No. 24-475

In the Supreme Court of the United States

BRAIDWOOD MANAGEMENT, INC., ET AL., PETITIONERS

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE CROSS-RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether 42 U.S.C. 300gg-13(a) violates the nondelegation doctrine.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-48a in No. 24-316)[1] is reported at 104 F.4th 930. The memorandum opinions and orders of the district court (Pet. App. 49a-84a, 85a-136a) are reported at 666 F. Supp. 3d 613 and 627 F. Supp. 3d 624.

JURISDICTION

The judgment of the court of appeals was entered on June 21, 2024. The petition for a writ of certiorari in No. 24-316 was filed on September 19, 2024. The conditional cross-petition for a writ of certiorari in No. 24-475

[1] All references in this brief to the petition appendix are to the petition appendix in No. 24-316.

was filed on October 21, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

A. Legal Background

1. The Patient Protection and Affordable Care Act (ACA or Act), Pub. L. No. 111-148, 124 Stat. 119, seeks to ensure that all Americans have access to quality, affordable health insurance coverage. One of the Act's reforms requires health insurance issuers and group health plans to cover certain preventive services without imposing copayments, deductibles, or other cost-sharing charges. 42 U.S.C. 300gg-13. Preventive services include screenings and medications to avoid serious health conditions. Such "services can help people avoid acute illness, identify and treat chronic conditions, prevent cancer or lead to earlier detection, and improve health." Department of Health and Human Servs., *Issue Brief—Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act* at 1 (Jan. 11, 2022), https://perma.cc/BGV4-N8U2.

Congress did not enact a fixed list of covered preventive services, but rather provided for coverage of four categories of services based on the recommendations of three bodies of medical experts within the Department of Health and Human Services (HHS). Specifically, Congress provided for coverage of: (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 [Task Force]"; (2) "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices [ACIP] of the Centers for Disease Control and Prevention [CDC] with respect to the individual involved"; (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 [HRSA]"; and (4) "with respect to women, such additional preventive care and screenings not" already covered by the Task Force's recommendations, "as provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. 300gg-13(a)(1)-(4).

2. The Task Force, ACIP, and HRSA all predate the ACA and have longstanding responsibilities tied to recommending and promoting preventive services. All three entities are supervised and directed by the HHS Secretary. See 42 U.S.C. 202; Reorganization Plan No. 3 of 1966, 80 Stat. 1610.

a. *Task Force*: In 1984, the Public Health Service within HHS convened the first panel of the Task Force, composed of "nationally recognized non-Federal experts in prevention and evidence-based medicine." D. Ct. Doc. 65, at 70 (Jan. 28, 2022). Congress codified the Task Force's role in 1999 by authorizing the Director of the Agency for Healthcare Research and Quality, an agency within the Public Health Service, to "periodically convene" the Task Force. Healthcare Research and Quality Act of 1999, Pub. L. No. 106-129, sec. 2(a), § 915(a)(1), 113 Stat. 1659.

For four decades, the Task Force has "worked to fulfill its mission of improving the health of all Americans" by evaluating the evidence for various treatments and services to promote public health. D. Ct. Doc. 65, at 70. The Task Force "review[s] the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care

community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services." 42 U.S.C. 299b-4(a)(1). The Task Force's current recommendations give "A" or "B" ratings to more than 50 preventive services. U.S. Preventive Services Task Force, *A & B Recommendations*, https://perma.cc/FC9Y-Y3DN.[2] Among many other things, those services include screenings to detect lung, cervical, and colorectal cancer; screenings to detect diabetes; statin medications to reduce the risk of heart disease and strokes; medications to prevent HIV; physical therapy for older adults to prevent falls; and eye ointment for newborns to prevent blindness-causing infections. *Ibid.*

b. *ACIP*: In 1964, the Surgeon General appointed ACIP to advise him on the use of immunizations to control communicable diseases. See Jean Clare Smith et al., *History and Evolution of the Advisory Committee on Immunization Practices–United States, 1964-2014*, (*History and Evolution of ACIP*), 63 Morbidity and Mortality Weekly Rep. 955, 955 (2014), https://perma.cc/XN23-8MFY. Since 1972, ACIP has been appointed "for the purpose of advising" the HHS Secretary (and, by delegation, the CDC Director) "in connection with * * * [their] functions." 42 U.S.C. 217a(a); see D. Ct. Doc. 65, at 152. Specifically, federal law requires the Secretary, and, by delegation, the CDC Director, to "assist States and their political subdivisions in the prevention and suppression of communicable diseases." 42 U.S.C. 243(a). And it further requires the Secretary,

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[2] The Task Force issues "A" recommendations for services that have a high certainty of a substantial net benefit, and "B" recommendations for services that have at least a moderate certainty of a moderate net benefit. D. Ct. Doc. 65, at 117.

and, by delegation, the CDC Director, to "use, for the purpose of the purchase, delivery, and administration of pediatric vaccines," the "list established (and periodically reviewed and as appropriate revised) by [ACIP]." 42 U.S.C. 1396s(e). Accordingly, ACIP advises the CDC Director "regarding use of vaccines and related agents for effective control of vaccine-preventable diseases"; and, when adopted by the CDC Director, ACIP's recommendations "are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report." D. Ct. Doc. 65, at 152; see 45 C.F.R. 147.130(a)(1)(ii).

For decades, ACIP's recommendations have helped prevent the transmission of serious diseases. For instance, in the early and mid-1900s, "rubella epidemics occurred regularly in the United States every six to nine years." U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions* xix (1989). A 1964 epidemic "resulted in over 12 million rubella infections, with over 11,000 fetal losses and about 20,000 infants born with congenital rubella syndrome." *Ibid.* But since the rubella vaccine was introduced in 1969 and then recommended by ACIP, "incidence of rubella has decreased 99%." *Ibid.* ACIP's current recommended vaccines protect against influenza, shingles, measles, mumps, rubella, rotavirus, and COVID-19, among other diseases. D. Ct. Doc. 65, at 321.

c. *HRSA*: In 1973, the Acting Secretary of Health, Education, and Welfare established the Health Services Administration and the Health Resources Administration. See 38 Fed. Reg. 18,261, 18,261-18,262 (July 9, 1973). In 1982, those two entities were consolidated into HRSA, which was "designed to improve the health

services for all people of the United States and to develop health care and maintenance systems which are adequately financed, comprehensive, interrelated and responsive to the needs of individuals and families." 47 Fed. Reg. 38,409, 38,410 (Aug. 31, 1982).

Before the ACA was enacted, HRSA had issued "[c]omprehensive guidelines" concerning "Pediatric Preventive Health Care" and screenings for "Heritable Disorders in Newborns and Children." 75 Fed. Reg. 41,726, 41,740 (July 19, 2010); see American Academy of Pediatrics, *About Bright Futures* (Sept. 5, 2024), https://perma.cc/87Q4-QGWJ. Those guidelines recommended, among other things, screening newborns and children for proper vision, hearing, height, and weight, as well as for congenital heart defects, anemia, cystic fibrosis, and autism spectrum disorder. See 75 Fed. Reg. at 41,740-41,754.

In addition, since 2011, HRSA has established preventive-services guidelines for women. See HRSA, *Women's Preventive Services Guidelines* (Mar. 2024), https://perma.cc/35U4-LNVG. Currently, those guidelines recommend, among other things, screening for breast cancer, cervical cancer, and gestational diabetes, as well as ensuring access to breastfeeding supplies and services, contraception, and counseling for interpersonal and domestic violence. *Ibid.*

B. The Present Controversy

1. Cross-petitioners are four individuals and two small businesses that object to Congress's directive that health insurance issuers and group health plans generally must cover preventive services without cost sharing. Pet. App. 7a. Five of the six cross-petitioners "do not currently participate in the health care market." *Id.* at 62a; see D. Ct. Doc. 111-1, at ¶ 5 (Jan. 6, 2023); D. Ct.

Doc. 111-2, at ¶¶ 5-6 (Jan. 6, 2023); D. Ct. Doc. 111-3, at ¶ 5 (Jan. 6, 2023). Those cross-petitioners nonetheless object to the ACA's requirement that issuers and plans cover preexposure prophylaxis (PrEP) medications, which the Task Force has assigned an "A" rating based on their effectiveness at preventing HIV infection in certain at-risk individuals. See D. Ct. Doc. 14, at 8, 10-11 (July 20, 2020). Those cross-petitioners state that PrEP medications "encourage and facilitate homosexual behavior," which conflicts with their religious beliefs. *Id.* at 8.

Braidwood Management is the only cross-petitioner that currently participates in the health insurance market. Pet. App. 55a. Braidwood offers coverage to its approximately 70 employees through a self-insured plan. *Ibid.* Its owner "object[s] on religious grounds to providing coverage of" various preventive services recommended by the Task Force, ACIP, and HRSA, including "PrEP drugs, contraception, the HPV vaccine, and the screenings and behavior counseling for STDs and drug use." D. Ct. Doc. 46, at 72 (Nov. 15, 2021). Braidwood does not allege, however, that any of its employees have ever sought coverage for these items or services.

2. Cross-petitioners filed this suit in the United States District Court for the Northern District of Texas. As relevant here, cross-petitioners contend that the preventive-services coverage provision in 42 U.S.C. 300gg-13(a) violates the nondelegation doctrine. Pet. App. 122a. Cross-petitioners assert that the Task Force, ACIP, and HRSA "are all exercising decisionmaking authority with no 'intelligible principle' to guide them." *Ibid.* (citation omitted).

The district court granted summary judgment to the government on cross-petitioners' nondelegation claim. Pet. App. 122a-128a. The court determined that the claim failed under the Fifth Circuit's decision in *Big Time Vapes, Inc.* v. *FDA*, 963 F.3d 436 (2020), cert. denied, 141 S. Ct. 2746 (2021), which rejected "a nondelegation challenge to the Family Smoking and Tobacco Control Act." Pet. App. 124a. The court explained that the statute there "delegated to the [Commissioner] of the Food and Drug Administration the power to 'deem' which tobacco products should be subject to the Act's mandates." *Ibid.* (citing 21 U.S.C. 387a(b) (Supp. IV 2022)). And the court noted that the Fifth Circuit found that statute constitutional because "Congress had delineated (1) 'its general policy' in the statute, (2) the public agency that is to apply that policy, and (3) the boundaries of the delegated authority." *Ibid.* (citation omitted). The district court concluded that "[t]he same is true here," because "Congress has delineated its general policy with respect to the preventive-care [provision], the public agencies applying the preventive-care [provision], and the boundaries of the delegated authority." *Ibid.*

"First," the district court explained, "Congress has delineated a general policy to expand insurance coverage for various preventive services." Pet. App. 124a. The court reasoned that Section 300gg-13(a) "set[s] the baseline services that insurance policies must cover" by "incorporat[ing] the directives of existing agencies—[the Task Force], ACIP, and HRSA." *Ibid.* "Because the agencies preexisted the ACA," the court observed, "Congress had already outlined an express purpose for each agency." *Id.* at 124a-125a.

Second, the district court determined that "the statute's text, context, and relevant factual background indicate a general policy to expand preventive-services coverage for a variety of medical services." Pet. App. 126a. And the court noted that "Congress has clearly delineated the public agencies"—the Task Force, ACIP, and HRSA—"to apply that policy." *Ibid.*

Third, the district court determined that "Congress limited the authority it delegated." Pet. App. 126a. The court explained that Congress required the Task Force's recommended "'items or services' [to] be 'evidence based,'" *ibid.* (quoting 42 U.S.C. 300gg-13(a)(1)), and to be developed based on "the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services," *id.* at 127a (quoting 42 U.S.C. 299b-4(a)(1)). "Likewise," the court reasoned, "ACIP's authority is limited to 'immunizations.'" *Ibid.* (citation omitted). And the court emphasized that HRSA's recommended "preventive care and screenings" for "infants, children, and adolescents" "must be 'evidence-informed' and provided for in [HRSA's] 'comprehensive guidelines,'" *ibid.* (quoting 42 U.S.C. 300gg-13(a)(3)), and that HRSA's recommended "preventive care and screenings" for women must be "not covered by [Task Force recommendations]" and "must also be provided for in [HRSA's] 'comprehensive guidelines,'" *ibid.* (quoting 42 U.S.C. 300gg-13(a)(4)). The court thus concluded that "Congress has demarcated the boundaries of agency decisionmaking in the statute." *Ibid.*

The district court noted that cross-petitioners' "nondelegation argument relies almost entirely on the majority's reflections * * * in *Little Sisters of the Poor* [*Saints Peter & Paul Home* v. *Pennsylvania*, 591 U.S.

657 (2020)]," about Section 300gg-13(a)(4), Pet. App. 128a—which addresses only HRSA's preventive-services recommendations "with respect to women," 42 U.S.C. 300gg-13(a)(4). But the court emphasized that this Court in *Little Sisters* "did not address" whether that provision "violates the nondelegation doctrine." Pet. App. 124a.

3. The court of appeals affirmed in relevant part. See Pet. App. 10a n.23. The court concluded that cross-petitioners' nondelegation "argument is foreclosed by [its] decision in *Big Time Vapes*." *Ibid.*

DISCUSSION

Cross-petitioners renew their contention (Cross-Pet. 15-20) that Section 300gg-13(a) violates the nondelegation doctrine. The district court and court of appeals correctly rejected that contention because, under this Court's precedents, Section 300gg-13(a) supplies ample guidance to the Task Force, ACIP, and HRSA for the exercise of their respective but parallel judgments in identifying appropriate preventive services across their four fields of expertise. The cross-petition does not ask the Court to revisit its nondelegation precedents, and it contains hardly any argument as to why Sections 300gg-13(a)(1), (a)(2), and (a)(3) are unconstitutional. Instead, the cross-petition focuses (Cross-Pet. 16-18) almost exclusively on this Court's description of Section 300gg-13(a)(4) in *Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania*, 591 U.S. 657 (2020). But that description was part of a discussion that addressed only a statutory question not at issue here; the Court did not consider a "constitutional challenge to the breadth of the delegation involved." *Id.* at 679.

In addition to lacking merit, cross-petitioners' nondelegation argument does not warrant this Court's

review. Cross-petitioners acknowledge (Cross-Pet. 19) "[t]he absence of a circuit split," and the procedures at issue here have produced recommendations for preventive services that form an established part of the health insurance coverage without cost sharing for millions of Americans. The conditional cross-petition for a writ of certiorari should be denied.

1. Both lower courts correctly held that Section 300gg-13(a) does not violate the nondelegation doctrine.

a. Article I vests Congress with "[a]ll legislative Powers" granted by the Constitution. U.S. Const. Art. I, § 1. Congress may not delegate those legislative powers to the Executive Branch. See *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 529 (1935). But Congress may authorize executive agencies to exercise substantial "discretion" in implementing and enforcing the laws that Congress enacts. *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 406 (1928).

So long as a statute sets forth an "intelligible principle" to guide the executive agency's actions, it effects a lawful grant of discretion rather than an unlawful delegation of legislative power. *J.W. Hampton*, 276 U.S. at 409. A statute satisfies that requirement if it identifies "the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946). That test is "not demanding." *Gundy* v. *United States*, 588 U.S. 128, 146 (2019) (plurality opinion). "Only twice in this country's history" has the Court held that a statute crossed that line—"in each case because 'Congress had failed to articulate *any* policy or standard' to confine discretion." *Ibid.* (citation omitted).

By contrast, this Court has "over and over upheld even very broad delegations." *Gundy*, 588 U.S. at 146

(plurality opinion). The Court has held, for example, that Congress may empower agencies to regulate in the "public interest," *National Broad. Co.* v. *United States*, 319 U.S. 190, 225 (1943); to set "fair and equitable" prices, *Yakus* v. *United States*, 321 U.S. 414, 422 (1944); or to establish air-quality standards that are "requisite to protect the public health," *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 472 (2001).

b. The statute at issue here is fully consistent with this Court's nondelegation decisions and the established constitutional principles they have applied. As explained above, Section 300gg-13(a) requires group health plans and health insurance issuers to provide coverage without cost sharing for four categories of preventive services. See 42 U.S.C. 300gg-13(a)(1)-(4). Congress provided intelligible principles to guide the relevant entities' exercise of discretion in recommending preventive services within the categories for which they are responsible.

First, Section 300gg-13(a)(1) requires coverage for "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the" Task Force. 42 U.S.C. 300gg-13(a)(1). That provision thus incorporates both the Task Force's preventive-services recommendations and the process through which they are promulgated, which requires that recommendations be based on "the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services" and be "for the purpose" of serving "the health care community." 42 U.S.C. 299b-4(a)(1). The reference to "A" or "B" recommendations also reflects the Task Force's extant standards: The Task Force issues "A" recommendations for services that have a high certainty of a

substantial net benefit, and "B" recommendations for services that have at least a moderate certainty of a moderate net benefit. D. Ct. Doc. 65, at 117. And Section 300gg-13(a)(1) additionally confirms that the Task Force's recommendations must be "evidence-based." 42 U.S.C. 300gg-13(a)(1). Accordingly, Section 300gg-13(a)(1) "fits comfortably within the scope of discretion permitted by [the Court's] precedent." *Whitman*, 531 U.S. at 476.

Second, Section 300gg-13(a)(2) requires coverage for "immunizations that have in effect a recommendation from the [ACIP] of [CDC] with respect to the individual involved." 42 U.S.C. 300gg-13(a)(2). That provision similarly incorporates the immunization recommendation process used and updated over the course of decades to help control the spread of communicable diseases. See pp. 4-5, *supra*. The process includes analysis of disease surveillance and epidemiology. See *History and Evolution of ACIP* 955.

As explained above, ACIP has long advised the CDC Director in carrying out her statutory duty to "assist States and their political subdivisions in the prevention and suppression of communicable diseases." 42 U.S.C. 243(a). And it has long provided a "list" of "pediatric vaccines" used by the CDC Director "for the purpose of the purchase, delivery, and administration" of such vaccines. 42 U.S.C. 1396s(e). In undertaking those responsibilities, ACIP recommends "vaccines and related agents for effective control of vaccine-preventable diseases," which, upon adoption by the CDC Director, "are published as official CDC/HHS recommendations." D. Ct. Doc. 65, at 152; see 45 C.F.R. 147.130(a)(1)(ii). Thus, in Section 300gg-13(a)(2), Congress adopted that

well-established framework for guiding ACIP's development and review of its recommendations.

Third, Section 300gg-13(a)(3) requires coverage for "evidence-informed preventive care and screenings" for "infants, children, and adolescents" as "provided for in the comprehensive guidelines supported by" HRSA. 42 U.S.C. 300gg-13(a)(3). Like the two provisions just discussed, this provision incorporates HRSA's preexisting process for establishing preventive-care guidelines for infants, children, and adolescents. See p. 6, *supra*. Before the ACA's enactment, HRSA had used that process to issue "[c]omprehensive guidelines" concerning "Pediatric Preventive Health Care" and screenings for "Heritable Disorders in Newborns and Children." 75 Fed. Reg. at 41,740. In Section 300gg-13(a)(3), Congress thus made clear that HRSA should continue using its longstanding guidelines process and confirmed that HRSA's recommendations must be "evidence-informed." 42 U.S.C. 300gg-13(a)(3).

Fourth, Section 300gg-13(a)(4) requires coverage, "with respect to women," for "such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by" HRSA. 42 U.S.C. 300gg-13(a)(4). That provision defines the relevant categories of medical treatments (preventive care and screenings), identifies the distinct population for the particular treatments to be recommended (women), and refers to comprehensive guidelines for which HRSA had already developed a process to recommend preventive care and screening for infants, children, and adolescents. In addition, the provision indicates that HRSA's recommendations for preventive services for women should take the same basic form as those "described in paragraph (1)," 42 U.S.C.

300gg-13(a)(4)—that is, the general evidence-based recommendations of the Task Force. In accordance with Congress's instructions, HRSA's guidelines for women's preventive services are developed through a transparent methodology by an expert panel. See Women's Preventive Services Initiative, *Methodology* (Apr. 2023), https://perma.cc/KH3Y-YMYD. Those guidelines generally focus on "conditions that affect a broad population of women," "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." *Id.* at 4.

Under this Court's precedents, the foregoing provisions supply ample guidance to satisfy the nondelegation doctrine. For instance, if Congress had imposed coverage requirements for medical services that an executive agency deemed to be in the "public interest," then that statute would comport with the nondelegation doctrine. *National Broad.*, 319 U.S. at 225. Here, Congress spoke in more precise terms—by specifying the categories of medical services, identifying the relevant populations for treatment, and invoking preexisting agency decisionmaking bodies and processes. See *Synar* v. *United States*, 626 F. Supp. 1374, 1389 (D.D.C.) (per curiam) (Scalia, J., Johnson, D.J., and Gasch D.J.), aff'd on other grounds *sub nom.*, *Bowsher* v. *Synar*, 478 U.S. 714 (1986) (explaining that "reference to past administrative practice" may help "provide[] an adequate 'intelligible principle' to guide and confine administrative decisionmaking"). And Congress did so in the context of a provision with a clear "general policy" of ensuring coverage for appropriate preventive services that will in turn be covered without cost sharing under the ACA. *American Power & Light*, 329 U.S. at 105. Indeed,

particularly in an evolving area like public health and medicine, "Congress simply [could not] do its job absent an ability to delegate power under" directives like those in Section 300gg-13(a). *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989). Accordingly, the lower courts correctly held that Section 300gg-13(a) is consistent with the nondelegation doctrine.

c. Cross-petitioners hardly dispute (Cross-Pet. 15-18) that Sections 300gg-13(a)(1), (a)(2), and (a)(3) are constitutional. They briefly assert (Cross-Pet. 16) that "*nothing* in the text" of those provisions "purports to guide the discretion" of the relevant entities. But that assertion ignores the textual and contextual indicia showing that Congress sought to incorporate the preexisting, evidence-based recommendation processes that the Task Force, ACIP, and HRSA had long used before the ACA's enactment.

Cross-petitioners instead focus (Cross-Pet. 16-18) almost exclusively on Section 300gg-13(a)(4), which this Court discussed in *Little Sisters*. See 591 U.S. at 675-677. But as cross-petitioners acknowledge (Cross-Pet. 18), the discussion in *Little Sisters* addressed only whether Section 300gg-13(a)(4) authorizes HRSA to create "religious and moral exemptions" to "the preventive care standards" for women. 591 U.S. at 679. The Court expressly did not consider a "constitutional challenge to the breadth of the delegation" in Section 300gg-13(a)(4). *Ibid.*

2. The court of appeals' nondelegation holding does not otherwise warrant this Court's review. As cross-petitioners admit (Cross-Pet. 19), there is no circuit conflict over whether Section 300gg-13(a) violates the nondelegation doctrine. And cross-petitioners err in asserting (Cross-Pet. 20) that it is "unrealistic to expect a

circuit split to develop" on a nondelegation-doctrine issue because "so many lower-court judges regard" that doctrine as "dormant or defunct." In fact, the en banc Fifth Circuit recently found a statute constitutionally defective based in part on what it characterized as "Congress's sweeping delegation to" an agency, *Consumers' Research* v. *FCC*, 109 F.4th 743, 778 (2024), cert. granted, No. 24-354, 2024 WL 4864036, and No. 24-422, 2024 WL 4864037 (Nov. 22, 2024), and that decision conflicts with decisions from two other courts of appeals, see *Consumers' Research* v. *FCC*, 67 F.4th 773, 778, 787-795 (6th Cir. 2023), cert. denied, 144 S. Ct. 2628 (2024); *Consumers' Research* v. *FCC*, 88 F.4th 917, 921 (11th Cir. 2023), cert. denied, 144 S. Ct. 2629 (2024). The Court recently granted the government's petition for a writ of certiorari in the Fifth Circuit's *Consumers' Research* case, see *FCC* v. *Consumers' Research*, No. 24-354, 2024 WL 4864036 (Nov. 22, 2024), along with a related petition raising the same issues, see *Schools, Health & Libraries Broadband Coal.* v. *Consumers' Research*, No. 24-422, 2024 WL 4864-37 (Nov. 22, 2024). The Court thus will presumably address the nondelegation doctrine later this Term.

There is accordingly no reason to grant review of the cross-petition here. In *Consumers' Research*, the Fifth Circuit invalidated an agency's implementation of a federal statute, and "when a lower court has invalidated a federal statute," this Court's "usual" approach is to grant review. *Iancu* v. *Brunetti*, 588 U.S. 388, 392 (2019). Here, by contrast, the Fifth Circuit *upheld* Section 300gg-13(a) against a constitutional challenge under the nondelegation doctrine, finding cross-petitioners' nondelegation argument to be "foreclosed by [the] decision in *Big Time Vapes, Inc.* v. *FDA*, 963 F.3d 436 (5th

Cir. 2020)." Pet. App. 10a n.23. This Court denied certiorari in *Big Time Vapes, Inc.* v. *FDA*, 141 S. Ct. 2746 (2021), and the same course is warranted here.

CONCLUSION

The cross-petition for a writ of certiorari should be denied.

Respectfully submitted.

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