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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
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September 22, 2015

Ben Van Handel, Ph.D.
Executive Director
Novogenix Laboratories, LLC
1425 San Pablo St. #205
Los Angeles, CA 90033

Dear Dr. Van Handel,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is continuing its investigation into practices related to the donation, collection, processing and distribution of human fetal tissue. We appreciate the information you provided to the Committee staff in an informal bipartisan briefing on September 3, 2015. As a result of that information, and other information the Committee has obtained, we are asking for your additional cooperation in responding to the following questions and requests for documentation.

It is our understanding that Novogenix works with abortion providers in Southern California to procure fetal tissue, and then processes that fetal tissue through a variety of scientific methods for the use of its clients – a majority of whom are scientific researchers. It is illegal under Federal law for "any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."[1] In a transaction involving a tissue procurement organization such as Novogenix, the prohibition on valuable consideration would apply to both the donor of the tissue, i.e., the abortion provider, and the ultimate recipient of the donated fetal tissue, e.g., the researcher.

Federal law allows the acceptance of reasonable payments associated with transportation, implantation, processing, preservation, quality control or storage of the human fetal tissue.[2] To ensure compliance with these provisions, organizations engaging in the collection and redistribution of donated human fetal tissue would expect to have processes and procedures in place. However, based on the September 3rd briefing, Novogenix appears to have little to no insight into how abortion providers like Planned Parenthood set fees for "reimbursement" of fetal tissue donation. It is also unclear how Novogenix sets its own fees for fetal tissue, or each "service" related to fetal tissue.

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[1] 42 USC 289g-2.
[2] 42 U.S. Code § 289g–2(e)

Federal law also mandates, in cases where federal funds are used to conduct or support research on the transplantation of human fetal tissue for therapeutic purposes, that the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research.[3] Even though this requirement is written to apply only to circumstances in which federal funds are used for research on human implantation of fetal tissue, it is our understanding that obtaining consent from the patient for the donation of fetal tissue after the patient has consented to the abortion procedure itself has become a widespread practice.

In the September 3rd briefing, you acknowledged that a Novogenix employee travels to the abortion provider to obtain donated fetal tissue. Your employee was not at the briefing to comment about whether or not the employee obtains consent for donating tissue from patients awaiting an abortion procedure. There is some risk that the tissue procurement organization obtaining consent presents a conflict of interest. Moreover, you informed committee staff that Novogenix created its own consent form to use at non-Planned Parenthood abortion providers, but it is unclear what provisions that consent form contains, as well as whether Novogenix or clinic personnel obtain consent from patients at non-Planned Parenthood providers.

Please provide the following documents and information by October 6, 2015:

1. Provide Novogenix's gross revenue for calendar years 2011 through 2014. Indicate what percentage of that revenue is from fetal tissue, services related to fetal tissue, or cells manufactured from fetal tissue.

2. Provide Novogenix's revenue from fetal tissue obtained from patients at Planned Parenthood facilities in 2013 and 2014.

3. Provide copies of agreements and/or contracts with all entities that have provided fetal tissue to Novogenix since January 1, 2010.

4. Provide documents and communications referring or relating to Novogenix's compliance with federal laws regarding valuable consideration for the donation or sale of fetal tissue, from January 1, 2010 to the present.

5. Identify which Planned Parenthood employees (by name and title) that Novogenix has worked with to create, finalize and implement the service agreements regarding reimbursement for donation of fetal tissue.

6. Provide a list and definition of each type of "service" that Novogenix has performed, including the frequency each service is performed, from August 1, 2011 to the present.

7. Provide a definition of the word "specimen" in the context of the cost breakdown provided to the Committee, entitled "Formalin Fixed Tissue-Related Services" and "Costs for Non-Formalin Fixed Tissue-Related Services."

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[3] 42 USC 289g-1

8. In the customer agreement provided to the Committee, Novogenix references a list of fees for services in a document referred to as "Schedule A." Provide copies of Novogenix "Schedule A" documents or lists of fees for services, from January 1, 2010 to the present.

9. Provide all documents and communications referring or relating to the cost incurred to Novogenix from the procurement of fetal tissue, from January 1, 2010 to the present.

10. Provide all documents and communications referring or relating to the direct or indirect cost of donating and/or selling fetal tissue, or services related to fetal tissue, from January 1, 2010 to the present.

11. Provide all documents and communications referring or relating to a Novogenix employee obtaining consent to donate fetal tissue from a patient, including but not limited to training materials, informal guidance, Novogenix consent forms, internal memoranda, employee emails, and informal understandings between Novogenix and abortion providers, from January 1, 2010 to the present.

12. Provide all documents and communications referring or relating to a Novogenix employee's knowledge that a patient has consented to donate fetal tissue before tissue is procured, including but not limited to training materials, informal guidance, Novogenix consent forms, internal memoranda, employee emails, and informal understandings between Novogenix and abortion providers, from January 1, 2010 to the present.

13. Provide information regarding the percentage of patients who consent to donate fetal tissue.

14. Provide information about the process by which Novogenix procures fetal tissue that contains specific characteristics requested by researchers, including whether Novogenix has procured human fetal tissue from a specific abortion provider in order to acquire tissue with specific characteristics required by a researcher.

15. Provide information about how Novogenix ascertains whether human fetal tissue is used for human transplantation purposes.

16. Identify any Novogenix employees, agents or contractors who have worked for Planned Parenthood as an employee, agent or contractor. Provide names, dates of employment at Novogenix and Planned Parenthood, and job titles at both companies.

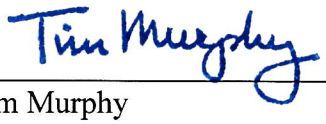
17. Provide copies of powerpoint presentations and/or other documents used to explain fetal tissue donation and research to potential donors, included but not limited to Planned Parenthood affiliates, from January 1, 2010 to the present.

18. Provide a list of researchers and/or clients receiving fetal tissue, and/or services related to fetal tissue from Novogenix, from January 1, 2010 to the present.

If you have any questions about this letter, please contact Charles Ingebretson or Emily Felder of the committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Frank Pallone, Jr., Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations