Nos. 19-840 & 19-1019

IN THE

Supreme Court of the United States

STATE OF CALIFORNIA, ET AL., *Petitioners,*
v.
STATE OF TEXAS, ET AL., *Respondents.*

STATE OF TEXAS, ET AL., *Petitioners,*
v.
STATE OF CALIFORNIA, ET AL., *Respondents.*

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

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE SUPPORTING PETITIONERS IN NO. 19-840 ON SEVERABILITY

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INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines, active pharmaceutical ingredients, as well as suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM's members provide patients with access to generic and biosimilar medicines that are as safe and effective as their brand-name counterparts at a substantially more affordable price. Generic drugs now constitute 90 percent of all prescriptions dispensed in the United States, yet they account for only 23 percent of total drug spending. Over the last decade, generic and biosimilar drugs have generated $1.68 trillion in savings for patients and taxpayers. AAM's core mission is to improve the lives of consumers by providing access to affordable medicines used for therapeutic purposes. To further that mission, AAM regularly participates in litigation as an *amicus curiae*, both as an organization and through the Biosimilars Council, a division of AAM. The Council submitted a brief in this Court's previous case examining the biosimilar statute, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017).

Biosimilars offer some of the largest opportunities for savings. Biosimilars are more-affordable alternatives to biologic medicines,[2] which account for as many

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[1] No counsel for a party authored any part of this brief, and no person other than *amicus*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this brief.

[2] A biologic "is a type of drug derived from natural, biological sources such as animals or microorganisms," as distinct from

as 40 percent of annual new drug approvals by the FDA. *See* Bernard Munos, *2015 New Drug Approvals Hit 66-Year High!*, Forbes (Jan. 4, 2016).[3] With annual U.S. spending on biologic drug therapies in the United States exceeding $100 billion,[4] the creation of a simpler pathway for approval of biosimilar medicines offered the potential for tens of billions of dollars in healthcare savings. And savings are not limited to consumers and private insurers: the federal government spends more than $5 billion each year on biologic drug therapies through such programs as Medicare and Medicaid.[5]

AAM members pursue lower-cost biosimilar alternatives by submitting applications to the Food and Drug Administration using the abbreviated pathway provided by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), enacted as a self-contained subtitle of the Patient Protection and Affordable Care Act ("ACA"). AAM and its members supported passage of the BPCIA and are deeply interested in its preservation. In addition to seeking approval from FDA through the BPCIA's speedier path-

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"traditional drugs, which are typically synthesized from chemicals." *Sandoz*, 137 S. Ct. at 1669-1670; *see* 42 U.S.C. § 262(i)(1).

[3] http://www.forbes.com/sites/bernardmunos/2016/01/04/2015-new-drug-approvals-hit-66-year-high/#4ecaa3 c11044

[4] *See* Biosimilars Council, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products* 14 (2015), http://www.biosimilarscouncil.org/wp-content/uploads/2017/03/Biosimilars-Handbook.pdf

[5] Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* (Jan. 3, 2017), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending

way for biosimilars, AAM member companies have invested considerable time, effort, and resources in navigating the complex set of rules that govern approval and related patent litigation with biologic manufacturers.

If a constitutional challenge to some provisions of the ACA resulted in the invalidation of the entire ACA, including the BPCIA, a decade of progress by AAM and its members would be lost—and at a crucial moment. Biosimilars are now being approved in greater numbers, and the cost-savings they offer are finally being realized. As this brief explains, over the next seven years biosimilars are expected to deliver at least *$54 billion* in savings to patients and the health-care system as a whole. Invalidating the BPCIA therefore would produce a host of negative consequences: FDA would lose its authority to approve biosimilars using the abbreviated pathway. AAM's members would lose the enormous investments they have made in developing new biosimilars for approval and marketing. And patients and payors would lose the chance at $54 billion in near-term savings.

AAM and its members therefore have a strong interest in ensuring that the BPCIA remains law.

INTRODUCTION AND SUMMARY OF ARGUMENT

This brief is limited to one specific issue: whether the BPCIA—legislation that no one has challenged and that benefits litigants on both sides—should remain undisturbed by the Court's decision on other provisions of the ACA. Although the Court need not reach the severability question if it does not invalidate any por-

tion of the ACA, that constitutional question is beyond the scope of this brief.

The BPCIA is exactly the type of legislation that should not be declared invalid based on a constitutional challenge to another part of the same public law. The BPCIA stands on its own and serves an important public purpose that is entirely disconnected from the insurance-related provisions of the ACA that are challenged here. No plaintiff in this case would have standing to challenge the BPCIA—far from it, considering that all the plaintiffs *benefit* from the BPCIA. Whatever the outcome of this case, therefore, the BPCIA should be unaffected.

I. The BPCIA does two things, both of them aimed at lowering the staggering price of biologic medicines by introducing lower-cost competition. First, it creates a pathway for speedier, less expensive approval of a biosimilar version of an already-approved biologic medicine: when the FDA has already reviewed and approved the biologic medicine, the biosimilar can be approved without requiring duplicative clinical trials. Second, it creates detailed procedures intended to allow the biologic and biosimilar manufacturers to resolve patent disputes before the biosimilar is ready for launch. By enabling patent disputes to be resolved before money damages for infringement are at issue, the legislation incentivizes challenges to biologic patents and lowers the litigation cost of launching a biosimilar.

The need for a biosimilar statute had been apparent for years. Biosimilars are exceptionally expensive, and their cost has been rising steeply. Spending on biologics increased by 65% over the five-year period between 2011 and 2016, a period when there were either no or almost no biosimilars. In recent years, the average

cost of a biologic has been as much as $45 per day, compared with $2 per day for other pharmaceuticals, with biologics costing anywhere from $50,000 to $400,000 annually *per person*.

Before the BPCIA, the FDA had no way to approve biosimilars through an expedited pathway like the one for generic drugs. Such a pathway had been successfully adopted in Europe, and the need to do the same in the United States was widely recognized.

The provisions of the BPCIA went through an extensive legislative process *before* the BPCIA was incorporated into the ACA. The draft biosimilar legislation had bipartisan support, and it was written as a free-standing bill that did not turn on any other legislation.

II. The BPCIA passes every test for severability. The ordinary rule is partial invalidation, not total invalidation, and this Court has consistently been careful not to invalidate more of a statute than is necessary to cure the identified violation. And there is no reason to slice more broadly here.

The BPCIA is fully operative as a law without regard to the challenged provisions (or any other provisions) of the ACA. The BPCIA's abbreviated pathway for FDA approval of biosimilars and its carefully-calibrated scheme for litigating patent disputes are not intertwined or connected with the mandate or other insurance reforms, and they will operate *exactly* as intended whether or not the mandate or any of the ACA's other insurance-related provisions stand.

The BPCIA's history provides further confirmation that Congress would have preferred to leave the BPCIA in place, even if a court invalidated the provisions of the ACA that the State respondents are chal-

lenging here, rather than have "no law at all." The need for a biosimilar pathway was widely recognized—by proponents and opponents of the ACA alike.

Developments since the ACA's enactment confirm that the BPCIA stands on its own. The legislative development that the State respondents emphasize—the 2017 legislation zeroing out the penalty for noncompliance with the individual mandate—occurred *after* this Court had treated the ACA as severable. It also occurred after the FDA and the entire health-care sector had invested tremendous time and energy in the development of biosimilar medicines using the abbreviated pathway the BPCIA created.

The State respondents have not provided *any* indication that Congress would have wanted the invalidation of part of the statute to drag down the BPCIA as well. Rather, they have merely asserted that all provisions of the ACA that they do not challenge are "minor," and that this Court should therefore assume none of those provisions would otherwise have been enacted. That is not remotely accurate as a description of the BPCIA, an important and independently justified piece of legislation that stands on its own.

III. Even if the Court were to apply a different approach to severability here, the BPCIA would readily survive. No party has standing to challenge the BPCIA, because no party is suffering any injury traceable to the BPCIA. To the contrary: the State respondents affirmatively *benefit* from the cost savings the biosimilar pathway creates, and they would be *harmed* by the closure of that pathway. As Justice Thomas has recently explained, declaring a provision invalid when no party has standing to challenge it "bring[s] courts dangerously close to issuing advisory

opinions." *Murphy v. NCAA*, 138 S. Ct. 1461, 1487 (2018) (Thomas, J., concurring). "In every other context, a plaintiff must demonstrate standing for each part of the statute that he wants to challenge," *id.*; here, where no party has standing to challenge the BPCIA, this Court's decision should not affect that provision.

Whatever this Court decides about the challenged provisions of the ACA, the BPCIA can continue to function in exactly the same way. This Court's decision therefore should leave uninterrupted the important work of developing and approving cost-saving and life-saving biosimilar medicines.

ARGUMENT

I. The BPCIA Was Enacted To Promote The Development Of Affordable, Life-Saving Drugs.

The BPCIA is a self-contained portion of the ACA that has nothing to do with public or private health insurance. *See* Pub. L. No. 111-148, Title VII, Subtit. A, §§ 7001-7003, 124 Stat. 119, 804-821 (2010). Congress' objective in adopting the BPCIA was to address problems with the development of biologic medicines—the enormous cost of obtaining approval, the resulting absence of competition, and the high prices patients pay as a result—and to establish "a biosimilars pathway" balancing innovation and consumer interests." *Id.* § 7001(b), 124 Stat. at 804. The BPCIA achieves this goal in two ways.

First, the BPCIA created an "abbreviated [pathway] for FDA approval of biosimilars"—*i.e.*, "a biologic product that is highly similar to [another] biologic product that has already been approved by the [FDA]."

Sandoz, 137 S. Ct. at 1669-1670. Biologics are approved based on a showing that they are "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). Thereafter, a biosimilar version of an already-approved biologic need not make this same showing—for example, by carrying out costly and redundant clinical trials to demonstrate the same propositions once again. Instead, the biosimilar "may piggyback on the showing made by the manufacturer . . . of a previously licensed biologic" by demonstrating that "its product is 'highly similar' to the reference product and that there are no 'clinically meaningful differences' between the two in terms of 'safety, purity, and potency.'" *Sandoz*, 137 S. Ct. at 1670 (citation omitted). In this way, "[t]he BPCIA . . . permits a biosimilar applicant to rely in part on the approved license of a reference product." *Amgen Inc. v. Sandoz, Inc.*, 877 F.3d 1315, 1321 (Fed. Cir. 2017).

Second, the BPCIA creates a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1670. Under this regime, *see* 42 U.S.C. § 262(*l*), litigation may commence "during the period preceding FDA approval" of the biosimilar, so that "the parties do not have to wait until commercial marketing [of the biosimilar] to resolve their patent disputes." *Sandoz*, 137 S. Ct. at 1670. "If the parties comply with each step outlined in the BPCIA, they will have the opportunity to litigate the relevant patents before the biosimilar is marketed." *Id.* at 1672.

Both of these features were necessary to authorize and facilitate the development of biosimilars in the United States, and thereby achieve the ultimate goal of curbing the rising costs of biologics through competi-

tion. "While expenditures on pharmaceuticals are increasing faster than other healthcare expenditures, they are increasing much faster for biologics." Steve Pociask, *NewConsumerGram: Lifesaving Drugs at Lower Costs*, Am. Consumer Inst. Ctr. for Citizen Research 2 (July 22, 2014).[6] Spending on biologics in the United States reached more than $105 billion in 2016, marking a 65 percent increase since 2011. *See* Biosimilars Council, *Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines* 2 (2017).[7] In 2017, spending on biologics increased again, totaling $120.1 billion—a 12.5 percent increase over the prior year. *See* Agata Dabrowska, Cong. Research Serv., *Biologics and Biosimilars: Background and Key Issues* 2 (June 6, 2019).[8] These rising expenditures are attributable in large part to the dramatically higher cost of biologics as compared to other drugs. In recent years, the average cost of a biologic has been as much as $45 per day, compared with $2 per day for other pharmaceuticals, with biologics costing anywhere from $50,000 to $400,000 annually *per person*. *See* Pociask, *Lifesaving Drugs*, *supra*, at 2 (listing biologics that cost $50,000, $200,000, $375,000, and $400,000 annually per patient); *see also* Dabrowska, *Biologics and Biosimilars*, *supra*, at 2 (Soliris (eculizumab) and Vimizim (elosulfase alfa) cost more than $250,000 annually per patient).

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[6] https://www.theamericanconsumer.org/wp-content/uploads/2014/07/Biosimilars-ConsumerGram-Final.pdf

[7] http://biosimilarscouncil.org/wp-content/uploads/2019/03/Biosimilars-Council-Patient-Access-Study.pdf

[8] https://crsreports.congress.gov/product/pdf/R/R44620

These costs burden government, as well as individuals and private insurers. For example, Medicare spending on biologics has increased substantially in recent years. Medicare Part D expenditures on biologics rose from $1.9 billion to $3.5 billion between 2009 and 2012. *See* Surya C. Singh & Karen M. Bagnato, *The Economic Implications of Biosimilars*, 21 Am. J. Managed Care S331, S331 (2015). Similar increases have occurred in Medicare Part B. *See, e.g.*, Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Drug Spending?* 3 (Jan. 2017) (stating that Medicare Part B spending on five biologics totaled nearly $5.5 billion in 2014).[9] And Medicaid outpatient pharmaceutical expenditures have exceeded $60 billion annually, with biologics making up between 11 and 14 percent of that amount even though they are consistently less than 1 percent of total Medicaid prescriptions annually. *See* Katherine Young, Kaiser Family Found., *Utilization and Spending Trends in Medicaid Outpatient Prescription Drugs* (Feb. 15, 2019).[10]

The introduction of biosimilars has already produced significant benefits for patients and the U.S. health-care system overall. Since 2010, FDA has approved at least twenty-six biosimilar products, U.S. FDA, *Biosimilar Product Information: FDA-Approved Biosimilar Products* (updated Feb. 24, 2020),[11] and over a dozen of those are currently being marketed in the United States, Aydin Harston, Rothwell Figg, *U.S.*

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[9] https://www.pewtrusts.org/-/media/assets/2017/01/leveraging-biosimilars-to-lower-medicare-part-b.pdf

[10] https://www.kff.org/medicaid/issue-brief/utilization-and-spending-trends-in-medicaid-outpatient-prescription-drugs/

[11] https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

Biosimilar Launches Accelerate with Five Launches in Q4 2019 and early 2020, tbl. 2 (Jan. 27, 2020).[12] These biosimilars have saved the U.S. health-care system hundreds of millions of dollars since the first biosimilar was marketed in the United States in 2015. *See* Wayne Winegarden, Pacific Research Institute Center for Medical Economics and Innovation, *The Biosimilar Opportunity: A State Breakdown* 13, tbl. 4 (October 2019).[13] Collectively, biosimilars are expected to deliver at least $54 billion in savings by 2027. Andrew W. Mulcahy et al., Rand Corp., *Biosimilar Cost Savings in the United States* 1, 10 (2017).[14] In turn, the "addition of biosimilars into the U.S. market is expected to increase patient access to biologic medicines across the board," including to potentially life-saving treatments. *See* Biosimilars Council, *Biosimilars in the United States*, *supra*, at 3, 5 (predicting that biosimilars will "make life-saving biologic medicines available" and "boost access to biologic treatments for an additional 1.2 million patients").

In short, the BPCIA had a life of its own, separate and apart from the rest of the ACA. Its adoption of an abbreviated approval pathway for biosimilar applications, and procedures to resolve patent disputes after an application is submitted, responded to a pressing need to bring about competition in the market for biologic medicines. Those changes are unrelated to the ACA's insurance-related reforms.

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[12] https://www.biosimilarsip.com/2020/01/28/u-s-biosimilar-launches-accelerate-with-five-launches-in-q4-2019-and-early-2020/

[13] https://www.pacificresearch.org/wp-content/uploads/2019/10/BiosimilarSavings_web.pdf

[14] https://www.rand.org/pubs/perspectives/PE264.html

II. Under This Court's Precedents, The BPCIA Should Be Severed From The Individual Mandate And Other Insurance Reforms.

A. There Is A Strong Presumption In Favor Of Severability.

This Court has repeatedly emphasized the care courts must take before invalidating an Act of Congress. It is "the gravest and most delicate duty that this Court is called on to perform," *Shelby Cty. v. Holder*, 570 U.S. 529, 556 (2013) (citation omitted), because it "frustrates the intent of the elected representatives of the people." *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 329 (2006) (quoting *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984)).

The Court's reluctance to frustrate the democratic process by striking down an Act of Congress applies equally to the question of severability. In those cases, the question becomes whether to strike down an *entire* Act of Congress because *only part* of it is unconstitutional.

Time and again, this Court has emphasized that courts must "refrain from invalidating more of [a] statute than is necessary." *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987) (citation omitted). "[W]hen confronting a constitutional flaw in a statute," this Court will endeavor "to limit the solution to the problem," severing any "problematic portions while leaving the remainder intact." *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010) (quoting *Ayotte*, 546 U.S. at 328-329). Indeed, "partial, rather than facial, invalidation" is the "normal rule." *Id.* (citation omitted). Thus, a Court must sever an unconstitutional portion of a statute from the remainder

"[u]nless it is evident that [Congress] would not have enacted those provisions which are within its power, independently of that which is not.'" *Alaska Airlines, Inc.*, 480 U.S. at 684 (quoting *Buckley v. Valeo*, 424 U.S. 1, 108 (1976) (per curiam)).

The "touchstone" of the severability analysis "is legislative intent": "Would the legislature have preferred what is left of its statute to no statute at all?" *Ayotte*, 546 U.S. at 328-330. To answer that question, the Court looks to whether, absent the stricken provision, the statute is "'fully operative as a law,'" and whether "the infirmity [of one part of the Act]" results in "the total frustration of Congress' basic purpose," *United States v. Jackson*, 390 U.S. 570, 585, 591 (1968). As detailed below, the legislative history unambiguously confirms that the BPCIA is severable from the individual mandate.

B. The BPCIA Is Not Connected To The Individual Mandate Or The Other Insurance Provisions And It Will Operate Exactly As Congress Intended If The Mandate Is Held Unconstitutional.

Whether or not the Court deems the individual mandate unconstitutional, the BPCIA can and should remain in effect. The BPCIA is "a functionally independent part" of the ACA, *Jackson*, 390 U.S. at 586, that has nothing to do with the challenged provisions. The BPCIA's abbreviated pathway for FDA approval of biosimilars and its carefully calibrated scheme for litigating patent disputes are not intertwined or connected with the mandate or other insurance reforms, and they will operate *exactly* as intended whether or not the mandate or any of the ACA's other insurance-

related provisions stand. Thus, the BPCIA will remain "fully operative as a law" if the individual mandate is invalidated, *Free Enter. Fund*, 561 U.S. at 509 (citation omitted), and striking down the provisions of the ACA that the State respondents are challenging would not "defeat[]" or result in the "total frustration of Congress' basic purpose" in passing the BPCIA, *New York v. United States*, 505 U.S. 144, 187 (1992); *Jackson*, 390 U.S. at 585, 591.

Further, the historical context of the ACA's passage gives no indication that Congress would have preferred "no [BPCIA] at all" if it could not also get the mandate and the ACA's other health insurance reforms, *Ayotte*, 546 U.S. at 328-330; much less is it "evident" that Congress would have favored that result. *Alaska Airlines, Inc.*, 480 U.S. at 684. To the contrary, there was broad and bipartisan support in Congress for creating a biosimilar pathway. President Obama's proposed budget noted that "[p]rescription drug costs are high and rising" and proposed to "accelerate access" with a "legal pathway for generic versions of biologic drugs." Office of Mgmt. & Budget, *A New Era of Responsibility* 28 (2009).[15] Moreover, multiple bipartisan proposals were introduced in Congress to provide an abbreviated pathway for biosimilars, and committees in both the House and Senate held hearings at which the broad-based support for a biosimilar pathway was clear. *See* Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 777-806 (2010); *see also, e.g.*, *Biologics and Biosimilars: Balancing Incentives for Innovation*: *Hearing Before the Sub-*

[15] https://www.govinfo.gov/content/pkg/BUDGET-2010-BUD/pdf/BUDGET-2010-BUD.pdf

comm. on Courts & Competition Policy of the H. Comm. on the Judiciary, 111th Cong. (July 14, 2009).

Legislators from both political parties also expressed support for creating a biosimilar pathway. *See, e.g.*, 155 Cong. Rec. H12914 (daily ed. Nov. 7, 2009) (statement of Rep. Shuler) (discussing the "moral obligation to provide a safe and effective pathway of bringing competition that will benefit patients"); 155 Cong. Rec. H12915 (daily ed. Nov. 7, 2009) (statement of Rep. Issa) (stating support for "establishing a market for biosimilars which balances the desire to provide cheaper biologics with the need to continue incentivizing investment in research and development"); 155 Cong. Rec. S6793 (daily ed. June 18, 2009) (statement of Sen. Brown) ("Perhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics. . . . [B]iologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments"); *Emerging Health Care Issues: Follow-On Biologic Drug Competition*: *Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 3 (June 11, 2009) (statement of Rep. Deal) ("Access to lower cost biologics represents a critical step forward in reducing the overall high cost of health care and will provide greater access to patients in need of these critical life-saving therapies."); 155 Cong. Rec. S5636 (daily ed. May 7, 2007) (statement of Sen. Clinton) (stating that a "follow-on biologics" pathway is necessary to "provide significant savings to patients, employers, and the government" on the order of "$14 billion over the next 10 years").

C. Developments Since 2010 Confirm That The BPCIA Stands On Its Own, Independent Of The Individual Mandate.

Even if Congress's intent that the BPCIA stand independently of the mandate were not evident in 2010, Congress made that intent even plainer in 2017, when it zeroed-out the mandate with a surgically precise amendment that left the remainder of the ACA—including the BPCIA—untouched. *See* Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 11081, 131 Stat. 2054, 2092. That is clear evidence of the legislature's desire to retain the BPCIA without the mandate. Indeed, the Congress that eliminated the mandate was well-aware of this Court's decision in *NFIB v. Sebelius* striking down a component of the Medicaid expansion but severing the unlawful portion from the remainder of the Act. *See* 567 U.S. 519, 586-587 (2012). It thus knew that the elimination of a central piece of the ACA would not doom the entire law.[16]

The Court should not lightly impute to Congress an intent to void the BPCIA in the event the individual mandate and other insurance reforms are held unconstitutional. Since 2010, the BPCIA has been integral to making affordable, life-saving medications available to patients. *See* pp. 10-11, *supra*. A decision invalidating the BPCIA could jeopardize the biosimilars that are currently approved or on the market—and the consequence could be exponentially worse if the Court's ruling were to call into question the FDA's *previous* bi-

[16] In *NFIB*, the Court noted a pre-existing severability provision preserving the rest *of the Medicaid statutes*. *See* 567 U.S. at 586. But that clause did not drive the Court's conclusion that the Medicaid expansion was severable from the rest *of the ACA*.

osimilar approvals issued under the authority of the BPCIA.

Invalidating the BPCIA would also pull the rug out from under the numerous biosimilar products that are currently in production. Over the decade since the BPCIA's adoption, *amici*'s member companies and others have invested *billions* of dollars in developing biosimilar medicines. Because of the size of the investment in each product, every anticipated biosimilar launch entails years of careful planning, for everything from patent litigation to marketing. Voiding the BPCIA would destroy that investment in a single stroke.

Invalidating the BPCIA would also put the United States even further behind the rest of the world in the development of biosimilars. The European Union, for example, approved its first biosimilar in 2006—nearly a decade prior to the first approval of a biosimilar in the United States. *See* European Medicines Agency, *Biosimilar Medicines: Overview* (accessed Apr. 29, 2020).[17] Though FDA approvals of biosimilars have increased, they still lag behind Europe. *See* European Medicines Agency, *Medicines* (accessed Apr. 29, 2020).[18] Invalidating the BPCIA with the mandate would halt the progress the United States has made in biosimilar development over the last decade and put the United States further behind our international competitors.

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[17] https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview

[18] https://www.ema.europa.eu/en/medicines/

The Court should therefore sever the individual mandate from the remainder of the ACA, including the BPCIA, if it holds the mandate unconstitutional.

D. Respondents' Arguments For Wholesale Invalidation Ignore The Bases For Severing The BPCIA.

The State respondents insisted below that "all other minor provisions" of the ACA must fall with the mandate. State Resps.' C.A. Br. 50; *see also* U.S. C.A. Br. 47. Relying on the joint dissent in *NFIB*, the State Respondents contend that these provisions must be voided because "'[t]here is no reason to believe that Congress would have enacted them independently.'" State Resps.' C.A. Br. 50 (quoting *NFIB*, 567 U.S. at 705 (joint dissent)).

As an initial matter, that argument disregards the history of the BPCIA. There is every reason to believe that Congress would have adopted this piece of bipartisan legislation whether or not it also adopted the rest of the ACA. The BPCIA had already been the subject of its own extensive legislative process, and it built on the success of the European biosimilar pathway. And most fundamentally, it fulfilled a longstanding need that the United States' pre-existing regulatory framework had proved inadequate to handle.

Furthermore, the State respondents' argument inverts the "presumption . . . in favor of severability." *Regan*, 468 U.S. at 653. Under this Court's cases, the "minor provisions" of the ACA—including the BPCIA—must be upheld "*[u]nless it is evident* that [Congress] *would not have* enacted" them "independently of" the mandate. *Alaska Airlines, Inc.*, 480 U.S. at 684 (emphasis added; citation omitted). So even if there were

no indication of congressional intent, the correct result under this Court's cases would be to sever the mandate from the BPCIA as long as the latter is "fully operative as a law," *Free Enter. Fund*, 561 U.S. at 509, and "will still function in a way 'consistent with Congress' basic objectives,'" *NFIB*, 567 U.S. at 587-588 (quoting *United States v. Booker*, 543 U.S. 220, 259 (2005)). Both are true of the BPCIA.

At bottom, the State respondents' argument rests on the assumption that all the "minor provisions" in the ACA were just the products of horse trading—provisions inserted into the ACA as part of a "*quid pro quo* for [a Senator's or Congressman's] needed support." *NFIB*, 567 U.S. at 705 (joint dissent). But the BPCIA had broad support in Congress and from the White House, based on the overwhelming consensus that a pathway for FDA approval of biosimilars was critically needed and would benefit the entire United States—not one state or one interest group. *See* pp. 14-15, *supra*. Whatever may be true of the ACA's other ancillary provisions, Congress had every intention of passing the BPCIA independent of the individual mandate or other insurance-related reforms in the ACA. It stood on its own; it was not just an "ornament[]" on the ACA's "tree." *NFIB*, 567 U.S. at 705 (joint dissent).

III. At A Minimum, The Court Should Sever The BPCIA From The Individual Mandate Because The Plaintiffs Lack Standing To Challenge It.

Some opinions have proposed analyzing severability as a question of justiciability rather than remedy. *See Murphy*, 138 S. Ct. at 1487 (Thomas, J., concurring); *Printz v. United States*, 521 U.S. 898, 935 (1997); *see also* J.A. 431-432, 446-448 (court of appeals discussing

tension between severability and standing doctrines and directing the district court on remand to consider the United States' argument that any remedy "should only reach ACA provisions that injure the plaintiffs"). If the Court were to adopt that approach, the BPCIA plainly would survive, because no party to this litigation alleges any injury traceable to it. Far from it: every one of the State respondents *benefits* from the cost savings that the BPCIA has produced and will produce.

1. The ordinary rule is that the "'plaintiff must demonstrate standing for each claim he seeks to press' and 'for each form of relief' that is sought." *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006)). "The same principle applies when there are multiple plaintiffs. At least one plaintiff must have standing to seek each form of relief requested in the complaint." *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1651 (2017). This standing requirement "is built on separation-of-powers principles," and "serves to prevent the judicial process from being used to usurp the powers of the political branches." *Id.* at 1650 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013)).

Applying those principles in this context would mean that if a plaintiff must establish injury from a provision of law before he may even *ask* the Court to strike it down, the Court will not *invalidate* that provision without a corresponding showing of injury. *Accord Murphy*, 138 S. Ct. at 1487 (Thomas, J., concurring). This should be especially true in the severability context, where a court is deciding whether provisions that *have not been challenged* are invalid because a sepa-

rate provision is unlawful. *Id*. Once a court resolves the constitutionality of the provisions of law that have been challenged, "the only live controversy between the parties" has been resolved. *Id*. There is no longer any basis to declare *other* provisions invalid.

This Court applied that principle to a severability question in *Printz*. The Court held that one provision of the Brady Handgun Violence Prevention Act, which required state law enforcement officers to assist in enforcing federal firearm regulations, was unconstitutional. 521 U.S. at 902-905, 935. The parties had briefed whether other provisions of the Brady Act that "burden[ed] firearms dealers and purchasers" must fall, but the Court held that it "ha[d] no business" addressing this question because "no plaintiff in either of those categories is before us here." *Id*. at 935. The Court thus "decline[d] to speculate regarding the rights and obligations of parties not before the Court." *Id*.

2. Here it is indisputable that no one before the Court has standing to challenge the BPCIA. Far from being harmed by the BPCIA, the State respondents are *beneficiaries* of the cost-savings that the BPCIA has produced and likely will continue to produce as more biosimilars receive FDA approval and enter the market.

Medicaid expenditures constitute a significant portion of each State's budget, averaging at least 15 percent of total state spending. *See* Medicaid and CHIP Payment and Access Commission, *Medicaid's Share of State Budgets* (2017)[19]; *see also* Kaiser Family Found., *Medicaid Expenditures as a Percent of Total State Ex-*

[19] https://www.macpac.gov/subtopic/medicaids-share-of-state-budgets/

penditures by Fund (accessed Apr. 29, 2020) (estimating total state Medicaid expenditures at 16 percent).[20] At the same time, Medicaid spending on biologics is between 11 and 14 percent of Medicaid prescription drug spending, even as biologics themselves constitute less than 1 percent of total Medicaid prescriptions. *See* Young, *Utilization and Spending Trends*, *supra*; *see also* Kaiser Family Found., *Medicaid's Prescription Drug Benefit: Key Facts* (May 1, 2019).[21]

States thus stand to benefit significantly from lower biologic prices that can result from competition between brand biologics and biosimilars. Biosimilars are already saving States millions in Medicaid expenditures. *See* Winegarden, *The Biosimilar Opportunity, supra*, at 8, tbl. 2 (estimating total annual biosimilar-generated savings for Medicaid programs at $47.5 million). And those savings are likely to increase exponentially as the market share of biosimilars grows over time. *Id*. (estimating annual Medicaid savings of $417.3 million, $801.6 million, and $1.2 billion as biosimilars have 25 percent, 50 percent, and 75 percent market share, respectively).

Thus, because none of the State respondents is injured by the BPCIA, none of them would have standing to challenge that law. The Court should not allow them to achieve that same result indirectly by arguing for an indiscriminate non-severability holding.

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[20] https://www.kff.org/medicaid/state-indicator/medicaid-expenditures-as-a-percent-of-total-state-expenditures-by-fund/

[21] https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/

CONCLUSION

If the Court reaches a decision on the merits that requires it to address the severability question, the Court should hold that the BPCIA remains valid.

Respectfully submitted.

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