No. 17-50282

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

PLANNED PARENTHOOD OF GREATER TEXAS FAMILY PLANNING AND PREVENTATIVE HEALTH SERVICES, INC; PLANNED PARENTHOOD SAN ANTONIO; PLANNED PARENTHOOD CAMERON COUNTY; PLANNED PARENTHOOD GULF COAST, INC; PLANNED PARENTHOOD SOUTH TEXAS SURGICAL CENTER; JANE DOE #I; JANE DOE #2; JANE DOE #3; JANE DOE #4; JANE DOE #7; JANE DOE #9; JANE DOE #10; JANE DOE #11,

Plaintiffs-Appellees,

v.

CHARLES SMITH, in his official capacity as Executive Commissioner of HHSC; SYLVIA HERNANDEZ KAUFFMAN, in her official capacity as Acting Inspector General of HHSC,

Defendants-Appellants.

On Appeal from the U.S. District Court for the Western District of Texas, Austin Division, No. 1:15-CV-01058, Hon. Sam Sparks

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BRIEF FOR *AMICUS CURIAE* KEVIN DONOVAN, M.D., IN SUPPORT OF CHARLES SMITH, ET AL.

C. BOYDEN GRAY*
ADAM R.F. GUSTAFSON
Counsel of Record
ANDREW R. VARCOE
JAMES R. CONDE
BOYDEN GRAY & ASSOCIATES
801 17th Street NW, Suite 350
Washington, DC 20006
(202) 955-0620
gustafson@boydengrayassociates.com
**Not admitted in this Court*.

August 14, 2017

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

17-50282

Planned Parenthood of Greater Texas, Inc., et al., v. Charles Smith, et al.

Pursuant to 5TH CIR. R. 29.2, the undersigned counsel of record for *Amicus Curiae* certifies that the following persons and entities have an interest in the outcome of this case, in addition to those identified by the parties. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

1. Kevin Donovan, M.D., Director of the Center for Clinical Bioethics and Professor of Pediatrics at Georgetown University Medical Center, *Amicus Curiae*.

2. C. Boyden Gray, counsel for *Amicus Curiae*.

3. Adam R.F. Gustafson, counsel for *Amicus Curiae*.

4. Andrew R. Varcoe, counsel for *Amicus Curiae*.

5. James R. Conde, counsel for *Amicus Curiae*.

6. Boyden Gray & Associates, PLLCC, counsel for *Amicus Curiae*.

Amicus appears in his individual capacity; his institutional affiliation is listed here for identification purposes only.

No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or

submitting this brief; and no person (other than counsel for *Amicus Curiae*) contributed money that was intended to fund preparing or submitting this brief.

/s/ Adam R.F. Gustafson
ADAM R.F. GUSTAFSON
BOYDEN GRAY & ASSOCIATES
801 17th Street NW, Suite 350
Washington, DC 20006
(202) 955-0620
gustafson@boydengrayassociates.com

August 14, 2017

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GLOSSARY

AMA .....American Medical Association

ACOG .....American College of Obstetricians and Gynecologists

CEJA .....Council on Ethical & Judicial Affairs

HHSC .....Texas Health and Human Services Commission

NIH .....National Institutes of Health

PPGC.....Planned Parenthood Gulf Coast

TMA .....Texas Medical Association

TMB .....Texas Medical Board

INTEREST OF *AMICUS CURIAE*

Amicus Kevin Donovan, M.D., is director of the Center for Clinical Bioethics and a Professor of Pediatrics at Georgetown University Medical Center. Dr. Donovan specializes in bioethics. He therefore presents an informed perspective on the ethical questions involved in the present case.

INTRODUCTION

Under the Medicaid Act, any eligible individual may obtain medical assistance from a provider "qualified to perform the service or services required." 42 U.S.C. § 1396a(a)(23). The Fifth Circuit has defined the term "qualified" to mean "capable of performing the needed medical services in a professionally competent, safe, legal, and *ethical* manner." *Planned Parenthood of Gulf Coast v. Gee*, 862 F.3d 445, 462 (5th Cir. 2017) (emphasis added) (quoting *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dept. of Health*, 699 F.3d 962, 978 (7th Cir. 2012)). As the District Court recognized below, under the Texas Medicaid program, a provider's Medicaid funding may be terminated if the provider "fails to provide health care services or items to Medicaid clients in accordance with accepted medical community standards." *Planned Parenthood of Greater Texas v. Smith*, No. A–15–CA–1058–SS, 2017 WL 692518, at 9 (W.D. Tex. Feb. 21, 2017) (quoting Defs.' Hr'g Ex. 20, (Provider Manual), at 13).

In this case, the Texas Health and Human Services Commission (HHSC) based its termination of Planned Parenthood Gulf Coast's (PPGC's) Medicaid funding in part on video footage showing that PPGC does not adhere to accepted medical standards of ethics. *See* ROA.1210 (Final Notice, at 2). Based on the evidence before it, HHSC found among other things that PPGC demonstrated:

> (1) "[A] history of deviating from accepted standards to procure samples that meet researcher's needs";
>
> (2) "a history permitting staff physicians to alter procedures to obtain target tissue samples needed for their specific outside research"; and
>
> (3) "a willingness to profit from procuring fetal tissue."

ROA.1210–11 (Final Notice, at 2–3). These findings, and the underlying facts supporting them, represent violations of well-established standards of medical ethics.

SUMMARY OF ARGUMENT

PPGC violated well-accepted ethical standards in the medical community for at least five independent reasons.

First, a physician's paramount ethical obligation is to the patient. This means that the well-being of the patient, not research interests, must dictate

every decision a physician makes about a medical procedure. PPGC's practice of altering abortion procedures for research purposes violates the rule that any medical abortion decisions must be solely "based on concern for the safety of the pregnant woman." AMA, Code of Medical Ethics § 7.3.5(c)(ii) (June 2016), https://www.ama-assn.org/delivering-care/ama-code-medical-ethics.

Second, and relatedly, physicians have an ethical obligation to avoid conflicts of interest that could influence medical decisions regarding patient care. PPGC's interest in securing intact fetal tissue for research purposes created a significant conflict of interest, which PPGC failed to resolve in favor of its patients or even to disclose, in violation of its duty of loyalty to its patients. *Id.* § 1.1.1.

Third, a physician violates those same ethical duties when she modifies abortion procedures to collect fetal tissue for her own research, as one of PPGC's physicians admittedly did.

Fourth, selling fetal tissue directly violates established rules of medical ethics, which prohibit "the sale of human fetal tissue for valuable consideration." *See* AMA, Code of Medical Ethics § 7.3.5.

Fifth, even if the evidence showed only that PPGC was *willing* to violate the relevant ethical standards, that willingness would itself be a violation of

medical and ethical standards that erodes the trust that is essential to the physician-patient relationship.

For each of these reasons, HHSC was justified in concluding that PPGC violated accepted standards of medical ethics.

ARGUMENT

I. ALTERING ABORTION PROCEDURES FOR RESEARCH PURPOSES VIOLATES ESTABLISHED MEDICAL AND ETHICAL STANDARDS OF PATIENT CARE.

The video footage relied on by HHSC in this case shows (1) that PPGC has altered abortion procedures "in the past" in order to collect "the best specimen" of fetal tissue possible for research purposes, ROA.5884; (2) that PPGC would be willing to "alter the standard of care" again in order to help researchers secure "intact fetal cadavers," ROA.5891, 6067; and (3) that PPGC knew that its alterations to secure fetal tissue for research cause patient discomfort and even pain. ROA.6159-60; *see also* Texas Br. 14–16, 35–38 (quoting the video transcript evidence at length).

In addition, Mikeal Love, a board-certified Texas Ob/Gyn, testified that the procedural alterations engaged in by PPGC require an "over-dilation of the cervix" which "increases the risk for future complications, including incompetent cervix, pregnancy loss, and preterm labor." Texas Br. at 43 (citing ROA.4485–86).

Worse, PPGC engaged in (and expressed willingness to engage in) this conduct while falsely telling its patients that "*no changes* will be made to the abortion procedure." ROA.8866 (emphasis added).

This evidence amply supports HHSC's finding that PPGC has " 'a history of' altering and a 'willingness' to alter abortion procedures for research purposes," in violation of accepted medical and ethical standards of patient care. *Planned Parenthood of Greater Texas*, *supra*, at 25 (quoting Final Notice, at 2).

A. Changing the timing or method of an abortion procedure to promote research unethically subordinates patient well-being.

Physicians must put patients first. This duty derives from the core ethical principles governing the practice of medicine. As recognized by the American Medical Association's (AMA's) *Principles of Medical Ethics*, the "body of ethical statements" held by the medical profession was developed "primarily for the benefit of the patient." AMA, Principles of Medical Ethics, Preamble (2016), https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf.[1] To that end, ethical principles require each physician to

[1] The American Medical Association is the largest association of physicians in the United States. *See* AMA, *Who We Are*, https://www.ama-assn.org/about/who-we-are. The AMA's Council on Ethical & Judicial Affairs (CEJA) is responsible for maintaining AMA's *Code of Medical Ethics*, which includes the Principles of Medical Ethics. AMA, *Council on Ethical & Judicial Affairs (CEJA)*, https://www.ama-assn.org/about-us/council-ethical-

"recognize responsibility to patients first and foremost." *Id.* Indeed, the practice of medicine itself, AMA states, "is fundamentally a moral activity that arises from the moral imperative to care for patients and to alleviate suffering." AMA, Code of Medical Ethics § 1.1.1. The Texas Medical Association (TMA) echoes AMA in affirming that a physician must "regard responsibility to the patient as paramount." TMA, *Board of Councilors Current Opinions*, https://www.texmed.org/Template.aspx?id=392 (hereinafter *TMA Board Opinions*) (quoting AMA, Principles of Medical Ethics VIII).[2]

The American College of Obstetricians and Gynecologists (ACOG) grounds its specialty-specific code of medical ethics on the same principle: "The welfare of the patient . . . is central to all considerations in the patient-physician relationship." ACOG, Code of Professional Ethics, Ethical

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judicial-affairs-ceja. CEJA promotes adherence to the professional ethical standards of the *Code of Medical Ethics* through its disciplinary function. Depending on the seriousness of a violation of the Principles of Medical Ethics, CEJA may respond with a denial of membership to an applicant or expulsion, probation, or suspension of a member. AMA, *CEJA Rules for Review of Membership*, https://www.ama-assn.org/rules-review-membership.

[2] The Texas Medical Association is the largest and one of the oldest and most influential state medical societies in the United States, representing more than 50,000 members. TMA, *Who is TMA?*, https://www.texmed.org/Who_Is_TMA.aspx. TMA partners with 110 county medical societies in Texas to set professional and ethical standards. TMA's Board of Councilors grants charters to county medical societies and makes decisions regarding medical ethics. The *Board of Councilors Current Opinions* are based on the AMA *Principles of Medical Ethics*, to which its Constitution requires all members to subscribe, and they are designed to supplement the opinions of CEJA. TMA, *TMA Board Opinions*, *supra*.

Foundations § I (July 2011), http://bit.ly/2urgJjW.[3] According to ACOG's code of ethics for Ob/Gyns, "the welfare of the patient must form the basis of *all* medical judgments," *id.*, Code of Conduct § I.1, meaning that the "obstetrician-gynecologist should serve as the patient's advocate and exercise all reasonable means to ensure that the most appropriate care is provided to the patient," *id.* § I.2 (emphasis added).

The AMA's *Code of Medical Ethics* articulates this principle in the specific context of fetal tissue research. According to the *Code*: "physicians who are involved in research that uses human fetal tissues should . . . [e]nsure that . . . decisions regarding the technique used to induce abortion and the timing of the abortion in relation to the gestational age of the fetus are based on concern for the safety of the pregnant woman." AMA, Code of Medical Ethics § 7.3.5(c)(ii).[4]

[3] The *Code of Professional Ethics* of the American College of Obstetricians and Gynecologists (ACOG) provides respected guidance on medical ethics within the Ob/Gyn medical specialty nationwide. ACOG, *About Us*, https://www.acog.org/About-ACOG/About-Us.

[4] Federal law governing government-funded fetal tissue research also reflects this ethical duty of patient care in the context of fetal research. Under federal law, the Secretary of Health and Human Services may support or conduct fetal tissue research only if the responsible attending physician affirms that "no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue." 42 U.S.C. § 289g-1(b)(2)(A)(ii). This safeguard was intended "[t]o prevent any possible abuse" in federally-funded fetal tissue research. S. Rep. No. 103-2, at 22 (1993). It was based on the expert "recommendations of the 1988 NIH task force" on human fetal transplantation research. *Id.*

PPGC's admitted modifications of abortion procedures to obtain better fetal tissue samples bears no relationship to—and actually compromises—"the safety of the pregnant woman," in violation of accepted ethical duties. AMA, Code of Medical Ethics § 7.3.5(c)(ii); *see* ACOG, Code of Professional Ethics § I.1–2. Indeed, PPGC *inverted* the proper hierarchy of a physician's ethical obligations when it allowed research objectives to displace patient well-being as a deciding factor. Even if—contrary to the record evidence—patients suffer no physical harm from PPGC's reordering of medical priorities in any given abortion procedure, PPGC's ethical obligations extend not just to preventing actual harm to the patient, but also to ensuring that any medical judgments "are based on concern for the safety of the pregnant woman." AMA, Code of Medical Ethics, § 7.3.5(c)(ii). PPGC's research-motivated medical decision-making clearly failed to meet this basic ethical obligation.

B. Modifying abortion procedures for research purposes violates a physician's duty of loyalty.

The duty of patient care creates a corollary duty of loyalty that requires medical professionals to scrupulously guard against conflicts of interest. A physician has an "ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others." AMA, Code of Medical Ethics § 1.1.1. When there is a competing interest, even a legitimate one like medical research, a physician must still act in the "patient's best medical

interests," in accordance with physicians' "high duty of loyalty to their patients." *TMA Board Opinions*, *supra*. So central to medical ethics is the duty to resolve actual conflicts in favor of the patient that "[t]his duty, unlike a contractual duty, cannot be waived, even if requested by the patient." *Id.*

A medical professional violates the duty of loyalty when she fails to resolve an actual conflict "in accordance with the best interest of the patient," or even when she fails to disclose a "potential" conflict to the patient. ACOG, Code of Professional Ethics, Ethical Foundations § III; *id.*, Code of Conduct § I.5 ("The [Ob/Gyn] has an obligation to obtain the informed consent of each patient.").

PPGC's practice of "alter[ing] the standard of care" to help secure "intact fetal cadavers" for research purposes—even at the risk of causing pain and long-term harm to the patient—creates an actual conflict that cannot be reconciled with the duty of loyalty that physicians owe to their patients.

C. Modifying abortion procedures in violation of PPGC's own assurances to its patients violates a physician's duty of truthful communication.

Physicians also have a duty of candor to their patients, which requires them "to disclose all risks and hazards which could influence a reasonable person in making his or her decision to consent to the procedure." *Tajchman v. Giller*, 989 S.W.2d 95, 98 (Tex. Ct. App. 1966). In seeking the informed

consent of their patients, physicians must "[p]resent relevant information accurately," including any information about "the nature and purpose of recommended interventions" and "the burdens, risks, and expected benefits of all options, including forgoing treatment," that could reasonably affect the patient's decision. AMA, Code of Medical Ethics § 2.1.1. The patient's consent must be documented "in some manner." *Id.*

Here not only did PPGC fail to seek informed consent by apprising its patients of the additional risks posed by donating fetal tissue, but PPGC also falsely promised, in its consent forms, that "no changes will be made to the abortion procedure." ROA.8866. This violates both PPGC's duty to disclose even "potential" conflicts to its patients, ACOG, Code of Professional Ethics § III.1, and its general duty to avoid misrepresentation "through any form of communication in an untruthful, misleading, or deceptive manner," *id.*, Ethical Foundations § II.

II. PERFORMING OR ALTERING AN ABORTION TO OBTAIN FETAL TISSUE SPECIMENS FOR THE PHYSICIAN'S OWN RESEARCH VIOLATES THE ETHICAL DUTIES OF CARE AND LOYALTY.

The video footage relied on by HHSC in this case also shows that at least one PPGC physician modified abortion procedures "to get . . . [fetal] specimens that are intact" and took the specimens "home with her in her

cooler" to advance her own private research interests. ROA.5978, 6180. This evidence shows that PPGC violated ethical duties of patient care and loyalty.

When a medical professional alters an abortion procedure for the purpose of obtaining a better specimen for her own research, she violates the duties of patient care and loyalty discussed above, no less than when she obtains a sample for an outside researcher. Indeed, the actual conflict of interest is *heightened* when the physician performing the abortion is a direct beneficiary of the research. That is why the AMA prohibits "health care personnel involved in the termination of a pregnancy" from "benefit[ing] from their participation in the termination." AMA, Code of Medical Ethics § 7.3.5.[5]

PPGC's physician performed abortions that directly benefited her own research, in violation of the AMA's code of ethics.

III. PROFITING FROM FETAL TISSUE VIOLATES ETHICAL NORMS AGAINST HUMAN COMMODIFICATION.

Established standards of medical ethics strongly oppose the sale of fetal tissue. "[P]hysicians who are involved in research that uses human fetal tissues" must "[a]bstain from offering money in exchange for fetal tissue." AMA, Code of Medical Ethics § 7.3.5. Likewise, they must "[e]nsure that

[5] This standard is reflected in federal law, which prohibits an individual conducting HHS-supported research on fetal tissue from taking "part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of research." 42 U.S.C. § 289g-1(c)(4).

health care personnel involved in the termination of a pregnancy do not benefit from their participation in the termination." *Id.* These rules are designed to avoid the "potential conflict of interest when there is a possible financial benefit to those who are involved in the retrieval, storage, testing, preparation, and delivery of fetal tissues." *Id.*[6]

In this case, PPGC's research director repeatedly affirmed PPGC's interest in profiting from the sale of fetal tissue. ROA.5987–91, 6067. The director affirmed PPGC's interest in getting paid per specimen. *See* ROA.5984 ("I think definitely a[n à la] carte approach would be the best"). And she touted her ability to conceal any profits through accounting gimmicks, stating that once PPGC had "alter[ed] [its] process . . . to obtain intact fetal cadavers" she could make the financial profit "part of the budget," because "it's all just a matter of line items." ROA.6067. The director also stated that in the past, PPGC had awarded "enrollment bonuses or finders fees" to officially promote its research needs among clinical staff, and that PPGC could continue to

[6] Federal and state law also prohibit the sale of fetal tissue. Federal law provides that "[i]t 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." 42 U.S.C. § 289g-2(a). This section, unlike companion sections, is not limited to federally supported research, but extends to any procurement of fetal tissue by any person. Likewise, Texas law provides that "[a] person commits an offence if he or she knowingly or intentionally offers to buy, offers to sell, acquires, receives, sells, or otherwise transfers any human organ for valuable consideration." Tex. Penal Code § 48.02.

incentivize its clinicians by hosting lunches and "totally writ[ing] it in" as a meeting cost expense. ROA.5992–94.

This evidence demonstrates that PPGC sought to benefit its bottom line and its clinical staff from the sale of fetal tissue, in violation of established standards of medical ethics. AMA, Code of Medical Ethics § 7.3.5.

IV. WILLINGNESS TO VIOLATE MEDICAL AND ETHICAL STANDARDS IS ITSELF A VIOLATION OF MEDICAL AND ETHICAL STANDARDS THAT ERODES THE CONFIDENCE NEEDED FOR PATIENTS TO ENTRUST THEMSELVES TO PHYSICIANS' CARE.

The video evidence shows that PPGC has altered abortion procedures "in the past" in order to collect "the best specimen" of fetal tissue possible for research. Texas Br. 30–31. The District Court dismissed this evidence and concluded that HHSC "had no evidence any PPGC doctor altered an abortion procedure." *Planned Parenthood of Greater Texas*, *supra*, at 26–27. Even if the District Court's characterization of the evidence were correct—and we find the court's conclusion implausible—PPGC's demonstrated willingness to entertain such actions violated its ethical duties.

A physician's ethical duties of care and loyalty are intended to maintain trust in the physician-patient relationship. AMA, Code of Medical Ethics § 1.1.1. According to the *Code*, physicians should in good conscience "[t]ake care that their actions . . . do not adversely affect patient or public trust." *Id.* § 1.1.7. The medical research community shares in the obligation of

"[m]inimizing and mitigating conflicts of interest in clinical research" for the very purpose of "maintain[ing] trust." *Id.* at § 7.1.4. PPGC's willingness to set aside its ethical duties for research purposes, particularly duties as foundational to the medical profession as the duties of patient care and loyalty, erodes the confidence necessary for patients to entrust themselves to the care of physicians.

V. TEXAS LAW PERMITS THE STATE TO HOLD PHYSICIANS ACCOUNTABLE FOR VIOLATING STANDARDS OF MEDICAL ETHICS.

As the Fifth Circuit has recognized, professional ethical standards provide a basis for state determinations of a medical professional's qualifications to practice. *See Gee*, 862 F.3d at 462. Texas law allows the Texas Medical Board to deny a medical license or initiate a disciplinary action against a person if in the Board's own judgment the person "fails to practice medicine in an acceptable professional manner consistent with public health and welfare." Tex. Occ. Code § 164.051(a)(6). The Fifth Circuit has correctly recognized that violations of ethical standards such as those described above can disqualify the violator from providing medical services. *See Gee*, 862 F.3d at 462.

CONCLUSION

The Court should reverse and vacate the preliminary injunction.

Respectfully submitted,

/s/ Adam R.F. Gustafson
C. BOYDEN GRAY*
ADAM R.F. GUSTAFSON
Counsel of Record
ANDREW R. VARCOE
JAMES R. CONDE
BOYDEN GRAY & ASSOCIATES
801 17th Street NW, Suite 350
Washington, DC 20006
(202) 955-0620
gustafson@boydengrayassociates.com
**Not admitted in this Court.*

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5), because the brief contains 3,208 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with typeface requirements of FED. R. APP. P. 32(a)(5) and the type-style requirements of FED. R. APP. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word in Calisto MT 14-point font.

/s/ Adam R.F. Gustafson
ADAM R.F. GUSTAFSON
BOYDEN GRAY & ASSOCIATES
801 17th Street NW, Suite 350
Washington, DC 20006
(202) 955-0620
gustafson@boydengrayassociates.com

August 14, 2017

CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2017, I electronically filed the foregoing Brief of Kevin Donovan, M.D., as *Amicus Curiae* in Support of Defendants-Appellants via the CM/ECF system, which will send notice of the filling to all counsel who are registered CM/ECF users.

/s/ Adam R.F. Gustafson
ADAM R.F. GUSTAFSON
BOYDEN GRAY & ASSOCIATES
801 17th Street NW, Suite 350
Washington, DC 20006
(202) 955-0620
gustafson@boydengrayassociates.com

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