

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 #1; JANE
DOE #2; JANE DOE #4; JANE DOE #7; JANE DOE #9; JANE DOE #10;
AND JANE DOE #11;

Plaintiffs,

v.

CHARLES SMITH, IN HIS OFFICIAL CAPACITY AS EXECUTIVE COM-
MISSIONER OF HHSC; AND SYLVIA HERNANDEZ KAUFFMAN, IN
HER OFFICIAL CAPACITY AS ACTING INSPECTOR GENERAL OF
HHSC,

Defendants-Appellants.

On Appeal from the United States District Court
for the Western District of Texas, Austin Division,
No. 1:15-cv-01058

REPLY BRIEF FOR APPELLANTS

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INTRODUCTION

Tellingly, Plaintiffs' brief omits any meaningful discussion of the startling contents of the video at the center of this dispute. Plaintiffs thus emphasize newspaper articles rather than the facts in evidence, and they parrot the district court's erroneous analysis rather than demonstrate its accuracy.

Furthermore, on the threshold issue of whether Plaintiffs even have a private right of action, Plaintiffs quote from *Planned Parenthood of Gulf Coast, Inc. v. Gee*, 862 F.3d 445 (2017), while simultaneously ignoring a key distinction: The state defendant in *Gee* conceded that Planned Parenthood Gulf Coast (PPGC) was competent to provide Medicaid services. *Id.* at 465-66. By contrast, this case turns on the state agency's determination that PPGC is *not* a qualified provider. That fact not only distinguishes this case from *Gee*, but also places it squarely within *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773 (1980), in which the Supreme Court held that the "qualified-provider" provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(23), does not confer a right on a recipient to continue receiving care from a provider that has been decertified. 447 U.S. at 784-85.

Even if the Jane Doe Plaintiffs have a private right of action—a proposition recently rejected by the Eighth Circuit¹—and no deference is due to the

¹ As noted in Appellants' Fed. R. App. P. 28(j) letter filed on August 17, 2017, the Eighth Circuit also held that that the "qualified provider" provision of the Medicaid Act, 42 U.S.C. § 1396a(a)(23), does not confer an enforceable federal right that supports a cause of action under 42 U.S.C. § 1983. *Planned*

agency's determination that the Texas Planned Parenthood affiliates are not qualified Medicaid providers, that determination was factually correct based on the extensive evidence in the video and other documents showing that PPGC violated medical and ethical standards. The district court's ruling to the contrary should be reversed.

ARGUMENT

I. The Plaintiffs Lack a Private Right of Action Under *Gee* and *O'Bannon*.

Plaintiffs make no argument that Medicaid providers have a private right of action, even though the providers themselves are plaintiffs in this lawsuit.² And as the Supreme Court held in *O'Bannon* and this Court recognized in *Gee*, patients also lack a private right of action when they challenge a state agency's determination on the merits that a provider is not "qualified" under the Medicaid Act. 42 U.S.C. § 1396a(a)(23).

A. *O'Bannon* controls this case.

Plaintiffs paint *O'Bannon* as solely a due process case because the patients argued that they had a property interest and a due process right to contest the merits of the state's decision through an evidentiary hearing. Appellees' Br.

Parenthood of Ark. & E. Okla. v. Gillespie, 867 F.3d 1034 (8th Cir. 2017). On November 13, 2017, the Eighth Circuit denied rehearing of this decision. *Id.*

² Both the *Gee* majority and dissent agreed that providers lack such a cause of action. *Gee*, 862 F.3d at 460, 486.

at 35. But before determining whether the patients were entitled to a hearing, the court first had to consider whether there was a private right of action under the qualified-provider provision that could give rise to a right to a hearing. The Court concluded there is not such a private right of action. *O'Bannon*, 447 U.S. at 784-85.

The Court held that 42 U.S.C. § 1396a(a)(23) only “gives recipients the right to choose among a range of *qualified* providers,” and “clearly does not confer a right on a recipient to enter an unqualified home and demand a hearing to certify it, nor does it confer a right on a recipient to continue to receive benefits for care in a home that has been decertified.” *Id.* at 785 (emphasis in original). In the Supreme Court’s view, the Third Circuit was wrong to conclude the qualified-provider provision conferred substantive rights on the patients because “while a patient has a right to continued benefits to pay for care in the qualified institution of his choice, he has no enforceable expectation of continued benefits to pay for care in an institution that has been determined to be unqualified.” *Id.* at 786.

O'Bannon therefore cannot be limited to the question of whether patients of a decertified provider are entitled to a hearing; the Supreme Court concluded the patients were not on the basis that the Medicaid Act conferred no private right entitling them to sue to obtain a hearing. And if there is no sub-

stantive right to the provider of one's choice if that provider has been disqualified, there is no right of action to challenge the merits of the state's disqualification. *O'Bannon* squarely controls this case.

B. *Gee* does not support a private right of action in this case.

This Court interpreted *O'Bannon* precisely that way in *Gee*.³ The *Gee* majority pointed out that the patients there were “*not challenging the merits of the decertification decision*, as did the plaintiffs in *O'Bannon*, because [in *Gee*] there was no decertification decision.” 862 F.3d at 461 (emphasis added; quotation marks omitted). This is because Louisiana “conceded” that PPGC was competent to provide Medicaid services. *Id.* at 465-66; *see id.* at 461 (“When, as here, a state terminates only a Medicaid provider agreement, independent of any action to enforce statutory and regulatory standards, *O'Bannon* is inapposite.”). Louisiana argued that it can terminate Medicaid provider agreements regardless of whether the provider is qualified. *Id.* at 468. That is the argument that *Gee* rejected and was among the “unique circumstances” the panel majority referred to when it emphasized the narrowness of its holding in that case. *Id.*

By contrast, Texas has made no concession that Plaintiffs are qualified providers. In complete contrast, the Texas Office of the Inspector General

³ As of November 17, 2017, this Court is still considering whether to grant en banc rehearing in *Gee*.

(OIG) conducted an investigation and concluded that the Texas Planned Parenthood affiliates are not qualified Medicaid providers because PPGC violated medical and ethical standards. ROA.1210-11. Medicaid providers can be terminated under Texas law for failing to adhere to “accepted medical community standards,” 1 Tex. Admin. Code § 371.1659(2), and so can their affiliates, as defined by state law. 1 Tex. Admin. Code §§ 371.1703(c)(7), 371.1605(a), 371.1(3). Thus, *Gee*’s holding with respect to Louisiana does not dictate the result in this case, and *O’Bannon* instead controls. Plaintiffs lack a private right of action and their claims should be dismissed.

C. The Provider Plaintiffs’ termination from Medicaid was based on their qualifications.

Plaintiffs mischaracterize the administrative process OIG followed in terminating the Provider Plaintiffs’ Medicaid agreements as somehow nefarious. Plaintiffs argue that it is akin to the “gamesmanship” the *Gee* court believed that Louisiana engaged in when it issued a new notice of termination after the district court dismissed the plaintiffs’ claims because the state rescinded the initial notice. Appellees’ Br. at 36-37; *Gee*, 862 F.3d at 468-69. But the OIG process is dictated by state law.

When a provider is terminated, OIG follows the same process it did in this case: an initial notice of termination is sent based on the initial investigation, which begins the process of termination. ROA.1202-06, 1239-43, 1310-14. The termination decision is not final until the final notice of termination is sent and

the time for appeal has elapsed. ROA.1213. The process is specifically designed to allow the provider to request an informal resolution meeting to address the initial findings in the notice and submit evidence and argument to aid in the agency's determination. ROA. 1205-06, 1242-43, 1313-14. If the initial findings cannot differ from the findings in a final notice, there is little reason to allow for the process to continue between the notices.⁴

There was one deviation from the normal process in this case, but it *favored* Plaintiffs. As indicated in the Initial Notice, if a provider fails to respond to the notice within 30 calendar days of receipt, a Final Notice can be issued on that basis. ROA.1205. But because the Plaintiffs filed the lawsuit in federal court on the Monday after the 30-day period expired, ROA.31-59, OIG continued its investigation, even though filing the lawsuit technically did not comply with the response requirements of the Initial Notice. During the period after the Initial Notice was sent and before the Final Notice was issued, OIG's investigation and Congressional investigations continued as well, concluding the same month that OIG sent the Final Notice of Termination. ROA.7328-7798, 8883. The Plaintiffs therefore received more consideration than they would have had OIG followed its process strictly and terminated them for not responding to the Initial Notice. Thus, the OIG's process of termination cannot be considered evidence that the Provider Plaintiffs' termination from

⁴ Plaintiffs made no due-process claim and did not challenge the adequacy of either Notice. ROA.39-50, 3227-47.

Texas Medicaid was unrelated to their qualifications. Because the termination was a result of a determination on the merits of the Provider Plaintiffs' qualifications, *O'Bannon* and not *Gee* controls, and Plaintiffs consequently lack a private right of action.

II. The District Court Erred in Concluding That Plaintiffs Were Likely to Succeed on the Merits.

A. OIG's interpretation of the qualified-provider provision is neither invalid nor foreclosed by federal law.

Plaintiffs posit that the correct interpretation of the term "qualified" in the Medicaid Act is "capable of performing the needed medical services in a professionally competent, safe, legal, and ethical manner," and argue that standard is clear and leaves no ambiguity. Appellees' Br. at 51. While this standard is included in the *Gee* opinion, 862 F.3d at 465, it is not found in the Medicaid Act itself.

Texas has interpreted the Medicaid Act to allow for the exclusion of providers who fail to meet medical and ethical standards, even if a court has not found a violation of a criminal or civil prohibition. ROA.1209-14. Specifically, Texas has interpreted the Medicaid Act to allow for termination of the agreement of a provider that has contravened federal standards regarding fetal-tissue research and made a false statement to law enforcement officials about their fetal-tissue activities, which were the subject of the criminal investigation. ROA.1209-14. Texas has also interpreted the Medicaid Act to allow for

the termination of affiliates of providers who fail to meet standards for qualifications. ROA.1209-14, 1 Tex. Admin Code § 371.1703(c)(7). The district court concluded that OIG's termination of the Provider Plaintiffs for these reasons was unrelated to their qualifications to provide medical services. ROA.3799.

OIG's interpretation and implementation of the Act to exclude the Provider Plaintiffs is valid unless the federal statutory language "plainly prohibit[s]" the State's interpretation. *Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 631 (5th Cir. 2014). That is because a clear statement of a condition on a federally funded program administered by the state is required by *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). See Amicus Curiae Br. of 42 Members of Congress in Supp. of Defs.-Appellants at 2-6.

The Medicaid Act does not contain a clear statement foreclosing the State's interpretation and implementation of the Act in this case. As this Court has previously stated, "States have broad discretion to implement the Medicaid Act." *Detgen*, 752 F.3d at 631. The term "qualified" is not defined in the Act, and the Act clearly contemplates that States will fill in the blanks. See 42 U.S.C. § 1320a-7(b)(5) (authorizing the Secretary to exclude providers who have been excluded on state law grounds); see also 42 C.F.R. § 1002.3(b) (State has authority to exclude a Medicaid provider as a state contractor "for any reason or period authorized by State law"). Without a clear statement from Congress foreclosing the State's interpretation of the Medicaid Act as to

the meaning of “qualified,” it cannot conflict with federal law, and Plaintiffs’ claim under the Medicaid Act cannot be sustained.

B. The district court erred in not applying arbitrary-and-capricious review to OIG’s termination decision.

Plaintiffs argue that this case is not an appeal of an agency action, Appellees’ Br. at 46-47, but it cannot be characterized any other way. The state agency charged with administration of the Medicaid program found evidence of violations of medical and ethical standards and decided to terminate the provider agreements of the Plaintiffs. ROA.1209-1214. The Plaintiffs disagreed with the initial determination and instead sought judicial review of the decision. According to *Gee*, the Plaintiffs did not have to exhaust administrative remedies prior to bringing a claim under 42 U.S.C. § 1983, but that does not mean that (1) there are no consequences for not putting any evidence in to the administrative record, and (2) Plaintiffs are guaranteed de novo review of the agency’s factfinding and conclusions.

The fact that the Jane Doe Plaintiffs would not have been able to participate in the administrative proceedings does not mean they are without relief. As *O’Bannon* pointed out, they may have a cause of action against the provider for losing certification, but they do not have a cause of action to challenge the government’s decertification decision. 447 U.S. at 787. Plaintiffs appear to believe they can ignore administrative proceedings, but this is not the case. The Medicaid Act is implemented by state agencies. State agencies are responsible

for determining the qualifications of providers. As such, their factfinding in that area is entitled to deference, and arbitrary-and-capricious review applies under Circuit precedent. *See Abbeville Gen. Hosp. v. Ramsey*, 3 F.3d 797, 803-04 (5th Cir. 1993)(per curiam).

Plaintiffs' argument that arbitrary-and-capricious review cannot apply because *Gee* did not apply it is specious. Appellees' Br. at 47-48. First, as has already been discussed, the Louisiana agency did not do any factfinding or make any conclusion as to the qualifications of the provider in *Gee*, so no deference was due. Moreover, it does not appear that the State in *Gee* even argued that deference should apply. The absence of arbitrary-and-capricious review in *Gee* says nothing about whether it should apply in this case.

Plaintiffs' assertion that the district court did the same review of OIG's decision as the *Abbeville* court is similarly unpersuasive. Appellees' Br. at 49-50. The district court did more than just determine whether there was "sufficient [evidence] for a reasonable mind to accept as adequate to support a conclusion." *El Paso Elec. Co. v. NLRB*, 681 F.3d 651, 656 (5th Cir. 2012). It weighed the evidence, and in doing so, the district court considered—and weighted more heavily—Plaintiffs' post hoc explanations for the statements on the video presented during the evidentiary hearing, which are not part of the administrative record. This Court's precedent makes clear that the agency may "rely on the opinions of its own experts, so long as the experts are quali-

fied and express a reasonable opinion.” *Sabine River Auth. v. U.S. Dep’t of Interior*, 951 F.2d 669, 678 (5th Cir. 1992). Even if the district court were inclined to disagree with the agency’s conclusion, when reviewing under the arbitrary-and-capricious standard, the court must still show it “the proper respect,” “even if the reviewing court finds the opinions of other experts equally or more persuasive.” *Id.*

Plaintiffs also argue that deference should only apply in situations involving specialized agency expertise, and determining whether the Provider Plaintiffs are qualified is a “simple” question. Appellees’ Br. at 48. But OIG does have specific expertise, as it is familiar with the federal law and regulations as well as the state regulatory scheme which governs the process and the requirements for qualification in the Medicaid program. Notably, elsewhere in their brief, Plaintiffs argue that OIG’s Chief Medical Officer Dr. Ted Spears was unqualified to review the video and make conclusions about it because he does not perform abortions and stated he would have to defer to an Ob/Gyn as to the technical aspects of abortion procedures. Appellees’ Br. at 24; ROA.4396. It is hard to see why a court is in a better position to evaluate the evidence and determine whether medical and ethical standards have been violated if, ac-

According to Plaintiffs, a medical doctor who has performed thousands of surgeries and works for the state agency tasked with ensuring Medicaid providers meet qualification standards is not capable of making that determination.⁵

C. The evidence shows that Planned Parenthood Gulf Coast violated medical and ethical standards.

The central evidence in this case is the undercover video footage, but Plaintiffs fail to address the content of the video in any meaningful way. As explained in the State’s opening brief, the video shows violations of medical and ethical standards. This is contrary to the district court’s clearly erroneous finding that the video discussion centered on clinic processes and tissue packaging rather than the abortion procedure itself; the video featured repeated discussion about the position of the fetus in the uterus, the risk to the patient, and the patient’s pain tolerance. Appellants’ Br. at 13-16, 33-40. Plaintiffs also make further incorrect claims regarding the evidence in the case.

⁵ Plaintiffs refer to Dr. Spears as a “sports medicine doctor,” Appellees’ Br. at 39, but he is an orthopedic surgeon who has performed thousands of surgeries over the course of his 30-year career—approximately 6,000—and is more than qualified to assess whether repeated assertions about modifying surgical procedures for the sake of research violates medical and ethical standards. ROA.4393, 4396.

1. Federal regulations on fetal tissue research are applicable in this case and inform as to what the relevant medical and ethical standards are.

Plaintiffs argue that federal regulations on fetal tissue research are inapplicable because they pertain to transplantation of fetal tissue. Appellees' Br. at 25. The regulations mention transplantation because at the time they were written, that was the primary way researchers used fetal tissue.⁶ In this case, the video makes clear that Dr. Regan Theiler was engaged in a research study on placental tissue⁷ and performed abortions to harvest tissue for her study. ROA.4208; DX-2 at 9:46:47-9:47:26. The conflict of interest inherent in a researcher performing abortions to harvest tissue for her own research is not somehow more salient if the tissue is being transplanted instead of being used for another purpose. At a minimum, the regulations provide ethical guidelines for this type of research. And regardless of the regulations, it is plain that a physician's undisclosed conflict of interest is a breach of medical and ethical norms. *See* 42 U.S.C. § 289g-1(b)(2)(C)(i).

⁶ It was hypothesized at that time that direct transplantation of fetal brain tissue into the brain of an individual with Parkinson's Disease could have therapeutic effects. *See* Rae, Scott B. and DeGiorgio, Christopher M., *Ethical Issues in Fetal Tissue Transplants*, The Linacre Quarterly, Vol. 58: No. 3, Art. 4 (1991) at 12-15, available for download at <https://perma.cc/R75Z-RV49> (last accessed Nov. 16, 2017).

⁷ The study involved "placental tissue," and at the gestational age the procedures were performed, fetal and placental tissue cannot be separated. ROA.4258, 8877.

Plaintiffs argue that 45 C.F.R. § 46.204 does not apply at all in the context of abortions. Appellees' Br. at 25. But it does: "Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy." 45 C.F.R. § 46.204(i).

Plaintiffs also claim that the Final Notice of Termination did not specify the violation of a researcher being involved with performing abortions to harvest fetal tissue for her own research. Appellees' Br. at 25 n.19. But they excised the end of the sentence they quote from the Notice—"needed for their specific outside research"—which includes this ground for termination. ROA.1210.

As a last resort, Plaintiffs argue that Institutional Review Board (IRB) approval for the research absolves them of any responsibility for the conflict of interest. Appellees' Br. at 40. But there is no evidence in the record as to whether the IRB would have even known that Dr. Theiler was doing abortions at PPGC for her research, and indeed her provision of abortions is not mentioned in the IRB-approved consent form used in the study. ROA.8866-80.

Whether Dr. Theiler knew she was performing an abortion on a patient from whom she desired a tissue sample is relevant to whether she could have altered the procedure in some way to facilitate her research, as Melissa Farrell, PPGC's Director of Research, describes on the video. ROA.5978; DX-2 at 9:48:05-9:48:27. The evidence in the record indicates that she did know.

ROA.5976; DX-2 at 9:46:47-9:47:26. Plaintiffs describe their witnesses' testimony as uncontroverted on this point (and several others), but they overlook that it is controverted by the video, which they fail to address in a meaningful way. Regardless of whether she altered a procedure, it violated ethical standards for Dr. Theiler to be involved with abortion procedures where tissue for her research may be harvested, especially without disclosure of that fact to her patients. *See* 42 U.S.C. § 289g-1(c)(4), (b)(2)(C)(i); 45 C.F.R. § 46.204(i); ROA.4486.

- 2. If the Court considers post-termination evidence of any kind, it should also consider the post-termination evidence presented by the Defendants, which shows further unethical behavior by Provider Plaintiffs supporting termination.**

As already explained, if the Court is reviewing the decision of the agency on the merits under the arbitrary-and-capricious standard, the only relevant evidence is the evidence in the administrative record. *See* Appellants' Br. 41-42. The validity of the agency's decision cannot be evaluated on the basis of evidence it did not have before it. *Luminant Generation Co. v. EPA*, 675 F.3d 917, 925 (5th Cir. 2012). But if the Court applies de novo review and is inclined to evaluate post-termination evidence from the Plaintiffs, it must also consider the post-termination evidence from the Defendants, which provides further support for the termination of the Provider Plaintiffs' Medicaid agreements.

Plaintiffs complain that the violations pertaining to informed consent were not in the Final Notice of Termination. Appellees' Br. at 41-42. But the

documents supporting that violation were not obtained by the Defendants until after the U.S. House of Representatives Select Investigative Panel issued its lengthy final report on December 30, 2016, which was ten days after the Final Notice was issued. ROA.7328-7798, 1209-14. It would have made little practical sense for Defendants to issue a new termination letter at that point given that the parties were already in litigation. Plaintiffs were not prejudiced by this because they had notice of that ground for termination by virtue of Defendants' Response in Opposition to the Preliminary Injunction motion, which was filed on January 12, 2017, and the additional ground served to bolster the termination decision that was already made. ROA.2382-84.

Telling patients one thing and doing another is blatantly unethical. The consent forms used in the University of Texas Medical Branch (UTMB) study that Dr. Theiler was involved in do not disclose that Dr. Theiler would be performing abortions, which is a conflict of interest. ROA.8866-80. The consent form mandated by Planned Parenthood Federation of America ("Federation") in June 2011, the time of the UTMB study, states that "*no changes*" will be made to the abortion procedure to facilitate fetal tissue donation. ROA.8866, 8877 (emphasis added). But the Federation's policy clearly states that doctors must certify only that no "*substantive*" changes were made. ROA.7835, 7837 (emphasis added). And there is evidence in the record suggesting that there may have been other research going on aside from the UTMB study. For instance, Farrell stated that the other doctors at PPGC do

research projects, and PPGC's website advertises that it engages in fetal tissue donation.⁸ ROA.5883-85; DX-2 at 8:04:08-8:05:35.

The discrepancy between the Provider Plaintiffs' practice and their consent form telling their patients "no changes would be made" was underscored by Dr. Fine's testimony at the evidentiary hearing. Dr. Fine, PPGC's Medical Director, testified that he believed there was no issue with modifying an abortion procedure to facilitate fetal tissue procurement because the patient consented to a general procedure, and as long as the patient was not at risk in the doctor's view, the doctor could make whatever changes he wished, despite the conflict of interest. ROA.4249-50, 4266, 4268.

Allowing alterations to the abortion procedure to facilitate tissue procurement is not just unethical according to federal regulations, but it is also unethical according to other abortion providers such as the National Abortion Federation, whose guidelines on fetal tissue donation explicitly states that *no* changes to the procedure should be made.⁹ And regardless of whether the practice of altering abortion procedures is unethical, or whether it was actually

⁸ Planned Parenthood Gulf Coast, Inc., *Clinical Research*, <https://perma.cc/MN98-ZVET> (last accessed Nov. 16, 2017).

⁹ National Abortion Federation, *National Abortion Federation Guidelines Relating to Fetal Tissue Donation*, <https://perma.cc/Q55Y-QJKD> (revised October 2015)(last accessed Nov. 17, 2017).

done by PPGC, the fact that Planned Parenthood Federation of America policies and forms did not disclose that this *may* be done to their patients is unethical in and of itself. ROA.4397, 4411, 4413-14, 4418-19, 4483-84.

OIG's decision to terminate as outlined in the Final Notice of Termination was correct. But it is further supported by the evidence that Planned Parenthood was not telling their patients the whole truth about their abortion procedures when they consented to donating fetal tissue. That is a serious breach of medical and ethical standards and alone supports termination of the Provider Plaintiffs' Medicaid agreements.

D. State law specifically allows for the termination of providers who violate medical and ethical standards and their affiliates.

As Appellants explained in their opening brief and below, Texas law allows for the termination of affiliates of Medicaid providers who commit program violations, or violate medical and ethical standards. Appellants' Br. at 12, 33; ROA.1211; 1 Tex. Admin. Code §§ 371.1703(c)(7), 371.1605(a). Appellants also explained how PPST and PPGT were involved in the additional grounds for termination that arose after the Final Notice was sent. Appellants' Br. at 43-45, 53-54. Plaintiffs complain about this as a violation of the qualified-provider provision of the Medicaid Act and argue that Planned Parenthood South Texas (PPST) and Planned Parenthood Greater Texas (PPGT) were not accused of wrongdoing, but they did not directly challenge these laws nor

the state's legal definition of "affiliate" for Medicaid purposes, and did not make a claim that these laws are preempted by federal law. ROA.3227-47.

As discussed above and in the opening brief, if a state's interpretation of federal program statutes and regulation do not conflict with a clear statement in those statutes and regulations, the state interpretation is valid. *See supra* Part II.A. Federal regulations permit termination of affiliates. *See* 42 C.F.R. § 1001.1001(a)(1)(iii) (States "may exclude an entity . . . if a person with a relationship with such entity . . . [h]as been excluded from participation in Medicare or any of the State health care programs.") The clear statement rule applies with equal force to Texas's interpretation of the federal regulation through its own laws and regulations permitting termination of affiliates and in OIG's implementation of these laws in excluding PPST and PPGT from Texas Medicaid. These interpretations of the federal law are reasonable and may not be set aside.

PPGT and PPST are affiliates of PPGC under state law, and their termination from Texas Medicaid was proper. When the OIG "establishes [a program violation] by prima facie evidence, the OIG may terminate or cancel the enrollment or contract from Medicaid, CHIP, or any other HHS program of . . . a person that is affiliated with a person who commits a program violation." 1 Tex. Admin Code § 371.1703(c)(7). An "affiliate" is someone who "is an agent or consultant of the person," or is "a consultant of the person and can control or be controlled by the person or a third party can control both the

person and the consultant.” *Id.* § 371.1(3)(E), (F). An “affiliate” is also someone who “has financial, managerial, or administrative influence over the operational decisions of a person,” or “shares any identifying information with another person, including . . . corporate or franchise names.” *Id.* § 371.1(3)(H), (I).

The Federation does not provide direct medical services itself, but instead provides them through approximately 50 affiliates nationwide, including PPGC, PPST, and PPGT. ROA.4112. The Federation has characteristics of a franchise operation, with affiliates paying annual dues. In exchange for these payments and provided that affiliates comply with Federation policies, affiliates can hold themselves out to the public by using the name “Planned Parenthood” and receive other benefits like monetary support and legal representation. *See* ROA. 1650, 4124, 4279-80, 8052-54, 8129-31, 8520-22. This connection is sufficient under state law to link all the entities in this action. *See* 1 Tex. Admin. Code § 371.1(3)(I) (defining an affiliate as someone who “shares any identifying information with another person, including . . . corporate or franchise names ”).

The Federation also exercises functional control over the affiliate entities. It sets medical and operational standards for affiliates. ROA.4121-22, 4195; 4201; DX-2 at 7:41:36-7:41:57; 12:26:50-12:27:35. The Federation requires all affiliates to provide certain core services. ROA.4121. In fact, the Federation requires that all affiliates provide abortions. ROA.4121, 4282. The Federation

must review and approve all affiliate research projects, including those involving fetal tissue. ROA.4121; 4281-82. The Federation must review and approve all affiliate research contracts. ROA.4281-82. And of particular relevance, the Federation sets policies that govern fetal tissue donation by affiliates. ROA.7831-37, 8866. The inadequate informed consent form and conflicting policy guidelines on fetal tissue research are mandated for use by PPFA and apply to all affiliates, including PPST and PPGT. ROA.7831-37, 8866. And the affiliates themselves work together and share best practices and industry information. ROA.4279-80.

This top-down control exercised by the Federation over its affiliates and the close relationship between the affiliates provides an additional sufficient basis for the OIG to terminate the provider agreement of not just PPGC, but each of the affiliates. *See* 1 Tex. Admin. Code § 371.1(3)(F) (defining an affiliate as someone who “can control or be controlled by the person or a third party can control both the person and the consultant”); *Id.* § 371.1(3)(H) (defining an affiliate as someone who “has financial, managerial, or administrative influence over the operational decisions of a person”). The fact that the practices at issue in this lawsuit are controlled by the Federation and not each individual affiliate provide a firm basis for exclusion of all the Federation affiliates from Texas Medicaid, given the ethical flaws in these policies and practices.

CONCLUSION

The Court should reverse and vacate the preliminary injunction.

Respectfully submitted.

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CERTIFICATE OF SERVICE

On November 17, 2017, this brief was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court. Counsel further certifies that: (1) any required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; (2) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1; and (3) the document has been scanned with the most recent version of Symantec Endpoint Protection and is free of viruses.

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CERTIFICATE OF COMPLIANCE

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5,044 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii); and (2) the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the same program used to calculate the word count).

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