

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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December 21, 2016

VIA EMAIL

The Honorable Hector H. Balderas, Jr.
Attorney General of New Mexico
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Dear Attorney General Balderas:

On June 23, 2016, I sent you a criminal referral report pursuant to the investigation of the Select Investigative Panel (the "Panel") authorized by the U.S. House of Representatives under H. Res. 461. I now write to submit for your attention a supplementary referral concerning additional allegations regarding the University of New Mexico ("UNM") and Southwestern Women's Options ("SWWO"), the entities that were the subjects of our June referral report. This referral is based on information obtained in document productions by UNM and SWWO, [REDACTED], [REDACTED], and a complaint and affidavit with supporting documents submitted by a former patient at SWWO.

Allegations Against SWWO and UNM

As noted in the June referral report and admitted by UNM, since 1995, SWWO has served as the only source of aborted infant tissue procured for the University of New Mexico Health and Sciences Center ("UNMHSC") for research purposes.² From the Panel's investigation, it is apparent that there were several deficiencies in the consent process used to procure fetal tissue. Although both SWWO and UNM provided the Panel a consent form that purported to give patients notice that tissue from their pregnancies would be donated to UNM,³ there is evidence that this form was not used. While *Doctor #5* testified that SWWO's practice was to provide women an opportunity to donate the tissue that resulted from their abortions and to obtain their

¹ Names in this letter are redacted with the same pseudonyms used in the June 23 letter. *See* redaction key.

² UNM Document, UNM00560, attachment 1; UNM First Submission to House Select Panel, Jan. 29, 2016, p. 1, attachment 2; UNM Second Submission to House Select Panel, Feb. 16, 2016, p. 1, attachment 3; UNM Response to House Select Panel Subpoena, Mar. 3, 2016, p.1, attachment 4.

³ Client Information for Informed Consent, Donation of Fetal Tissue for Medical Research, SWWO000524, attachment 5. UNM produced the same form with Bates number UNM01103.

consent to do so, she admitted she had never gotten a consent from a patient at SWWO to make a fetal tissue donation—and did not even recognize the consent form that SWWO and UNM produced to the Panel.⁴ She also admitted she was unaware of whether consent was required prior to the donation of fetal tissue.⁵

Further evidence supports the inference that patients were not regularly given a fetal tissue donation consent form at SWWO. *Patient*, a patient who obtained an abortion from SWWO, has brought suit against the clinic and attested in an affidavit that she was never given a “consent to donate tissue that was separate from the consent for the [abortion] procedure.”⁶ Moreover, she alleges she was never informed by the doctors and staff at SWWO that her infant’s remains were to be donated to UNM or another entity.⁷ Neither, she alleged, was she informed of the nature and extent of any use of such remains, “which body parts were going to be used or donated,” or what benefits could be expected from such use.⁸ She added that she was not informed by SWWO doctors or staff that the doctor who treated her, *Doctor #6*, and the director of SWWO, *Doctor #3*, were volunteer faculty members at UNM, or that the clinic and the university had been collaborating on fetal tissue research since 1995.⁹

Even more problematically, the only semblance of consent SWWO allegedly sought from *Patient* for fetal tissue research was a phrase mentioning the use of “tissue and parts . . . in medical research” within a two-page consent form provided to her for the abortion procedure itself.¹⁰ Thus, the only consent sought from her for fetal tissue donation came during what should have been a separate process of consent to the abortion procedure itself. A letter from *Patient* to SWWO dated December 2, 2015, requested “all information regarding the disposal, donation or sale of any medical waste,” but she allegedly never received any records regarding the disposition of her infant’s remains.¹¹ In September 2016, *Patient* read procurement notes dated October 17, 2012, that were attached to the Panel’s referral of UNM and SWWO to your office that indicated brain tissue had been taken from one infant estimated at 11.5 weeks gestation and another at 12.7 weeks gestation.¹² Because *Patient’s* ultrasound taken on October 5, 2012, stated she was 12 weeks and two days pregnant, and because she obtained her abortion five days later on October 10—when staff informed her she was between 12 and 13 weeks pregnant—she believed her “baby was one of the two babies given to the University of New Mexico for their research.”¹³ This belief is consistent with SWWO’s practice of storing fetal tissue in an on-site

⁴ [REDACTED]

⁵ [REDACTED]

⁶ Affidavit of *Patient*, Nov. 18, 2016 (“*Patient Aff.*”), ¶ 30, attachment 6. See also Complaint ¶ 47, *Patient v. Doctor #3*, No. [REDACTED] (N.M. Dis. Ct. Bernalillo County Nov. 30, 2016) (“*Patient Compl.*”), attachment 7. In an email dated Nov. 28, 2016, *Patient* gave permission to the Panel to disclose her identity publicly, but the Panel decided nonetheless to redact her name in the instant letter.

⁷ *Patient Aff.* ¶ 10; *Patient Compl.* ¶ 32.

⁸ *Patient Aff.* ¶¶ 21-22, 26; *Patient Compl.* ¶¶ 35-38.

⁹ *Patient Aff.* ¶¶ 15, 18-20; *Patient Compl.* ¶ 32.

¹⁰ *Patient Aff.* ¶ 8 & Ex. A, at 1; *Patient Compl.* ¶¶ 11-12 & Ex. A.

¹¹ *Patient Aff.* ¶¶ 32-33 & Ex. B; *Patient Compl.* ¶¶ 54-57.

¹² Compare *Patient Aff.* ¶¶ 35-36 and Procurement notes, UNM00029. See also *Patient Compl.* ¶ 52.

¹³ *Patient Aff.* ¶¶ 7, 12-13, 37-38; *Patient Compl.* ¶¶ 49-53.

freezer until it is periodically picked up for transfer to UNM.¹⁴ *Patient* attested, “If I had known my baby was going to be used for research I would have probably changed my mind about going through with the abortion,” and added that the actions of SWWO and its doctors caused her “emotional distress and mental anguish.”¹⁵ *Patient* additionally alleged that she was advised by staff that she could apply for Medicaid funding for her abortion procedure and that the paperwork supporting such funding was prepared by a doctor she never saw, *Doctor #7*, and not her treating physician, *Doctor #6*.¹⁶

Violations of Applicable Laws

If true, *Patient’s* allegation that the only informed consent to tissue donation sought from her was the cursory reference to the use of “tissue and parts . . . in medical research” in SWWO’s abortion consent form amounts to violations of federal and state law by UNM and SWWO.

HHS regulations, which govern much of the human subject research conducted at UNM, requires in 45 C.F.R. § 46.116 a number of basic elements of informed consent:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and

¹⁴ SWWO letter responding to document request (Feb. 12, 2016), at 5; [REDACTED] [REDACTED]. According to SWWO’s Feb. 12 letter, pickup occurred weekly, but procurement notes record that pickup occurred an average of 39 times per year since 2010, 45 times in 2012.

¹⁵ *Patient Aff.* ¶¶ 39, 42; *Patient Compl.* ¶¶ 60, 142.

¹⁶ *Patient Aff.* ¶¶ 14-17; *Patient Compl.* ¶¶ 61-64, 110.

whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.¹⁷

According to *Patient's* allegations, both SWWO and UNM failed to provide any of these elements of informed consent, in violation of 45 C.F.R. § 46.116, accompanied by a violation of 45 C.F.R. § 46.117 for failing to present such consent in writing.

To the extent the research of the fetal tissue acquired by UNM related to transplantation for therapeutic purposes, any violations by SWWO and UNM would include violation of 42 U.S.C. § 289g-1(b)(1), which requires written consent from the woman acknowledging the nature of the research, the lack of “restriction regarding the identity of individuals who may be the recipients of transplantation of the tissue,” and that the woman was not informed of any such recipients’ identities. Moreover, the use of a consent form that simultaneously seeks consent for abortion and for fetal tissue donation under the alleged circumstances would appear to violate 42 U.S.C. § 289g-1(b)(2)(A)(i), which requires the abortion consent to be “obtained prior to requesting or obtaining consent for a donation of the tissue”

UNM’s own oversight policy provided as of 2015 that “appropriate informed consent by the mother” is required for “[t]he collection and storage of all fetal tissue for research.”¹⁸ The policy as revised April 11, 2016, further clarifies that UNMHSC

will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC’s use of them.¹⁹

¹⁷ 45 C.F.R. § 46.116(a). These elements are the minimum required, subject to exceptions for public benefit or service programs under § 46.116(c) and potentially additional requirements under § 46.116(b).

¹⁸ UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Sept. 16, 2015), UNM03420-UNM03428 at UNM03423.

¹⁹ UNMHSC, Oversight of Human Tissue in Research, Policy # RC.05.002.PP (Apr. 11, 2016), at 3. This revised policy additionally reinforces the Panel’s June 23, 2016, referral regarding violation of the Spradling Act by requiring that fetal tissue for research be acquired “in accordance with the provisions of the” Spradling Act “and/or with contractual assurance that it was obtained in accordance with” that statute. *Id.* at 3-4.

UNM did not produce this revised policy to the Panel.

Despite SWWO's inclusion of a fetal tissue donation consent form in its production, *Patient's* allegation that it was never shown to her, combined with *Doctor #5's* admission that she did not even recognize the form, raises a serious question as to whether SWWO and UNM systematically violated the law, not to mention UNM's own internal policy, by conducting fetal tissue donations without more than the perfunctory reference to tissue research in SWWO's abortion consent form.

The same alleged deficiencies in the consent process at SWWO would constitute a violation of New Mexico's state law. Regardless of whether government funding or transplantation research is involved, N.M. Stat. Ann. § 24-9A-5, which is part of the Maternal, Fetal and Infant Experimentation Act, prohibits any "clinical research activity involving fetuses, live-born infants or pregnant women" unless the woman

has been fully informed of the following:

- (1) a fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
- (2) a description of any attendant discomforts and risks reasonably to be expected;
- (3) a description of any benefits reasonably to be expected;
- (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
- (5) an offer to answer any inquiries concerning the procedure; and
- (6) an instruction that the person who gave the consent is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.²⁰

²⁰ N.M. Stat. Ann. § 24-9A-5(C). As discussed in the Panel's June 23 referral, the Spradling Act prohibits use of fetal tissue resulting from induced abortion, but this informed consent provision provides a basis for liability separate from the underlying use of such tissue. It additionally should be noted that the Maternal, Fetal and Infant Experimentation Act defines the term "clinical research" as follows:

"clinical research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in human beings and includes research involving human in vitro fertilization, but shall not include diagnostic testing, treatment, therapy or related procedures conducted by formal protocols deemed necessary for the care of the particular patient upon whom such activity is performed and shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to ensure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a child with a disability. Provided that emergency medical procedures necessary to

This statute is notably cited in the standard operating procedures of UNM's Office of the Institutional Review Board, but UNM failed to produce that document to the Panel.²¹ Other sections of the Maternal, Fetal and Infant Experimentation Act make clear that neither a pregnant woman nor a fetus shall be involved as subjects in clinical research activity unless "the mother is legally competent and has given her informed consent,"²² subject to penalties of imprisonment for less than one year and/or payment of a fine up to \$1,000.²³

I urge your office to conduct a thorough investigation into whether the University of New Mexico and Southwestern Women's Options violated federal and state law, and, if you conclude that such violations occurred, to take all appropriate action. If you have any questions about this request, please contact Frank Scaturro, at (202) 225-2927, Frank.Scaturro@mail.house.gov.

Sincerely yours,



Marsha Blackburn
Chairman
Select Investigative Panel

Attachment(s)

cc: The Honorable Jan Schakowsky, Ranking Member
Select Panel on Infant Lives

The Honorable Susana Martinez
Governor of New Mexico

The Honorable John A. Sanchez
Lieutenant Governor of New Mexico

The Honorable Steve Pearce
Second Congressional District, New Mexico

preserve the life or health of the mother or the fetus shall not be considered to be
clinical research"

N.M. Stat. Ann. § 24-9A-1(D).

²¹ See UNM Office of the Institutional Review Board, Standard Operating Procedures, effective Mar. 1, 2016, at 1-2, <http://irb.unm.edu/sites/default/files/511.0%20Compliance%20with%20Applicable%20Laws%20and%20Regulations.pdf>, attachment 8.

²² N.M. Stat. Ann. §§ 24-9A-2(B), 24-9A-3(B).

²³ N.M. Stat. Ann. § 24-9A-6.