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July 23, 2015

The Honorable Doug Lamborn
United States House of Representatives
2402 Rayburn House Office Building
Washington, D.C. 20515

Congressman Lamborn:

I am writing in response to your letter dated July 17, 2015, which concerns the allegations against Planned Parenthood Federation of America and Colorado State University's use of fetal cells in federally funded research. I fully understand the concerns that have been expressed by you and others. As you know, Congress has now announced its intent to investigate the practices of those engaged in the acquisition of human tissue for research purposes, and it is our sincere hope that this will lead to greater transparency for all involved. As a research university, we welcome all efforts that allow us access to more information as we navigate the ethical waters associated with several research areas.

Since receiving your letter, I have reviewed the video that was released by the Center for Medical Progress; sought clarification on the points of law you've raised; and discussed the issue further with Colorado state Senator Kevin Lundberg, who provided additional insight. We also convened our Bioethics Advisory Committee to assess the known facts and make a recommendation directly to me regarding University practices going forward. The report of that committee is attached.

With respect to the legal question in your letter, we do not believe that Colorado State University has violated federal or Colorado state law. The Colorado law referenced in your letter, C.R.S. § 25-2-111.5, is directed at physicians and institutions that perform procedures for the induced termination of pregnancy, which Colorado State University does not perform. CSU is also compliant with federal law on this issue. CSU follows all federal regulations and protocols related to the use of human tissue samples, and federal regulators and other officials regularly review CSU's research programs to ensure bioethical and legal compliance.

Colorado State has only one research project that uses human fetal tissue in research, for an NIH-funded investigation into a cure for HIV/AIDS. This research is fully compliant with state and federal law, and this project does not obtain any tissue directly from physicians or institutions that perform procedures for the induced termination of pregnancies, including Planned Parenthood. Any tissue used for research must be obtained legally and in compliance with federal and state regulations, and CSU only obtains tissue from FDA regulated and approved providers. The tissue is obtained in very minute sample sizes for research conducted at the cellular level using cells extracted from these small amounts of liver and thymus tissue; we do not obtain or use full organs or body parts in this research program, although we can understand how someone could mistakenly reach that conclusion based on the wording of the StemExpress invoices in question.

In the past, Colorado State University has obtained donated fetal tissue from StemExpress, which is FDA regulated and approved, although we have not received any tissue samples from StemExpress since 2013. The invoices related to the acquisition of donated fetal tissue from StemExpress in 2013 are attached. We had not been aware of any issues concerning StemExpress until this recent controversy – nor had we seen the company’s promotional flyer that has since been shared with us. The source of tissue for the CSU research since 2013 is ABR. It is our understanding that ABR does not work via a for-profit model for fetal tissues; they only reimburse for costs incurred.

In light of your and other concerns, and while CSU has appropriately followed all state and federal laws in regard to conduct of this research, I am accepting the recommendation of CSU’s Bioethics Advisory Committee to suspend any further acquisition of fetal tissue from StemExpress or other vendors implicated in the Planned Parenthood investigation pending the outcome of the Congressional inquiry.

The committee also recommended that all efforts should be made to seek alternatives to aborted fetal tissue sources, where such alternatives allow key research to continue – a recommendation that we will implement immediately. In addition, we also will request from all tissue providers all available information regarding the source of fetal tissue. With this information, our institution and researchers can continue to assure that when research is conducted, we do so meeting our ethical standards.

As I noted at the beginning of this letter, and as our Bioethics committee states in the attached report, we also want to encourage further federal oversight of fetal tissue providers that would result in greater transparency of their sources. This is an appropriate role for the federal government, and it would be a benefit to CSU and the hundreds of other research universities actively and more fully engaged in this field.

We are unable to address your specific questions related to tissue sources, as these are questions for the providers. We work diligently to ensure we are working with regulated, compliant providers, but we are not regulators and do not have access to the specific information you are seeking.

Colorado State University is a leader in the ethical conduct of research, and we always welcome concerns such as yours as we seek to uphold our academic and research missions. The research in question is medically important and fully compliant with all federal and university regulation, and CSU is proud that this program already has led to significant breakthroughs in the fight against HIV/AIDS. The faculty involved, and the university, care deeply about their ethical obligations and the importance of obtaining tissue only from compliant sources. This is not an issue that any of us takes lightly, and we will be closely following the Congressional investigation.

Thank you for alerting us to your concerns and providing CSU an opportunity to respond.

Sincerely,



Tony Frank
President

E-mail Addendum to Earlier Message

July 28, 2015

Subject: Addendum to my response to your inquiry

Congressman Lamborn,

After I e-mailed my previous message to your staff member, we have become aware of an expired CSU project with Planned Parenthood that did not involve fetal tissue. I wanted to bring this project to your attention in the interest of full disclosure.

Through an archival search, we have identified an agreement from 2010 in which one of our researchers worked with a Planned Parenthood affiliate to obtain placental tissue for a project supporting healthy pregnancies. This agreement has ended and no placental tissues have been received for a number of years. This project involved no fetal tissue; however, in reviewing the agreement, its language incorrectly uses the term "human fetal tissue." This project was never intended to obtain fetal tissue and, in fact, Colorado State never requested or acquired such tissue as part of this project, which again was specifically examining placental abnormalities with a goal of promoting healthy pregnancies.

We have now looked at all avenues including material transfer agreements, sponsored agreements, procurements, publications, patents and licenses and to the best of our analysis there are no other others arrangements between CSU and Planned Parenthood or related affiliates.

If you have other questions or concerns, please let me know.

Tony Frank
President

MEMORANDUM

To: Dr. Tony Frank, CSU President
From: Bioethics Advisory Committee
Date: July 22, 2015
Re: CSU Research Using Fetal Tissues

Background:

The committee met during the week of July 13, 2015 in response to a press release from Lifenews.com alleging that a CSU researcher ([REDACTED]) had acquired tissue from fetal sources, specifically stating allegations of impropriety with respect to one vendor, StemExpress. The committee convened to attempt to determine the facts of the matter and to discuss key issues that the allegations presented. As a public institution, we are bound to scrupulously work within the law.

Facts known to the committee:

Only one investigator at CSU is using fetal tissue in research ([REDACTED]) and has been doing so for over 15 years. CSU is ranked 145th nationally (by number of papers and investigators) of all Universities doing fetal tissue research. The research is supported by the National Institutes of Health Institute of Allergy and Infectious Disease. The model used by the investigator requires the use of fetal tissue to construct hematopoietic (blood) stem cells derived from different tissues (liver and thymus) and is used to induce a human-like immune system in an immune-deficient mouse to study HIV. The research has produced significant results regarding HIV infection, pathogenesis, and treatments, and has resulted in many research publications over the lifetime of the projects. In the course of the research, many students have been trained and supported as part of the land grant mission of CSU. All of the research performed was executed under the appropriate human and animal use committee requirements and reviewed by relevant CSU committees to assure compliance with federal regulations. The research is regulated by the NIH and is frequently reviewed by federal sponsors through the use of detailed reports the investigator provides on the execution of the sponsored research. The committee encourages federal oversight of current fetal tissue vendors to result in greater transparency of their sources.

The procurement of fetal tissue for the research has used various vendors through the years of its execution. The procurement of fetal tissue is supported by NIH through research grants and execution of the research and is reimbursed as part of the sponsored research grants. In the acquisition of fetal tissue from vendors, neither the researchers nor their staff involved in procurement from vendors are provided information regarding the source of fetal tissue. There is no way for them to know if the source is from spontaneous or elected abortions, or other causes related to the mother or unborn baby.

The committee is aware that federal law dictates the practice of acquisition and use of fetal tissue. The committee is also aware that Colorado State law extended aspects of this law for vendors selling such materials within the state. The committee has no information that suggests that CSU violated any federal or state laws in the procurement of the fetal tissue in question for the research project by [REDACTED]. The committee is also aware of CSU's long history of human research fully compliant with all federal and state laws.

The committee is also aware that congressional investigations are pending to investigate the practices of vendors that are supplied fetal tissue from Planned Parenthood.

Committee Recommendations:

The committee recommends that CSU suspend acquisition of fetal tissue from StemExpress or any other vendor in question with Planned Parenthood until the congressional investigations are concluded and there is affirmation that all vendors used by CSU under NIH support are in compliance with federal law regarding the acquisition and use of fetal tissue.

The committee recommends that if vendor sources of fetal materials can be determined that this information is provided to any investigator executing fetal tissue research. All efforts should be made to seek alternatives to aborted fetal tissue sources where such alternatives allow key research discoveries to proceed.

Bioethics Advisory Committee:

Bernie Rollin, PhD, University Distinguished Professor, Professor of Philosophy,
Professor of Animal Sciences, Professor of Biomedical Sciences, University Bioethicist

Mark Stetter, Dean, College of Veterinary Medicine & Biomedical Sciences

C. Wayne McIlwraith, BVSc, PhD, DSc, FRCVS, Diplomate ACVS, Diplomate ACVSMR,
University Distinguished Professor, Clinical Sciences, College of Veterinary Medicine &
Biomedical Sciences

R. Kraig Peel, PhD, Associate Professor, Department of Animal Sciences, College of
Agricultural Sciences

Matthew S. Hickey, PhD, University Distinguished Teaching Scholar, Professor, Dept. of
Health and Exercise Science, College of Health & Human Sciences

Jennifer Nyborg, PhD, Professor, Department of Biochemistry & Molecular Biology, College
of Natural Sciences

Alan S. Rudolph, PhD, MBA, Vice President for Research, Institutional Official (ex officio)