

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 4, 2026

Decided July 31, 2026

No. 25-5200

ARTHUR SOOKRA AND APRIL BURCH-SOOKRA, ON BEHALF OF
THEIR DECEASED MINOR CHILD TAYLOR ROSE SOOKRA,
APPELLANTS

v.

PFIZER INC., ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:24-cv-01249)

E. Scott Lloyd argued the cause and filed the briefs for appellants.

Caroline W. Tan, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With her on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Brad Hinschelwood*, Attorney.

David J. Weiner argued the cause for appellee Pfizer, Inc. With him on the brief were *William Hoffman* and *Sharon D. Mayo*.

Jodi V. Terranova and *Teresa Pike Tomlinson* were on the response brief for appellees Mitchell Weiler, M.D. and South Island Pediatrics P.C., joining in the brief of appellee Pfizer, Inc.

Before: MILLETT, KATSAS, and WALKER,* *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* MILLETT.

MILLETT, *Circuit Judge*: Fourteen-year-old Taylor Rose Sookra fell ill and passed away in December 2021, four months after receiving Pfizer, Inc.’s COVID-19 vaccine. Taylor’s parents, Arthur Sookra and April Burch-Sookra (collectively, “Sookras”) filed a lawsuit against certain federal-government officials and Pfizer, alleging that they engaged in willful misconduct in violation of the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d. The Sookras also brought state-law tort claims against those defendants, as well as the physician who vaccinated and treated Taylor, and the pediatric practice where he worked.

The district court dismissed the federal-law claims on the grounds of sovereign immunity or lack of exhaustion of administrative remedies, and it declined to exercise supplemental jurisdiction over the remaining state-law claims. The Sookras appeal, challenging the dismissal of their claims against Pfizer and the government on the ground, among others, that the law required that the decision whether to dismiss the complaint be made by a three-judge court.

Because the Sookras’ federal-law claims could not be

* Circuit Judge Walker was a member of the panel at the time the case was argued but did not participate in the opinion.

dismissed by a single-judge court, we vacate the district court's judgment and remand with directions for the district court to initiate the procedures to convene a three-judge court under 42 U.S.C. § 247d-6d(e)(5). We do not reach the Sookras' remaining challenges.

I

A

In 2005, Congress enacted the Public Readiness and Emergency Preparedness Act ("PREP Act") to encourage the rapid deployment of medical countermeasures during public health emergencies. *See* 42 U.S.C. §§ 247d-6d, 247d-6e; *Cannon v. Watermark Ret. Cmty., Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022). The PREP Act authorizes the Secretary of Health and Human Services to issue a declaration identifying a public health emergency and recommending the development of one or more medical "countermeasures." 42 U.S.C. § 247d-6d(b)(1). When the Secretary issues such a declaration, the Act immunizes certain "covered person[s]" from "suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]" *Id.* § 247d-6d(a)(1).

Recognizing that PREP Act immunity may cut off relief that is otherwise available to individuals who are harmed by a covered countermeasure, Congress provided two avenues of redress.

First, the PREP Act provides a federal cause of action against covered persons "for death or serious physical injury" that is proximately caused by "willful misconduct." 42 U.S.C. § 247d-6d(d)(1). A plaintiff bringing a willful-misconduct

claim, though, must follow a “carefully limited procedural path[.]” *Cannon*, 45 F.4th at 139. Among other requirements, “such actions * * * must be filed in the [United States District Court for the District of Columbia] and are subject to special pleading, discovery, and damages limitations.” *Id.*; see 42 U.S.C. § 247d-6d(e)(1)–(9). In addition, the PREP Act provides that “[a]ny” willful-misconduct action “shall be assigned initially to a panel of three judges[.]” which “shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto.” 42 U.S.C. § 247d-6d(e)(5).

Second, Congress established the Covered Countermeasure Process Fund, from which harmed individuals or their representatives may apply for compensation. 42 U.S.C. § 247d-6e(a). If the Secretary determines that an individual qualifies for compensation, that individual either may accept the offered compensation and forgo a willful-misconduct claim, or may reject the offer and sue. *Id.* § 247d-6e(d)(5). The PREP Act further provides that, with certain exceptions, a plaintiff may not bring a willful-misconduct action “unless such individual has exhausted” the available administrative remedies by applying for compensation from the Fund. *Id.* § 247d-6e(d)(1).

B

In March 2020, the Secretary of Health and Human Services issued a PREP Act declaration to provide “liability immunity for activities related to medical countermeasures against COVID-19.” Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,198 (March 17, 2020). The covered countermeasures include “any vaccine” used to treat or prevent COVID-19. *Id.*

at 15,201–15,202. As all parties in this case agree, Pfizer’s COVID-19 vaccine is a “covered countermeasure” within the meaning of the March 2020 declaration.¹

In July and August 2021, Taylor received two doses of Pfizer’s COVID-19 vaccine from Dr. Mitchell Weiler at South Island Pediatrics in Cedarhurst, New York. J.A. 70. Four months later, in December 2021, Taylor began experiencing flu-like symptoms and sought treatment from Dr. Weiler. J.A. 70. Taylor seemed to be recovering well, but she then took a turn for the worse. On December 25th, Taylor was found unresponsive by her mother and taken to the hospital, where she was pronounced dead. J.A. 70. The Medical Examiner reported her cause of death as acute cardiac failure due to myocarditis (inflammation of the heart muscle), adding that “COVID-19 infection with pneumonitis” (inflammation of lung tissue) was a “significant condition.” J.A. 70 (formatting modified).

C

Taylor’s parents, Mr. Sookra and Ms. Burch-Sookra, filed suit in the United States District Court for the Eastern District of New York, asserting both state- and federal-law claims against Pfizer, the Secretary of Health and Human Services, and the Berkeley Carroll School (which had required the vaccination of its students, including Taylor). *See* Compl. at

¹ *See* Second Am. Compl. at 3, *Sookra*, No. 24-cv-1249, ECF No. 47 (“Pfizer’s vaccine was * * * a ‘covered countermeasure’ under the meaning of the [PREP] Act[.]”); Gov’t Resp. Br. 8 (“[T]he government has not disputed[] that the Secretary * * * listed Pfizer’s COVID-19 vaccine as a covered countermeasure.”); Pfizer Resp. Br. 6 (“[T]he COVID-19 vaccine is a covered countermeasure under the PREP Act.”); Weiler & South Island Pediatrics Resp. Br. 1 (joining Pfizer’s brief).

5–6, *Sookra v. Berkeley Carroll School*, No. 23-cv-9491 (E.D.N.Y. Dec. 26, 2023), ECF No. 1. As the suit proceeded, the Sookras sought to add a PREP Act willful-misconduct claim. Because such a claim may be brought only in the United States District Court for the District of Columbia, 42 U.S.C. § 247d-6d(e)(1), the Sookras moved to transfer their case. The district court granted the transfer request.

The case, along with the Civil Cover Sheet from the District Court for the Eastern District of New York, was docketed in the District Court for the District of Columbia. There was no option on that form for the Sookras to request a three-judge court, and the Sookras did not separately request one. *See generally* Civil Cover Sheet, *Sookra v. Pfizer, Inc.*, No. 24-cv-1249 (D.D.C. March 26, 2025), ECF No. 2.

The Sookras then twice amended their complaint to assert a PREP Act willful-misconduct claim against Pfizer, the Secretary of Health and Human Services, and the Commissioner of the Food and Drug Administration. *See* Am. Compl. at 10–12, ECF No. 17; Second Am. Compl. at 11–13, ECF No. 47. The second amended complaint also included various state-law tort claims against those same defendants, as well as Dr. Weiler and South Island Pediatrics. *See* Second Am. Compl. at 11–16. The Sookras dropped the Berkeley Carroll School as a defendant. *See* Am. Compl. at 1.

The Defendants moved to dismiss the Sookras' complaint. Those motions were referred to a magistrate judge who recommended dismissing the claims against (1) the federal government on sovereign-immunity grounds, and (2) Pfizer due to the Sookras' failure to exhaust administrative remedies. *Sookra v. Pfizer, Inc.*, No. 24-cv-1249, 2025 WL 341732, at *3, *6 (D.D.C. Jan. 30, 2025), *report and recommendation adopted*, No. 24-cv-1249, 2025 WL 1545354 (D.D.C. Mar. 26,

2025). The magistrate judge then recommended dismissal of the state-law claims against Pfizer on the basis of its PREP Act immunity. *Id.* at *6–7. Finally, the magistrate judge recommended that the district court decline to exercise supplemental jurisdiction over the remaining state-law claims against Dr. Weiler and South Island Pediatrics. *Id.* at *7. The magistrate judge observed in passing that the Sookras had “neglected other PREP Act requirements[.]” including a “fail[ure] to apply for a three-judge court, as required by both statute and this Court’s Local Civil [Rule 9.1].” *Id.* at *6 n.4.

The Sookras filed objections to the magistrate judge’s Report & Recommendation and also applied for a three-judge court. *See generally* Pltfs.’ Objs. to R&R, ECF No. 65; Appl. for Three-Judge Ct., ECF No. 66. The district court adopted the magistrate judge’s recommendations in full and granted the motions to dismiss. *Sookra v. Pfizer, Inc.*, No. 24-cv-1249, 2025 WL 1545354, at *1–2 (D.D.C. Mar. 26, 2025). The court then dismissed the motion for a three-judge court as moot. *Id.* at *2.

The Sookras timely appealed.²

II

This court has jurisdiction under 28 U.S.C. § 1291. We review *de novo* a dismissal for lack of jurisdiction, *Pueschel v. Chao*, 955 F.3d 163, 165 (D.C. Cir. 2020), and independently determine the proper interpretation of federal laws, *Campaign*

² While the appeal was pending, Kyle Diamantas was named Acting Commissioner of the Food and Drug Administration. Acting Commissioner Diamantas has been substituted as Appellee. *See* FED. R. APP. P. 43(c)(2).

for Accountability v. Department of Justice, 155 F.4th 724, 733 (D.C. Cir. 2025).

III

The Sookras argue that the district court erred by dismissing their claims against the federal government on sovereign immunity grounds, and dismissing their claims against Pfizer for failure to exhaust administrative remedies. The Sookras further contend that the district court improperly dismissed the complaint instead of referring the motions to dismiss to a three-judge court.

The Sookras are correct that the district court improperly dismissed the complaint. The plain text of Section 247d-6d(e)(5) of the PREP Act requires a three-judge court to rule on motions to dismiss willful-misconduct claims, regardless of whether the requested dismissal is for lack of jurisdiction or for failure to state a claim. The only exception to the three-judge requirement is when the claim is so wholly insubstantial that it fails to raise a substantial federal question at all, which is not this case.

We accordingly vacate the district court's dismissal order and remand the case to the district court with instructions to request that the Chief Judge of the Circuit convene a three-judge court to adjudicate the motions to dismiss and related matters within its jurisdiction. Because of that threshold error, we do not address the parties' remaining arguments.

A

At the outset, both the magistrate judge and district court faulted the Sookras for not timely requesting a three-judge court. *See Sookra*, 2025 WL 341732, at *6 n.4 (magistrate

judge recommendation that the Sookras failed to apply for a three-judge court as required by 42 U.S.C. § 247d-6d(e)(5) and D.D.C. Local Civil Rule 9.1); *Sookra*, 2025 WL 1545354, at *1–2.

At least on its face, Section 247d-6d(e)(5) of the PREP Act does not require a plaintiff asserting willful misconduct to apply for a three-judge court, rather than for the court either to *sua sponte* provide it or to set a deadline for the application. A local district court rule, though, provides that any application for a three-judge court “shall be filed with the complaint[.]” D.D.C. Local Civil Rule 9.1. Yet the Sookras filed their request only after the issuance of the Report and Recommendation. *See* Appl. for Three-Judge Ct. at 1.

Because no party presented the question to the district court or to us, we need not—and do not—decide whether either the PREP Act or Local Civil Rule 9.1 imposes a timeliness requirement for requesting a three-judge court, or whether a request must be made at all.

None of the Defendants asked the district court to dismiss the complaint or deny the Sookras’ application for a three-judge court on timeliness grounds. Quite the opposite. The federal government defendants said that they “*do not object* to the Plaintiffs’ Application for Three-Judge Court[.]” Gov’t Resp. to Obj. at 8 n.2, ECF No. 67 (emphasis added). Similarly, Pfizer acknowledged that the “Plaintiffs [have] filed a motion to convene a three-judge panel” without arguing that the motion was barred as untimely. Pfizer Resp. to Obj. at 7 n.3, ECF No. 69. Dr. Weiler and South Island Pediatrics did not mention the application at all. *See generally* Weiler & South Island Pediatrics Resp. to Obj., ECF No. 70.

Nor have the Defendants argued to this court that the Sookras' application was untimely. They seek affirmance solely on the grounds of sovereign immunity (as to the federal defendants) and lack of exhaustion (as to all defendants). *See* Gov't Resp. Br. 16–29; Pfizer Resp. Br. 12–14; Weiler and South Island Pediatrics Resp. Br. 1.

Accordingly, we assume without deciding that the Sookras timely requested a three-judge court. *See District of Columbia v. Air Florida, Inc.*, 750 F.2d 1077, 1084 (D.C. Cir. 1984) (“[I]ssues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal.”); *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 497 (D.C. Cir. 2004) (“[A]rguments that parties do not make on appeal are deemed to have been waived.”).

B

Turning to the heart of this appeal, we hold that the single district court judge could not dismiss the Sookras' complaint. Section 247d-6d(e)(5) of the PREP Act explicitly requires a three-judge court to rule on all motions to dismiss, unless the plaintiffs' claims are so wholly insubstantial as to not even colorably arise under the PREP Act. *See Shapiro v. McManus*, 577 U.S. 39, 44–46 (2015). Because the Sookras' claims are not insubstantial, the single-judge district court lacked authority to dismiss the complaint.

1

The PREP Act generally requires a three-judge court to rule on motions to dismiss, whether on jurisdictional grounds or for failure to state a claim, in any willful-misconduct case brought under the Act.

First, the statutory language says so. It expressly and unambiguously requires motions to dismiss in willful-misconduct actions to be decided by a three-judge court.

The opening proviso of Section 247d-6d(e)(5) states that “[a]ny” willful-misconduct action brought under the PREP Act “shall be assigned initially to a panel of three judges.” 42 U.S.C. § 247d-6d(e)(5). We need not decide in this case how early that “initial[.]” assignment to a three-judge court must be because the PREP Act makes clear that a three-judge court—and only a three-judge court—must preside at least by the time a motion to dismiss, or a “matter[] related” to such a motion, is to be “consider[ed.]” *Id.* The statute says in no uncertain terms that “a panel of three judges * * * shall have jurisdiction over such [willful-misconduct] action for purposes of considering *motions to dismiss*, motions for summary judgment, and matters related thereto.” *Id.* (emphasis added).

That directive is mandatory—the case “*shall* be assigned” to a panel of three judges, and that panel “*shall* have jurisdiction over the action” for purposes of deciding motions to dismiss and related matters. 42 U.S.C. § 247d-6d(e)(5) (emphases added). Congress’s use of the word “shall” “normally creates an obligation impervious to judicial discretion.” *Shapiro*, 577 U.S. at 43 (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)); see *National Ass’n. of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661–662 (2007) (similar); *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016) (“[T]he word ‘shall’ usually connotes a requirement.”). That is why the Supreme Court has held that a statute that provides generally applicable procedures for many three-judge-court review schemes, 28 U.S.C. § 2284, sets out a non-discretionary “prescription” when it says that a “district court

of three judges *shall* be convened[.]” *Shapiro*, 577 U.S. at 43 (quoting 28 U.S.C. § 2284(a)).

Section 247d-6d(e)(5)’s language is also categorical. The assignment of a three-judge court applies to “[a]ny action” for willful misconduct under the PREP Act. 42 U.S.C. § 247d-6d(e)(5). And it applies to “motions to dismiss” without any qualification. *Id.* The statute does not say or suggest that its assignment rule applies only to some types of motions to dismiss, or only in some circumstances. Given the PREP Act’s unflinching language, at the very least, the assignment to a three-judge court must occur in time for the required multi-member panel to rule on any motions to dismiss the complaint, or “matters related thereto.” *Id.*

Congress’s mandatory language no doubt was purposeful. The surrounding subsections of Section 247d-6d repeatedly vary between “may” and “shall” in their directions. One subsection, for instance, states that the Secretary “may” issue a declaration triggering PREP Act immunity. 42 U.S.C. § 247d-6d(b)(1). This provision affords the Secretary some measure of discretion over whether to take that action. *See also, e.g., id.* § 247d-6d(b)(3)(A). But elsewhere, Congress employs language of command. For example, in issuing a declaration, the Secretary “shall” identify, among other things, the time period(s) during which the declaration is in effect for each countermeasure. *Id.* § 247d-6d(b)(2). Together, those provisions illustrate that Congress granted discretion when it meant to in the PREP Act, and denied it when it intended no such choice. *See Kingdomware Techs.*, 579 U.S. at 172 (“When a statute distinguishes between ‘may’ and ‘shall,’ it is generally clear that ‘shall’ imposes a mandatory duty.”).

Second, the PREP Act expressly overrides some of the procedures laid out in the generally applicable three-judge-

court statute, 28 U.S.C. § 2284, under which a single judge “may conduct all proceedings *except* the trial,” *id.* § 2284(b)(3) (emphasis added). *See* 42 U.S.C. § 247d-6d(e)(5) (stating that “paragraph (3) of subsection (b) of Section 2284 of title 28 shall not apply”). In other words, Congress went out of its way to invert the usual order of operations for three-judge courts. Under Section 2284(b)(3), a single judge handles pre-trial motions, handing the reins to a three-judge court only for trial. Under the PREP Act, in contrast, a three-judge court handles pretrial matters like motions to dismiss and for summary judgment, and then “refer[s] the action to the chief judge for assignment for further proceedings, including any trial.” 42 U.S.C. § 247d-6d(e)(5). That inversion of the usual three-judge court procedure indicates that Congress acted with deliberation in designing the PREP Act’s three-judge-review scheme.

Third, past practice in this circuit accords with this natural understanding of Section 247d-6d(e)(5). In *Estate of George Watts, Jr. v. Hegseth*, a single judge dismissed a PREP Act action on the ground that the federal-government defendant was immune to suit. *See* Order at 2, No. 23-cv-1544 (D.D.C. Feb. 18, 2026), ECF No. 17. The plaintiff sought relief from that judgment under Federal Rule of Civil Procedure 60(b), arguing that Section 247d-6d(e)(5) required the case to be assigned to a three-judge court from the outset. Mot. for Relief from J. at 2–3, ECF No. 18. Agreeing with the plaintiff, the district court vacated its own order and requested that the Chief Judge of the Circuit convene a three-judge court. Order at 2, ECF No. 25. The newly convened panel then ruled on the motion to dismiss. *See generally* Order, ECF No. 32.³

³ In the only other PREP Act case of which we are aware, the single-judge district court granted a motion to dismiss. But the

Fourth, as far as we can tell, the PREP Act’s trial court scheme is unique. The parties have not cited any statute—and we have found none—where Congress provided that a case must go “initially” to a three-judge court, including for motions to dismiss. Of the other three-judge-review statutes, some simply adopt the procedures provided under Section 2284, whereas others require a particular party to request a three-judge court. The distinctiveness of the PREP Act’s review scheme indicates that Congress deliberately designed Section 247d-6d(e)(5) differently, and so Congress meant exactly what it said in mandating that PREP Act willful-misconduct cases must go “initially” to a panel of three judges for a motion to dismiss.⁴

plaintiff in that case did not file an opposition to dismissal and the parties did not address the necessity of a three-judge court. *See generally* Mem. Op., *Zelig v. City Medical of New Jersey PC*, No. 21-cv-961 (D.D.C. July 9, 2021), ECF No. 12.

⁴ Some three-judge-court statutes state that the action shall be heard “in accordance with section 2284 of title 28[.]” or similar language. *E.g.*, Gramm-Rudman-Hollings Act, 2 U.S.C. § 922; *see also, e.g.*, Act of June 25, 1948, 3 U.S.C. § 5(d)(1)(B); Prison Litigation Reform Act, 18 U.S.C. § 3626(a)(3)(B); Cable Television Consumer Protection and Competition Act of 1992, 47 U.S.C. § 555(c)(1); Voting Rights Act of 1965, 52 U.S.C. §§ 10303, 10304, 10306; Bipartisan Campaign Reform Act of 2002, Pub. L. No. 107-155, § 403, 116 Stat. 81, 113; Children’s Internet Protection Act, Pub. L. No. 106-554, § 1741, 114 Stat. 2763, 2763A–351 to 2763A–352 (2000); Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1998, Pub. L. No. 105-119, § 209(e)(1), 111 Stat. 2440, 2482 (1997); Act of Dec. 10, 1973, Pub. L. No. 93-178, § 2(b), 87 Stat. 697, 697; Act of July 22, 1958, Pub. L. No. 85-547, § 1, 72 Stat. 403, 403.

Finally, the requirement of promptly assigning the case to a three-judge court to address a preliminary matter such as a motion to dismiss makes sense in light of statutory and historical context. In the PREP Act, Congress carefully balanced the urgent incentivization, development, and deployment of medical countermeasures during public health emergencies with the need to fairly compensate individuals who suffer harm associated with those countermeasures. *See Cannon*, 45 F.4th at 139; *cf.* Hearing on Funding Needs for Pandemic Influenza Preparedness Before the Subcomm. on Labor, Health and Human Servs., and Educ. of the H. Comm. on Appropriations, 109th Cong. 10, 78 (2005) (statement of Michael O. Leavitt, Sec’y of Health & Human Servs.) (“The draft legislation we have submitted to Congress” “strikes an appropriate balance of removing the liability risks that dissuade companies from producing pandemic countermeasures, while still retaining appropriate access to court remedies.”). Congress considered bringing the collective judgment of a three-judge court to bear on willful-misconduct cases to be the

Other statutes require a request for a three-judge court from a particular party. *See, e.g.*, Prison Litigation Reform Act, 18 U.S.C. § 3626(a)(3)(C) (request by party seeking prisoner release order); Presidential Election Campaign Fund Act of 1971, 26 U.S.C. §§ 9010, 9011 (by Federal Election Commission); Customs Courts Act of 1970, 28 U.S.C. § 255(a) (by any party to a civil action or upon the initiative of the chief judge of the Court of International Trade); Civil Rights Act of 1964, 42 U.S.C. §§ 2000a-5(b), 2000e-6(b) (by Attorney General); Regional Rail Reorganization Act of 1973, 45 U.S.C. § 719(b)(1) (by U.S. Railway Association); Voting Rights Act of 1965, 52 U.S.C. § 10101(g) (by Attorney General).

Finally, a statute pertaining to the United States Court of Federal Claims states that, upon the referral of certain bills from Congress, the chief judge shall designate a three-judge court according to procedures under 28 U.S.C. § 2509(a).

most efficient and effective means of accomplishing those ends while underscoring the importance of cases arising from necessarily rapid responses to public health crises. *Cf.* 17A WRIGHT & MILLER’S FEDERAL PRACTICE & PROCEDURE § 4235 (3d ed. April 2026) (noting that the Senate Judiciary Committee deemed three-judge courts necessary for reapportionment cases because “these issues are of such importance that they ought to be heard by a three-judge court”); *Swift & Co. v. Wickham*, 382 U.S. 111, 127 (1965) (Congress’s use of a three-judge court “show[s] quite clearly what sort of cases were of concern to [it.]”); *see* David P. Currie, *The Three-Judge District Court in Constitutional Litigation*, 32 U. CHI. L. REV. 1, 1–2 (1964) (similar).

2

a

The Defendants argue that Congress surely did not intend that every claim, no matter how frivolous, would warrant the devotion of such significant judicial resources. They invoke a line of cases in which the Supreme Court has held that a “three-judge court is not required where the district court itself lacks jurisdiction of the complaint or the complaint is not justiciable in the federal courts.” Gov’t Resp. Br. 14 (quoting *Gonzalez v. Automatic Emps. Credit Union*, 419 U.S. 90, 100 (1974)); *see* Pfizer Resp. Br. 14–18.

Perhaps a single-judge district court can dismiss a case or claim if it is so “wholly insubstantial and frivolous” that it does not “raise a substantial federal question” under the PREP Act sufficient for federal court jurisdiction even to attach. *Shapiro*, 577 U.S. at 45. But that is a very low threshold. The “exception for insubstantial claims is narrow.” *Independence Inst. v. FEC*, 816 F.3d 113, 116 (D.C. Cir. 2016). It applies

“only when the case is ‘essentially fictitious, wholly insubstantial, obviously frivolous, and obviously without merit.’” *Id.* (quoting *Shapiro*, 577 U.S. at 45–46); *see also Shapiro*, 577 U.S. at 46 (“[T]he adverbs [are] no mere throwaways; the limiting words ‘wholly’ and ‘obviously’ have cogent legal significance.”) (formatting modified) (quoting *Goosby v. Osser*, 409 U.S. 512, 518 (1973)).

In short, under the PREP Act, a single-judge district court may dismiss, at most, if the case is so friebbling that it does not even amount to “an[] action under [Section 247d-6d(d) of the PREP Act.]” 42 U.S.C. § 247d-6d(e)(5). Absent such frivolity, the single-judge district court must initiate the procedures for a three-judge court under Section 247d-6d(e)(5) to address any motion to dismiss. *See, e.g., Independence Inst.*, 816 F.3d at 117 (remanding for convening of three-judge court).

But that point gains the Defendants no ground. The Sookras’ assertion of federal-question jurisdiction over their PREP Act claims easily clears that “low bar.” *Shapiro*, 577 U.S. at 46. Indeed, the Defendants do not even suggest that the Sookras’ claims fail to arise under the PREP Act, 42 U.S.C. § 247d-6d(d)(1). Nor is there any colorable argument that the Sookras’ claims are entirely frivolous or wholly insubstantial. In addition, all agree that Pfizer’s COVID-19 vaccine was a “covered countermeasure” that was administered to Taylor, *id.* § 247d-6d(i)(1), and that each Defendant is a “covered person” within the meaning of the statute, *id.* § 247d-6d(i)(2).

Given all of that, the Sookras’ case required the appointment of a three-judge court to decide the Defendants’ motions to dismiss and any related matters. Whether the Sookras’ claims are foreclosed by sovereign immunity, barred for lack of exhaustion, warrant pendent jurisdiction, or

otherwise warrant dismissal is for that three-judge court to decide.

b

The Defendants' remaining arguments do not change anything.

i

The Defendants point to the holding in *Gonzalez v. Automatic Employees Credit Union*, 419 U.S. 90 (1974), that a single-judge district court may dismiss a complaint for lack of jurisdiction (there, lack of standing), *id.* at 100. They argue that this holding extends to dismissals on the grounds of sovereign immunity or lack of exhaustion of administrative remedies. *See* Gov't Resp. Br. 20–22; Pfizer Resp. Br. 11–12, 14–16.

There are four significant problems with that argument.

First, *Gonzalez* and all the other cases on which the Defendants rely involve Section 2284 or statutes that borrow its procedures. As relevant here, Section 2284 provides:

Upon the filing of a request for three judges, the judge to whom the request is presented shall, *unless he determines that three judges are not required*, immediately notify the chief judge of the circuit, who shall designate two other judges * * * [to] serve as members of the court to hear and determine the action or proceeding.

28 U.S.C. § 2284(b)(1) (emphasis added); *see Shapiro*, 577 U.S. at 44 (involving Section 2284); *Gonzalez*, 419 U.S. at 92,

100 (now-repealed 28 U.S.C. § 2281, borrowing Section 2284’s procedures); *McLucas v. DeChamplain*, 421 U.S. 21, 28 (1975) (now-repealed 28 U.S.C. § 2282, borrowing Section 2284’s procedures); *Community Oncology Alliance, Inc. v. Office of Mgmt. & Budget*, 987 F.3d 1137, 1142 (D.C. Cir. 2021) (2 U.S.C. § 922, borrowing Section 2284’s procedures); *Independence Inst.*, 816 F.3d at 115–116 (52 U.S.C. § 30110 note, borrowing Section 2284’s procedures); *Wertheimer v. FEC*, 268 F.3d 1070, 1072 (D.C. Cir. 2001) (26 U.S.C. § 9011, borrowing Section 2284’s procedures); *Eastern States Petroleum Corp. v. Rogers*, 265 F.2d 593, 595–597 (D.C. Cir. 1959) (older version of Section 2284).

The language in Section 2284 expressly contemplates a role for the single judge, including preliminary matters like singlehandedly resolving motions to dismiss, *see* 28 U.S.C. § 2284(b)(3). In addition, the statute expressly allows the single-judge court to retain the case if it “determines that three judges are not required[.]” *Id.* § 2284(b)(1); *cf. Shapiro*, 577 U.S. at 43–44.

That language is pointedly absent from the PREP Act. The district court is given no license to decide if a three-judge court is warranted, and the statute itself expressly and unambiguously assigns motions to dismiss and for summary judgment to three-judge courts. The PREP Act does not even contemplate a potential role for a single-judge district court until after those motions and related matters have been resolved. *See* 42 U.S.C. § 247d-6d(e)(5) (requiring the three-judge court to “refer the action to the chief judge for further proceedings, including any trial[.]” after the panel “has denied [the relevant] motions, or if the time for filing such motions has expired”). Given the material differences in how the PREP Act is written, the Defendants’ reliance on cases involving a differently worded statute is beside the point.

Second, all but two of the Defendants’ cases predate the Supreme Court’s decision in *Shapiro v. McManus*, 577 U.S. 39 (2015), which significantly narrowed the role of a single-judge district court even under Section 2284. *Shapiro* held that a single judge’s statutory authority to “determine[] that three judges are not required” is confined to the narrow question of determining “whether the ‘request for three judges’ is made in a case covered by § 2284(a)—no more, no less.” 577 U.S. at 43–44; *see Independence Inst.*, 816 F.3d at 116 (Kavanaugh, J.) (“[A]s the *Shapiro* Court stressed, the exception for insubstantial claims is narrow.”).

The remaining two cases read and apply *Shapiro* in the same way we do. In one, this court held that the single-judge district court had properly retained a case because the three-judge provision at issue there “d[id] not cover the claims in th[at] case.” *Community Oncology All.*, 987 F.3d at 1142 (“[A]lthough [2 U.S.C. § 922(a)(5)] requires the merits of ‘any action brought under’ section 922(a)(2) to be ‘heard and determined by a three-judge court,’ that provision did not bar the district court from determining whether this action was properly ‘brought under’ section 922(a)(2) in the first place.”) (formatting modified) (internal citations omitted) (citing *Shapiro*, 577 U.S. at 43–45). In the other, the court held as we do that the plaintiff’s case cleared the “low bar” for raising a substantial federal question, and thus “entitled [the plaintiff] to make its case to a three-judge district court.” *Independence Institute*, 816 F.3d at 116–117.

Third, the Defendants retort that *Gonzalez*’s holding was rooted in the background practice of having single-judge district courts decide jurisdictional questions in the first instance. That argument has two fundamental flaws.

To start, absent a constitutional limitation—which is not raised here—Congress is free to displace such background understandings. *See, e.g., Mississippi ex rel. Hood v. AU Optronics Corp.*, 571 U.S. 161, 175 (2014). And that is what the PREP Act does by mandating that “motions to dismiss” go to a three-judge court. 42 U.S.C. § 247d-6d(e)(5); *see Babb v. Wilkie*, 140 S. Ct. 1168, 1177 (2020) (“[W]here, as here, the words of a statute are unambiguous, the judicial inquiry is complete.”) (formatting modified).

ii

The Defendants separately argue that the district court properly dismissed this complaint for lack of jurisdiction due to the Sookras’ failure to exhaust the PREP Act remedy by seeking compensation through the Covered Countermeasure Process Fund.

That argument assumes, however, that the exhaustion requirement is jurisdictional. Yet exhaustion requirements are commonly not jurisdictional. *See Santos-Zacaria v. Garland*, 143 S. Ct. 1103, 1111–1114 (2023); *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 515 (2006). The Defendants have not presented any meaningful argument to this court that the PREP Act’s exhaustion requirement is jurisdictional. *See* Gov’t Resp. Br. 15, 26 (referring only to the exhaustion requirement as “mandatory”); Pfizer Resp. Br. 13 (one-sentence argument that the exhaustion requirement is jurisdictional); Oral Arg. Tr. 52:18–48 (no argument from Pfizer’s counsel that the exhaustion requirement is jurisdictional, even when questioned directly on the issue). That omission leaves a fatal hole in Defendants’ argument. *See also Government of Manitoba v. Bernhardt*, 923 F.3d 173, 179 (D.C. Cir. 2019) (“A party forfeits an argument by mentioning it only in the most skeletal way, leaving the court to do counsel’s work, create the ossature

for the argument, and put flesh on its bones.”) (quotation marks omitted).

iii

Pfizer, Dr. Weiler, and South Island Pediatrics ask this court to affirm the district court’s judgment of dismissal on the alternative ground that the Sookras failed to file certified medical records or physician affidavits with their complaint, as required by Section 247d-6d(e)(4). Pfizer Resp. Br. 16; Weiler & South Island Pediatrics Resp. Br. 1.

To be clear, the PREP Act requires only “*substantial*[] compl[iance]” with that obligation. 42 U.S.C. § 247d-6d(e)(4)(A) (emphasis added). More to the point, whether the Sookras substantially complied with that provision is an argument in support of a motion to dismiss that must be decided by a three-judge court.

IV

For the foregoing reasons, we vacate the district court’s order granting the Defendants’ motions to dismiss, reverse its denial of the Sookras’ motion for a three-judge court, and remand with directions for the district court to initiate the procedures to convene a three-judge court.

So ordered.