No. 16-722

In the Supreme Court of the United States

MAREK MILIK, JOLANTA MILIK, LEGAL GUARDIANS AND PARENTS OF A.M., PETITIONERS

v.

THOMAS PRICE, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

JEFFREY B. WALL
Acting Solicitor General
Counsel of Record
CHAD A. READLER
Acting Assistant Attorney General
MICHAEL S. RAAB
NITIN SHAH
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, established a "no-fault" compensation program to serve as a nonexclusive remedy for individuals claiming to have been injured by vaccines. Special masters in the Court of Federal Claims award compensation if they determine that an individual has injuries caused by a vaccine, and the Court of Federal Claims may review a decision of a special master to determine whether it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. 300aa-12(e)(2)(B). The Federal Circuit may review that determination de novo. The question presented is whether this standard of review violates the requirement that "[t]he judicial Power of the United States" be vested in courts established pursuant to Article III of the Constitution. U.S. Const. Art. III, § 1.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 3a-30a) is reported at 822 F.3d 1367. The opinion of the Court of Federal Claims (Pet. App. 31a-79a) is reported at 121 Fed. Cl. 68. The decision of the special master (Pet. App. 82a-158a) is unreported, but is available at 2014 WL 6488735.

JURISDICTION

The judgment of the court of appeals was entered on May 20, 2016. A petition for rehearing and rehearing en banc was denied on August 31, 2016. The petition for a writ of certiorari was filed on November 29, 2016. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. 300aa-1 *et seq.*, "[t]o stabilize the vaccine market" and to "facilitate compensation" of those injured by vaccines, by providing a "no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'" *Bruesewitz* v. *Wyeth LLC*, 562 U.S. 223, 228 (2011) (quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). "A person injured by a vaccine, or his legal guardian, may file a petition for compensation in the United States Court of Federal Claims [CFC], naming the Secretary of Health and Human Services as the respondent." *Ibid.*; see 42 U.S.C. 300aa-11(a)(1). "Successful claimants receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering; and $250,000 for vaccine-related deaths." *Bruesewitz*, 562 U.S. at 229. "These awards are paid out of a fund created by an excise tax on each vaccine dose." *Ibid.*

"Unlike in tort suits, claimants under the Act are not required to show that the administered vaccine was defectively manufactured, labeled, or designed." *Bruesewitz*, 562 U.S. at 229. Instead, compensation depends solely on injury-in-fact and causation. First, the Act establishes a Vaccine Injury Table, "which lists the vaccines covered under the Act; describes each vaccine's compensable, adverse side effects; and indicates how soon after vaccination those side effects should first manifest themselves." *Id.* at 228; see 42 U.S.C. 300aa-14(a) and (e)(2); 42 C.F.R. 100.3. "Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation."

Bruesewitz, 562 U.S. at 228. "No showing of causation is necessary; the Secretary bears the burden of disproving causation." *Ibid.* Second, "[a] claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation." *Id.* at 228-229; see 42 U.S.C. 300aa-11(c)(1)(C)(ii).

The Act establishes an office of special masters within the CFC. 42 U.S.C. 300aa-12(c)(1). When a person files a petition for compensation, a special master decides whether to award compensation and, if so, the amount. 42 U.S.C. 300aa-12(d)(3). The special master's decision is reviewable by the CFC and, in turn, by the Federal Circuit. 42 U.S.C. 300aa-12(e) and (f). The CFC may set aside the special master's findings of fact or conclusions of law that are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. 300aa-12(e)(2)(B). The Federal Circuit reviews the CFC's decision de novo, thus applying the same arbitrary-and-capricious standard of review to the special master's determination. See *Andreu* v. *Secretary of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009).

If review is unsuccessful, "a claimant has two options: to accept the court's judgment and forgo a traditional tort suit for damages, or to reject the judgment and seek tort relief from the vaccine manufacturer." *Bruesewitz*, 562 U.S. at 228. As a *quid pro quo* under the no-fault system described above, however, the Act provides vaccine manufacturers significant protection from tort liability. *Id.* at 229-230. Specifically, the Act immunizes manufacturers from liability for design-defect claims and for failure to warn if they "have complied

with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant's physician." *Id.* at 229 (citing 42 U.S.C. 300aa-22(b)). Other claims, including that the vaccine was defectively manufactured, are not preempted. See 42 U.S.C. 300aa-22(e). A person can thus litigate in a non-preempted tort suit any issues of injury-and-fact and causation that were previously determined by a special master.

2. In 2001, petitioners filed a petition for vaccine compensation on behalf of their son, A.M., who suffers "a severe neurological condition, involving developmental delay, spastic diplegia, and motor difficulties." Pet. App. 4a. Petitioners contend that a childhood vaccination for measles, mumps, and rubella (MMR) caused A.M.'s condition. *Ibid.* A.M.'s condition is not among those listed on the Injury Table for the MMR vaccine. See 42 C.F.R. 100.3(a). Petitioners were thus required to prove that the MMR vaccine caused A.M.'s injuries.

At petitioners' request, proceedings were delayed for several years "to allow time to obtain counsel and file expert reports." Pet. App. 8a. On October 29, 2014, after an evidentiary hearing with testimony from expert witnesses for both petitioners and the government, and after post-hearing briefing and the submission of a supplemental expert report by petitioners, the special master denied the petition for compensation. *Id.* at 82a-158a. The special master concluded that petitioners had "fallen far short" of proving the requisite causal link between the vaccine and A.M.'s injuries. *Id.* at 158a.

Reviewing the evidence as a whole, the special master found that it was "substantially more likely than not that A.M. had a developmental delay that *pre-dated* his MMR vaccination" and therefore was not caused by it.

Pet. App. 125a. The special master noted that, among other things, when A.M. was examined five weeks after his MMR vaccination and one week after developing "acute symptoms of 'limping,'" the physician described him as having a "longstanding issue" that he is "globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills." *Id.* at 91a-92a (citation and emphasis omitted). The special master interpreted the physician's use of the word "longstanding" to mean that those conditions predated the vaccine. *Id.* at 105a-106a. The special master also found that A.M.'s limping began outside a medically accepted timeframe to attribute causation to the vaccine, and that the government's expert was more persuasive than petitioners' expert. *Id.* at 105a, 132a.

3. The CFC sustained the special master's decision. Pet. App. 31a-79a. First, the CFC rejected petitioners' argument that the arbitrary-and-capricious standard of review violated Article III of the Constitution. *Id.* at 37a n.11. "[A] Vaccine Act claim does not bar a petitioner from later filing a claim in an Article III federal court," it stated. *Ibid.* The court also found petitioners' reliance on *Bruesewitz* to be "misplaced." *Ibid.*

Second, the CFC concluded that the special master's decision was not arbitrary or capricious. Pet. App. 59a-79a. Among other things, the court determined that it was "sound" for the special master to interpret the word "longstanding" to mean that A.M.'s condition predated the vaccine, *id.* at 70a; see *id.* at 65a-68a; and it found unavailing petitioners' argument that the special master should not have found the government's expert to be more persuasive, *id.* at 70a-72a. The CFC stated that "the special master's decision shows that he carefully

considered the relevant evidence," "drew plausible inferences, and articulated a rational basis" for concluding that A.M.'s "global developmental delays preceded his MMR vaccination." *Id.* at 76a.

4. The court of appeals affirmed. Pet. App. 3a-30a. First, the court rejected petitioners' argument that Article III mandated that a federal court review the special master's decision de novo. *Id.* at 17a-22a. Specifically, petitioners argued that this Court's decision in *Bruesewitz* "rendered the Vaccine Act unconstitutional because it" made judicial remedies outside of the no-fault administrative program unavailable in many circumstances, and they argued that this "t[ook] away access to Article III courts for resolution of common law claims" in derogation of the principles articulated in *Stern* v. *Marshall*, 564 U.S. 462 (2011). Pet. App. 20a. The court of appeals disagreed. *Ibid.*

"The separation of powers concerns at play in *Stern* are not implicated by *Bruesewitz*," the court of appeals explained. Pet. App. 20a. "In the Vaccine context," it stated, "the only questions the special master addresses are those related to the fact of injury and causation." *Ibid.* "[I]t is a no fault statute that assumes the right to recovery whenever injury and causation are established." *Ibid.* "The 'design defect' question is never addressed by the Article I court or its special master program." *Ibid.* The Act also does not prohibit new adjudication of the questions of injury and causation that the special master has decided. *Id.* at 21a. A claimant can file a non-preempted tort suit, the court explained, including "a manufacturing defect claim," in which those same issues "can be revisited" in an Article III court. *Ibid.*

The court of appeals further explained that *Stern* was inapplicable and that *Bruesewitz* had no bearing on the standard of review. Pet. App. 21a-22a. *Bruesewitz* only concerned the scope of the Vaccine Act's preemption provision, the court stated, and "[t]here is no doubt Congress has authority under the Supremacy Clause to preempt state law causes of action which conflict with the federal standards and policies set forth in a duly authorized federal statute." *Id.* at 21a. "*Stern* simply does not address the preemption of state law claims; it only addresses who may decide claims that are not otherwise preempted." *Id.* at 22a.

Second, the court of appeals held that the special master's findings were neither arbitrary nor capricious. Pet. App. 22a-30a. The court concluded that "the special master thoroughly reviewed all of the relevant evidence, including the expert witnesses' testimonies and reports," and the court concluded that "the record supports his finding that A.M.'s developmental delay predated the MMR vaccination." *Id.* at 29a.

ARGUMENT

Petitioners renew their contention that this Court's decision in *Bruesewitz* v. *Wyeth LLC*, 562 U.S. 223 (2011), rendered the arbitrary-and-capricious standard of review in Vaccine Act cases unconstitutional, and that, under *Stern* v. *Marshall*, 564 U.S. 462 (2011), Article III entitles them to de novo review in federal court of the special master's determination. The court of appeals correctly rejected that argument. The court's holding does not conflict with any decision of this Court or any other court of appeals, and requiring de novo review would seriously undermine a core of purpose of the Vaccine Act: to provide a no-fault compensation scheme that "work[s] faster and with greater ease than the civil

tort system." *Bruesewitz*, 562 U.S. at 228 (quoting *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995)). Further review is unwarranted.

1. The court of appeals correctly held that the Vaccine Act's standard of judicial review is constitutional in light of *Bruesewitz* and *Stern*.

a. In *Bruesewitz*, this Court held that the Vaccine Act "pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects." 562 U.S. at 243. As the court of appeals explained, "[t]here is no doubt Congress has the authority under the Supremacy Clause to preempt state law causes of action which conflict with the federal standards and policies set forth in a duly authorized federal statute." Pet. App. 21a; see, *e.g.*, *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604 (2011); *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Cipollone* v. *Liggett Grp., Inc.*, 505 U.S. 504 (1992). Petitioners do not contend otherwise.

b. Moreover, as the court of appeals explained, "[t]he separation of powers concerns at play in *Stern* are not implicated by *Bruesewitz*" or the Vaccine Act more broadly. Pet. App. 20a. In *Stern*, the Court reiterated that Congress generally may not assign to an Article I tribunal the authority to decide "any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty." *Stern*, 564 U.S. at 484 (quoting *Murray's Lessee* v. *Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856)). But *Bruesewitz* did not assign any authority to decide common-law claims to an Article I tribunal. It merely held that the Vaccine Act preempted state-law design-defect tort claims.

Bruesewitz did not then hold that Article I special masters would instead adjudicate the preempted common-law design-defect claims. They do not. "The 'design defect' question is never addressed by the Article I court or its special masters." Pet. App. 20a. Indeed, special masters do not adjudicate any common-law claims against vaccine manufacturers or anyone else. As the court of appeals explained, "[n]o liability issues are determined by the special master; it is a no fault statute that assumes the right to recovery whenever injury and causation are established." *Ibid.* "[T]he only questions the special master addresses are those related to the fact of injury and causation." *Ibid.*

The Vaccine Act also does not prevent a federal (or state) court from deciding de novo the injury-in-fact and causation questions that a special master actually does decide. Pet. App. 21a. Rather, if unsuccessful before the special master, a claimant may "reject the judgment and seek tort relief from the vaccine manufacturer" on grounds that are not preempted, *Bruesewitz*, 562 U.S. at 228, and "revisit the very issues" of injury-in-fact and causation decided by the special master. Pet. App. 21a.

c. Petitioners contend (Pet. 20-21) that "Vaccine Act cases such as [theirs] are a substitute for actions at the common law," and that, absent preemption, they would sue "the vaccine's manufacturer for products liability design defect." Compensation under the Vaccine Act may serve a function similar to compensation under a state-law design-defect claim, but that does not mean that petitions for compensation from the United States under the Vaccine Act must be resolved de novo by an Article III court. Rather, deferential review of the special master's determination is fully consistent with Article III because a petition for compensation from the

United States under the Vaccine Act involves "public rights," where de novo review is not required. *E.g.*, *Stern*, 564 U.S. at 488-490 (discussing the distinction between "public rights" and "private rights").

"Article III does not confer on litigants an absolute right to the plenary consideration of every nature of claim by an Article III court." *Commodity Futures Trading Comm'n* v. *Schor*, 478 U.S. 833, 848 (1986). In particular, where a claimant seeks funds from the United States pursuant to a federal statute authorizing such payments, "Congress may attach to its consent such conditions as it deems proper, even to requiring that the suits be brought in a legislative court specially created to consider them. The Court of Claims is such a court." *Ex parte Bakelite Corp.*, 279 U.S. 438, 452 (1929) (footnote omitted); see *Murray's Lessee*, 59 U.S. (18 How.) at 284 (matters involving public rights "may be presented in such form that the judicial power is capable of acting on them, and which are susceptible of judicial determination, but which congress may or may not bring within the cognizance of the courts of the United States, as it may deem proper").

A Vaccine Act claim involves public rights because it arises "between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." *Crowell* v. *Benson*, 285 U.S. 22, 50 (1932); see *United States* v. *Jicarilla Apache Nation*, 564 U.S. 162, 174 (2011) (government's management of tribal trust funds is a matter of public rights, and thus government as trustee was not subject to common law disclosure duties). "[T]he Government is involved in its sovereign capacity under an otherwise valid statute creating enforceable public rights." *Atlas Roofing Co.* v.

Occupational Safety & Health Comm'n, 430 U.S. 442, 458 (1977).*

A Vaccine Act claim is also fundamentally different from "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789." *Stern*, 564 U.S. at 484 (quoting *Northern Pipeline Constr. Co.* v. *Marathon Pipe Line Co.*, 458 U.S. 50, 90 (1982) (Rehnquist, J., concurring in judgment)). It is an administrative petition filed with a federal official (the Secretary) pursuant to an administrative scheme established by federal statute, for compensation from a federal trust fund that is financed by a federal excise tax. The vaccine's manufacturer is not a party—indeed, the identity of the manufacturer need not be established and is entirely irrelevant. Compensation also does not depend on adjudication of any common-law cause of action or notion of fault, and thus it is immaterial whether the vaccine was designed or manufactured defectively. Instead, the federal government provides compensation under a no-fault scheme depending solely on questions of injury-in-fact and causation.

It thus does not create any constitutional problem that, in some cases, compensation under the Vaccine Act displaces compensation that might have been available, absent preemption, in a state-law design-defect claim. As this Court has explained in a related context,

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* A case between purely private parties may also involve "public rights" if "the right is integrally related to particular Federal Government action." *Stern*, 564 U.S. at 490-491 (discussing *Jicarilla Apache Nation*, 564 U.S. at 174). This Court's decisions do not always "provide concrete guidance" for determining whether a claim between purely private parties falls into this category. *Id.* at 494. But this Court has never called into question the principle that, when a private party seeks compensation from the federal government pursuant to a federal statute, such claims are matters of public rights.

"Congress may effectively supplant a common-law cause of action carrying with it a right to a jury trial with a statutory cause of action shorn of a jury trial right if that statutory cause of action inheres in, or lies against, the Federal Government in its sovereign capacity." *Granfinanciera, S.A.* v. *Nordberg*, 492 U.S. 33, 53 (1989) (discussing *Atlas Roofing*, 430 U.S. at 458). That is essentially what Congress has done here. The court of appeals thus correctly rejected petitioners' challenge.

2. For the reasons set forth above, the court of appeals' decision is correct and does not conflict with *Stern* or any other decision of this Court. Petitioners' position also would seriously undermine Congress's goal of deciding vaccine-injury compensation via "[f]ast, informal" administrative resolution of claims under a no-fault scheme "designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 562 U.S. at 228 (quoting *Whitecotton*, 514 U.S. at 269). Under petitioners' approach, any individual who is disappointed with a special master's decision would have a powerful incentive to appeal not just to the CFC (where review would be deferential), but also to the Federal Circuit (where they could get a second bite at the apple, with full de novo adjudication).

The Federal Circuit is also poorly equipped to conduct de novo review of special masters' compensation decisions under the Vaccine Act. Those determinations do not involve questions warranting precedential appellate decisions by a three-judge court; they involve intensely factual disputes relating to medical evidence of injury-in-fact and causation. Petitioners' approach thus would cause the Federal Circuit to duplicate the special master's effort, contributing little "to the accuracy of fact determination at a huge cost in diversion of judicial

resources." *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 575 (1985).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

JEFFREY B. WALL
Acting Solicitor General
CHAD A. READLER
Acting Assistant Attorney General
MICHAEL S. RAAB
NITIN SHAH
Attorneys

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