No. 21-10302

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

VICTOR LEAL; PATRICK VON DOHLEN; KIM ARMSTRONG,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services; JANET YELLEN, Secretary, U.S. Department of Treasury; MARTIN WALSH, Secretary, U.S. Department of Labor; UNITED STATES OF AMERICA; KENT SULLIVAN; TEXAS DEPARTMENT OF INSURANCE,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Texas

BRIEF FOR THE FEDERAL APPELLEES

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STATEMENT REGARDING ORAL ARGUMENT

The district court correctly applied settled principles of law to the facts of this case. The government stands ready to present oral argument if the Court would find it useful.

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STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1367. The court entered final judgment on March 26, 2021. ROA.514. Plaintiffs timely filed a notice of appeal the same day. ROA.516. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether plaintiffs' claims against the federal defendants fail for lack of standing and, with respect to plaintiffs Leal and Von Dohlen, are also barred by *res judicata*.

2. Assuming the issue is properly before the Court, whether Congress engaged in an unconstitutional delegation of legislative power by giving an agency a role in supporting the development of guidelines for additional preventive care and screenings for women that, by statute, insurance plans must cover without cost sharing requirements.

STATEMENT OF THE CASE

I. Statutory Background

The Patient Protection and Affordable Care Act (ACA) requires that a group health plan and an issuer offering group or individual

health coverage provide coverage for certain preventive services without "cost sharing" requirements (such as copayments and coinsurance). 42 U.S.C. § 300gg-13(a. The ACA specifies that the preventive services that must be covered without cost sharing are:

> (1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;
>
> (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and
>
> (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.
>
> (4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

Id.

By structuring this provision to incorporate standards developed by experts, Congress ensured that the types of preventive services that are covered without cost sharing would evolve in light of new medical conditions, new medical evidence, and other scientific developments. For example, COVID-19 vaccines must be covered without cost sharing

because, when those vaccines received emergency-use authorization from the Food and Drug Administration (FDA), they were added to the list of immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control & Prevention (CDC).[1]

Similarly, in 2016, the Health Resources and Services Administration (HRSA), which is a component of the U.S. Department of Health and Human Services (HHS), updated its guidelines for women's preventive services to recommend that women who are at average risk for breast cancer begin annual or biennial mammography screenings as early as age 40 and no later than age 50 and continue through at least age 74. HRSA, *Women's Preventive Services Guidelines* (2016).[2] These updates were based on the recommendations of an expert panel of national health professional organizations and consumer and patient advocates with expertise in women's health across the lifespan, which was engaged by the American College of Obstetricians and

[1] Advisory Comm. on Immunization Practices, CDC, *COVID-19: Vaccine Recommendations and Guidelines of the ACIP*, https://go.usa.gov/xFZJf (last updated May 17, 2021).

[2] https://www.hrsa.gov/womens-guidelines-2016/index.html.

Gynecologists under a cooperative agreement with HRSA. *Id*.

II. Factual Background

Plaintiffs are three individuals—Kim Armstrong, Victor Leal, and Patrick Von Dohlen—who reside in Texas. ROA.11-12, ¶¶ 6-8. The complaint alleged that Ms. Armstrong "does not need or want contraceptive coverage in her health insurance because she had a hysterectomy at age 21 and is incapable of becoming pregnant" and also because she was 50 years old in 2020 and likely "past her childbearing years even apart from her hysterectomy." ROA.16-17, ¶ 32. The complaint alleged that, for religious reasons, Mr. Leal and Mr. Von Dohlen do not want contraceptive coverage in their health insurance plans. ROA.16, ¶ 31.

The complaint alleged that plaintiffs face multiple barriers to purchasing the plans they want. Since 2001, Texas law has generally required every health plan that covers prescription drugs and devices to cover every FDA-approved prescription drug or device. ROA.15, ¶ 24 (citing Tex. Ins. Code § 1369.104(a)). Plaintiffs alleged that this Texas law is "forcing private health insurers to cover contraception even when their customers do not need it and do not want it." ROA.10.

In addition, since 2011, the HRSA guidelines for women's preventive services that are referenced in 42 U.S.C. § 300gg-13(a)(4) have included (among other services) FDA-approved contraceptives as prescribed by a health care provider. *See* 77 Fed. Reg. 8725 (Feb. 15, 2012). This contraceptive-coverage requirement has been the subject of much litigation. *See, e.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2376-77 (2020). In 2018, HHS issued a final regulation that, as relevant here, allows a "willing health insurance issuer" to offer a separate policy excluding contraceptive coverage to any individual who objects to such coverage based on sincerely held religious beliefs. 83 Fed. Reg. 57,536, 57,537 (Nov. 15, 2018) (codified at 45 C.F.R. § 147.132(b)). Separately, a certified class that included Mr. Leal and Mr. Von Dohlen obtained a permanent injunction providing the same relief under the Religious Freedom Restoration Act (RFRA). *See* Pl. Br. 10 (describing the injunction entered in *DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019), *appeal pending sub nom.*, *DeOtte v. Nevada*, No. 19-10754 (5th Cir.)). In this case, plaintiffs alleged that, despite the *DeOtte* injunction, "few if any insurance companies are currently offering health insurance that

excludes coverage for contraception because a policy of this sort can only be offered to religious objectors rather than to the public at large." ROA.15, ¶ 23.

III. The District Court's Rulings

The complaint filed in this action alleged claims against state and federal defendants. It alleged that the Texas insurance law discussed above violates the rights of Mr. Leal and Mr. Von Dohlen under the Texas Religious Freedom Restoration Act, ROA.21-23, ¶¶ 51-57, and named as defendants the Texas Insurance Commissioner and Texas Department of Insurance, ROA.12, ¶¶ 13-14. The district court ruled that these state-law claims were barred by state sovereign immunity and potentially time barred. ROA.448-460. Plaintiffs have explicitly declined to challenge these rulings in this appeal. Pl. Br. 14 n.4.

The complaint alleged that the federal contraceptive-coverage requirement violates RFRA. ROA.21, ¶¶ 48-50. It also alleged that the role that Congress assigned to HRSA to support the development of guidelines for additional preventive services for women not described in the current recommendations of the U.S. Preventive Services Task Force is an unconstitutional delegation of lawmaking power, ROA.20-

21, ¶¶ 45-47, and results in a violation of the Appointments Clause, ROA.18-20, ¶¶ 38-44.

As relevant to this appeal, the district court concluded that the allegations of the complaint established standing, ROA.425-429; that the claims of Mr. Leal and Mr. Von Dohlen were barred by *res judicata*, ROA.432-441, and that Ms. Armstrong failed to state a claim under the nondelegation doctrine, ROA.445-447. (The district court allowed Ms. Armstrong's Appointments Clause claim to proceed, but she dismissed that claim voluntarily, ROA.510, and it is not at issue here.)

In addressing standing, the district court reasoned that the complaint adequately alleged that plaintiffs' inability to obtain a plan excluding contraceptives was caused by the federal contraceptive-coverage requirement, ROA.426-427, and adequately alleged that "insurance companies will expand their insurance policies to include contraceptive-free policies" if the federal requirement is invalidated, ROA.428. However, the district court concluded that *res judicata* barred the claims alleged by Mr. Leal and Mr. Von Dohlen because their claims were "based on the same nucleus of operative facts" as the claims they asserted in *DeOtte* "and could have been brought in the first lawsuit."

ROA.432 (quoting *Houston Prof'l Towing Ass'n v. City of Houston*, 812 F.3d 443, 447 (5th Cir. 2016)).

The district court rejected on the merits Ms. Armstrong's claim that HRSA's role in supporting the development of guidelines for preventive services for women reflects an unconstitutional delegation of legislative power to the agency. ROA.445-447. The district court noted this Court's recent admonition that "[t]he Supreme Court 'has found only two delegations to be unconstitutional. Ever. And none in more than eighty years.'" ROA.447 (quoting *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 446 (5th Cir. 2020), *cert. denied*, __ S. Ct. __, 2021 WL 2302098 (June 7, 2021)). The district court explained that, under the controlling precedent of this Court and the Supreme Court, "delegations are constitutional so long as Congress 'lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform.'" ROA.446 (emphasis omitted) (quoting *Big Time Vapes*, 963 F.3d at 441 (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928))). The district court concluded that this standard was satisfied here. ROA.446-447.

SUMMARY OF ARGUMENT

This Court should affirm the dismissal of plaintiffs' claims against the federal defendants. As a threshold matter, the claims fail for lack of standing because the complaint did not allege facts showing that insurers would offer the plans that plaintiffs want if the challenged federal-law requirements were enjoined. On the contrary, the complaint admitted that Texas law independently prevents insurers from offering the plans that plaintiffs want. Furthermore, the complaint alleged no facts supporting its conclusory assertion that insurers would be willing to customize their plans to cover only the services that a particular enrollee is likely to need.

The claims of Mr. Leal and Mr. Von Dohlen are also barred by *res judicata* because their claims rest on the same injury as the claims that they previously asserted as part of a certified class and could have been asserted in that earlier lawsuit. For purposes of *res judicata*, it is irrelevant that "a different legal theory of recovery is advanced in the second suit." *Cemer v. Marathon Oil Co.*, 583 F.2d 830, 832 (6th Cir. 1978) (per curiam); *see also Restatement (Second) of Judgments* § 24 (Am. Law. Inst. 1982).

Moreover, even if it were properly before the Court, plaintiffs' nondelegation claim is foreclosed by controlling Supreme Court and Circuit precedent that plaintiffs' brief neglects to cite. "Delegations are constitutional so long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized [to exercise the authority] is directed to conform.'" *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (citation omitted), *cert. denied*, __ S. Ct. __, 2021 WL 2302098 (June 7, 2021)). Furthermore, "[t]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 475 (2001).

Here, Congress "constrict[ed]" HRSA's authority "to a narrow and defined category," *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009), by making "the key regulatory decisions itself," *Big Time Vapes*, 963 F.3d at 445. Congress itself determined that specified categories of preventive services should be covered without cost sharing requirements. 42 U.S.C. § 300gg-13(a). And Congress confined HRSA's role to supporting guidelines for a category of preventive services that is narrowly defined: "with respect to women," such "additional preventive

care and screenings" that are not otherwise encompassed by the current recommendations of the United States Preventive Services Task Force," *id*. § 300gg-13(a)(4). Accordingly, HRSA has since 2011 updated its women's preventive services guidelines to reflect new medical evidence and scientific developments relating to, for example, screening for cervical cancer, screening for gestational diabetes mellitus, and well-woman preventive visits, and has done so using a transparent methodology that relies on a rigorous evidence-review process under the auspices of an expert panel. *See infra* pp. 23-25. HRSA's role falls well within the range of delegations approved by the Supreme Court and this Court.

STANDARD OF REVIEW

This appeal presents questions of law that are subject to de novo review. *See Williams v. Parker*, 843 F.3d 617, 620 (5th Cir. 2016) (standing); *Davis v. Dallas Area Rapid Transit*, 383 F.3d 309, 313 (5th Cir. 2004) (*res judicata*); *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (nondelegation).

ARGUMENT

I. Plaintiffs' Claims Fail On Threshold Grounds

A. The complaint's allegations did not establish standing

Plaintiffs are not directly regulated by the provisions they challenge here. Instead, they claim to be indirectly injured by the actions of third parties (insurance companies), a theory that makes standing "substantially more difficult to establish." *California v. Texas*, 141 S. Ct. 2104, 2117 (2021) (quotation marks omitted).

Plaintiffs alleged that, "[w]ithout the federal Contraceptive Mandate, insurers will have the freedom to offer policies that exclude contraceptive coverage to the general public, just as they did before the Contraceptive Mandate." ROA.17, ¶ 34. However, that allegation was contradicted by other allegations in the complaint, which admitted that a Texas law that predated the federal requirement by a decade independently prevents insurers in Texas from selling plans without contraceptive coverage. ROA.15, ¶ 24 (citing Tex. Ins. Code § 1369.104(a)); ROA.10 (alleging that "Texas is … forcing private health insurers to cover contraception even when their customers do not need

it and do not want it").[3] Thus, the complaint failed to allege facts showing that plaintiffs' alleged injuries were caused by the federal requirement or would be redressed if that requirement were enjoined. *See*, *e.g.*, *White v. United States*, 601 F.3d 545, 552 (6th Cir. 2010) (holding that plaintiffs could not satisfy traceability or redressability elements of standing to challenge federal statute prohibiting activities associated with conduct that was "banned to a greater or lesser degree in all fifty states and the District of Columbia"); *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir. 1996) (concluding that any finding that challenged federal statute had a "significant impact" on plaintiffs' alleged injury "would be tantamount to sheer speculation" where state statute prohibited similar conduct).

Furthermore, the complaint also rested on implausible assumptions about the conduct of insurance companies. It assumed that insurers tailor their plans to cover only those health care services that a particular enrollee is likely to need. For example, the complaint alleged

[3] Mr. Leal has a separate action pending in state court that challenges the Texas insurance law, but that challenge has not been adjudicated. *See Leal v. Azar*, 489 F. Supp. 3d 593 (N.D. Tex. 2020) (remanding the state-law claim to state court), *appeal dismissed as moot*, No. 20-11083 (5th Cir. June 3, 2021).

that "[m]illions of Americans have no need for contraceptive coverage in their health insurance," including, for example, "unmarried men," "women who are past their childbearing years," "men who are married to women who are incapable of becoming pregnant," and "most members of the LGBTQ community." ROA.18, ¶ 35. The complaint assumed that, if there were no requirement to cover contraceptives, insurers would give such individuals "the option of acquiring less expensive health insurance that excludes contraceptive coverage." ROA.18, ¶ 35.

The complaint did not allege any facts to support that conclusory assertion, which rests on the "counterintuitive theory" that insurers would offer to sell discounted customized plans to individuals who are unlikely to use contraceptives. *California*, 141 S. Ct. at 2119. Insurance plans routinely cover services that a particular enrollee will not need: for example, women do not need coverage for prostate cancer screening; and adults without children do not need coverage for the childhood vaccinations listed by the Advisory Committee on Immunization Practices. Insurers would lose money if they tailored their plans to the medical needs of particular enrollees, and plaintiffs did not allege any

facts showing that insurers would be willing to sell them the customized plans they want. Thus, the complaint failed to allege facts demonstrating plaintiffs' standing.

B. *Res judicata* bars the claims of Mr. Leal and Mr. Von Dohlen

The claims of Mr. Leal and Mr. Von Dohlen are also precluded by the doctrine of *res judicata*, which "bars the litigation of claims that either have been litigated or should have been raised in an earlier suit." *Houston Prof'l Towing Ass'n v. City of Houston*, 812 F.3d 443, 447 (5th Cir. 2016) (quoting *Test Masters Educ. Servs., Inc. v. Singh,* 428 F.3d 559, 571 (5th Cir. 2005)). This doctrine "insures the finality of judgments and thereby conserves judicial resources and protects litigants from multiple lawsuits." *Procter & Gamble Co. v. Amway Corp.*, 376 F.3d 496, 499 (5th Cir. 2004) (quoting *United States v. Shanbaum*, 10 F.3d 305, 310 (5th Cir. 1994)). *Res judicata* applies where (1) the parties are identical or in privity; (2) the judgment in the prior action was rendered by a court of competent jurisdiction; (3) the prior action was concluded by a final judgment on the merits; and (4) the same claim or cause of action was involved in both actions. *Houston Prof'l Towing*, 812 F.3d at 447. A final judgment on appeal has

preclusive effect unless and until it is reversed. *Comer v. Murphy Oil USA, Inc.*, 718 F.3d 460, 467 (5th Cir. 2013).

Mr. Leal and Mr. Von Dohlen were class members in *DeOtte*, and they do not dispute that the first three elements described above are satisfied here. The only disputed issue is whether this suit and *DeOtte* involve the "same claim." In determining whether two suits involve the same claim, this Court employs the transactional test that the *Restatement (Second) of Judgments* adopted. *See Houston Prof'l Towing*, 812 F.3d at 447 & n.4. Under this test, "a prior judgment's preclusive effect extends to all rights of the plaintiff with respect to all or any part of the transaction, or series of connected transactions, out of which the original action arose," and the particular factual grouping that constitutes a "transaction" or "series of transactions" is determined "pragmatically." *Davis v. Dallas Area Rapid Transit*, 383 F.3d 309, 313 (5th Cir. 2004) (brackets and quotation marks omitted). This approach focuses on "whether the two actions are based on the same nucleus of operative facts." *Id.* (quotation marks omitted). "It is the 'nucleus of operative facts, rather than the type of relief requested, substantive

theories advanced, or types of rights asserted[,]' that defines the claim." *Houston Prof'l Towing*, 812 F.3d at 447.

The district court correctly held that the claims of Mr. Leal and Mr. Von Dohlen are barred by *res judicata* because their claims are "based on the same nucleus of operative facts" as those in *DeOtte* and "could have been brought in th[at] first lawsuit." ROA.432 (quoting *Houston Prof'l Towing*, 812 F.3d at 447). Plaintiffs asserted the same injury in both cases: the inability to purchase health insurance that excludes contraceptive coverage.

It is irrelevant that plaintiffs have in this action alleged new theories for invalidating the contraceptive-coverage requirement. Where, as here, "two successive suits seek recovery for the same injury, a judgment on the merits operates as a bar to the later suit, even though a different legal theory of recovery is advanced in the second suit." *Cemer v. Marathon Oil Co.*, 583 F.2d 830, 832 (6th Cir. 1978) (per curiam); *see also Restatement (Second) of Judgments* § 24 (*res judicata* "extinguish[es] a claim by the plaintiff against the defendant even though the plaintiff is prepared in the second action" to "present evidence or grounds or theories of the case not presented in the first

action" (quotation marks omitted)). A challenge to the constitutionality of a statute can and should be raised in the same action challenging regulations implementing the statute. It would undermine the pragmatic policy underlying *res judicata* to allow the sort of piecemeal challenges plaintiffs propose here. As the district court observed, "this sort of litigation is exactly what the traditional test for *res judicata* bars." ROA.435; *see also Chicot Cty. Drainage Dist. v. Baxter State Bank*, 308 U.S. 371, 375 (1940) (holding that *res judicata* barred litigant from raising constitutional challenge to statutory scheme governing conduct at issue where the prior litigation "proceeded to decree on the assumption by all parties and the court itself that the statute was valid").

Plaintiffs' reliance on *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), is misplaced. There, the statutory provisions that were the subject of two different suits established "different, independent requirements" and "serve[d] two different functions." *Id.* at 2308. By contrast, the contraceptive-coverage requirement that plaintiffs challenged here and in *DeOtte* was established pursuant to the statutory provision that plaintiffs sought to challenge here. As the

district court explained, the contraceptive-coverage requirement and the statute are thus "inextricably intertwined." ROA.434.

Nor did changed circumstances permit plaintiffs to renew the RFRA claim that was adjudicated in *DeOtte*. As the district court explained, the situation in *Hellerstedt*—where the Supreme Court concluded that an unsuccessful pre-enforcement facial challenge to a statute did not bar a later as-applied challenge based on new facts and circumstances, *see* 136 S. Ct. at 2306-07—"is nothing like this case." ROA.439. Mr. Leal and Mr. Von Dohlen, as class members in *DeOtte*, brought a successful as-applied claim under RFRA and received an injunction barring enforcement of the contraceptive-coverage requirement against them. They cannot relitigate their RFRA claim in this action. The district court correctly held that the claims of Mr. Leal and Mr. Von Dohlen are barred by *res judicata*.

II. Plaintiffs' Nondelegation Challenge Is Meritless

Even if the issue were properly before the Court, there is no merit to plaintiffs' contention that Congress impermissibly delegated legislative power to HRSA by giving the agency responsibility for supporting the development of guidelines for additional preventive

services for women that, by statute, insurance plans must cover without cost sharing.

A. The delegation to HRSA is narrower than delegations upheld by this Court and the Supreme Court

1. The delegation at issue here is narrower than delegations that have been upheld by this Court and the Supreme Court in cases that plaintiffs neglect to cite. *See* Pl. Br. 40-43. Just last year, this Court rejected a nondelegation challenge to a federal statute. In *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436 (5th Cir. 2020), this Court upheld the provision of the Family Smoking and Tobacco Control Act that made certain tobacco products (like cigarettes) subject to the Act's requirements and provided that the Act's requirements also would apply "to any other tobacco products that" the agency "by regulation deems to be subject to [the Act]." *Id*. at 438 (brackets in original) (footnote omitted) (quoting 21 U.S.C. § 387a(b)).

Rejecting that nondelegation challenge, this Court set out principles established by more than 80 years of Supreme Court precedent. This Court explained that "[d]elegations are constitutional so long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized [to exercise the authority] is

directed to conform.'" *Big Time Vapes*, 963 F.3d at 441 (citation omitted). "It is 'constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority.'" *Id.* (brackets in original) (quoting *American Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

This Court emphasized that "[t]hose standards ... are not demanding." *Big Time Vapes*, 963 F.3d at 442 (ellipsis in original) (quotation marks omitted). Even though Congress has delegated authority since "the beginning of the government," *id.* (quotation marks omitted), the Supreme Court "has found only two delegations to be unconstitutional," *id.* at 446. One "provided literally no guidance for the exercise of discretion," and the other "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (referring to *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)).

By contrast, in the more than 80 years since those decisions, the Supreme Court has consistently upheld "Congress' ability to delegate

power under broad standards," *Mistretta v. United States*, 488 U.S. 361, 373 (1989), and "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,'" *American Trucking*, 531 U.S. at 474-475 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). The Supreme Court has upheld statutes authorizing the Secretary of War to determine and recover "excessive profits" from military contractors, *Lichter v. United States*, 334 U.S. 742, 785-86 (1948) (quotation marks omitted); authorizing the Price Administrator to fix "fair and equitable" commodities prices, *Yakus v. United States*, 321 U.S. 414, 420 (1944) (quotation marks omitted)); authorizing the Federal Communications Commission to regulate broadcast licensing as "public interest, convenience, or necessity" requires, *National Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943) (quotation marks omitted); authorizing the Securities and Exchange Commission to ensure that a holding company's structure does not "unfairly or inequitably distribute voting power among security holders," *American Power & Light*, 329 U.S. at 104-05; directing the Sentencing Commission to promulgate then-binding Sentencing Guidelines for

federal crimes, *Mistretta*, 488 U.S. at 374-77; and directing the Environmental Protection Agency to set nationwide air-quality standards limiting pollution to the level required to "protect the public health," *American Trucking*, 531 U.S. at 472 (quotation marks omitted).

This Court has likewise "uniformly upheld Congress's delegations." *Big Time Vapes*, 963 F.3d at 442 n.17 (citing, as examples, *United States v. Jones*, 132 F.3d 232, 239-40 (5th Cir. 1998) (upholding delegation of authority to the Department of Justice to "define nonstatutory aggravating factors" to determine which offenders were "death-eligible" under the Federal Death Penalty Act); and *United States v. Mirza*, 454 F. App'x 249, 256 (5th Cir. 2011) (per curiam) (upholding International Emergency Economic Powers Act's delegation, which authorizes the President to declare a national emergency and limit certain types of economic activity related to that threat)).

2. The grant of authority to HRSA to support guidelines for women's preventive care and screenings that are subject to coverage without cost sharing falls well within the range of delegations approved by the Supreme Court and this Court and is consistent with established limits on Congress's power to delegate. "[T]he degree of agency

discretion that is acceptable varies according to the scope of the power congressionally conferred." *American Trucking*, 531 U.S. at 475. Here, Congress "constrict[ed]" HRSA's authority "to a narrow and defined category," *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009), "by making many of the key regulatory decisions itself," *Big Time Vapes*, 963 F.3d at 445. Congress made the "critical policy decision[]," *id*. at 443, that issuers offering group or individual health coverage provide coverage for preventive services without "cost sharing requirements," 42 U.S.C. § 300gg-13(a). And Congress confined HRSA's role to supporting guidelines for a narrow category of services—"with respect to women," such "additional preventive care and screenings" that are not otherwise encompassed by the current recommendations of the United States Preventive Services Task Force," *id*. § 300gg-13(a)(4).

Pursuant to that instruction, the HRSA guidelines for women's preventive services are developed through a transparent methodology by an expert panel.[4] Items are only eligible to be considered for inclusion in the guidelines if they "include conditions that affect a broad

[4] https://www.womenspreventivehealth.org/wp-content/uploads/WPSI-Methodology-1.pdf.

population of women; that are specific, more common, more serious, or differ in women; and for which prevention would have a large potential impact on women's health and well-being."[5] There is a rigorous evidence-review process for assessing such items.[6] Using that methodology, HRSA has since 2011 updated its women's preventive services guidelines to reflect new medical evidence and scientific developments relating to, among other items, breastfeeding services and supplies, screening for cervical cancer, screening for gestational diabetes mellitus, screening for interpersonal and domestic violence, well-woman preventive visits, and screening for diabetes mellitus after pregnancy.[7] This is a narrow and defined group of preventive services for women.

HRSA's authority to support guidelines for additional preventive care and screenings for women is more cabined than, for example, the authority to set "fair and equitable" commodities prices, *Yakus*, 321 U.S. at 420, or to regulate broadcast licensing as "public interest,

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[5] *Id.*

[6] *Id.*

[7] https://www.hrsa.gov/womens-guidelines-2016/index.html; https://www.hrsa.gov/womens-guidelines-2019.

convenience, or necessity" requires, *National Broad. Co.*, 319 U.S. at 225-26. "Congress painted much of the regulatory canvas," permissibly "leaving the finishing touches" to HRSA. *Big Time Vapes*, 963 F.3d at 446; *see also Gundy v. United States*, 139 S. Ct. 2116, 2136 (2019) (Gorsuch, J., dissenting) ("[A]s long as Congress makes the policy decisions when requiring private conduct, it may authorize another branch to 'fill up the details.'") (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 43 (1825)).

Plaintiffs make no serious effort to reconcile their position here with the delegations upheld by this Court and the Supreme Court. Moreover, plaintiffs incorrectly assert that, in assigning HRSA responsibility to support guidelines for additional preventive care and screenings for women that should be covered without cost sharing, the ACA "does not even require HRSA to make these decisions based on the 'public interest' or the 'public health.'" Pl. Br. 39. In defining the scope of delegated authority, a court looks at the text in context and in light of the statute's purpose. *Big Time Vapes*, 963 F.3d at 443 (citing *Gundy*, 139 S. Ct. at 2126 (plurality)). The ACA was designed to "expand health insurance coverage," *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S.

519, 567 (2012), and "broaden access to healthcare," *Morris v. California Physicians' Serv.*, 918 F.3d 1011, 1016 (9th Cir. 2019). The provision at issue here was intended to "enhance and improve women's health care," 155 Cong. Rec. S11987 (daily ed. Dec. 3, 2009) (statement of Sen. Mikulski), by filling gaps in the statute's other categories of preventive-care guidelines, *see, e.g.*, 155 Cong. Rec. S12271 (statement of Sen. Franken) (explaining that "several crucial women's health services are omitted" from the U.S. Preventive Services Task Force recommendations and that paragraph (4) "closes this gap"). And as the Supreme Court observed, a HRSA guideline would be arbitrary and capricious if the agency's explanation ran "counter to the evidence before [it]." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania,* 140 S. Ct. 2367, 2384 (2020) (brackets in original) (quotation marks omitted).

B. As in *Big Time Vapes*, plaintiffs' invitation to disregard controlling precedent must be declined

Rather than grapple with controlling precedent, plaintiffs invite this Court to ignore it. Plaintiffs note one commentator's statement that "nondelegation doctrine has had 'one good year' and more than 200 bad ones," Pl. Br. 42 n.29, and emphasize that "the justices have at least

some discomfort with the delegation of authority in section 300gg-13(a)(4)," Pl. Br. 40 (citing *Little Sisters*, 140 S. Ct. at 2380). But as this Court recognized in *Big Time Vapes*, a lower court is supposed to apply existing Supreme Court precedent, "'not ... read tea leaves to predict where it might end up.'" 963 F.3d at 447 (quoting *United States v. Mecham*, 950 F.3d 257, 265 (5th Cir. 2020)). Indeed, in *Big Time Vapes* itself, the plaintiffs filed a petition for a writ of certiorari urging the Supreme Court to review this Court's decision and revisit the nondelegation doctrine. *See* Petition for Writ of Certiorari at 39-39, *Big Time Vapes, Inc. v. FDA*, No. 20-850, 2020 WL 7714425 (U.S. Dec. 18, 2020). The Supreme Court denied that petition. *See* __ S. Ct. __, 2021 WL 2302098 (June 7, 2021).

Moreover, even if the Supreme Court were to revisit its existing nondelegation precedent, the Supreme Court could interpret the provision at issue here in a way that would avoid constitutional concerns even under a more demanding standard. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) ("When 'a serious doubt' is raised about the constitutionality of an act of Congress, 'it is a cardinal principle that this Court will first ascertain whether a construction of

the statute is fairly possible by which the question may be avoided.'") (quoting *Crowell v. Benson*, 285 U.S. 22, 62 (1932)). That available interpretation makes plaintiffs' invitation to ignore existing precedent all the more unwarranted.

In *Little Sisters*, the Supreme Court did not resolve any constitutional questions, noting that no party had "pressed a constitutional challenge to the breadth of the delegation." *Little Sisters*, 140 S. Ct. at 2382. If the Supreme Court were to consider such a constitutional challenge in the future, the Court could reinterpret the delegation to HRSA in a manner that would provide an even more robust "intelligible principle" than the statute already contains. For example, although *Little Sisters* suggested that HRSA's guidelines for women need not be "evidence-based," *id*. at 2380 (quotation marks omitted), that interpretation is not compelled by the statutory text. Congress specified that HRSA support guidelines for women's preventive care and screenings that are "not described in paragraph (1)" of § 300gg-13(a), and paragraph (1), in turn, refers to "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force."

The Supreme Court thus could interpret the cross-reference to paragraph (1) to require that HRSA's guidelines likewise be evidence-based and that they cover preventive care and screenings not otherwise encompassed in the "items or services that have in effect a rating of 'A' or 'B' in the" Task Force recommendations.

Indeed, the regulations that were issued shortly after the ACA's enactment specified that the HRSA women's preventive-services guidelines must be "evidence-informed." *See* 75 Fed. Reg. 41,726, 41,759 (July 10, 2010) (adding 45 C.F.R. § 147.130(a)(1)(iv) (requiring coverage without cost sharing for, "[w]ith respect to women," "*evidence-informed* preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration") (emphasis added); *id.* at 41,731 (stating that the ACA requires coverage without cost sharing for "*evidence-informed* preventive care and screening" for women as "provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force)") (emphasis added); *see also* 76 Fed. Reg. 46,621, 46,626 (Aug. 3, 2011) (amending 45 C.F.R. § 147.130(a)(iv) to allow for an exemption for religious employers but

retaining the requirement that the guidelines be "*informed by evidence*") (emphasis added).

Accordingly, the types of services included in the HRSA guidelines are evidence-based. *See, e.g.*, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 697 (2014) (noting that HRSA's 2011 guidelines were based on recommendations of the Institute of Medicine, now known as the National Academy of Medicine); *Women's Preventive Services Guidelines*, *supra* (explaining that HRSA awarded a five-year cooperative agreement to the American College of Obstetricians and Gynecologists, which convened an expert panel of national health professional organizations and consumer and patient advocates with expertise in women's health across the lifespan, to recommend updates to the HRSA-supported women's preventive services guidelines based on "advancements in science" and "scientifically rigorous review").

Thus, any alteration in existing nondelegation precedent could result in a reinterpretation of the statute, guided by principles of constitutional avoidance, under which plaintiffs' challenge to the delegation to HRSA would still fail.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 5,847 words, excluding the parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word.

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CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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