

**In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS**

No. 17-2020V
(to be published)

SARAH NEAL *and* RICHARD C. NEAL *
parents of deceased infant, C.N., *

Special Master Corcoran

Petitioners, *

Filed: July 24, 2018

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Decision without Hearing;
Dismissal; Vaccine Act
Construction; 1 U.S.C. § 8
definition of child; Claim
based on *in utero* receipt of
vaccine.

Respondent. *

Phyllis Widman, Widman Law Firm LLC, Ocean City, NJ, for Petitioners.

Traci Patton, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION DISMISSING CASE¹

On December 22, 2017, Sarah and Richard Neal, parents of deceased infant, C.N., filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² In it, the Neals alleged that the Tdap vaccine Mrs. Neal received on December 22, 2015, while C.N. was in gestation, caused him to be delivered stillborn on December 24, 2015. Petition at 1. At the same time this matter was initiated, Mrs. Neal filed a

¹ This Decision will be posted on the Court of Federal Claims’s website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act.

separate petition on her own behalf but based upon the same tragic factual occurrence. *See Neal v. Sec’y of Health & Human Servs.*, No. 17-2021, filed Dec. 22, 2017 (ECF No. 1).

Respondent interposed a motion to dismiss this case (but not the simultaneously-filed matter)³ on April 6, 2018. *See* Motion to Dismiss (ECF No. 10) (“Mot.”). In it, he stresses the undisputed fact that C.N. was delivered deceased. Ex. 2 at 57. As a result, a recent amendment to the Vaccine Act permitting claims filed on behalf of children alleging injuries sustained *in utero* after a mother’s vaccination did not apply – because the Vaccine Act (through its incorporation of a federal statutory definition of “child”) requires that an allegedly injured child be born alive to maintain such a claim. Mot. at 2-3, *citing* 21st Century Cures Act, Pub. L. No. 115-255, 130 Stat. 1033, 1152 (Dec. 13, 2016) (hereinafter, the “Vaccine Act Amendment”); 1 U.S.C. § 8(a) and (b). Accordingly (and although Mrs. Neal’s individual claim was not similarly deficient), Petitioners had failed to state a cognizable claim on C.N.’s behalf, and this action warranted dismissal.

Petitioners filed a brief opposing the motion to dismiss on May 24, 2018. *See* Petitioners’ Opposition (ECF No. 14) (“Opp.”). Their opposition includes both attacks against Respondent’s construction of the Vaccine Act Amendment and policy arguments. Opp.at 1. With respect to the former, Petitioners maintain that the same definition section of the U.S. Code for “child” includes additional language suggesting that the “born alive” provision cannot be interpreted to limit the rights of the child before birth – meaning that the alleged *in utero* effects of a vaccine should be actionable regardless of whether a fetus is ever later born. *Id.* at 2-3, *citing* 1 U.S.C. § 8(c).

Next, Petitioners make a lengthy series of arguments maintaining that Respondent’s proposed interpretation of the Vaccine Act Amendment is contrary to, or unreasonable in light of, established law. Thus, they reference “many examples of states in the U.S. that recognized a torts claim on behalf of an unborn child who died *in utero*,” citing a single case decided by Ohio’s Supreme Court. Opp. at 5-6. They note the existence of fetal homicide laws, as well as dictionary definitions that allow for the possibility of an “unborn” child. *Id.* at 7-8. And they invoke common law principles that they argue also support the reasonableness of understanding the extent of an unborn child’s rights. *Id.* at 8-9.

Finally, Petitioners propose that if in fact Respondent’s interpretation of the Vaccine Act Amendment is accurate, then the Amendment *itself* constitutes a violation of the U.S. Constitution in several ways. First, it violates the due process clause of the Fifth Amendment to the U.S. Constitution, because the interpretation offered by Respondent would serve to “deprive”

³ Indeed, Respondent’s Reply, dated June 29, 2018 (ECF No. 18), in support of the present motion to dismiss expressly acknowledges that Mrs. Neal’s claim meets the pleading requirements of the Vaccine Act Amendment (although he does not concede that she will ultimately succeed in proving entitlement). Reply at 4 n.5.

C.N. of life without due process, by denying Petitioners the opportunity to obtain redress for an *in utero*-suffered injury. Opp. at 9. Second, the Vaccine Act Amendment violates the equal protection clause of the Fourteenth Amendment (as incorporated in the Fifth Amendment) by distinguishing the rights of unborn from delivered-live children. *Id.* at 10-11. Third, the Vaccine Act Amendment is overly broad in application, resulting in an unlawful denial of a right of redress for C.N.'s injury under the First Amendment (which guarantees the right to petition the Government). *Id.* at 10. And it discriminates on the basis of age. *Id.* at 11.⁴

Respondent filed a reply in support of his motion to dismiss on June 29, 2018. Reply (ECF No. 18). He reiterates, with additional quotation of the operable language from the Vaccine Act Amendment (as well as an administrative rulemaking process seeking input on what vaccines should be added to the Table to effect the Amendment's purpose) that the scope of the additional cause of action was limited to "live-born" children. Reply at 2-3. He also maintains that this somewhat exclusionary understanding of what a "child" is comports with the requirement to construe narrowly the relevant language, given that a Vaccine Act claim reflects Congress's determination to waive sovereign immunity. *Id.* at 5-6. Beyond this, Respondent questions the relevance of conflicting state or common law definitions of "child," noting that federal law definitions preempt application of alternative definitions from such other sources. *Id.* at 4-5. Respondent otherwise rejects Petitioners' Constitutional arguments, noting that the cause of action created by the Vaccine Act is only subject to review under a "rational basis" standard. *Id.* at 6-7 (citing *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 787-88 (1996)).

ANALYSIS

Construing the terms and provisions of the Vaccine Act entails balancing broad policy concerns against the application of long-held, oft-repeated rules for careful statutory construction in the federal courts. On the one hand, it is surely the case that "[r]emedial legislation like the Vaccine Act should be construed in a manner that effectuates its underlying spirit and purpose." *Cloer v. Sec'y of Health & Human Servs.*, 675 F.3d 1358, 1362 (Fed. Cir. 2012), *aff'd sub nom.*, *Sebelius v. Cloer*, 569 U.S. 369 (2013). At the same time, there is ample authority for the proposition - especially where a claim may be brought against the United States, as here, and thus constitutes a partial waiver of sovereign immunity - that strict construction of the Act's provisions is required. *Hoffman v. Sec'y of Health & Human Servs.*, No. 90-3451V, 1995 WL 103334, at *2 (Fed. Cl. Spec. Mstr. Feb. 21, 1995) (collecting case law supporting proposition); *but see Burch v. Sec'y of Health & Human Servs.*, No. 99-946V, 2010 WL 1676767, at *7 (discussing above jurisprudential concepts but concluding, in light of more recent Supreme Court case law and in connection with interpretation of the Vaccine Act, that there has occurred a

⁴ Petitioners' Opposition also addresses arguments raised by Respondent about the underlying merits of the claim, irrespective of whether it fails to state a cause of action based on the amendment's definition of "child." Opp. at 11-13. My decision does not turn on these matters, however (and it is likely they will be relevant to the parallel claim brought solely by Mrs. Neal), and I therefore do not address them at this time.

“general relaxation” in how strictly the sovereign immunity doctrine should be applied when constructing statutes effecting waiver of it like the Vaccine Act).

The portion of the 21st Century Cures Act pertaining to the Vaccine Act and relevant to the pending motion states as follows:

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended by adding at the end the following:

<< 42 USCA § 300aa–11 >>

“(f) MATERNAL IMMUNIZATION.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant *and any child who was in utero at the time such woman received the vaccine* shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

“(2) DEFINITION.—As used in this subsection, the term ‘child’ shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term ‘include’ in subsection (a) of such section were replaced with the term ‘mean’.”.

<< 42 USCA § 300aa–11 >>

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding “A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.” at the end.

Vaccine Act Amendment (130 Stat. at 1152) (emphasis added). The question of whether an infant *in utero* had in fact been “administered” a vaccine, for purposes of bringing a Vaccine Act claim, had in the past limited many otherwise-meritorious claims and caused a great deal of perplexed reasoning by special masters. *See, e.g., Burch*, 2010 WL 1676767, at *7-8. As the above statutory language suggests, a goal in amending the Vaccine Act in this manner was to codify the availability of a cause of action for receipt of a vaccine both to the expecting mother and her infant (with, of course, the proper parties in interest acting as representative petitioners),

even though that infant received the vaccine indirectly, from his mother and while *in utero*. See Mot. at 2-3. But this language does not resolve the present question.

The other relevant statutory provision bearing on the present motion is the United States Code’s definition of “child.” 1 U.S.C. § 8. As that provision states,

(a) In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words “person”, “human being”, “child”, and “individual”, shall include [or “mean,” as the Vaccine Act Amendment specifies] every infant member of the species homo sapiens who is *born alive* at any stage of development.

(b) As used in this section, the term “born alive”, with respect to a member of the species homo sapiens, means *the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles*, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.

(c) Nothing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being “born alive” as defined in this section.

1. U.S.C.A. § 8 (2018) (emphasis added).

Here, Petitioners argue against a plain reading of the definition of the term “born alive,” which expressly modifies what a “child” is for purposes of the Vaccine Act Amendment. There is no dispute that C.N. was *not* “born alive” -- and a reasonable reading of Section 8(b) suggests this is a precursor element of the definition of child in Section 8(a). Accordingly, because the facts of this case do not fit the requirements of the Vaccine Act Amendment for bringing a claim on an infant’s behalf for *in utero* vaccine injury, the claim cannot be maintained.

My interpretation is consistent with what other federal courts⁵ have determined, in construing different federal statutes that might be read to create a cause of action to a child while *in utero*. In *Sheff v. United States Dep’t of Justice – Civil Div., Rad. Exp. Comp. Pgm.*, No. 17-

⁵ I have not found any Federal Circuit or Court of Federal Claims decisions interpreting the relevant “born alive” definition.

2153, 2018 WL 2058180 (10th Cir. May 2, 2018), for example, the 10th Circuit ruled that a particular federal statute - (the Radiation Exposure Compensation Act (“RECA”)) - intended to create a cause of action for individuals injured as a result of nuclear testing or employment in the uranium industry - did not apply to individuals negatively exposed *in utero* to radiation, since that exposure had occurred “prior to birth.” *Sheff*, 2018 WL 2058180, at *2. In so holding, the *Sheff* court distinguished RECA from the Vaccine Act amendment, which *did* create a cause of action arising *in utero*. But RECA, like the present Vaccine Act Amendment, relies on the same Section 8 definitions relevant herein – definitions that the *Sheff* court recognized *required* a live birth for the cause of action to be viable.

Federal statutes also creating liability for *in utero* harm to infants similarly illustrates the propriety of my construction of the Vaccine Act Amendment. The Unborn Victims of Violence Act, 18 U.S.C. § 1841, not only applies to injurious acts committed against a child *in utero*, like the Vaccine Act Amendment, but specifically includes its own definition of “unborn child” that does *not* incorporate or refer to the “born alive” language from Section 8(b). 18 U.S.C.A. § 1841 (d) (2018) (“As used in this section, the term “unborn child” means a child *in utero*, and the term “child *in utero*” . . . means a member of the species homo sapiens, at any stage of development, who is carried in the womb”). The Act Amendment, by contrast, does not go that far in extending its views about harms done to infants *in utero* to permit causes of action to be brought on their behalf even if they are never “born alive.”

It is worth noting that the seeming unfairness of this construction of the Vaccine Act Amendment should be weighed against the existence of Mrs. Neal’s parallel claim (which Respondent has not moved to dismiss). Even if the facts of this case prevent the Neals from asserting a claim on C.N.’s direct behalf, Mrs. Neal still has her own claim, with all attendant damages (including pain and suffering) available for that loss. As a result, the tragedy for which the Neals presently seek recompense under the Vaccine Act has not been rendered beyond remedy (and thus in contravention of the remedial purposes of the Act and this particular amendment) simply because construction of the Amendment does not permit the claim.

Petitioners’ other arguments in favor of their preferred construction of the Vaccine Act Amendment are no more successful than the more direct challenges discussed above. First, arguments that certain provisions of the Vaccine Act could violate the Constitution have been raised, and disposed of, before numerous times. *See, e.g., Black v. Sec’y of Health & Human Servs.*, 93 F.3d 781, 787-88 (1996) (“the Vaccine Act does not implicate any fundamental right, for a noncontractual claim to receive funds from the public treasury enjoys no constitutionally protected status”) (citing *Weinberger v. Salfi*, 422 U.S. 749, 772 (1975) (internal quotations omitted)); *see also Leuz v. Sec’y of Health & Human Servs.*, 63 Fed. Cl. 602, 607-612 (2005) (finding the same). At bottom, the Court of Federal Claims has repeatedly recognized that the remedial nature of the Vaccine Act means that its provisions are only subject to review on a

rational basis standard, and has upheld its provisions repeatedly on that basis. *Black*, 93 F.3d at 787.

The Court has also affirmed the special masters's decisions that the Act's statute of limitations did not violate petitioner's "due process" and "equal protection" rights. *See Cloer v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 141 (2008), *rev'd on other grounds*, 603 F.3d 1341, *aff'd en banc*, 654 F.3d 1322 (Fed. Cir. 2011). A "rational basis" test applies because no fundamental right is at stake, and the statute of limitations is rationally related to the purposes of the Vaccine Act: (1) settling the claims quickly and easily, and (2) protecting manufacturers from uncertain liability and thus discouraging the production of vaccines. *Id.* at 151-52.

Second, Petitioners' arguments about the Vaccine Act Amendment's definition of child as contrary to state or common law are unpersuasive. As Respondent has observed, Congress has the authority under the Supremacy Clause to preempt state or common law when it conflicts with policies set forth in a federal statute. Reply at 4-5; *see Milik v. Sec'y of Health & Human Servs.*, 822 F.3d 1367, 1378 (Fed. Cir. 2016) ("[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 . . ."). Accordingly, the availability of relief under state law to an infant *not* "born alive" does not invalidate a contrary definition of the scope of such relief under federal law. In any event, as observed above there *are* other federal statutes that incorporated their own definition of "child" despite the language in 1 U.S.C. § 8. That did not occur here, and it cannot be said to contravene the purposes of the Vaccine Act that Congress did not so choose to do in this case.

Accordingly, and for the reasons set forth above, the present matter fails to state a proper claim under the requirements of the Vaccine Act Amendment, and it is accordingly DISMISSED.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master