ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

Majority (202) 225-2927 Minority (202) 225-3641

VIA EMAIL TO ATTORNEY OF RECORD

April 28, 2016

Ms. Cate Dyer Founder & CEO StemExpress Placerville, CA 94501

Dear Ms. Dyer:

Over the last several months, we have made numerous attempts to acquire business and accounting documents from StemExpress that are necessary to complete our work at the Select Investigative Panel. All of these requests have been met with verbal and written objections from your attorneys. In light of recent public comments you have made and the consensus reached by witnesses at our April 20 hearing on *The Pricing of Fetal Tissue* that a complete review of StemExpress business and accounting documents was necessary, I am writing to personally request you turn this information over to our investigators.

On October 6, 2015, the Committee on Rules issued Report 114-288 establishing the basis for a *Select Investigative Panel* of the Energy and Commerce Committee. In that Report's "Background and Need for Legislation" section it identified several video tapes that were made public that "raise[d] most troubling questions . . ." with regard to the procurement and sale of fetal tissue. Prior to the creation of the *Select Investigative Panel*, a precursor investigation requested information and testimony from several entities, including StemExpress, a biotech company that procures fetal tissue and then resells it to researchers.

You recently were quoted in the media as saying:

"I am appalled by Chairman [Marsha] Blackburn's statement," Cate Dyer, founder of StemExpress, told POLITICO. "StemExpress has provided over 2000 pages of material to the Senate and House committees which clearly illustrate we do not profit from the provision of fetal tissue to researchers. Unfortunately, the Select Panel continues to ignore the evidence - instead citing documents that courts have already found to be fabricated and falsified."

At our hearing held on April 20, 2016, the consensus among witnesses was that in order to get to the bottom of StemExpress involvement in the fetal tissue industry it would require the following:

- 1) A majority of witnesses agreed that banking records were necessary;
- 2) A majority of witnesses agreed that a forensic accounting review of Stem Express financial records was necessary;
- 3) Witnesses pointed out that although exhibits were redacted, a complete production of unredacted StemExpress business records is necessary to gain a complete understanding of whether StemExpress was profiting from the sale of baby body parts.

Although your press statement, if accurate, states that you have produced 2000 pages of documents, we have yet to receive accounting, banking and other business documents, for which subpoenas were issued to StemExpress. Instead, we have received attorney created estimates and summaries without back up materials. These summaries provide insufficient information to complete the Panel's review of the fetal tissue industry and they ignore the advice of the experts who testified at our April 20 hearing.

A comparison of "documents requested" and "documents received" was undertaken by the panel. The results of this review is visually displayed at Appendix A, attached with this letter.

Additionally, for your convenience please find documentation of the Panel's 4 month attempt to obtain compliance with its request and subpoenas attached at Appendix B.

Finally, your attorney raised a number of objections to our subpoena. Having reviewed all of these written and verbal objections, I find all of StemExpress' objections to the subpoena to be invalid and without legal merit. Please see Appendix C.

To fully comply with the subpoena, we require the production of the following missing documents:

1) Documents sufficient to reflect StemExpress' organization chart, including information detailing StemExpress personnel who procure(d) fetal tissue at the clinic level and the supervisory personnel for those procurers of fetal tissue.

- 2) All communications, whether internal or external, that direct or relate to a direction to StemExpress personnel to procure fetal tissue, including, but not limited to memoranda, emails, telephone messages, and purchase orders or bills of sale.
- 3) All StemExpress accounting records, including but not limited to accounting memoranda related to the cost and pricing of fetal tissue.
- 4) Copies of all invoices (by month and year), reflecting the billing that StemExpress issued to all institutions or entities to which StemExpress donated or provided fetal tissues for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.
- 5) Copies of all invoices (by month and year) reflecting the billing or payment of funds for fetal tissues obtained by StemExpress for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.
- 6) A copy of any chart of accounts for StemExpress, including but not limited to account descriptions from any financial recording system relating to StemExpress.
- 7) StemExpress' end of year trial balance report and trial balance details for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.
- 8) All documents reflecting StemExpress' statement of revenues (i.e., a breakdown by product categories) for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.
- 9) All documents reflecting StemExpress' record of costs and expenses (i.e., a breakdown by operations, including fetal tissue acquisition) for administrative costs and expenses as well as compensation and benefits, for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Where applicable, records should include identification of vendors and descriptions of expenses.
- 10) StemExpress' balance sheets for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.
- 11) StemExpress' income statements, including but not limited to any profit and loss statements, statements of operations and statements of activities for the following years: 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.
- 12) Copies of StemExpress' filed tax returns for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.
- 13) All StemExpress bank statements from any financial institution where StemExpress has maintained an account for the following years: 2010, 2011, 2012, 2013, 2014 and 2015.

14) Documents sufficient to show how StemExpress calculates(d) the cost of a fetal tissue and all factors applied in determining pricing of fetal tissue. In lieu of these documents, you may provide a written explanation.

Please produce them no later than the close of business on May 12, 2016. Failure to comply will leave the Panel with no choice but to pursue all means necessary to compel compliance.

Respectfully yours,

Marsha Blackburn

Select Investigative Panel

cc: The Honorable Jan Schakowsky

Appendix A

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STEMEXPRESS PRODUCTION LOG Document Requested	Received
A list of all entities, including firms, corporations, non-profit organizations, and educational institutions, from which StemExpress receives or procures fetal tissue.	ON
A list of all entities, including firms, corporations, non-profit organizations, and educational institutions, to which StemExpress sells or donates fetal tissue	ON
A list of all entities, including firms, corporations, non-profit organizations, and educational institutions, to which StemExpress transferred, subcontracted or sold any business interest or business assets related to the procurement or sale of fetal tissue.	ON
An organization chart that details StemExpress personnel that procure fetal tissue at the clinic level and the supervisory personnel for those procurers of fetal tissue	YES (both with no names)
All communications, whether internal or external, that direct StemExpress personnel to procure fetal tissue, including, but not limited to memoranda, emails, telephone messages, and purchase orders or bills of sale.	ON
All specific requests made to StemExpress for fetal tissue made by any and all firms, corporations, non-profit organizations, educational institutions, or other entities, including, but not limited to, order lists, billing records, payment vouchers, and receipts.	ON

Document Requested	Received
All documents relating to the purchase, ownership, or rental by StemExpress of equipment involving fetal tissue research, the preparation of fetal tissue for research, the modification of fetal tissue into cell lines, or any other actions taken by StemExpress related to fetal tissue, including but not limited to, the date the equipment was purchased, its purchase price, its maintenance costs, and records of the depreciation treatment under the tax code of any such equipment.	ON
All accounting records including accounting memoranda related to the cost and pricing of fetal tissue.	ON
All specific requests made to StemExpress for fetal tissue made by any and all firms, corporations, non-profit organizations, educational institutions, or other entities, including, but not limited to, order lists, billing records, payment vouchers, and receipts.	ON
All documents relating to the purchase, ownership, or rental by StemExpress of equipment involving fetal tissue research, the preparation of fetal tissue for research, the modification of fetal tissue into cell lines, or any other actions taken by StemExpress related to fetal tissue, including but not limited to, the date the equipment was purchased, its purchase price, its maintenance costs, and records of the depreciation treatment under the tax code of any such equipment.	ON
An inventory record of all fetal tissues obtained, sold, or retained by StemExpress, as well as an inventory of current fetal tissue including, in particular, any records that refer to multiple tissue samples or organs or body parts harvested from a single fetus.	ON

Document Requested	Received
List of all institutions or entities to whom you have donated or provided fetal tissues for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015.	NO
Copies of all transaction logs and invoices (by month and year) you issued to all institutions or entities to whom you have donated or provided fetal tissues for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015.	NO
List of all institutions or entities from whom you have obtained fetal tissues for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015.	YES
A copy of your chart of accounts including account descriptions from your financial recording system.	NO
Trial balance and trial balance details for the five years ended 2010, 2011, 2013, 2014 and 2015.	ON
Statement of revenues – breakdown by product (fetal tissue) categories for the five years ended 2010, 2011, 2013, 2014 and 2015.	NO
Record of expenses – breakdown by operations (including fetal tissue acquisition), administration, as well as compensation and benefits for the five years ended 2010, 2011, 2013, 2014 and 2015. Where applicable, record should include vendors and description of expenses.	ON
Balance sheet for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.	NO

Document Requested	Received
Income statement (or profit & loss statement, or statement of operations) or statement of activities) for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015. Audited statements should be provided, if available.	NO
Copies of filed tax returns for the five years ended 2010, 2011, 2012, 2013, 2014 and 2015.	ON
All monthly bank statements from all banks where you own accounts for the five years ended 2010, 2011, 2013, 2014 and 2015.	ON
Explain your cost structure and factors applied in determining the cost of a fetal tissue.	ON
All communications and documents relating to StemExpress employee compensation resulting from or relating to fetal tissue samples procured by current and former StemExpress personnel or other persons or entities that transact business with StemExpress.	ON
All communications and documents that identify any federal, state, or local government funds received, directly or indirectly, by StemExpress.	YES
All communications referring or relating to abortion or fetal tissue between StemExpress and any federal, state, or local government officials or employees.	YES
All communications and documents regarding any direction to StemExpress current or former personnel with respect to the procurement or disposal of fetal tissue.	ON.

Document Requested	Received
All communications and documents that StemExpress utilizes to obtain patient consent for fetal tissue at any clinic.	YES
All communications and documents, including but not limited to accounting memoranda, referring or relating to the cost and pricing of fetal tissue by StemExpress	ON
All communications and documents, sorted by customer, referring or relating to requests or orders made to StemExpress regarding fetal tissue and the amount paid by each customer to StemExpress.	ON
All communications and documents referring or relating to the purchase, ownership, or rental by StemExpress of equipment for the storage, disposal, modification, or research of fetal tissue, including equipment price, purchase date, maintenance costs, and records of the depreciation treatment under the tax code of any such equipment.	OZ.
Documents sufficient to show any known litigation in which StemExpress is named as a party, including any threatened or anticipated litigation. Should StemExpress wish to produce a list of such litigation, including appropriate docket information, in lieu of documents, it may do so.	YES
All communications and documents referring or relating to Independent Review Board consents for the period of March 29, 2012 through January 26, 2013.	YES
All communication and documents referring or relating to Biomedical Research Institute of America, BioMed IRB, or BioMed Institutional Review Board.	ON

Document Requested	Received	pa
The name(s) of all persons who serve as Director of Finance, Finance Manager, Accountant Manager, or equivalent position(s).	ON	
All communications and documents to or from the Director of Finance, Finance Manager, Accountant Manager, or equivalent position(s).	NO	

Appendix B

History of Select Panel Attempt to Gain Cooperation for Stem Express.

The Select Panel requested on December 17, 2015, documents since January 1, 2010, from StemExpress, including a list of where it obtained fetal tissue, where it distributed fetal tissue, and all communications related to the procurement and distribution of fetal tissue. In a December 18, 2015, letter to the Select Investigative Panel, StemExpress' attorneys called the original document request "overbroad." In a December 21, 2015 conference call with Panel staff, the attorneys for StemExpress explained that they would not produce the identity of any names of the entities from which they received fetal tissue, and that StemExpress' clients (those to whom they distributed fetal tissue) were covered by non-disclosure agreements (NDAs) and, thus, they would not produce those names. During that conference call, the Panel agreed to narrow the scope of its request, and to a rolling production, but did not agree to forego the identity of the sources or end uses of fetal tissue.

During a January 11, 2016 conference call with Panel staff, counsel for StemExpress stated it would not produce the names of entities from which it received fetal tissue, or the clients that were covered by NDAs; staff explained that was unacceptable. In a January 15, 2016, production (the second of its rolling productions), StemExpress stated it "will not be voluntarily providing the names" of where it obtained fetal tissue, and repeated that its contracts with clients "are subject to non-disclosure agreements and, therefore, cannot be voluntarily produced." In a February 1, 2014 production (the third of its rolling productions) StemExpress only produced communications dating from 2014, and those were replete with large redactions. In at least two instances, entire pages were redacted. During a February 9, 2016, the Select Panel's Staff Director told StemExpress' attorney that refusing to produce the names of the entities from which it received, and to whom it distributed, fetal tissue was unacceptable, as was redacting large portions of the requested communications.

As a result, the Select Investigate Panel was forced to issue a subpoena on February 12, 2016 which required the production in an unredacted form of 12 items. Despite that explicit legal instruction, StemExpress' production was replete with redations. Your firm flatly refused to produce one item, and produced an attorney-created accounting report, rather than required accounting documents.

On April 11, 2016, the Select Investigative Panel issued two additional subpoenas: one to the firm, and the other to you personally. The subpoenas collectively called for the production of four items. You outright refused to fully comply with the subpoena issued to you personally; and, once again, produced an attorney-created accounting report, rather than required documents.

Appendix C

Objections to Congressional Subpoenas are Invalid

Your attorney has made numerous objections to the Panel's document requests and subpoenas. Please take notice of the materials below that explain the law with respect to Congressional investigations.

Scope Objections

As best we can discern, your communication through counsel make four general objections. First, that the vast majority of documents demanded "are far outside the seeming scope of [the Panel's] Congressional purpose " Such an objection is wholly without merit, and documents responsive to the Subpoena must be produced forthwith.

The Panel's investigation and its Subpoena are well within its constitutional power and within the scope of its authority. The U.S. House of Representatives performs a quintessentially legislative role. See, e.g., U.S. Const. art. I, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."); see also, e.g., id. art. I, § 7 (outlining legislative process). Inherent in its legislative role, the House maintains a "power of inquiry . . . as penetrating and far-reaching as the potential power to enact and appropriate under the Constitution." Eastland v. U.S. Servicemen's Fund, 421 U.S. 491, 504 n.15 (1975); see also McGrain v. Daugherty, 273 U.S. 135, 174 (1927) ("the power of inquiry—with process to enforce it—is an essential and appropriate auxiliary to the legislative function"). Indeed, the Supreme Court "has often noted that the power to investigate is inherent in the power to make laws because a legislative body cannot legislate wisely or effectively in the absence of information respecting the conditions which the legislation is intended to affect or change." Eastland, 421 U.S. at 504 (quotation marks and brackets omitted).

To be constitutionally valid, a congressional subpoena must only (i) be properly authorized in accordance with House Rules, and (ii) seek information pertinent to a valid legislative purpose within the jurisdiction of the particular committee. See Wilkinson v. United States, 365 U.S. 399, 408-09 (1961). Such is the case here.

The House, through its rules, has delegated relevant substantive legislative jurisdiction, and its full investigative powers to the Select Panel. *See generally* Rules of the House of Representatives, 114th Cong. (2015) ("House Rules"), *available at* http://clerk.house.gov/legislative/house-rules.pdf. As adopted by the House, H. Res. 461

The House Rules are promulgated pursuant to the Rulemaking Clause, U.S. Const. art. I, § 5, cl. 2 ("Each House may determine the Rules of its Proceedings . . ."). The Rulemaking Clause provides a "broad grant of authority," Consumers Union of the U.S., Inc. v. Periodical Correspondents' Ass'n, 515 F.2d 1341, 1343 (D.C. Cir. 1975), that sits "[a]t the very core of our constitutional separation of powers," Walker v. Jones, 733 F.2d 923, 938 (D.C. Cir. 1984) (MacKinnon, J., concurring in part and dissenting in

created the Panel and "authorized and directed [the Panel] to conduct a full and complete investigation . . . regarding—(1) medical procedures and business practices used by entities involved in fetal tissue procurement; [and] (2) any other relevant matters with respect to fetal tissue procurement" To this end, House Rules authorize the Chairman of the Panel "to authorize and issue subpoenas."

Here, the Chairman of the Select Panel authorized the issuance of the Subpoena to StemExpress. That Subpoena seeks materials pertinent to the Committee's investigation into the fetal tissue industry, which plainly is within its legislative and oversight jurisdiction. The Select Committee's investigative judgment, of course, generally cannot be questioned. *See Eastland*, 421 U.S. at 506 (citing *Tenney v. Brandhove*, 341 U.S. 367, 378 (1951)).

Safety & Security Objections

Stem Express objects on the ground that it desires to stem the risk of harm that might flow from the public disclosure of materials. However, the Panel is not "the public," and, as a legal matter, disclosure of these materials to the Panel does not implicate the stated concerns. Courts repeatedly have held that disclosure of information to a congressional committee is not a "public disclosure." See, e.g., F.T.C. v. Owens-Corning Fiberglass Corp., 626 F.2d 966, 970 (D.C. Cir. 1980) (holding that executive agency "may not deny Congress access to confidential documents, including those that contain trade secrets," because "[r]elease to a congressional requestor is not a public disclosure forbidden by section 6(f) of the [Federal Trade Commission] Act"); Exxon Corp., 589 F.2d at 585-86 (similar); Ashland Oil, Inc. v. F.T.C., 548 F.2d 977, 979 (D.C. Cir. 1976) (per curiam) (similar). Indeed, courts have presumed just the opposite is true—that "[o]nce documents are in congressional hands . . . 'committees of Congress will exercise their powers responsibly and with due regard for the rights of affected parties." Owens-Corning Fiberglass Corp., 626 F.2d at 970 (quoting Exxon Corp., 589 F.2d at 589); see also, e.g., Jaymar-Ruby, Inc. v. F.T.C., 496 F. Supp. 838, 845 (N.D. Ind. 1980) ("[W]hile Courts have held that as a matter of law, it cannot be presumed that private persons will honor commitments not to disclose information, Courts do presume that government officials will honor similar commitments.") (internal citation omitted).

This presumption reflects the general deference due to a coordinate branch of government, as well as the specific concern that "the judiciary must refrain from slowing or otherwise interfering with the legitimate investigatory functions of Congress." *Owens-Corning Fiberglass Corp.*, 626 F.2d at 970; see also Exxon Corp., 589 F.2d at 588-89. Thus, absent some actual showing that Congress intends to make documents public—a showing which plainly is lacking here—courts have rejected the notion that documents provided to Congress inevitably will be made public. See, e.g., Exxon Corp., 589 F.2d at 589; Ashland Oil, Inc., 548 F.2d at 979.

part). Rules promulgated pursuant to the Rulemaking Clause, within constitutional limitations, are "absolute and beyond the challenge of any other body or tribunal." *United States v. Ballin*, 144 U.S. 1, 5 (1892); see also United States v. Smith, 286 U.S. 6, 33 (1932) (same).

² Consistent with this principle, the judiciary has deferred to congressional interests in two other areas of federal law involving access to private or confidential information. First, courts routinely have permitted congressional committees to obtain secret grand jury materials protected under Rule 6(e) of the Federal Rules of Criminal Procedure. See, e.g., In re Request for Access to Grand Jury Materials, 833 F.2d 1438,

1444 (11th Cir. 1987); In re Grand Jury Investig. of Ven-Fuel, 441 F. Supp. 1299, 1307-08 (M.D. Fla. 1977); In re Report & Recommendation of June 5, 1972 Grand Jury, Concerning Transmission of Evidence to the House of Representatives, 370 F. Supp. 1219, 1226 (D.D.C. 1974). Second, courts have recognized that executive agencies do not forfeit their ability to withhold documents from public scrutiny under the Freedom of Information Act simply by providing the information to congressional committees. See, e.g., Fla. House of Representatives v. U.S. Dep't of Commerce, 961 F.2d 941, 946 (11th Cir. 1992); Murphy v. Dep't of Army, 613 F.2d 1151, 1158-60 (D.C. Cir. 1979).