirements apply only when donated tissue is used in federally-funded research involving the “transplantation of human fetal tissue for therapeutic purposes.”⁹⁵

The federal government has not funded this type of research since 2007.⁹⁶ This means that additional rules requiring, among other things, informed donor consent and certification that there has been no alteration of the “timing, method, or procedures used to terminate the pregnancy” have not applied to tissue donated in the United States over the past nine years.⁹⁷ Though not legally required, PPFA guidance nonetheless incorporates these additional rules as recommended practices,⁹⁸ and the Select Panel found no evidence that these rules have been violated.

The Panel also uncovered no evidence that providers and tissue procurement organizations are violating patient privacy rights or that infants are surviving abortion procedures, as Panel Republican have alleged.

1. No Wrongdoing Regarding Patient Consent by Planned Parenthood

The law governing federally-funded transplantation research requires written consent and additional donor statements – including affirmation that the patient made the decision to have an abortion before considering tissue donation – that are not required where donation is not made for this federally-funded purpose. While these requirements do not apply to its programs, PPFA has nonetheless voluntarily captured these requirements on its sample consent form,⁹⁹ which includes the following preamble:

Research using the blood from pregnant women and tissue that has been aborted has been used to treat and find a cure for such diseases as diabetes, Parkinson’s disease, Alzheimer’s disease, cancer, and AIDS.¹⁰⁰

Panel Republicans repeatedly criticized this statement because none of the listed diseases have yet been cured, and questioned the validity of patient consent as a result.¹⁰¹ However, while the providers interviewed by the Panel generally agreed that the statement “has been used” to find a cure was “inaccurate,” none had ever been told by a patient that she did not understand the form or had been coerced or misled into donating tissue. For example, one PPFA-affiliated physician (PP Witness #1) acknowledged that “to my knowledge there is no cure for AIDS” so

“that is probably an inaccurate statement.”¹⁰² PP Witness #1 further explained, however, that none of her patients had ever asked for more information or complained about their decision to donate tissue:

Minority counsel: [Y]ou were asked a number of questions about that first paragraph. In particular, just more broadly speaking, has any patient ever come in and asked you for more information about that first paragraph and what it says about research that can be done using blood from pregnant women and tissue that has been aborted?

Witness: No, they have not.

Minority counsel: Did any patient ever come in and indicate to you that they felt that was misleading, that first paragraph?

Witness: No, they have not.

Minority counsel: Or that they felt that they had somehow been convinced, hoodwinked, misled into donating because of what’s in that first paragraph.

Witness: No, they have not.¹⁰³

She also explained that “[i]f anything, the most common question I get is, ‘Can I donate my tissue?’” and provided the following example:

I had a patient who was terminating for fetal indication. There was an abnormality in the pregnancy and her and her partner both expressed to me that if there was anything good that could come out of their terrible experience, they’d like to, you know, add to the information on this disease so that other families didn’t have to experience what they did.¹⁰⁴

PP Witness #1 also acknowledged that the option to donate fetal tissue for research provides an alternative for women given that the tissue would otherwise be disposed of.¹⁰⁵

Panel Republicans and some witnesses also questioned whether an Institutional Review Board (“IRB”) – a committee designated to approve, monitor, and review research involving human subjects – would approve PPFA’s standard consent form because of the statements about cures.¹⁰⁶ In their interim update, Panel Republicans contended that testimony from the Panel’s first hearing “raised concerns that the principles embodied in the Belmont Report, and later incorporated into federal regulations, are not being followed by abortion providers seeking consent for the donation of human fetal tissue.”¹⁰⁷

Documents produced to the Panel disprove this contention and show that PPFA’s standard form was approved by an IRB. In that case, a medical college’s IRB approved the form

for use in a proposed project involving donation of tissue from a PPFA affiliate to researchers working on vaccines for infectious diseases including “HIV, Hepatitis, Malaria, and Dengue” fever.¹⁰⁸ As the researcher had explained, fetal tissue was critical to this study: “Basically because we have been limited to human peripheral blood samples for our studies, it has been very difficult to develop successful therapies to prevent or treat these diseases.”¹⁰⁹

After determining that the research project did not involve human subjects, the IRB approved PPFA’s standard consent form for use by patients donating to this project.¹¹⁰ In addition, the IRB found that because “samples will be obtained and the information obtained will be de-identified, no authorization or waiver of authorization by patients for the release of individually identified protected health information will be required.”¹¹¹ This example is consistent with information obtained by the Panel regarding other PPFA affiliate donation programs, which similarly appear not to involve human subject research and to require de-identified donations, and there is no evidence that consent was inadequate.

Unfortunately, and as PP Witness #2 further explained, the PPFA affiliate decided not to move forward with this project because “all the controversy and all the inquiries and all the allegations and all the questions” caused by the deceptively-edited Daleiden/CMP videos.¹¹²

2. Providers Do Not Alter Timing or Method of Abortions for Fetal Tissue Donation

As with the consent requirement, the requirement that there be no alteration to the method of abortion applies only to federally funded transplantation research. Yet PPFA guidance also voluntary includes the recommendation that “no substantive alteration in the timing of terminating the pregnancy or the method used was made for the purpose of obtaining the blood and/or tissue.”¹¹³

In August 2015, PPFA and some of its providers addressed the inflammatory claims perpetuated in the Daleiden/CMP videos that doctors were altering methods used to terminate pregnancies and violating the Partial-Birth Abortion Ban in order to obtain “intact fetuses” for donation.¹¹⁴ As PPFA explained, “there are only a few methods of abortion,” and – Planned Parenthood health centers – provide only (1) for early abortions, “medication abortion or surgical abortion involving mechanical or manual aspiration,” and (2) for abortions from approximately 13 weeks of gestation, dilation and extraction (“D&E”). PPFA does not perform inductions or hysterotomies, and “a decision about the method to be used is made by the physician in consultation with the woman, taking into account the relevant variables that would bear on that decision.”¹¹⁵

PPFA’s Chief Medical Officer explained to the Energy and Commerce Committee in the fall of 2015 that fetuses are not removed intact during D&E procedures and, as another PPFA-affiliated physician explained, no PPFA doctor would intentionally perform an intact D&E because doing so might violate the Partial-Birth Abortion Act.¹¹⁶

While performing a procedure, providers sometimes make small adjustments in technique for clinical reasons, including – for example – adjustments in how the physician is holding or

positioning a surgical instrument. These adjustments are not changes to the timing, method, or procedure of an abortion and do not put patient safety at risk. As PPFA had explained to Congress in August 2015:

In performing the selected method, a physician may need to make multiple adjustments to the method as the surgery proceeds. These adjustments are clinical judgments – not a change of method – made by the physician as the abortion proceeds and are always intended to achieve the women’s desired result as safely as possible. The key point, as the 1988 blue-ribbon commission [on fetal tissue research] recognized, is that there be no change that would impact the safety or well-being of the patient.¹¹⁷

When re-interviewed by Panel Republicans, one of the same PPFA-affiliated doctors (PP Witness #1) who already had briefed the Energy and Commerce Committee more than a year earlier again explained:

If a patient has consented to donate her tissue I do not change the timing, method, or procedure that I use when completing her abortion.

Each provider uses different techniques to complete a given medical procedure, and I am no different. How I complete a particular abortion procedure may be quite different from how another abortion provider completes the same procedure. This is common in the medical profession and it’s a practice designed to make the abortion safer for a given patient and set of circumstances.

The D&E abortion method involves removing the fetus in multiple parts using forceps. If a patient has decided to have an abortion and wants to donate the tissue, of course I abide by her wishes, and while during a particular D&E I may try not to damage certain tissue sought for research, I am not always able to satisfy my patient’s request.

First and foremost, my patient’s safety always comes before any tissue donation. Moreover, every patient is different. Sometimes I simply am not able to procure usable tissue during an abortion even if my patient has consented to the donation of her tissue.¹¹⁸

As PP Witness #1 further explained, “there are a variety of situational and patient factors that might cause a surgeon to change their technique,” including – for example – “if there is not adequate dilation, that provider may change their technique by using a different instrument and a different size or shape so that they can accomplish the procedure.”¹¹⁹ Where a patient has expressed a desire to donate tissue, any adjustments were to “accommodate the patient’s wishes

the best that I can” and that she “ha[d] not,” and she “would never” make an adjustment that would put a patient’s safety at risk.¹²⁰

Panel Republicans asked PP Witness #1 several times whether she – or other doctors – ever adjust the position of the fetus from a head-first (vertex) presentation to feet-first (breech) to enhance tissue donation, as has been alleged by Daleiden/CMP. She made clear that she had never done so and was not aware of anyone else who had either.

Majority counsel: So are you aware of any instances where a physician has altered a procedure to procure a particular body part.

Witness: I am not.¹²¹

As PP Witness #1 also explained, neither she nor any other PPFA-affiliated physician violate the Partial-Birth Abortion Ban.

Minority counsel: . . . Have you ever relied on the illegal partial birth abortion procedure to get a more intact specimen?

Witness: No, I have not.

Minority counsel: Have any of your colleagues to the best of your knowledge ever relied on, “illegal partial birth abortion procedures” for fetal tissue donation or any other purpose?

Witness: No. In fact, all of my Planned Parenthood colleagues have to document how they complied with the ban. So, no, they have not.¹²²

Another doctor (PP Witness #3) similarly told the Panel “I know of no one violating the [“Partial Birth Abortion”] ban, period, and then I certainly don’t know of anyone violating the ban for the purpose of collecting tissue.”¹²³

3. No Evidence of Privacy Violations

In their interim update, Panel Republicans claimed to have discovered “systematic violations” of patient privacy rules by StemExpress and several PPFA health centers. These claims were subsequently dismissed by the Department of Health and Human Services (“HHS”) for lack of evidence.

On May 31, 2016, Panel Republicans leaked to FOX News an advance copy of a June 1, 2016, letter to HHS that had not yet been sent to the Department or shared with Panel

Democrats. In that letter, Chair Blackburn alleged that the Panel had “uncovered information” indicating “systematic violations” of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and asked HHS to investigate.¹²⁴

In making these claims, Chair Blackburn relied upon a staff-created “work sequence” that purportedly represents the “daily routine” of a StemExpress tissue procurement technician as the basis of alleged wrongdoing.¹²⁵ But the Select Panel never interviewed any StemExpress employees or otherwise verified this staff-created narrative with the company.

On August 18, 2016, HHS’ Office of Civil Rights (“OCR”) sent a letter to the Panel seeking further information to support Chair Blackburn’s claims. In that letter, OCR explained that, without further information, OCR “will not be able to investigate your cases” and the file would be closed.¹²⁶ Panel Republicans never responded.

On September 12, 2016, Panel Democrats responded to the OCR’s letter and explained that the Panel had no evidence that patient privacy rights were violated and that documents produced to the Panel removed the possibility of any ongoing HIPAA violations.¹²⁷ On November 16, HHS confirmed that this matter has been closed.¹²⁸ Nonetheless, Chair Blackburn repeated these same allegations in a November 2, 2016, letter to the Department of Justice urging them to conduct an investigation into whether StemExpress violated various federal laws.¹²⁹

4. No Evidence of “Babies Born Alive During Abortions”

In their interim update, Panel Republicans claimed that “the induction abortion procedure has increased the likelihood that infants will be born alive during abortions” and expressed concern about “babies being born alive and the sale of baby body parts at some late-term abortion clinics.”¹³⁰

These claims were rebutted by doctors and clinic staff interviewed by the Panel. For example, Panel Republicans questioned one clinic’s staff about an alleged “surprise event” that Republicans claimed to have learned about from “two former employees,” as captured in the following exchange:

Majority counsel: One last question then. Were you in the clinic when there was a little surprise event related to a second twin that might not have been seen initially on the sonogram and so the digoxin was inserted into one twin, but then, during delivery, there was another heartbeat, a missed twin?

Minority counsel: So, [counsel], if there was such an instance, we have seen no documentation of it. So can you either put an actual instance in front of her or make clear this is a –

Majority counsel: I’m asking, I’m suggesting to you that a former employee of your clinic told us – two former employees of your clinic told us they were in the clinic when this happened.

Minority counsel: And I want to make clear that this information has not been shared with the minority.

Witness counsel: And I want to point out that [the witness] has testified that, to her knowledge, there has never been a baby born alive at the clinic.

Majority counsel: I just want to – I understand. I’m not sure the second baby was born alive. I just want to know if you were in the clinic? According to the two former employees, this created a little conflict in the clinic. Were you there at the time that this happened?

Witness: No, sir. I have never heard of such a thing in my clinic.

Majority counsel: Never heard of it.

Witness: Never.

Majority counsel: Okay. I just want to make sure.¹³¹

The witness subsequently confirmed that during her eleven years in the clinic – including the last five years, during which the doctor targeted by Panel Republicans had practiced at the clinic – “there has never been an infant born alive in our office ever, not even once.”¹³²

She and other staff from this same clinic also testified that, while they had never had an infant survive a failed abortion procedure, if it ever happened they would call 911 immediately and take steps to keep the fetus alive until the ambulance arrived.¹³³

A doctor interviewed by the Panel (PP Witness #1) similarly told the Panel that she had never heard of any instances where babies were born alive following abortion procedures at any Planned Parenthood clinic. As she made clear:

So in my experience I have never had a viable infant, a viable fetus born with signs of life. If it were to happen to me, I would call an ambulance and give the fetus comfort care until the ambulance arrived if it was viable or looked like it was perivable.¹³⁴

Another doctor who practices in a university setting was asked and told the Panel *fourteen times* that she had never experienced a baby born alive following an abortion procedure.¹³⁵

These witnesses debunked all of the Republican’s claims regarding infants “born alive” following abortion procedures.

ENDNOTES

¹ National Organ Transplant Act, Pub. L. No. 98-507; 42 U.S.C. §274e (1984); *see also* Memorandum by Select Investigative Panel Democratic Staff Re: Hearing on “The Pricing of Fetal Tissue” (Apr. 19, 2016) (noting that HHS said “the average cost of transplantation in 2011 ranged from \$262,000 for a single kidney to over \$1,148,000 for a heart-lung transplant.”).

² 42 U.S.C. § 289g-2.

³ Dave Levitan, *Unspinning the Planned Parenthood Video*, FACTCHECK.ORG (July 21, 2015), <http://www.factcheck.org/2015/07/unspinning-the-planned-parenthood-video/>.

⁴ *Planned Parenthood Exposed: Examining Abortion Procedures and Medical Ethics at the Nation’s Largest Abortion Provider*, Hearing Before the H. Comm. on Judiciary, 114th Cong. 64 (Oct. 8, 2015).

⁵ Letter from Cecile Richards, President, Planned Parenthood Fed’n of America to Speaker John A. Boehner, et al. (Aug. 27, 2015).

⁶ *Id.*

⁷ Letter from K. Lee Blalack II, O’Melveny & Myers LLP to Hon. Fred Upton, Chairman, H. Comm on Energy and Commerce, et al. (Nov. 10, 2015).

⁸ *See* Response from Planned Parenthood Fed’n of America to H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, “*Follow-Up Questions Dated Aug. 20, 2015*”; Letter from K. Lee Blalack II, O’Melveny & Myers LLP to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce, et al. (Nov. 10, 2015).

⁹ Specimen Donation Agreement between Novogenix Laboratories, LLC and Planned Parenthood Los Angeles (Sept. 2, 2015) (NOVOEC-0000165–NOVOEC-0000171).

¹⁰ *See* Agreement between Advanced Bioscience Resources, Inc. and Planned Parenthood Mar Monte (SP000011–SP000012); Agreement between StemExpress LLC and Planned Parenthood Mar Monte (STEM.HOUSE.SELECT_0004–0006).

¹¹ Letter from Cecile Richards, President, Planned Parenthood Fed’n of America to Dr. Francis Collins, Director, Nat’l Inst. of Health (Oct. 13, 2015).

¹² As of November 2013, affiliates have been permitted to facilitate fetal tissue donation without prior approval from PPFA. Prior to that time, PPFA guidance instructed affiliates to submit requests for fetal tissue donation programs for review and approval. The November 2013 change was part of a broader overhaul designed to reduce administrative burdens on affiliates and support expansion of services by allowing affiliates to offer a range of non-core services without prior approval. *See e.g.*, Response from Planned Parenthood Federation of America to H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, “*Follow-Up Questions Dated Aug. 20, 2015.*”; Planned Parenthood Federation of America, Manual of Medical Standards and Guidelines, Programs for Donation for Blood And/OR Aborted Pregnancy Tissue for Medical Research, Education, and Treatment (June 2011).

¹³ Letter from Cecile Richards, President, Planned Parenthood Fed’n of America to Dr. Francis Collins, Director, Nat’l Inst. of Health (Oct. 13, 2015).

¹⁴ Letter from K. Lee Blalack II, O’Melveny & Myers LLP to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce, et al. (Nov. 10, 2015), at 3; Planned Parenthood Fed’n of America Memorandum *Re: Federal Regulations for Aborted Pregnancy Tissue Donation Programs* (PPFA-HOU_E&C-000150).

¹⁵ Letter from K. Lee Blalack II, O’Melveny & Myers LLP to Planned Parenthood Fed’n of America to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce, et al. (Nov. 10, 2015), at 3.

¹⁶ *Id.* at 2.

¹⁷ *See* U.S. Gov’t Accountability Office, Letter to Sens. Arlen Specter, Tom Harkin, and Bob Smith, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (Oct. 4, 2000).

¹⁸ Letter from K. Lee Blalack II, O’Melveny & Myers LLP to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce, et al. (Nov. 10, 2015), at 4.

¹⁹ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 6, 2016).

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 19, 2016).

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 19, 2016).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 19, 2016).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Nat'l Abortion Fed'n v. Ctr. for Med. Progress, No. 15-cv-03522-WHO, 2016 U.S. Dist. LEXIS 14485 at *28-29 (N.D. Cal. Feb. 5, 2016) (granting motion for preliminary injunction).

⁴¹ Letter from Stephen M. Ryan, McDermott Will & Emery LLP to Hon. Marsha Blackburn, Chair, and Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (Jan. 29, 2016)

⁴² THE ENERGY AND COMMERCE COMM., SELECT INVESTIGATIVE PANEL, *Select Investigative Panel Issues 12 New Subpoenas to Fetal Tissue Procurement Organizations* (Mar. 30, 2016), <https://energycommerce.house.gov/news-center/press-releases/select-investigative-panel-issues-12-new-subpoenas-fetal-tissue>.

⁴³ April 2016 Monthly Report to Comm. on H. Administration (May 18, 2016),

https://cha.house.gov/sites/repUBLICANS.cha.house.gov/files/4_16%20Energy%20and%20commerce.pdf.

⁴⁴ See Letter from Hon. Marsha Blackburn, Chair, Select Investigative Panel to Hon. Hector H. Balderas, Jr., Attorney General of New Mexico (June 23, 2016).

⁴⁵ See Letter from Select Panel Democrats to Hon. Hector H. Balderas, Jr. Attorney General of New Mexico (July 12, 2016) [Appendix B, Correspondence from Select Panel Democrats to Outside Entities].

⁴⁶ Dep't of Justice, Office of Legal Counsel, *Legality of Alternative Organ Donation Practices Under 42 U.S.C. §274e* (Mar. 28, 2007).

⁴⁷ *Id.*

⁴⁸ Letter from Stephen M. Ryan, McDermott Will & Emery LLP to Hon. Marsha Blackburn, Chair, and Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel, (June 27, 2016), at 3.

⁴⁹ *Id.*

⁵⁰ *Id.* at 3-4.

⁵¹ *Id.* at 3.

⁵² See Letter from Stephen M. Ryan, McDermott Will & Emery LLP to Hon. Marsha Blackburn, Chair, and Hon. Jan Schakowsky, Ranking Member, Select Investigative Panel (June 27, 2016).

⁵³ See Letter from Select Panel Democrats to Hon. Hector H. Balderas, Jr., Attorney General of New Mexico (July 12, 2016) [Appendix B, Correspondence from Select Panel Democrats to Outside Entities].

⁵⁴ U.S. Gov't Accountability Office, Letter to Sens. Arlen Specter, Tom Harkin, and Bob Smith, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (Oct. 4, 2000), at 5-6.

⁵⁵ See e.g., *id.* at 2, n.1 (explaining that its definition of fetal tissue excludes “research involving derivatives of human fetal tissue such as human fetal cell cultures and human fetal cell lines...”).

⁵⁶ See e.g., *Criminal Contempt Report of the Select Investigative Panel of the Comm. on Energy and Commerce* (Sept. 19, 2016); Republican Interim Update.

⁵⁷ StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) (STEM.HOUSE.SELECT_ 0228).

⁵⁸ StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) (STEM.HOUSE.SELECT_ 0232).

⁵⁹ Letter from Amandeep S. Sidhu, McDermott Will and Emery LLP to Hon. Marsha Blackburn and Hon. Jan Schakowsky *Re: Call for Withdrawal or Amendment of Proposed Exhibits for April 20, 2016 Hearing on ‘The Pricing of Fetal Tissue’* (Apr. 19, 2016), at 4.

⁶⁰ Letter from Amandeep S. Sidhu, McDermott Will and Emery LLP to Hon. Marsha Blackburn and Hon. Jan Schakowsky *Re: StemExpress Statement Regarding Select Investigative Panel and April 20, 2016 Hearing on ‘The Pricing of Fetal Tissue’* (Apr. 19, 2016), at 5.

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- ⁶¹ *Id.* at 3.
- ⁶² *Id.*
- ⁶³ StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) (STEM.HOUSE.SELECT_ 0232).
- ⁶⁴ StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) (STEM.HOUSE.SELECT_ 0238).
- ⁶⁵ “Fetal Tissue Sales by Client Detail, January – December 2015” (May 10, 2016) (STEM.HOUSE.SELECT_ 0948).
- ⁶⁶ “Sales by Product/ Service Detail, January – December 2011” (May 10, 2016) (STEM.HOUSE.SELECT_ 0916).
- ⁶⁷ See Letter from Amandeep S. Sidhu, McDermott Will and Emery LLP to Hon. Marsha Blackburn and Hon. Jan Schakowsky *Re: StemExpress Statement Regarding Select Investigative Panel and April 20, 2016 Hearing on “The Pricing of Fetal Tissue”* (Apr. 19, 2016), at 4; StemExpress First Response to House Select Panel Document Requests (Jan. 15, 2016) (STEM.HOUSE.SELECT_ 0238).
- ⁶⁸ See StemExpress Sixth Response to House Select Panel Subpoenas (May 10, 2016) (STEM.HOUSE.SELECT_ 0916 - 0948).
- ⁶⁹ THE ENERGY AND COMMERCE COMM., SELECT INVESTIGATIVE PANEL, *Select Investigative Panel Issues Subpoenas for StemExpress Accounting and Banking Records* (May 5, 2016), <https://energycommerce.house.gov/news-center/press-releases/select-investigative-panel-issues-subpoenas-stemexpress-accounting>.
- ⁷⁰ See Letter from Amandeep S. Sidhu, McDermott Will and Emery LLP to Hon. Marsha Blackburn and Hon. Jan Schakowsky *Re: StemExpress Response to Chairman Blackburn’s April 28 Letter to StemExpress*” (May 6, 2016); See also Appendix C, Overview of Select Panel Interactions with StemExpress.
- ⁷¹ See e.g. Letter from Hon. Marsha Blackburn, Chair, Select Investigative Panel, to Hon. Loretta Lynch, Attorney General, U.S. Dep’t of Justice (Nov. 2, 2016), at 7; *Criminal Contempt Report of the Select Investigative Panel of the H. Comm. on Energy and Commerce* (Sept. 19, 2016), at 11-12; Republican Interim Update, at 41.
- ⁷² See StemExpress Sixth Response to House Select Panel Subpoenas (May 10, 2016) (STEM.HOUSE.SELECT_ 0909 - 0911).
- ⁷³ *StemExpress Fourth Response to House Select Panel Subpoena* (Mar. 28, 2016) (STEM.HOUSE.SELECT_ 0706); *StemExpress Third Response to House Select Panel Subpoena* (Mar. 14, 2016) (STEM.HOUSE.SELECT_ 0666).
- ⁷⁴ Memorandum from Comm. on Energy and Commerce Democratic Staff *Re: Update on the Committee’s Ongoing Investigation of Planned Parenthood Federation of America* (Sept. 9, 2015), at 8-9.
- ⁷⁵ Letter from Amandeep S. Sidhu, McDermott Will and Emery LLP to Hon. Marsha Blackburn and Hon. Jan Schakowsky *Re: Call for Withdrawal or Amendment of Proposed Exhibits for April 20, 2016 Hearing on “The Pricing of Fetal Tissue”* (Apr. 19, 2016), at 6.
- ⁷⁶ See. “Advanced Bioscience Resources, Inc.” (Feb. 24, 2016) (SP000756); Letter from Johnathan E. Lopez, Orrick Herrington and Sutcliffe LLP to Hon. Marsha Blackburn, Chair, Select Investigative Panel *Re: Select Panel on Infant Lives Document Request – December 17, 2015* (Jan. 8, 2016).
- ⁷⁷ “ABR Financials” (Oct. 6, 2015) (SP000063).
- ⁷⁸ Letter from Jonathan E. Lopez, Orrick Herrington and Sutcliffe LLP to Hon. Fred Upton, Chairman, Comm. on Energy and Commerce, *Re: Advanced Bioscience Resources, Inc.* (Oct. 6, 2015) (SP000060).
- ⁷⁹ Republican Interim Update, at 43.
- ⁸⁰ *Id.* at 44-45.
- ⁸¹ “Novogenix Research Summary” (Sept. 2, 2015) (NOVOEC-0000173).
- ⁸² Letter from Joshua A. Levy, Cunningham Levy Muse LLP to Select Panel Republican staff *Re: Novogenix Laboratories, LLC* (Dec. 22, 2015).
- ⁸³ Letter from Joshua A. Levy, Cunningham Levy Muse LLP to Energy and Commerce Comm. Republican staff *Re: Novogenix Laboratories, LLC* (Sept. 2, 2015), at 4.
- ⁸⁴ See “Follow-up to September 22, 2015 letter” (Oct. 6, 2015) (NOVOEC – 0000174); Letter from Joshua A. Levy, Cunningham Levy Muse LLP to Energy and Commerce Comm. Republican staff *Re: Novogenix Laboratories, LLC* (Sept. 2, 2015) at 2, n.3; see also See Memorandum from Comm. on Energy and Commerce Democratic Staff *Re: Update on the Committee’s Ongoing Investigation of Planned Parenthood Federation of America* (Sept. 9, 2015).
- ⁸⁵ DV BIOLOGICS, ABOUT US, <http://www.dvbiologics.com/about-us> (last visited Nov. 29, 2016).
- ⁸⁶ Letter from R. Joseph Burby IV, Bryan Cave LLP to Hon. Marsha Blackburn, Chair, Select Investigative Panel *Re DV Biologics, LLC* (Jan. 29, 2016), at 1.

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- ⁸⁷ Letter from Michael R. Tein, Lewis Tein PL to Select Panel Republican staff *Re: In the Matter of the Subpoena to DV Biologics, LLC* (May 16, 2016), at 2.
- ⁸⁸ “*DaVinci Biosciences LLC Characterization of Human Fetal Stem Cells and Determination of Research and Therapeutic Tool Potential* (Jan 29, 2016) (DVB_00001611).
- ⁸⁹ Letter from R. Joseph Burby IV, Bryan Cave LLP to Hon. Marsha Blackburn, Chair, Select Investigative Panel *Re DV Biologics, LLC* (Jan. 29, 2016), at 3.
- ⁹⁰ Letter from Michael R. Tein, Lewis Tein PL to Select Panel Republican staff *Re: In the Matter of the Subpoena to DV Biologics, LLC* (May 16, 2016), at 2.
- ⁹¹ Republican Interim Update, at 87.
- ⁹² See THE ENERGY AND COMMERCE COMM., SELECT INVESTIGATIVE PANEL, *Blackburn Statement on Lawsuit Filed by CA District Attorney Against Tissue Procurement Businesses* (Oct. 12, 2016), <https://energycommerce.house.gov/news-center/press-releases/blackburn-statement-lawsuit-filed-ca-district-attorney-against-tissue>; Christopher Goffard and Soumya Karlamangla, *Orange County prosecutors file suit against biological suppliers, alleging unlawful pricing of fetal tissue*, LA TIMES (Oct. 13, 2016) (“He [District Attorney Rackauckas] said there was no evidence that the companies exchanged money with Planned Parenthood, or that Planned Parenthood did anything unlawful.”), <http://www.latimes.com/local/lanow/la-me-ln-fetal-tissue-charges-orange-county-20161012-snap-story.html>.
- ⁹³ Email correspondence from Select Panel Democratic staff to Select Panel Republican staff (Oct. 13, 2016), on file with the Democratic Members.
- ⁹⁴ Letter from DaVinci Biosciences VP of Operations to Select Panel Republican staff *Re: DV Biologics* (Aug. 10, 2016).
- ⁹⁵ 42 U.S.C. § 289g-1(b).
- ⁹⁶ Letter from Jim R. Esquea, Assistant Sec’y for Legislation, Dep’t of Health and Human Services to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce (July 14, 2015).
- ⁹⁷ 42 U.S.C. § 289g-1(b)(1) and (2).
- ⁹⁸ Planned Parenthood Fed’n of America, *Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research* (May 2015) (PPFA-HOU_E&C-000043-44) (“Federal law establishes additional requirements applicable whenever the research involving fetal tissue is conducted or supported by the federal government. PPFA recommends that these requirements be adhered to without regard to whether the tissue donation program is federally supported or not.”).
- ⁹⁹ *Sample Consent for the Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research* (May 2015) (PPFA-HOU_E&C-000045). Variations of this basic form have been used by Planned Parenthood affiliates that facilitated fetal tissue donation, with slight modifications, since at least 2001.
- ¹⁰⁰ Planned Parenthood Fed’n of America, *Manual of Medical Standards and Guidelines: Programs for Donation of Blood And/Or Aborted Pregnancy Tissue for Medical Research, Education, or Treatment* (June 2011) (PPFA-HOU_E&C-000031).
- ¹⁰¹ See, e.g., *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. On Energy and Commerce*, 114th Cong. (unedited transcript 115) (Mar. 2, 2016) (statement by Rep. Harris).
- ¹⁰² Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 6, 2016).
- ¹⁰³ *Id.*
- ¹⁰⁴ *Id.*
- ¹⁰⁵ *Id.*
- ¹⁰⁶ *Bioethics and Fetal Tissue: Hearing Before the Select Investigative Panel, H. Comm. On Energy and Commerce*, 114th Cong. (unedited transcript 92) (Mar. 2, 2016).
- ¹⁰⁷ Republican Interim Update, at 4.
- ¹⁰⁸ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 19, 2016).
- ¹⁰⁹ *Id.*
- ¹¹⁰ *Id.*
- ¹¹¹ *Id.*
- ¹¹² *Id.*
- ¹¹³ Planned Parenthood Fed’n of America, *Programs for Donation of Blood and/or Aborted Pregnancy Tissue for Medical Research* (May 2015) (PPFA-HOU_E&C-000043-44).
- ¹¹⁴ See Memorandum from Comm. on Energy and Commerce Democratic Staff *Re: Update on the Committee’s Ongoing Investigation of Planned Parenthood Federation of America* (Sept. 9, 2015); Letter from Cecile Richards, President, Planned Parenthood Fed’n of America to Speaker John A. Boehner, et al. (Aug. 27, 2015).

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- ¹¹⁵ Letter from Cecile Richards, President, Planned Parenthood Fed'n of America to Speaker John A. Boehner, et al., at 6 (Aug. 27, 2015).
- ¹¹⁶ Memorandum from Comm. on Energy and Commerce Democratic Staff Re: Update on the Committee's Ongoing Investigation of Planned Parenthood Federation of America, at 10 (Sept. 9, 2015).
- ¹¹⁷ Letter from Cecile Richards, President, Planned Parenthood Fed'n of America to Speaker John A. Boehner, et al., at 6 (Aug. 27, 2015).
- ¹¹⁸ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct. 6, 2016).
- ¹¹⁹ *Id.*
- ¹²⁰ *Id.*
- ¹²¹ *Id.*
- ¹²² *Id.*
- ¹²³ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Nov. 1, 2016).
- ¹²⁴ Letter from Hon. Marsha Blackburn, Chair, Select Investigative Panel to Ms. Jocelyn Samuels, Director, Office for Civil Rights, Dep't of Health and Human Services (June 1, 2016).
- ¹²⁵ *Id.* at 2-3.
- ¹²⁶ Letter from Michael Leoz, Regional Manager, Office for Civil Rights, Dep't of Health and Human Services, to Hon. Marsha Blackburn, Chair, Select Investigative Panel (Aug. 18, 2016).
- ¹²⁷ Letter from Select Panel Democrats to Mr. Michael Leoz, Regional Manager, Office for Civil Rights, Dep't of Health and Human Services (Sept. 12, 2016).
- ¹²⁸ Email correspondence from Dep't of Health and Human Services staff to Select Panel Democratic staff (Nov. 16, 2016), on file with the Democratic Members.
- ¹²⁹ *See* Letter from Hon. Marsha Blackburn, Chair, Select Investigative Panel to Hon. Loretta Lynch, Attorney General, U.S. Dep't of Justice (Nov. 2, 2016), at 8.
- ¹³⁰ Republican Interim Update, at iv.
- ¹³¹ Transcribed Interviews of the Select Investigative Panel, H. Energy and Commerce Comm. (July 21, 2016).
- ¹³² *Id.*
- ¹³³ *Id.*
- ¹³⁴ Transcribed Interview of the Select Investigative Panel, H. Energy and Commerce Comm. (Oct 6, 2016).
- ¹³⁵ Deposition of [Dr. Administrator] by the Select Investigative Panel, H. Energy and Commerce Comm. (May 11, 2016).