Nos. 99-1747 and 99-1749

In the Supreme Court of the United States

FRANK O'CONNELL AND LISA O'CONNELL,
LEGAL REPRESENTATIVES OF THEIR DAUGHTER,
KELLI-ANN O'CONNELL, PETITIONERS

v.

DONNA E. SHALALA, SECRETARY OF
HEALTH AND HUMAN SERVICES

MICHELE Y. TERRAN, AS LEGAL REPRESENTATIVE
OF JULIE F. TERRAN, A MINOR, PETITIONER

v.

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998), a provision of the National Childhood Vaccine Injury Act of 1986 that allows the Secretary of Health and Human Services to promulgate regulations embodying modifications to an initial Vaccine Injury Table set out in the Act, violates the Presentment Clause of the Constitution Art. I, § 7, Cl. 2, or represents an unconstitutional delegation of legislative power.

2. In No. 99-1749, whether the United States Court of Appeals for the Federal Circuit applies a permissible standard for proof of causation in compensation proceedings under the Act.

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OPINIONS BELOW

The opinion of the court of appeals in No. 99-1749 (99-1749 Pet. App. 1a-40a) is reported at 195 F.3d 1302. The opinion of the Court of Federal Claims in that case (99-1749 Pet. App. 41a-58a) is reported at 41 Fed. Cl. 330, and the opinion of the Special Master (99-1749 Pet. App. 59a-92a) is unreported.

The opinion of the court of appeals in No. 99-1747 (99-1747 Pet. App. 1-5) is unreported. The opinion of the Court of Federal Claims (99-1747 Pet. App. 34-41) is reported at 40 Fed. Cl. 891. The opinion of the Special Master (99-1747 Pet. App. 7-33) is unreported.

JURISDICTION

The judgments of the court of appeals were entered on October 27, 1999 (No. 99-1749) and November 1, 1999 (No. 99-1747). Petitions for rehearing were denied on February 2, 2000 (99-1747 Pet. App. 45-46; 99-1749 Pet. App. 93a-94a). The petitions for a writ of certiorari were filed on May 1, 2000 (No. 99-1749) and May 2, 2000 (No. 99-1747). 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 (the Vaccine Act or the Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (codified at 42 U.S.C. 300aa-1 *et seq.* (1994 & Supp. IV 1998)), to promote national childhood immunization programs by establishing a tax-based federal compensation scheme for children injured by vaccines, thus reducing the number of traditional tort actions filed against vaccine manufacturers. See Pet. App. 5a-6a.[1] The Act first creates a National Vaccine Program, "to achieve optimal prevention of naturally occurring human infectious diseases through immunization and to achieve optimal prevention of the adverse reactions to vaccines." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. I, at 9 (1986); see 42 U.S.C. 300aa-1 to 300aa-6. It then establishes a National Vaccine Injury Compensation Program (the

[1] Unless otherwise noted, appendix citations are to the appendix to the petition in No. 99-1749.

Program), funded by a special tax on vaccines, under which "compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-15(i); see also 26 U.S.C. 9510 (1994 & Supp. IV 1998).

Claimants under the Program may establish a right to compensation in one of two ways. An injury is presumed to have been caused by a vaccine, and therefore to be compensable, if it is listed on the Program's Vaccine Injury Table (the Table) and first manifests itself within a set period of time, also prescribed by the Table, after administration of the vaccine. See 42 U.S.C., 300aa-14(a) (1994 & Supp. IV 1998); 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(A); 42 C.F.R. 100.3(a). The Table is supplemented by a set of "qualifications and aids to interpretation" providing relevant definitions and explanations. See 42 U.S.C. 300aa-14(b) (1994 & Supp. IV 1998); 42 C.F.R. 100.3(b). The presumption of causation, where it applies, may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). If a claimant's injury is not presumed compensable under the Table, the claimant may nonetheless obtain compensation by demonstrating, by a preponderance of the evidence, that the vaccine in fact caused or significantly aggravated the injury. 42 U.S.C. 300aa-11(c)(1)(C)(ii), 300aa-13(a).

A claimant under the Program is never required to demonstrate that a vaccine was defective or that its manufacturer was negligent. The compensation available includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a) and (e). A claimant who is dis-

satisfied with an award made under the Program may reject the award and litigate her claim under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21. Applicable statutes of limitations are tolled while the claimant exhausts the alternative remedy provided by the Act. 42 U.S.C. 300aa-16(c).

The Act itself establishes an "initial" Vaccine Injury Table (the Initial Table), and it authorizes the Secretary of Health and Human Services to "promulgate regulations to modify" the Table by adding or deleting injuries or changing the onset periods that trigger a presumption of compensability. See 42 U.S.C. 300aa-14(c)(1) to (3) (1994 & Supp. IV 1998). The legislative history indicates Congress's expectation that the Secretary would make appropriate changes to the Initial Table once "research on vaccine injury and vaccine safety * * * provide[d] more definitive information about the incidence of vaccine injury." H.R. Rep. No. 908, *supra*, at 18. Changes to the Table apply to petitions for compensation that are filed after the effective date of the final regulation adopting the change. 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998).

The Act establishes an Advisory Commission on Childhood Vaccines (ACCV) that includes health professionals, legal experts, interested citizens (including parents of children with vaccine-related injuries), and federal officials. See 42 U.S.C. 300aa-5, 300aa-19. The Secretary is required to provide the ACCV with a copy of proposed regulations before issuing them for notice and comment. 42 U.S.C. 300aa-14(d) (1994 & Supp. IV 1998). The ACCV may also ask the Secretary to propose regulations to amend the Table, and it reviews such requests made by others. The Secretary must publicly explain any decision not to undertake a rule-

making proceeding in response to a request. 42 U.S.C. 300aa-14(c)(2) (1994 & Supp. IV 1998).

2. Section 312 of the Act, 100 Stat. 3779-3780, directs the Secretary to "complete a review of all relevant medical and scientific information" on the relationship between certain vaccines and illnesses, to make and publish findings on specified questions, and to "propose regulations to amend the Vaccine Injury Table * * * as a result of such findings." The Secretary arranged for the Institute of Medicine (IOM), an arm of the National Academy of Sciences, to conduct the required study, and the Institute released its report in 1991. See Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* (Christopher P. Howson et al. eds., 1991) (the IOM Report).

The Secretary referred the IOM Report to the National Vaccine Advisory Committee (NVAC), a Public Health Service task force (the Task Force), and the ACCV. Based on the report's conclusion that there was no credible evidence of prolonged neurological damage from diphtheria-pertussis-tetanus (DPT) vaccines, the Task Force and the NVAC recommended that the Table be revised to delete encephalopathy, hypotonic hyporesponsive episode (HHE), and residual seizure disorders (RSD) as conditions presumptively associated with DPT vaccination. The ACCV concurred with respect to HHE and RSD, but it recommended that the Table continue to cover some forms of encephalopathy, under a more precise standard. In 1992 the Secretary issued proposed regulations adopting the ACCV approach. See *O'Connell* v. *Shalala*, 79 F.3d 170, 174-175 (1st Cir. 1996).[2] In 1995,

[2] In 1993, the Secretary requested that the IOM review a newly published follow-up study of acute childhood neurological

the Secretary issued a final rule removing HHE and RSD from the Table, and modifying the definition of encephalopathy. See 42 C.F.R. 100.3(a) and (b)(2); 60 Fed. Reg. 7678-7696. The revised Table became effective on March 10, 1995, for all petitions filed after that date. See 42 C.F.R. 100.3(c).

Petitioners Francis and Lisa O'Connell sought judicial review of the 1995 regulation under the procedure set out in 42 U.S.C. 300aa-32. The United States Court of Appeals for the First Circuit concluded that "[t]he Secretary had authority to issue the regulations * * *, and she exercised that authority in a procedurally appropriate and substantively permissible manner." *O'Connell*, 79 F.3d at 182. In that proceeding, the O'Connell petitioners did not challenge the constitutionality of the Act.

3. *No. 99-1749* (*Terran*). Petitioner Terran sought compensation under the Act on the ground that her daughter Julie first showed signs of RSD and encephalopathy on the day after her third DPT vaccination. Neither RSD nor Julie's non-acute encephalopathy gave rise to a presumption of compensability under the revised Table. Pet. App. 79a. After considering the evidence, the Special Master concluded that petitioner had not shown by a preponderance of the evidence that the DPT vaccine caused Julie's chronic encephalopathy or her afebrile seizures. *Id.* at 87a-91a. He accordingly denied compensation. *Id.* at 91a.

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illnesses. See 60 Fed. Reg. 7685 (1995). The IOM concluded that the evidence suggested a causal relation between DPT vaccines and certain nervous system dysfunctions in children who experienced acute neurologic illness shortly after vaccination. The Secretary reopened the regulatory comment period to allow comment on the new IOM report. See *O'Connell*, 79 F.3d at 175.

a. The Court of Federal Claims sustained the Special Master's decision. Pet. App. 41a-58a. The court concluded that it lacked jurisdiction to consider petitioner's constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 47a-48a. It also held that petitioner's challenge to the revising regulations was untimely or foreclosed by previous litigation, *id.* at 48a-49a, and that application of the revised Table to petitioner's case was not impermissibly retroactive, *id.* at 49a-51a. On the merits, the court applied the standard of review set out in 42 U.S.C. 300aa-12(e)(2), and concluded that the Special Master's determinations with respect to causation were not arbitrary or capricious. Pet. App. 51a-58a.

b. The court of appeals affirmed. Pet. App. 1a-40a. Unlike the Court of Federal Claims, the court of appeals held (*id.* at 10a-16a) that petitioner was not barred from challenging the validity of the Secretary's 1995 regulations modifying the Initial Table, and that the court had jurisdiction over petitioner's claim that Congress could not constitutionally allow the Secretary to make those modifications.

Reviewing the history of the Vaccine Act (Pet. App. 5a-9a), the court explained (*id.* at 7a) that "Congress included the Initial Table in the * * * legislation, rather than delegating the creation of the first injury table to the Secretary, because it was concerned that the administrative process would significantly delay the implementation of the Vaccine Compensation Program." Congress gave the Secretary authority to promulgate regulations modifying the Table, however, because it "intended the Secretary to revise and update the Initial Table with more accurate information that would become available as a result of the research on

vaccine injuries mandated by the Vaccine Act" itself. *Id.* at 8a.

The court rejected petitioner's contention that such an arrangement violates the Presentment Clause of the Constitution (Art. I, § 7, Cl. 2). Pet. App. 17a-23a. Considering the matter in context, the court was "convinced that the Vaccine Act does not authorize the Secretary to amend or repeal portions of the Act, but rather merely grants her the power to promulgate new regulations as contemplated in the Act." *Id.* at 18a. The court noted that regulations promulgated by the Secretary "do[] not change in any way the original injury table," but rather promulgate a new Table that applies only prospectively. *Id.* at 19a. Analogizing that process to a routine "sunset" provision, the court reasoned that Congress had merely "itself decided to render the Initial Table ineffective upon the Secretary's action" in promulgating a replacement Table by regulation. *Id.* at 20a.

The court distinguished this case from *Clinton* v. *City of New York*, 524 U.S. 417 (1998), which invalidated the Line Item Veto Act, on three grounds. First, the line-item veto had to be exercised quickly, and was therefore "necessarily based on the same conditions contemplated by Congress" when it passed the affected legislation. Pet. App. 21a. In contrast, replacement of the Initial Table set out in the Vaccine Act itself by a later regulatory Table is "contingent on conditions that did not exist when [the Act] was passed." *Ibid.* Congress simply "anticipated that the facts underlying its legislation might change in the future," and granted the Secretary appropriate authority to establish a superseding Table, through the usual administrative process, "when more accurate information linking vaccines to injuries became available." *Ibid.*

Second, unlike the Line Item Veto Act, which "provided little constraint on the President's discretion to cancel a particular appropriation line item," the Vaccine Act sets forth "detailed procedures and substantive considerations" that "channel" the Secretary's discretion. Pet. App. 21a-22a. And third, whereas *Clinton* concluded that the President was "clearly contravening Congress's policy judgment when he canceled spending items under the Line Item Veto Act," under the Vaccine Act "the Secretary was executing congressional policy when she promulgated the 1995 Table." *Id.* at 22a.

The court of appeals also rejected petitioner's claim that the Vaccine Act effects an unconstitutional delegation of legislative power. Pet. App. 23a-25a. The court noted the existence of various "substantive guideposts and procedural requirements" (*id.* at 23a) under the Act: Revised Tables "must adhere to [the] same format" as the Initial Table; the Secretary must consult with the ACCV before proposing revised regulations; the compensation program automatically terminates if the total number of awards exceeds a specified number within a specified period; and the Act establishes a "broad program to study and reduce the risk of childhood vaccines," which "Congress clearly intended [to guide] the Secretary * * * when she decides to promulgate regulations to revise the injury table." *Id.* at 24a- 25a. Under those circumstances, the court concluded, "Congress provided ample guidance and limits on the Secretary's authority to promulgate revised vaccine injury tables," and therefore stayed within the permissible bounds of delegation. *Id.* at 25a.

Turning to the merits of petitioner's case, the court rejected the argument that the Special Master should have evaluated the claim using the Initial Table be-

cause Julie Terran's condition manifested itself before the effective date of the 1995 regulations. Pet. App. 25a-26a. The court explained that the Act's specific direction that new regulations would govern "petitions for compensation * * * filed after the[ir] effective date" was sufficient to "conclusively resolve[] the question" of applicability against petitioner. *Id.* at 26a.

Finally, the court considered and rejected petitioner's argument that the Special Master erred by "discounting the causation-in-fact testimony of [petitioner's] expert" and resolving the causation question against petitioner. Pet. App. at 26a-29a. The court held that the Master's conclusions with respect to the expert testimony were reasonable (*id.* at 26a-28a), and its "review of the record [did] not uncover[] any finding of fact or conclusion of law that [was] 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 29a (quoting 42 U.S.C. 300aa-12(e)(2)(B)). The court accordingly affirmed the Master's rejection of petitioner's claim.

Judge Plager dissented. Pet. App. 30a-40a. In his view, because Congress "included the initial Vaccine Injury Table in the statute itself," its further provisions "purport[ing] to empower the Secretary to modify the statutorily-created" Table were inconsistent with the Presentment Clause. *Id.* at 39a.

4. *No. 99-1747* (*O'Connell*). The O'Connell petitioners sought Vaccine Act compensation on the ground that their daughter Kelli-Ann first showed signs of RSD and encephalopathy on the day after her second DPT vaccination. 99-1747 Pet. App. 8-9 & n.2. Her symptoms did not create a presumption of compensability under the revised Table. *Id.* at 8 n.2. After considering the evidence, the Special Master concluded that petitioners had not shown by a preponderance of

the evidence that the DPT vaccine caused Kelli-Ann to suffer from encephalopathy (*id.* at 26-29) or RSD (*id.* at 30-32). She accordingly denied compensation. *Id.* at 33.

The Court of Federal Claims sustained the Special Master's decision. 99-1747 Pet. App. 34-41. As in *Terran*, the court concluded that it lacked jurisdiction to consider petitioners' constitutional argument that the Secretary could not modify the Initial Table. *Id.* at 37-38, 39-41. The court rejected petitioners' argument that the Special Master had applied too high a standard of proof to their off-Table causation claim, and instead sustained the Master's judgment that petitioners had failed to demonstrate the existence of post-vaccine symptoms meeting "any generally accepted definition of acute encephalopathy." *Id.* at 38; see *id.* at 36-39.

The court of appeals affirmed for the reasons given in its opinion in *Terran*. 99-1747 Pet. App. 1-5. Judge Plager dissented, also for the reasons given in his opinion in *Terran*. *Id.* at 4-5. The court did not reach the Secretary's argument that petitioners' constitutional claim was precluded by their failure to raise it in their previous challenge to the validity of the 1995 regulations. *Id.* at 4.

ARGUMENT

1. Petitioners argue that the Vaccine Act violates the Presentment Clause by authorizing the Secretary to promulgate a revised Vaccine Injury Table that supersedes the Initial Table set out in the Act itself. 99-1747 Pet. 9-17; 99-1749 Pet. 16-21. The court of appeals correctly rejected that contention.

The Presentment Clause regulates the enactment of laws, not Executive rulemaking or other steps in the administration of enacted laws. See, *e.g.*, *INS* v. *Chadha*, 462 U.S. 919, 953 n.16 (1983). While Congress

may not confer on the Executive the power to amend or repeal laws, see *Clinton*, 524 U.S. at 438-441, bicameral passage and presentment are not required as a check on Executive rulemaking because such "administrative activity cannot reach beyond the limits of the statute that created it." *Chadha*, 462 U.S. at 953 n.16.

In this case, the Vaccine Act expressly authorizes and contemplates the issuance of revised Vaccine Injury Tables through administrative rulemaking. See 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998). The only distinction between the authority granted to the Secretary to promulgate those Tables and innumerable other statutory conferrals of regulatory authority on the Executive is that in this instance Congress set out an "Initial Table" in the Act itself, so that there would be a basis for providing compensation under the Act during the period after its passage and before the Secretary could complete the study, consultation, and public comment steps necessary to consider and adopt a revised Table. That distinction is not enough to turn an authorized rulemaking into a statutory "amendment" that would require passage by Congress and presentment to the President.

As the court of appeals recognized (Pet. App. 17a-23a), the Secretary's exercise of her statutory authority to promulgate regulations superseding the Initial Table does not amount to an amendment or partial repeal of the Vaccine Act. The 1995 regulations, which the Act makes applicable to petitions filed after their effective date (see 42 U.S.C. 300aa-14(c)(4) (1994 & Supp. IV 1998)), simply implement Congress's direction to issue regulations making appropriate adjustments to the Initial Table in light of research conducted after the enactment of the Act. See Pet. App. 19a. Congress itself provided that once such regulations were issued

they would supersede contrary provisions in the Initial Table, although only for proceedings commenced after the effective date of the new regulations. Compare *Clinton*, 524 U.S. at 446 n.40 (provision of Rules Enabling Act, 28 U.S.C. 2072(b), that "[a]ll laws in conflict with [procedural] rules [adopted by this Court] shall be of no further force or effect after such rules have taken effect" is valid because "Congress itself made the decision to repeal prior rules upon the occurrence of a particular event—here, the promulgation of procedural rules by this Court"). Such a statutory provision is constitutionally permissible, even if it in some respects "alter[s] the substantive rights" (99-1749 Pet. 17) otherwise conferred by a particular statute. See *Touby* v. *United States*, 500 U.S. 160 (1991) (upholding conferral on the Attorney General of authority to add or remove substances from the schedules of controlled substances initially prescribed by statute); *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394 (1928) (upholding provision authorizing President to raise tariffs, above amounts fixed by statute, under certain conditions); *Field* v. *Clark*, 143 U.S. 649, 680, 690-694 (1892) (upholding provision authorizing President to "suspend" the Tariff Act "for such time as he shall deem just," thereby raising tariffs, if foreign governments were imposing "reciprocally unequal and unreasonable" tariffs on specified commodities).

The court of appeals also properly distinguished the table revision provision in the Vaccine Act from the "line-item veto" provision struck down by this Court in *Clinton* v. *City of New York*. See Pet. App. 20a-22a. Unlike the Vaccine Act, the Line Item Veto Act at issue in *Clinton* did purport to give the President the power to "cancel in whole" certain types of provisions

contained in duly enacted legislation. See 524 U.S. at 436; see also *id.* at 446-447. As the court below explained, this Court's invalidation of that authority turned in large part on the Court's conclusions that the Line Item Veto Act provided few constraints on the President's discretion to cancel particular appropriation items for his own policy reasons; required the President to act within five days of the enactment of a law, so that "the President's action was necessarily based on the same conditions contemplated by Congress" in enacting the measure; and authorized exercises of "veto" authority through which the President was "clearly contravening Congress's policy judgment" concerning the canceled items. Pet. App. 21a-22a. In the present case, by contrast, "Congress set forth detailed procedures and substantive considerations in the Vaccine Act that channel [the Secretary's] discretion" to supersede the Initial Table by regulation; regulations are to be issued under Section 300aa-14(c) after study and consultation and "when more accurate information linking vaccines to injuries bec[omes] available"; and the Secretary is implementing—not contravening—congressional policy when she issues superseding regulations in conformance with the plain provisions of the Act. *Id.* at 21a; compare *Clinton*, 524 U.S. at 443-444, 445.

2. The court of appeals also correctly rejected (Pet. App. 23a-25a) petitioners' argument (97-1747 Pet. 18-25; 99-1749 Pet. 21-26) that the Vaccine Act unconstitutionally delegates legislative power to the Secretary. While Congress may not delegate its legislative power to the Executive Branch, this Court's cases reflect "a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job

absent an ability to delegate power under broad general directives." *Mistretta* v. *United States*, 488 U.S. 361, 372 (1989). Congress may authorize the Executive to promulgate legally binding regulations, so long as it "clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Id.* at 373 (quoting *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946)).

As the court of appeals recognized, the Vaccine Act's directions to the Secretary with respect to revising the Vaccine Injury Table satisfy these requirements. As the court explained, "the Initial Table in the Act itself operates as an intelligible principle that governs subsequent, administratively created tables," because "[i]n the Initial Table, Congress identified the vaccines covered by the table, the illnesses or conditions for which compensation might be had, and the time period required for the first symptom or onset of each illness," and "revised tables must adhere to this same format." Pet App. 24a. In addition, the Act requires the Secretary to undertake further scientific study and to consult with experts and interested parties (compare *Mistretta*, 488 U.S. at 376 n.10), and then to consider, through the normal public notice-and-comment process, whether and how to modify the conditions and symptom-appearance times set out in the Initial Table. See 42 U.S.C. 330aa-1 note (Related Studies); 42 U.S.C. 300aa-14(c) (1994 & Supp. IV 1998).[3] This sensible use of the

[3] In Section 312(a) and (b) of the Act, 100 Stat. 3779-3780, for example, Congress directed the Secretary to "complete a review of all relevant medical and scientific information * * * on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis" and certain specified illnesses and conditions, and to make and publish findings (through a public consultative process) concerning whether, under what

administrative process properly combines an assignment of regulatory authority to an Executive official with more-than-adequate "substantive guideposts and procedural requirements" (Pet. App. 23a) to guide and limit its exercise—limits that are enforceable through appropriate judicial review. 42 U.S.C. 300aa-32. See, *e.g.*, *Skinner* v. *Mid-America Pipeline Co.*, 490 U.S. 212, 218-219 (1989) (citing various examples of valid conferrals of broad regulatory authority on administrative agencies).[4]

Petitioners object (see 99-1749 Pet. 23-26; 99-1747 Pet. 20-21) to Congress's decision to vest the Secretary with the authority to narrow the coverage of the Initial Table, at least in the absence of new scientific evidence definitively establishing the absence of any causal connection between a vaccine and a type of injury or condition. Nothing in the Constitution or in the text or purposes of the Act, however, supports that suggested limitation on the scope of the Secretary's authority to "add to, or delete from, the [Table's] list of injuries, conditions, and deaths for which compensation may be provided or [to] change the time periods for the first

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conditions, and how quickly such vaccines could reasonably be expected to cause or significantly aggravate those illnesses or conditions. Section 312(c) of the Act then directed the Secretary, at the same time she published those findings, to "propose regulations to amend the [Initial Table] * * * as a result of such findings." *Ibid.*

[4] See also *American Power & Light Co.* v. *SEC*, 329 U.S. 90, 105 (1946) ("Private rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations."); cf. *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 532-533 (1935) (distinguishing cases upholding broad legislative authorizations on the ground that the statutes considered in those cases provided notice and hearing procedures).

symptom or manifestation" of a compensable condition. 42 U.S.C. 300aa-14(c)(3) (1994 & Supp. IV 1998). To the contrary, Congress presumably conferred regulatory authority in those broad terms because it understood that adapting the Initial Table, in light of developing scientific knowledge, would require the exercise of informed administrative judgment that might either increase or decrease the scope of presumptive, Table-based compensability (always, of course, leaving claimants the opportunity to receive compensation by showing that a causal relationship is more likely than not on the facts of a particular case). Cf. *Touby*, 500 U.S. at 162 (upholding provisions authorizing the Attorney General to remove or add substances to initial statutory schedules of controlled substances); *Yakus* v. *United States*, 321 U.S. 414, 425 (1944) (authorized activities may "call for the exercise of judgment, and for the formulation of subsidiary administrative policy within the prescribed statutory framework").

3. Petitioner Terran contends (99-1749 Pet. 26-30) that this Court should grant review to resolve differences in the way different panels of the Federal Circuit have approached the question of "causation-in-fact" in Vaccine Act cases. Even if there were such an intra-circuit conflict, it would be a matter for the court of appeals itself to resolve. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957). But the cases petitioner cites do not announce materially different standards of proof. Compare *Knudsen* v. *Secretary of the Dep't of HHS*, 35 F.3d 543, 548-549 (Fed. Cir. 1994) (citing *Bunting* v. *Secretary of the Dep't of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991), and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)) ("The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause

and effect is 'logical' and legally probable, not medically or scientifically certain," but that conclusion must be supported by a sound and reliable medical or scientific explanation.), with *Grant* v. *Secretary of the Dep't of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (requiring "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury").

The cases petitioner Terran cites do differ in that the first two, *Grant* and *Strother* v. *Secretary of the Dep't of HHS*, 21 Cl. Ct. 365 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991), involved causation in "off-Table" cases, where the petitioner is not entitled to a presumption of compensability, while the latter two, *Knudsen* and *Bunting*, were Table cases, where the petitioner is entitled to compensation unless the Secretary can show that the claimant's condition is more likely than not traceable to an identifiable cause other than the vaccine.[5] Thus, while all four cases require the same proof of causation, they properly allocate the burden of persuasion to different parties, based on whether the claimant is entitled to a Table-based presumption of compensability. In the present cases, petitioners had the burden of showing causation-in-fact to support their non-Table claims. The Special Master and the courts

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[5] In demonstrating that "factors unrelated to the administration of the vaccine" caused a child's injury, 42 U.S.C. 300aa-13(a)(1)(B), the Secretary must meet the same standard of proof that applies to a petitioner's proof of causation in "off-Table" cases. See *Knudsen*, 35 F.3d at 548. It is not enough for the Secretary to identify some other possible cause of an injury; rather, she must show, by a preponderance of the evidence, that an identifiable alternate cause "in the particular case [was] shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." *Ibid.* (quoting 42 U.S.C. 300aa-13(a)(2)).

below concluded, after reviewing the relevant evidence, that petitioners had not borne that burden. That fact-bound determination does not warrant review by this Court.

4. We note, finally, three additional factors that weigh against review in these cases.[6] First, as the Secretary argued in the court of appeals, the O'Connell petitioners' constitutional claims are barred because they could have been, but were not, raised in petitioners' previous lawsuit, brought under the statutory provision for judicial review set out in 42 U.S.C. 300aa-32, challenging the validity of the Secretary's 1995 regulations. See p. 6, *supra*; 99-1747 Pet. App. 4 (declining to reach preclusion question in light of resolution of merits issue in *Terran*); Gov't C.A. Br. 22-29 (No. 98-5134); see generally, *e.g.*, *Federated Dep't Stores, Inc.* v. *Moitie*, 452 U.S. 394, 398-399 (1981).

Second, as the Secretary also argued below, petitioner Terran did not challenge the validity of the Secretary's 1995 regulation in the manner and within the time specified by Congress in 42 U.S.C. 300aa-32. See Pet. App. 13a-16a (rejecting this argument), 48a-49a (accepting the argument, at least for non-constitutional claims); Gov't C.A. Br. 18-20 (No. 98-5161). Although the court of appeals disagreed with the Secretary's argument that the failure to bring such a challenge precluded petitioner Terran's present suit, that question would remain open should the Court

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[6] In light of these factors, and because petitioners do not rely upon (or even cite) the District of Columbia Circuit's decision in *American Trucking Associations* v. *United States Environmental Protection Agency*, 175 F.3d 1027 (1999), there is also no reason to hold the petitions in these cases pending this Court review of that decision in No. 99-1257, *Browner* v. *American Trucking Associations*, cert. granted (May 22, 2000).

grant review. See, *e.g.*, *Northwest Airlines, Inc.* v. *County of Kent*, 510 U.S. 355, 364 (1994); *Thigpen* v. *Roberts*, 468 U.S. 27, 29-30 (1984).

Third, Section 322 of the original Vaccine Act, 100 Stat. 3783, sets out a somewhat unusual "nonseverability" clause: "If any provision of this title [including provisions codified at 42 U.S.C. 300aa-1 through 300aa-34] or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid."[7] The existence of that provision underscores that petitioners' constitutional challenge to the Act's grant of regulatory authority to the Secretary also raises potentially difficult questions of remedy, severability, and redressability. Compare *Chadha*, 462 U.S. at 931-935 (addressing severability and related standing argument); *McCorkle* v. *United States*, 559 F.2d 1258, 1261 (4th Cir. 1977) (concluding that legislative veto provision was not severable and dismissing action), cert. denied, 434 U.S. 1011 (1978); cf. *Friends of the Earth, Inc.* v. *Laidlaw Envtl. Servs., Inc.*, 120 S. Ct. 693, 703-704, 706-708 (2000) (treating redressability as an aspect of Article III standing); Israel Friedman, *Inseverability Clauses in Statutes*, 64 U. Chi. L. Rev. 903 (1997). The possible need to address those issues before reaching the questions petitioners seek to present counsels against granting review in these cases.

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[7] Section 322 has been amended in ways not material to the point made here. See 42 U.S.C. 300aa-1 note (severability).

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted.

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