

MEMORANDUM

April 19, 2016

To: Democratic Members of the Select Investigative Panel

Fr: Select Panel Democratic Staff

Re: Hearing on “The Pricing of Fetal Tissue”

On Wednesday, April 20, 2016, at 10:00 a.m. in room HVC-210 in the U.S. Capitol, the Select Panel will hold a hearing on the federal law that prohibits the sale of fetal tissue for profit. This is the second hearing of the Select Investigative Panel, created by House Republicans last October to continue investigating the allegations of anti-abortion activist David Daleiden whose elaborate entrapment scheme resulted in the creation and release of a series of deceptively-edited videos last July.

From the outset, this investigation has not been an objective, fact-based inquiry for the truth, but a political weapon to harass and intimidate healthcare providers and researchers. Republicans have refused to adopt an investigative plan, refused to adopt rules to protect individual privacy and safety, denied Democrats access to Committee records, and refused to consult with the Ranking Member before issuing unilateral and unjustifiable subpoenas to universities and healthcare providers. We expect more of the same at Wednesday’s hearing.

The Republicans told us that they will be using “materials from the Panel’s document production, open source materials, and panel staff research” to question the witnesses on Wednesday. Yesterday, they sent the packet of documents that they plan to use. Some of these documents are Republican staff work-product. The underlying facts used to create those documents have not been identified and the conclusions that Republicans seek to draw from these materials are inaccurate and misleading. Other documents, including those that Republican staff identified as relating to a “procurement business” cannot be properly understood without further information from individuals with actual knowledge of the information that they contain. Nevertheless, we anticipate that the Republicans will claim – and invite their witnesses to agree – that these documents indicate possible criminal misconduct that warrants this Panel’s and the Justice Department’s investigation. In reality, the documents themselves are not evidence of unlawful conduct as any dollar amounts that they contain or discussion of pricing and costs may represent lawful, reimbursable costs associated with fetal tissue research.

Sixteen years ago, similar materials were used as alleged evidence of unlawful profiteering from fetal tissue sales during a hearing before the Health and Environment Subcommittee of the House Committee on Commerce.¹ During that hearing, the key witness

¹ *Fetal Tissue: Is it Being Sold in Violation of Federal Law: Hearing Before the Subcomm. on Health and the Env’t of the H. Comm. on Commerce*, 106th Cong. (2000).

acknowledged that he had lied when he claimed to have witnessed the unlawful sale of fetal tissue and other misconduct. That hearing – as will be true Wednesday – featured invoices, inventory logs, and agreements that were supposed to show the unlawful sale of fetal tissue; but the Justice Department investigated those claims and found no evidence that laws had been broken.

I. Fetal Tissue and Adult Organ Donation are Subject to the Same Prohibition on Profit, but Reimbursement for Costs is Expressly Allowed.

In 1993, Congress voted on an overwhelmingly bipartisan basis in favor of fetal tissue research, with a 93-4 vote in the Senate and 290-130 vote in the House.² In doing so, Congress followed the core recommendations of a blue-ribbon research panel convened under President Reagan to study the ethics of fetal tissue research and advise the Administration. That panel found that fetal tissue research is ethical and voted in favor of federal funding for it.³ Many leading Republicans agreed and spoke passionately about the value of fetal tissue research in urging their colleagues to vote for the NIH Revitalization Act of 1993.⁴

The NIH Revitalization Act of 1993’s provisions regarding donation of fetal tissue are modeled on the National Organ Transplant Act (NOTA).⁵ Introduced in the House by Democrat Al Gore and in the Senate by Republican Orrin Hatch, the NOTA also enjoyed overwhelming bipartisan support and passed by voice vote in both chambers.⁶ The NOTA prohibits the transfer of any human organ for transplantation for “valuable consideration” but allows “reasonable payments” associated with organ donation, which can be considerable.⁷

Nine years later, Congress adopted the same core standard for fetal tissue donation. As is the case for human organs, fetal tissue cannot be transferred for “valuable consideration” but

² National Institutes of Health Revitalization Act of 1993, Roll Call Votes, S.1, 103d Congress (1993), *available at* http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=103&session=1&vote=00015; <http://clerk.house.gov/evs/1993/roll178.xml> (other current Senators who also voted for the bill include Sens. Coats (R-IN), Cochran (R-MS), Grassley (IA), Hatch (UT), McCain (AZ) and Shelby (AL). Representative Lamar Smith (R-TX) also voted in favor of the legislation).

³ National Institutes of Health, Report of the Advisory Committee to the Director, Human Fetal Tissue Transplantation Research (Dec. 14, 1988).

⁴ See, e.g., statements of Senators Bob Dole (R-KS) and Strom Thurmond (R-SC) and Representative John Porter (R-IL), *available at* <https://selectpanel.dems-energycommerce.house.gov/our-work/benefits-fetal-tissue-research>.

⁵ National Organ Transplant Law, Pub. L. No. 98-507; 42 U.S.C. §274e (1984).

⁶ National Organ Transplant Act of 1984, S.2048, 98th Cong. (1984); Legislative Information System Bill Summary & Status, *available at* <http://www.lis.gov/cgi-lis/bdquery/z?d098:SN02048:@@X:dbn>.

⁷ U.S. Department of Health and Human Services, Organ Transplantation: The Process, *available at* <http://www.organdonor.gov/about/transplantationprocess.html> (noting that “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.”).

reimbursement for the costs associated with donation is allowed. As the House Committee report accompanying the bill explained:

The Committee adopts the prohibition on the sale of human fetal tissue to make the treatment of such tissue parallel to the treatment of other human organs intended for transplantation (as provided in the Organ Procurement and Transplantation Act, P.L. 98-507). Indeed, the Committee has dealt with fetal tissue more restrictively than other transplantation, for although current organ transplant law prohibits the sale of organs, it allows for payment for the removal of the organ. The Committee, sensitive to the controversies surrounding Federal payment for abortion services, (which would in this instance be tantamount to the organ removal), has not allowed for such payment.⁸

Thus, the overall intent was to make the treatment of fetal tissue parallel to the treatment of other human organs. In an effort to steer clear of ongoing controversy regarding federal funding of abortion services – an issue that remains hotly debated to this day – the Committee wanted to ensure that care provided as part of the underlying abortion itself was not considered a cost associated with the donation of fetal tissue and, therefore, did not cover the costs of “removal” permitted for other organ transplantation. While the Committee acknowledged that, in this regard, it was dealing with fetal tissue “more restrictively than other transplantation,” it did not thereby disallow payment for other costs such as processing, preservation, or quality control – all of which may vary depending on the particular specimen or tissue that is needed for research purposes.

Thus, and to the extent Republicans seek to change existing standards for fetal tissue donation, Congress must examine whether departing from the nearly identical standard that currently governs both fetal tissue and adult organ donation is warranted. Without objective, fact-based evidence to support altering the legal standard for fetal tissue donation – but not adult organ donation – the single-minded focus on fetal tissue is nothing more than a continued effort to attack legal abortion and women’s healthcare choices, including the choice to donate fetal tissue for research purposes.

For purposes of this hearing, the following requirements are most relevant.

- *Valuable consideration is prohibited:* 42 U.S.C. § 289g-2(a) provides: “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.”
- *But reimbursement for reasonable costs is permitted:* 42 U.S.C. § 289g-2(e)(3) provides: “The term ‘valuable consideration’ does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”

⁸ H.R. Rep. No. 103-28 at 76 (1993).

II. There is No Evidence of an Unlawful Marketplace for Fetal Tissue, as Anti-Abortion Extremists and Republican Leaders have Alleged.

So far, the Chair has used this investigation to target abortion clinics and researchers in addition to the “middleman tissue procurement businesses.”

As explained in more detail below, there is no evidence that Planned Parenthood or other healthcare providers or researchers have done anything wrong. In fact, with regard to the university researchers and the clinic that the Chair has targeted with unilateral subpoenas, the Panel has known since late January – before any subpoenas were issued – that the clinic does not receive any money for fetal tissue that is donated to University researchers.

With regard to the tissue procurement organizations, the Chair has targeted one company through issuance of multiple unilateral subpoenas. For its part, that company has offered to have its procurement director explain its costs to the Panel. So far, the Chair has declined that offer, choosing instead to hold a public hearing with witnesses that lack the firsthand knowledge to bring this investigation to an end.

A. No Evidence of Wrongdoing by Healthcare Providers or Researchers.

In his deceptively-edited videos, David Daleiden and his anti-abortion associates allege that doctors who perform abortions are selling fetal tissue for profit. Republican lawmakers continue to parrot these allegations despite the fact that Planned Parenthood has been investigated repeatedly and cleared of wrongdoing.

Nothing in the documents that we have seen since the start of this investigation alters this conclusion. In fact, with regard to the university and the clinic subject to unilateral subpoenas from Chair Blackburn, the Panel has known since late January that the clinic receives no money – not even for expenses as expressly permitted by law – related to fetal tissue that is donated to university researchers. This information was provided voluntarily, before the Chair issued her subpoenas and falsely declared that these entities had failed to cooperate in her investigation.

Documents received from other clinics similarly show that many do not accept reimbursement for expenses related to fetal tissue donation. This means that these healthcare providers receive no payment – not even for their expenses as expressly permitted by law – when a woman chooses to donate tissue for research purposes.

Other clinics recover amounts similar to the costs identified by the Government Accountability Office (GAO) sixteen years ago.⁹ In its study of the acquisition of fetal tissue for biomedical research, the GAO reported in October 2000 that researchers paid fees per sample to health clinics ranging between \$2 and \$75 dollars. Researchers had “additional expenses for

⁹ U.S. Government Accountability Office, Letter to Sens. Arlen Specter, Tom Harkin, and Bob Smith, Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research (Oct. 4, 2000).

transporting, processing, preserving, storing, and ensuring the quality of human fetal tissue specimens, even if they paid nothing to acquire the tissue.”¹⁰ These additional costs include:

[C]osts associated with transporting tissue samples from the supplier to the researcher by any means, including by personal delivery or commercial shipping company, and shipping supplies such as sample containers or sterile media provided by the researcher. Other direct costs include renting space at a supplier’s facility, in-kind services or donations of staff time or supplies to the tissue supplier, and any other financial considerations as a result of acquiring fetal tissue that they would not have otherwise, such as equipment for storing the tissue.¹¹

Overall, the GAO found that “federal human fetal tissue procurement policies and guidance are consistent with federal law.”¹² It also noted that review boards at research institutions play the primary role in ensuring that fetal tissue procurement complies with federal, state, and local laws.

In an August 2015 letter to Congress, Planned Parenthood explained that only two of its 59 affiliates - less than 1% of Planned Parenthood clinics - facilitate donation for women who want to donate tissue for research. One of the two affiliates received no reimbursement for its costs. The second affiliates "recover[ed] only their costs, as allowed under the federal law and our [Planned Parenthood's] guidance." Those amounts were a modest \$60 per tissue specimen for one affiliate and, for another, just \$45-\$55 per tissue specimen. Thus, even before Planned Parenthood announced in October 2015 that its health centers that facilitate fetal tissue donation will no longer accept any reimbursement (not even the reimbursement of costs permitted by law), Planned Parenthood was operating well within the range reported by GAO sixteen years ago.

When asked about fees in the range of \$30-\$100, one expert in the use of fetal tissue for research responded that “there’s no way there’s a profit at that price.”¹³ As she further explained, “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.”¹⁴ Documents that we have seen indicate that, as with Planned Parenthood, far from profiting through the “sale” of fetal tissue, health clinics are most likely losing money in connection with fetal tissue donation programs. This is not what Congress intended when it passed a law that expressly permits reimbursement for costs. These clinics should not have to operate at a loss in order to facilitate fetal tissue donation. The fact that, even when they do, Republican lawmakers continue to make inflammatory and baseless claims of unlawful profiteering is further evidence that this is not an objective or fact-based search for the truth.

¹⁰ *Id.* at 6.

¹¹ *Id.*, n. 10.

¹² *Id.* at 2.

¹³ Dave Levitan, *Unspinning the Planned Parenthood Video*, FactCheck.org (July 21, 2015).

¹⁴ *Id.*

B. Tissue Procurement Organizations have Been Cooperating and the Chair’s Primary Target has Sought to Explain its Costs to the Panel.

Not surprisingly, the Chair has targeted the same company (StemExpress) that received the most attention in the Daleiden videos. Some of those videos feature a former independent contractor – Holly O’Donnell – claiming to have witnessed misconduct during the course of her employment. Her claims are highly reminiscent of the claims made sixteen years ago by Dean Alberty, who worked for two tissue procurement organizations. Alberty’s inflammatory claims triggered a House hearing that collapsed when Alberty admitted that his inflammatory claims contradicted testimony that he had given under oath.¹⁵ When asked to explain that difference, Alberty admitted that what he had said under oath was the truth, not what he had said in a videotaped interview with an anti-abortion group.

Representative Waxman: So your statements under oath seem to contradict your statements that you gave for purposes of a propaganda piece I which you appeared and were paid for appearing by an anti-abortion organization. Is that an accurate statement?

Mr. Alberty: That is an accurate statement. When I was under oath I told the truth. Anything I said on the video when I’m not under oath, that is a different story.¹⁶

There is no reason to believe that Daleiden and his associates do any better under oath, particularly after a Texas grand jury has already indicted Daleiden for breaking the law in his efforts to entrap Planned Parenthood and others. Just last month, the Los Angeles Times reported that:

Unreleased footage filed in a civil court case shows that O’Donnell’s apparently spontaneous reflections were carefully rehearsed. David Daleiden, the anti-abortion activist who made the videos, is heard coaching O’Donnell through repeated takes, instructing her to repeat anecdotes, add details, speak “fluidly” and be “very natural.”¹⁷

However, and while the Chair has not hesitated to serve subpoenas on doctors and researchers who are performing life-saving healthcare and research, the Republicans remain unwilling to put Daleiden or his associates to the test. Republicans have also roundly condemned tissue procurement organizations – particularly StemExpress – again before testing the source of those claims and without affording these organizations a meaningful opportunity to

¹⁵ *Fetal Tissue: Is it Being Sold in Violation of Federal Law: Hearing Before the Subcomm. on Health and the Env’t of the H. Comm. on Commerce*, 106th Cong. 2 (2000).

¹⁶ *Id.* at 72.

¹⁷ Jeremy Brenningstall et. al, *How anti-abortion activists used undercover Planned Parenthood videos to further a political cause*, Los Angeles Times, (Mar. 30, 2016).

explain their costs, something that StemExpress offered to do more than a month ago. As the company informed the Panel, its procurement director could answer questions from the Panel regarding the fetal tissue procurement process at StemExpress.

Ignoring the actual facts available to them, the Majority intends to use a public hearing to show witnesses who lack firsthand knowledge a variety of documents and claim that these documents support their inflammatory allegations and the need for this investigation.

Sixteen years ago, the Subcommittee on Health and Environment of the House Commerce Committee considered similar materials during its hearing on unlawful fetal tissue sales. During that hearing, Republicans used similar documents – for example, a “fee for service schedule” showing amounts charged for types of tissue, “transaction logs” with charges for tissue on particular dates, and agreements between providers and procurement organizations – as evidence of criminal conduct by tissue procurement organizations.¹⁸ The Department of Justice investigated the allegations of unlawful profiteering at the heart of that hearing and concluded that no laws had been broken.¹⁹

The Chair’s treatment of Southwestern Women’s Options, the University of New Mexico, and StemExpress indicate that this is not an actual search for the facts or the truth. A public hearing – where the majority intends that no one will be able to provide an actual explanation of the costs reflected on various exhibits that might be used -- is not necessary or designed to achieve any legitimate aim of this investigation.

III. WITNESSES

Panel 1 – Members of Congress

- Senator Ben Sasse (R-NE)
- Senator Jeanne Shaheen (D-NH)

Panel 2

Majority Witnesses

- Brian Lennon, Partner, Warner Norcross & Judd
- Michael Norton, President and General Counsel, Colorado Freedom Institute
- Catherine Glenn Foster, Charlotte Lozier Institute and Sound Legal
- Kenneth Sukhia, Founder, Sukhia Law Group

Minority Witnesses

- Fay Clayton, Founding Partner, Robinson Curley & Clayton, P.C.
- Robert Raben, President and Founder, The Raben Group

¹⁸ *Fetal Tissue: Is it Being Sold in Violation of Federal Law: Hearing Before the Subcomm. on Health and the Env't of the H. Comm. on Commerce*, 106th Cong. 2 (2000).

¹⁹ *FBI ends investigation into fetal tissue marketing*, Associated Press (Sep. 2, 2001).