

Nos. 19-840 & 19-1019

IN THE
Supreme Court of the United States

CALIFORNIA, ET AL.,

Petitioners,

v.

TEXAS, ET AL.,

Respondents.

TEXAS, ET AL.,

Petitioners,

v.

CALIFORNIA, ET AL.,

Respondents.

**On Writs of Certiorari to the United States
Court of Appeals for the Fifth Circuit**

**BRIEF OF PATIENT-CENTERED OUTCOMES
RESEARCH INSTITUTE AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONERS**

MARY C. HENNESSEY
PATIENT-CENTERED
OUTCOMES RESEARCH
INSTITUTE
1828 L Street, N.W.
Suite 900
Washington, D.C. 20036
(202) 827-7700

VIRGINIA A. SEITZ*
PETER D. KEISLER
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
vseitz@sidley.com

Counsel for Amicus Curiae

May 13, 2020

* Counsel of Record

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF <i>AMICIUS CURIAE</i>	1
BACKGROUND	4
SUMMARY OF ARGUMENT	13
ARGUMENT	16
I. THE PROVISIONS OF THE ACA AUTHORIZING PCORI ARE SEVERABLE FROM ANY UNCONSTITUTIONAL PROVISIONS OF THE ACT	17
A. Under This Court’s Established Approach, Congress’s Intent That PCORI Continue To Operate Is Clear.....	17
B. None Of The General Or Specific Concerns About ACA Severability Applies To The ACA Provisions Authorizing PCORI.....	20
CONCLUSION	23

TABLE OF AUTHORITIES

CASES	Page
<i>Alaska Airlines, Inc. v. Brock</i> , 480 U.S. 678 (1987).....	2, 3, 13, 17
<i>Ayotte v. Planned Parenthood of N. New Eng.</i> , 546 U.S. 320 (2006)	14, 17, 20
<i>Exec. Benefits Ins. Agency v. Arkison</i> , 134 S. Ct. 2165 (2014)	17
<i>Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.</i> , 561 U.S. 477 (2010)	14, 15, 19
<i>INS v. Chadha</i> , 462 U.S. 919 (1983)	19
<i>Legal Servs. Corp. v. Velazquez</i> , 531 U.S. 533 (1991).....	19
<i>Murphy v. NCAA</i> , 138 S. Ct. 1461 (2018).....	3, 20, 22
<i>Nat'l Fed'n of Indep. Bus. v. Sebelius</i> , 567 U.S. 519 (2012).....	1, 10
<i>Regan v. Time, Inc.</i> , 468 U.S. 641 (1984).....	13, 17, 20
STATUTES	
26 U.S.C. § 5000A(a)	1
Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, 133 Stat. 2534 (2019).....	2, 12, 13
Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, 131 Stat. 2054	10
Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).....	<i>passim</i>
American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.....	7
Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066	5

TABLE OF AUTHORITIES—continued
LEGISLATIVE MATERIALS Page

PATIENT Act, H.R. 3439, 116th Cong. (2019).....	11
Patient-Centered Outcomes Research Extension Act of 2019, H.R. 3030, 116th Cong. (2019).....	11
Community Health Investment, Modernization, and Excellence Act of 2019, H.R. 2328, 116th Cong. (as amended July 11, 2019)	11
Patient-Centered Outcomes Research Institute Reauthorization Act, S. 2897, 116th Cong. (2019).....	12
Comparative Effectiveness Research Act of 2009, H.R. 2502, 111th Cong. (2009).....	7
Comparative Effectiveness Research Act of 2008, S. 3408, 110th Cong. (2008).....	7
H.R. Rep. No. 109-687 (2006)	5
Cong. Budget Office, Pub. No. 2975, <i>Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role</i> (Dec. 2007)	6
155 Cong. Rec. S6371 (daily ed. June 9, 2009)	7

SCHOLARLY AUTHORITIES

Michael A. Fisher & Steven M. Asch, <i>The Future of the Patient-Centered Outcomes Research Institute (PCORI)</i> , 34 J. Gen. Internal Med. 2291 (2019)	8, 9
Gail R. Wilensky, <i>Developing a Center for Comparative Effectiveness Information</i> , 25 Health Aff. W572 (2006)	4

TABLE OF AUTHORITIES—continued	
OTHER AUTHORITIES	Page
Inst. of Med., Nat'l Acad. of Scis., <i>Knowing What Works in Health Care: A Roadmap for the Nation</i> (Jan. 2008).....	6
Medicare Payment Advisory Comm'n, <i>Report to the Congress: Promoting Greater Efficiency in Medicare</i> (June 2007)	5, 6

INTEREST OF *AMICUS CURIAE*¹

Amicus curiae is the Patient-Centered Outcomes Research Institute (“PCORI”), a Washington, D.C. not-for-profit corporation whose purpose is increasing the credible, empirically-based information available to patients and their physicians so that they can make informed and effective treatment decisions.² Congress initially authorized PCORI in 2010 in section 6301 of the Patient Protection and Affordable Care Act (“ACA”).³ This brief addresses only the question whether the ACA’s individual mandate,⁴ if unconstitutional, is severable from other provisions of the ACA, specifically the provisions of the ACA authorizing PCORI.

For two reasons, PCORI files this *amicus* brief, even though the parties will address the general

¹ Pursuant to Supreme Court Rule 37, *amicus curiae* states that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amicus curiae* and its counsel made any monetary contribution toward the preparation and submission of this brief. All parties consented to the filing of this brief.

² PCORI’s stakeholders are broad and include not only patients and physicians, but also clinicians, community members, hospitals and health systems, payers, health-care purchasers, industry, policy makers, training institutions, and researchers. For purposes of this brief, PCORI stakeholders will be referred to as “patients and their physicians.”

³ See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, sec. 6301(a), § 1181(b), 124 Stat. 119, 728 (2010) [hereinafter ACA].

⁴ PCORI uses the term “individual mandate” to describe section 5000A(a) of the ACA, 26 U.S.C. § 5000A(a), because this Court uses that term. See, e.g., *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012).

severability issues presented: First, as the Court of Appeals for the Fifth Circuit highlighted, the ACA “spans over 900 pages of legislative text and is divided into ten titles.” Pet. App. 57a. PCORI seeks to ensure that its unique, deep, and strong case for severability based on specific Congressional actions ensuring its continued existence and funding is not overlooked in a case focused on other provisions of the ACA. Second, PCORI’s particular circumstances—and Congress’s actions with respect to PCORI’s operations and funding—illustrate the importance of a granular analysis of severability that focuses on Congress’s intent and actions with respect to *individual* provisions of omnibus legislation. See *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987) (courts have a “duty” to “maintain the act in so far as it is valid” if it “contains unobjectionable provisions separable from those found to be unconstitutional”).

Amicus respectfully submits that the chronology of Congress’s actions with respect to PCORI—including Congress’s independent reauthorization of PCORI in 2019 *after* setting the ACA’s shared-responsibility payment at zero in 2017 and *after* the District Court in this case invalidated the individual mandate and the remainder of the ACA—conclusively demonstrates that the provisions of the ACA authorizing PCORI are severable if this Court decides that the individual mandate is no longer constitutional. PCORI’s original funding provisions were subject to a sunset provision; but in December 2019, Congress expressly reauthorized PCORI’s funding and amended its governing statute as part of the omnibus appropriations bill for 2020. See Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 104, 133 Stat. 2534, 3097-3100 (2019) [hereinafter 2020 Appropriations Act] (“Extension of Appropriations to the Patient-Centered

Outcomes Research Trust Fund; Extension of Certain Health Insurance Fees”). Thus, there can be no doubt that Congress would have “enacted [the ACA sections authorizing PCORI] independently of [the invalid portion],” if any, of the ACA, *Alaska Airlines*, 480 U.S. at 684, and that the ACA provisions authorizing PCORI “remain[] ‘fully operative’ without the invalid provisions” of the ACA, if any. *Murphy v. NCAA*, 138 S. Ct. 1461, 1482 (2018) (quoting *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 509 (2010)).

In addition, *amicus*’s analysis of the ACA provisions authorizing PCORI demonstrates by example that the ACA may not be deemed inseverable in its entirety under this Court’s established precedent: If the individual mandate falls, at the very least, an individualized severability inquiry examining provisions of the ACA unrelated to the individual mandate will be required.

Finally, PCORI’s compelling—indeed, existential—interest in the severability issue that this Court may address is evident. However, PCORI is also fulfilling a national priority in the health-care sector. After hearing from numerous stakeholders, Congress determined that there was a national need for an independent institution to set the agenda for the conduct of comparative clinical effectiveness research, also known as CER. Both the health-care sector and Congress recognized that traditional research generally had inadequately addressed the questions patients and their physicians face about what care works best in the particular circumstances they confront. Congress authorized PCORI to determine priorities for CER and fund research that compares which care works best for whom and under what circumstances, while engaging patients, physicians,

and other stakeholders throughout the process to ensure that the studies produce useful information. See ACA sec. 6301(a), § 1181(c) (codified at 42 U.S.C. § 1320e(c)). Congress's recent reauthorization of PCORI's funding and amendments to its governing statute affirms the importance and effectiveness of PCORI's work. The significance of that work in improving health-care decisions will not change based on the fate of the individual mandate and related provisions. Failure to sever the ACA provisions authorizing PCORI would contradict Congress's clear intent and halt PCORI's critical efforts.

BACKGROUND

The chronology of Congressional actions with respect to PCORI demonstrates that the ACA provisions authorizing PCORI are severable from any unconstitutional provision of the ACA.

Origins of PCORI. As the number of new health-care technologies and treatments increased significantly in the 2000s, momentum grew within the health-care sector for a research center that would “provide an independent assessment of the comparative effectiveness of alternative therapies and procedures for use by various payers and ... supporting information so that both patients and providers c[ould] improve their decision making.” Gail R. Wilensky, *Developing a Center for Comparative Effectiveness Information*, 25 Health Aff. W572, W577 (2006).

Congress likewise recognized the need for increased federal investment in and coordination of comparative clinical effectiveness research to answer the most pressing treatment questions of patients and their physicians at the point of care. This recognition predated by several years the enactment of the ACA. Before Congress authorized PCORI, it funded

comparative clinical effectiveness research through multiple government agencies (including the Veterans Health Administration (“VHA”), and the National Institutes of Health (“NIH”) and the Agency for Healthcare Research and Quality (“AHRQ”), both within the Department of Health and Human Services (“HHS”). In 2003, for example, Congress enacted the Medicare Modernization Act (“MMA”). Section 1013 of that Act increased the funding for AHRQ by \$50 million for “systematic reviews of existing evidence” on the comparative clinical effectiveness of drugs and “other treatments.” Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1013, 117 Stat. 2066, 2438 (codified at 42 U.S.C. § 299b-7); H.R. Rep. No. 109-687, at 25 (2006).

However, in the early 2000s, there was no federal coordination of CER, no consistent definition of CER or measurement of its outcomes, and no meaningful involvement of patients or their physicians in determining what CER was most urgently required.

As time passed, several key Congressional advisory bodies, think tanks, and thought leaders published notable reports and articles promoting the creation of a distinct entity capable of funding and directing comparative effectiveness research. Illustrative of such reports was a 2007 Report of the Medicare Payment Advisory Commission (“MedPAC”) that asserted “not enough credible, empirically based information [is available] for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions.” Medicare Payment Advisory Comm’n, *Report to the Congress: Promoting Greater Efficiency in Medicare* 29 (June 2007). MedPAC argued that such information is a public good, under-

produced by the private sector, and therefore that the federal government had to play a leading role in the production of unbiased information and make it publicly available. *Id.* at 30-32. MedPAC recommended that Congress create an independent entity to disseminate credible CER about health-care services, funded through an all-payer approach. *Id.*

Likewise, in December 2007, at the request of the Senate Budget and Finance Committees, the Congressional Budget Office (“CBO”) published a report entitled *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role*.⁵ That report “examine[d] options for expanding federal support for research on comparative effectiveness.” *Id.* at Preface. In January 2008, the Institute of Medicine of the National Academy of Sciences, published *Knowing What Works in Health Care: A Roadmap for the Nation*.⁶ Both reports outlined the CER issue and potential approaches that closely resembled the MedPAC Report’s recommendations. See, e.g., *id.* at 12 (recommending a single national clinical effectiveness assessment program that is “stable over the long term; [whose] output is judged as objective, credible, and without conflict of interest or bias; and [whose] operations are independent of external political pressures”).

From these reports and a related health-care-sector focus on the need for CER emerged legislative proposals for the entity that would become PCORI. In

⁵ Cong. Budget Office, Pub. No. 2975, *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role* (Dec. 2007).

⁶ Inst. of Med., Nat’l Acad. of Scis., *Knowing What Works in Health Care: A Roadmap for the Nation* (Jan. 2008).

2008, then-Finance Committee Chairman Max Baucus and then-Budget Committee Chairman Kent Conrad introduced the Patient-Centered Outcomes Research Act. See Comparative Effectiveness Research Act of 2008, S. 3408, 110th Cong. (2008). The Chairmen worked extensively with a wide group of stakeholders, as well as the Congressional Research Service, MedPAC, the CBO, and the Government Accountability Office, to develop legislation and solicit feedback. A companion bill was introduced in the House. See Comparative Effectiveness Research Act of 2009, H.R. 2502, 111th Cong. (2009).

Neither of these bills was enacted, but, in 2009, Congress passed the American Recovery and Reinvestment Act of 2009 (“ARRA”) and made an initial federal investment in CER and in federal coordination of CER. ARRA funded coordinated efforts across the Department of Health and Human Services. Pub. L. No. 111-5, § 804, 123 Stat. 115, 187-88 (codified at 42 U.S.C. § 299b-8). Specifically, it divided funding among NIH, AHRQ, and the HHS Office of the Secretary, among others; established a federal coordinating council on CER; and required the National Academy of Sciences’ Institute of Medicine to provide input into the top CER funding priorities. *Id.* See also 155 Cong. Rec. S6371-80 (daily ed. June 9, 2009) (outlining reasons and stakeholder support for establishment of a CER center).

Thus, when Congress began the development of the ACA, it had already focused on the need for an increased federal role in both coordinating and funding CER. Its authorization of PCORI thus built on those prior enactments and appropriations and was the culmination of a lengthy dialogue among Congress, other government agencies and stakeholders in the health-care sector, about the neglect of, and need for,

national priorities for and investment in CER, and about the need for coordination of CER efforts.

ACA Authorization and Funding of PCORI. Congress authorized PCORI in 2010 as part of Title VI of the ACA, which is entitled “Transparency and Program Integrity.” Subtitle D is called “Patient-Centered Outcomes Research” and it sets forth PCORI’s purpose, structure, priorities and funding. As described above, all parties recognized that health-care research had not adequately addressed the relative clinical effectiveness of various treatments. Yet, that is the vital question that patients and their physicians face daily when deciding what treatment course to follow. Congress authorized PCORI to coordinate and determine the priorities for such research and to fund research that compares which care works best for whom and under what circumstances.⁷ PCORI also invests in defining and discovering the best methods of comparative-effectiveness and patient-centered outcomes research. Examples of “[r]ecently published findings include interventions to reduce harmful medical errors in the hospital, to improve pain management and address opioid overprescribing, and improve emergency care for patients with chest pain.” Michael A. Fisher &

⁷ Congress articulated PCORI’s purpose: “to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in [the law].” ACA sec. 6301(a), § 1181(c) (codified at 42 U.S.C. § 1320e(c)).

Steven M. Asch, *The Future of the Patient-Centered Outcomes Research Institute (PCORI)*, 34 J. Gen. Internal Med. 2291, 2291-92 (2019) (footnotes omitted).

PCORI differs from other research funders in important ways that are central to its mission. First, although its Board of Governors is appointed by the Comptroller General who leads the Government Accountability Office, ACA sec. 6301(1), § 1181(f)(1)(C) (codified at 42 U.S.C. § 1320e(f)(1)(C)), PCORI is not part of the federal government, unlike NIH. Nor is it a federal contractor or federal grantee. It is an independent institution. Second, PCORI's important role in coordinating national CER efforts is reflected in Congress's determination of its governance structure: PCORI's Board of Governors includes both the Director of NIH and the Director of AHRQ, as well as representatives of multiple categories of stakeholders in the health-care sector, including at least one member representing a Federal health program or agency. See *id.* § 1181(f)(1)(A)-(B) (codified at 42 U.S.C. § 1320e(f)(1)(A)-(B)). Third, PCORI incorporates patients, physicians, and other stakeholders in the research process at all stages. PCORI has been a "pioneer in increasing the role of patients in research" and in "develop[ing] the best methods for doing so." Fisher & Asch, *supra*, at 2291-92.

PCORI is funded solely through the Patient-Centered Outcomes Research Trust Fund ("PCOR Trust Fund"). The Trust Fund originally received funds from a fee assessed on specified health insurance policies and self-insured health plans ("the PCOR fee"), statutory appropriations, and transfers from the Medicare trust funds. See ACA sec. 6301(e), § 9511(a) & (b) (codified at 26 U.S.C. § 9511(a) & (b)).

The ACA expressly states: “No amounts shall be available for expenditure from [the PCOR Trust Fund] after September 30, 2019, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.” ACA sec. 6301(e), § 9511(f) (codified at 26 U.S.C. § 9511(f)). Under this sunset provision, absent Congressional action, PCORI’s ability to commit to additional research contracts with new funding would have ended in 2019, and PCORI would have ceased to function once its then-on-going research contracts concluded.

Origins of This Litigation. This Court upheld the constitutionality of ACA’s individual mandate and the shared-responsibility payment as a valid exercise of Congress’s taxing power in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012). In December 2017, Congress enacted the Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, tit. I, 131 Stat. 2054 (“TCJA”). In that Act, Congress reduced the amount of the shared-responsibility payment to zero. TCJA § 11081, 131 Stat. at 2092. Following passage of the TCJA, Texas, seventeen other states, and two individuals brought suit challenging the constitutionality of the individual mandate and the enforceability of the ACA. On December 14, 2018, the District Court agreed with Texas; it held that the individual mandate was unconstitutional and that the ACA was entirely inseverable, invalidating the Act in its entirety. Pet. App. 231a. That order was stayed. *Id.* at 162a.

On December 18, 2019, the Court of Appeals for the Fifth Circuit affirmed the District Court’s decision that the ACA had become unconstitutional, but remanded the District Court’s determination that the unconstitutional provisions could not be severed from any other provisions of the ACA. Pet. App. 39a, 52a. It ordered the District Court to conduct a granular

severability analysis. *Id.* at 59a, 68a-69a. As described below, two days later—*i.e.*, years after Congress amended the ACA to make the shared-responsibility payment zero and the District Court found the ACA unconstitutional as a result—Congress enacted legislation that reauthorized PCORI's funding and amended its governing provisions.

Congressional Actions Leading to PCORI's Reauthorization. As stated, under the ACA's sunset provision, PCORI funding would have been effectively terminated in 2019 had Congress not decided to reauthorize it. The PCORI reauthorization effort was the product of a bipartisan effort in both the House of Representatives and the Senate.

In May 2019, in the House, Representatives Diana DeGette (D-CO-1) and Don Beyer (D-VA-8) introduced the first bill to reauthorize PCORI, the Patient-Centered Outcomes Research Extension Act of 2019, H.R. 3030, which provided for a ten-year reauthorization of PCORI. See H.R. 3030, 116th Cong. (2019). In late June, the House Ways and Means Committee took up another PCORI reauthorization bill and passed it out of Committee with bipartisan support from Committee Democrats and Representative Tom Reed (R-NY-23). This bill, the PATIENT Act, H.R. 3439, provided for a seven-year reauthorization and proposed three new research priorities for PCORI: substance abuse (including opioid use disorder), mental health, and maternal morbidity and mortality. See H.R. 3439, 116th Cong. (2019).

Shortly thereafter, in early July 2019, the Energy and Commerce Committee's Subcommittee on Health held a mark-up of legislation that included a three-year reauthorization of PCORI. See Community Health Investment, Modernization, and Excellence Act of 2019, H.R. 2328, 116th Cong. (as amended July

11, 2019). One week later, the Full Energy and Commerce Committee held its own markup and passed the Subcommittee's legislation by unanimous voice vote. Thus, by mid-summer 2019, two PCORI reauthorization bills had passed out of House Committees.

As the summer advanced and numerous Congressional questions about the budget remained unresolved, it became clear that a larger Congressional deal on the budget, including PCORI reauthorization, was unlikely to occur before the PCOR Trust Fund's September 30, 2019 sunset date. Congress passed a stopgap spending measure in late September 2019 that included funding for a number of programs through November 21, 2019, and extended the PCOR Trust Fund.

In November 2019, a bipartisan group of four Senators formally introduced reauthorization legislation, S. 2897, the Patient-Centered Outcomes Research Institute Reauthorization Act. See S. 2897, 116th Cong. (2019). That same week, Congress passed another short-term funding measure through December 20, 2019, and again extended the life of the PCOR Trust Fund.

After intense negotiations in mid-December 2019, Congress reached agreement on bills funding the federal government.

Congress Reauthorizes PCORI and Amends Its Governing Statute. On December 20, 2019, Congress reauthorized PCORI's funding and amended its governing statute as part of the bipartisan omnibus federal budget law for 2020. See 2020 Appropriations Act § 104. This reauthorization provided PCORI with funding for ten additional years (2020-2029), *id.* § 104(a)-(c), and revised the authorizing law in certain

respects, addressing PCORI’s research priorities, the composition of PCORI’s Board, and the content of the required Comptroller General report to Congress about PCORI’s activities. See, *e.g.*, *id.* § 104(d) (adding to national priorities “research with respect to intellectual and developmental disabilities and maternal mortality”); *id.* § 104(e) (requiring PCORI’s funded research to “be designed, as appropriate, to take into account and capture ... the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively”); *id.* § 104(f) (altering Board composition); *id.* § 104(h) (adding component to required Comptroller General Report).

In sum, Congress independently reauthorized PCORI and amended its governing statute in 2019 as part of its overall 2020 budget agreement legislation. It did so *after* the 2017 legislation setting the shared-responsibility payment at zero and, indeed, *after* the District Court had found the individual mandate and related provisions unconstitutional and declined to sever them from the rest of the ACA. In this context, Congress’s intent—that PCORI should continue—is clear.

SUMMARY OF ARGUMENT

If this Court reaches the question of severability, it should find that the provisions of the ACA authorizing PCORI can be severed from any unconstitutional provisions of the Act.

Because courts “should refrain from invalidating more of [a] statute than is necessary,” *Alaska Airlines*, 480 U.S. at 684, this Court has established a longstanding “presumption ... in favor of severability,” *Regan v. Time, Inc.*, 468 U.S. 641, 653 (1984) (plurality

opinion). Severability turns on “legislative intent.” *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 330 (2006). And, this Court decides whether Congress intended some portions of a statute to survive when other portions are unconstitutional with a two-part test: First, the Court asks whether the surviving provisions remain “fully operative as a law.” *Free Enter. Fund*, 561 U.S. at 509. Second, the Court assures itself that it is not “evident” from the statutory text and context that Congress would have preferred no statute at all to the continuing operation of the severed provision. *Id.*

Asking these questions about the ACA provisions authorizing PCORI yields clear and easy answers. If the individual mandate and all related provisions of the ACA were invalidated, the provisions authorizing PCORI would remain “fully operative” as law. These provisions authorize PCORI, establish its governance structure, provide for its funding, and ensure its oversight by the government. They are entirely unrelated to any other provisions of the ACA; they operate independently. Indeed, they include a sunset provision that required Congress to reauthorize PCORI after ten years, and Congress did so in 2019 in the omnibus budget law for 2020, in provisions wholly independent of any provision of the ACA.

Likewise, nothing in the text or context of the provisions authorizing PCORI even hints at any Congressional intent that PCORI’s existence was somehow conditioned on any other provisions of the ACA. In, fact, the relevant textual and contextual evidence make it “evident” that Congress wanted PCORI to continue operating whatever developed with respect to the individual mandate and associated provisions. Specifically, Congress reauthorized PCORI in 2019, while providing it with funding for another

decade of work and amending its governance structure and mission. Moreover, Congress did so only *after* it amended the ACA in 2017 to set the shared-responsibility payment at zero and *after* the District Court held the individual mandate and the rest of the ACA unconstitutional. This 2019 reauthorization of PCORI is thus the clearest possible evidence that Congress intended PCORI to continue to operate. At a minimum, “nothing in the statute’s text or historical context makes it ‘evident’” that, without the individual mandate, Congress would have preferred no PCORI at all. *Free Enter. Fund*, 561 U.S. at 509.

In sum, allowing PCORI to continue fulfilling its important mission faithfully reflects Congress’s intent with respect to PCORI and serves the important judicial goal of preserving Congress’s duly enacted statute to the extent possible.

Both the District Court and plaintiffs below asserted that the ACA is entirely inseverable, but PCORI’s example illustrates that these arguments are overbroad and incorrect.

The District Court thought that there was too much “legislative guesswork” involved in assessing which miscellaneous provisions of the ACA Congress would have enacted absent the individual mandate. Pet. App. 224a. But no “guesswork” is now required with respect to PCORI: Congress reauthorized PCORI in 2019 as part of the bipartisan budget legislation for 2020, after its 2017 amendments to the ACA and wholly apart from the ACA’s provisions.

Texas and other state plaintiffs characterized the ACA provisions unrelated to the individual mandate and shared-responsibility provisions as “mere adjuncts’ of the more important provisions” that “would not have been independently enacted.” Pet.

App. 63a (citing State Plaintiffs' Br. at 50). But the circumstances of Congress's pre-ACA appropriations for comparative clinical effectiveness research and its subsequent authorization and reauthorization of PCORI (*supra* at 12-13) convincingly demonstrate that Congress separately chose to enact the provisions that resulted in PCORI's existence, structure, funding and continuation. PCORI's work is not an "adjunct" to any other ACA provision, and Congress so signified by reauthorizing it in 2019.

PCORI's situation thus shows that in this case, the courts must conduct "a careful, granular approach to carrying out the inherently difficult task of severability analysis." Pet. App. 59a. Indeed, PCORI's situation illustrates the perils of the broad-brush approach to severability taken by the District Court, and the ways in which that approach risks producing outcomes that would be directly contrary to Congress's intent and its bipartisan policy objectives.

ARGUMENT

If this Court holds that the individual and state plaintiffs in this case have established Article III standing to challenge the individual mandate and that reducing the shared-responsibility payment to zero renders the individual mandate unconstitutional, it will confront the question whether that provision is severable from all or some of the rest of the ACA. PCORI demonstrates below that under this Court's established precedent, the ACA provisions authorizing PCORI should be severed from any unconstitutional provisions of the ACA, and that Congress has clearly

indicated that PCORI should be allowed to continue its important work.⁸

I. THE PROVISIONS OF THE ACA AUTHORIZING PCORI ARE SEVERABLE FROM ANY UNCONSTITUTIONAL PROVISIONS OF THE ACT.

A. Under This Court’s Established Approach, Congress’s Intent That PCORI Continue To Operate Is Clear.

This Court has long mandated a “presumption ... in favor of severability.” *Regan*, 468 U.S. at 653 (plurality opinion). The presumption arose from the view that courts “should refrain from invalidating more of the statute than is necessary.” *Alaska Airlines*, 480 U.S. at 684.

The “touchstone” of any inquiry into severability “is legislative intent.” *Ayotte*, 546 U.S. at 330; *Alaska Airlines*, 480 U.S. at 683 n.5. In *Executive Benefits Insurance Agency v. Arkison*, 134 S. Ct. 2165 (2014), this Court summarized its severability precedent as follows: “We ordinarily give effect to the valid portion of a partially unconstitutional statute so long as it ‘remains ‘fully operative as a law,’” and so long as it is not ‘evident’ from the statutory text and context that Congress would have preferred no statute at all.” *Id.*

⁸ California and other petitioner states and the House of Representatives argue that “the 2017 Congress’ decision not to repeal or otherwise undermine any other provision of the ACA shows that it intended the rest of the ACA to remain operative,” even if the individual mandate is unconstitutional. Pet. App. 64a. That argument is accepted by the dissenting opinion in the Court of Appeals. *Id.* at 105a-106a. If that argument is successful, no granular severability analysis would be necessary. PCORI anticipates the parties will fully brief this issue and thus will not address it.

at 2173 (citations omitted) (quoting *Free Enter. Fund*, 561 U.S. at 509 (quoting *New York v. United States*, 505 U.S. 144, 186 (1992) and *Alaska Airlines*, 480 U.S. at 684)).

Applying this framework to the ACA provisions authorizing PCORI clearly demonstrates that those provisions should be severed from any unconstitutional provision of the ACA. If the individual mandate and all related provisions of the ACA were invalidated, the provisions authorizing PCORI would remain “fully operative” as law. Indeed, those provisions constitute the statutory framework that authorizes PCORI and establishes its purpose, governance structure, and funding through amendments to the Social Security Act and the Internal Revenue Code. These provisions are not related to other provisions of the ACA and they have not been affected by subsequent amendments to the ACA. They stand on their own. Indeed, in 2019, Congress reauthorized PCORI, provided mechanisms for a decade of additional funding (through the PCOR Trust Fund), and amended PCORI’s governing provisions—not through an ACA amendment, but as part of the omnibus 2020 budget agreement. PCORI operates pursuant to a statutory framework wholly independent of the provisions of the ACA that are the focus of this litigation.

Relatedly, nothing in the text or context of the provisions authorizing PCORI suggests that they have any relationship with the potentially invalid provisions of the ACA, let alone any Congressional intent that PCORI’s existence was somehow conditioned on the invalid provisions. Indeed, all textual and contextual evidence points to the contrary conclusion—it is “evident” that Congress wanted PCORI to continue operating without regard to the fate of the individual mandate and associated

provisions. As Justice Scalia stated, “[o]ne determines what Congress would have done by examining what it did.” *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 560 (2001) (Scalia, J., dissenting). Congress’s intent was conclusively evinced when it reauthorized PCORI in 2019, specified its funding and amended aspects of its governance structure and mission. And Congress took this action *after* the 2017 amendments to the ACA that gave rise to this case, demonstrating Congress’s intent to authorize PCORI even after Congress reduced the shared-responsibility payment to zero. What “Congress did” shows that it wanted PCORI to continue to operate.

Indeed, it is difficult to imagine how Congress could have more clearly indicated its intent that PCORI continue to operate without regard to what happened to unrelated provisions of the ACA, particularly since it reauthorized PCORI after the District Court invalidated the individual mandate and the rest of the ACA. At the very least, “nothing in the statute’s text or historical context makes it ‘evident’ that Congress, faced with the limitations imposed by the Constitution, would have preferred no [PCORI] at all.” *Free Enter. Fund*, 561 U.S. at 509. See also *INS v. Chadha*, 462 U.S. 919, 931-32 (1983) (“[T]he invalid portions of a statute are to be severed ‘[u]nless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not.’” (second alteration in original)).

In sum, here, there is no need to do a hypothetical analysis of whether Congress would have authorized PCORI without regard to the other provisions of the ACA. We know that Congress did in fact act to reauthorize PCORI independent of the ACA.

B. None Of The General Or Specific Concerns About ACA Severability Applies To The ACA Provisions Authorizing PCORI.

The severability question with respect to PCORI does not place courts between the proverbial rock and hard place occasionally created by severability issues. Cf. Pet. App. 53a-54a. Specifically, this Court has sometimes identified a tension between acting as a faithful agent for Congress—and thus not rewriting a statute to “give it an effect altogether different from that sought by the measure viewed as a whole,” *Murphy*, 138 S. Ct. at 1482 (quoting *R.R. Ret. Bd. v. Alton R.R.*, 295 U.S. 330, 362 (1935))—and “limit[ing] the solution to the problem,” *Ayotte*, 546 U.S. at 328, by “refrain[ing] from invalidating more of the statute than is necessary,” *Regan*, 468 U.S. at 652 (plurality opinion). There is no such tension here. Leaving the ACA provisions authorizing PCORI intact faithfully reflects Congress’s intent with respect to PCORI at all times from 2009 forward, and also serves the judicial goal of preserving Congress’s duly enacted statute to the extent possible.

Moreover, none of the arguments advocating the inseverability of the entire ACA applies to the ACA provisions authorizing PCORI.

First, in addressing the severability of ACA’s provisions not related to the individual mandate, the District Court declined to sever, stating that it is “impossible to know which minor provisions Congress would have passed absent the Individual Mandate” and that such inquiry involves too much “legislative guesswork.” Pet. App. 224a. Respectfully, as subsequent events confirmed, this blanket assertion was wrong. Congress’s intent with respect to PCORI’s authorization is clear based on Congress’s actions—including reauthorizing PCORI in 2019 as part of the

bipartisan budget legislation for 2020. Again, PCORI's circumstances show why a granular inquiry is required. The District Court's sweeping treatment of the numerous provisions of the ACA unrelated to the individual mandate was inconsistent with this Court's approach to severability.

Second, in the Court of Appeals, Texas and other state plaintiffs argued that the ACA provisions unrelated to the individual mandate and shared-responsibility provisions were “mere adjuncts’ of the more important provisions and would not have been independently enacted.” Pet. App. 63a (citing State Plaintiffs’ Br. at 50). Again, PCORI's circumstances contradict this characterization. The events leading to the initial authorization of PCORI in the ACA and the circumstances of Congress's reauthorization of PCORI in 2019 (*supra* at 12-13) conclusively show that PCORI's authorization was the culmination of Congressional actions wholly separate from its consideration of the individual mandate and that Congress would have chosen to authorize—and then did independently choose to reauthorize—PCORI's funding and operations.

PCORI's situation thus illustrates the wisdom of the Court of Appeals' insight that, with respect to the ACA, the severability issue “involves a challenging legal doctrine applied to an extensive, complex, and oft-amended statutory scheme,” and “highlight[s] the need for a careful, granular approach to carrying out the inherently difficult task of severability analysis in the specific context of this case.” Pet. App. 59a.

Indeed, for the same reasons, severing any unconstitutional provisions from the ACA provisions authorizing PCORI does not implicate the concerns that Justice Thomas has expressed with the Court's approach to severability. This analysis does not

require “a nebulous inquiry into hypothetical congressional intent.” *Murphy*, 138 S. Ct. at 1486 (Thomas, J., concurring) (quoting *United States v. Booker*, 543 U.S. 220, 320 n.7 (2005) (Thomas, J., dissenting in part)). Congress’s 2019 reauthorization of PCORI is Congressional action that confirms Congress’s intent that PCORI continue to operate. And, of course, allowing PCORI to continue would not invalidate “statutory provisions that no party [in this litigation] has standing to challenge.” *Id.* at 1487.

PCORI’s circumstances here also provide a useful contrast with those at issue in *Murphy*, where this Court found the provisions of the Professional and Amateur Sports Protection Act (“PASPA”) inseverable. *Id.* at 1484 (majority opinion). There, the Court concluded that section 3701(1) of PASPA violated the constitutional anti-commandeering rule by prohibiting states from authorizing sports gambling, *id.* at 1478, and concluded that the remaining statutory prohibitions could not be severed, *id.* at 1482-84. The Court decided that Congress would not have wanted to prevent states from running sports-betting lotteries if they could authorize sports betting in casinos, and that the other provisions of the law—prohibiting private individuals from operating or promoting sports gambling schemes under state law—were meant “to work together” with the invalid provisions to achieve PASPA’s goal of preventing “state legalization of sports gambling.” *Id.* at 1483. Thus, the Court found all of PASPA inseverable.

Here, in contrast, the ACA provisions authorizing PCORI are wholly *unrelated* to the individual mandate and all provisions connected with it. The invalidation of these provisions would have no effect on the operation of any ACA provisions involving PCORI; nor would Congress’s intent with respect to PCORI’s

authorization be affected in any way by the invalidation of these unrelated provisions of the ACA. In no sense did Congress intend that the individual mandate and related provisions “work together” with the provisions authorizing PCORI. Finally, of course, Congress never independently authorized any prohibition in PASPA. Here, in a bipartisan enactment of the 2020 budget, Congress reauthorized PCORI separate and apart from the ACA. PCORI’s authorizing provisions represent the strongest possible case for severability.

CONCLUSION

The provisions of the ACA addressing PCORI are severable from any unconstitutional or invalid provision of that Act.

Respectfully submitted,

MARY C. HENNESSEY
 PATIENT-CENTERED
 OUTCOMES RESEARCH
 INSTITUTE
 1828 L Street, N.W.
 Suite 900
 Washington, D.C. 20036
 (202) 827-7700

VIRGINIA A. SEITZ*
 PETER D. KEISLER
 SIDLEY AUSTIN LLP
 1501 K Street, N.W.
 Washington, D.C. 20005
 (202) 736-8000
 vseitz@sidley.com

Counsel for Amicus Curiae

May 13, 2020

* Counsel of Record