

Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Guam in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated on-scene representative.

(2) This safety zone is closed to all persons and vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

(d) *Enforcement period.* This safety zone will be enforced at a specified date between February and April. The Coast Guard will provide advance notice of enforcement and a broadcast notice to mariners to inform public of specific date.

Dated: January 12, 2021.

**Christopher M. Chase,**

*Captain, U.S. Coast Guard, Captain of the Port, Guam.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### 42 CFR Part 100

RIN 0906-AB24

### National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

**AGENCY:** Public Health Service, Health Resources and Services Administration (“HRSA”), Department of Health and Human Services (“HHS” or the “Department”).

**ACTION:** Final rule.

**SUMMARY:** The Secretary finalizes the proposed rule to amend the Vaccine Injury Table (Table) by regulation. This

final rule will have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after this final rule become effective. This final rule does not impact COVID-19 vaccines or PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID-19 vaccines.

**DATES:** This final rule is effective on February 22, 2021.

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program’s website, <https://www.hrsa.gov/vaccinecompensation/>, or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at [vaccinecompensation@hrsa.gov](mailto:vaccinecompensation@hrsa.gov); or by telephone at (855) 266-2427.

**SUPPLEMENTARY INFORMATION:** This is a final rule by which HHS amends the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration, vasovagal syncope, and Item XVII from the Vaccine Injury Table.

#### I. Background and Purpose

Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. Almost all individuals who are vaccinated have no serious reactions.<sup>1</sup> Nonetheless, in the 1980s, Congress became concerned that a small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.<sup>2</sup> Claimants alleging vaccine-related injuries in civil litigation encountered a time-consuming, expensive, and often inadequate system.<sup>3</sup> Moreover, increased litigation against vaccine manufacturers resulted in difficulties in their ability to secure affordable product liability insurance,

<sup>1</sup> National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., <https://www.hrsa.gov/vaccine-compensation/index.html> (last reviewed Jan. 2020).

<sup>2</sup> H.R. Rep. No. 99-908, pt. 1, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends that individuals be vaccinated against a wide range of illnesses and diseases. See Recommended Vaccines by Age, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (last reviewed Nov. 22, 2016).

<sup>3</sup> H.R. Rep. No. 99-908, at 6.

stabilize vaccine prices and supply, and enter the market.<sup>4</sup>

Therefore, Congress enacted the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. 300aa-1 *et seq.*) (“Vaccine Act” or “the Act”), which established the National Vaccine Injury Compensation Program (VICP). The objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated. Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), rather than the civil tort system, with a copy served on the Secretary, who is the Respondent. The U.S. Department of Justice (DOJ) represents HHS in Court, and the Court, acting through judicial officers called Special Masters, makes the final decision as to eligibility for, and the type and amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating what is referred to as a “Table injury.” That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the “Vaccine Injury Table” (Table)—corresponding to the vaccination in question; and (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor unrelated to the vaccination (*see* 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(B), and 300aa-14(a)).

42 U.S.C. 300aa-14(c) and (e) permit the Secretary to revise the Table. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illnesses, disabilities, injuries, or conditions covered, and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the Table’s legal presumption of causation. The final category of the Table, “Item

<sup>4</sup> *See id.* at 4-6.

XVII,” includes “[a]ny new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.”<sup>5</sup> Two injuries—Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope—are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are deemed covered under the VICP prior to being added to the Table as a separate vaccine category through Federal rulemaking.

The Department previously issued a notice of proposed rulemaking that proposed to remove SIRVA, vasovagal syncope, and Item XVII from the Vaccine Injury Table found at 42 CFR 100.3. The Department did so for the reasons set forth in the proposed rule.<sup>6</sup>

Pursuant to the Vaccine Act, HHS provided the proposed revisions to the Vaccine Table to the ACCV.<sup>7</sup> The ACCV considered the proposed changes set forth in the proposed rule on March 6, 2020 and May 18, 2020. Four members of the ACCV also held a workgroup meeting on April 3, 2020 to discuss the proposed changes. On July 16, 2020, the proposed rule went on public display, with a comment period that ended on January 12, 2021.<sup>8</sup> On November 9, 2020, the Department held a public hearing pursuant to 42 U.S.C. 300aa–14(c)(1) via teleconference to discuss the proposed rule.<sup>9</sup>

The Department now finalizes the proposed rule to remove SIRVA and vasovagal syncope from the Table found at 42 CFR 100.3(a) and to remove the corresponding descriptions of those injuries—“Qualifications and Aids to Interpretation” (QAI)—from 42 CFR 100.3(c). This decision is based upon a review of the relevant statutory provisions and the scientific literature, as well as the Department’s experience since SIRVA and vasovagal syncope were added to the Table. The Department also finalizes its proposal to remove Item XVII from the Table found at 42 CFR 100.3(a), because the Department has serious concerns that Item XVII is contrary to applicable law,

for the reasons set forth below. The Department finalizes this final rule for the reasons set forth in the proposed rule. This final rule does not impact COVID–19 vaccines or PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID–19 vaccines.

## II. Discussion of, and Response to, Public Comments

What follows is a summary of the public comments the Department received on the notice of proposed rulemaking for this rule, which had a comment period that ended on January 12, 2021, and the comments received at the public hearing on the proposed rule. The Department received 763 comments on the proposed rule. Commenters included patients, family and friends of patients, vaccine lawyers, rehabilitation counselors, nurses, doctors, legal clinics, law firms, law schools, biotech trade associations, pharmacist acclimations, drug store associations, and non-profits. The majority of commenters made statements in opposition to the proposed rule, although some commenters supported the proposed rule.

The public hearing was conducted on November 9, 2020 from 10:00 a.m. till 3 p.m. via Adobe connect teleconference. 34 comments were provided during the public hearing on the proposed rule. Commenters included those who experienced SIRVA injuries, doctors, vaccine lawyers, representatives from vaccine legal clinics, law professors, representatives from biotechnical associations, and representatives from vaccine information associations. All commenters who spoke at the public hearing were in opposition to the proposed rule. Below are summaries of the comments and the Department’s responses.

### Section I: Comments Regarding Vaccines in General

*Comment:* Many commenters expressed concerns over the safety of vaccines in general. Some believe that all chemicals in vaccines are harmful to the body and cause bone and organ deterioration. Some believe that all vaccines should be stopped entirely. Others called for a complete moratorium on vaccines until all negative side effects are gone. Some commenters believe that vaccine and pharmaceutical companies are evil and have bought the government to push unsafe vaccines. They stress that vaccines are useless and unsafe and the very fact that the VICP

is in existence proves that vaccines are unsafe.

*Response:* Vaccines are one of the greatest success stories in public health. Through use of vaccines, we have eradicated smallpox and nearly eliminated wild polio virus. The number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough is at an all-time low. The United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)’s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC’s ISO data show that the current U.S. vaccine supply is the safest in history.<sup>10</sup> Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

*Comment:* Some commenters described bad reactions they, or their children, personally experienced from a range of vaccines to argue that there should be an end to mandated vaccines for children.

*Response:* The Department sympathizes with all those who have experienced negative reactions to vaccines. Vaccination is one of the best ways to protect against potentially harmful diseases that can be very serious, may require hospitalization, or even be deadly. Almost all individuals who are vaccinated have no serious reactions.<sup>11</sup> Nonetheless, in the 1980s, Congress became concerned that a small number of children who received immunizations had serious reactions to them, and it was not always possible to predict which children would have reactions, or what reactions they would have.<sup>12</sup> Therefore, Congress enacted the

<sup>10</sup> <http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html>.

<sup>11</sup> National Vaccine Injury Compensation Program, Health Resources & Servs. Admin., <https://www.hrsa.gov/vaccine-compensation/index.html> (last reviewed Jan. 2021).

<sup>12</sup> H.R. Rep. No. 99–908, pt. 1, at 6 (1986). Even though in rare instances individuals may have adverse reactions to vaccines, the Centers for Disease Control and Prevention (CDC) recommends

<sup>5</sup> 42 CFR 100.3(a).

<sup>6</sup> See 85 FR 43794 (July 20, 2020) (“proposed rule”).

<sup>7</sup> The Department first provided the proposed revisions to the Table and requested recommendations and comments by the ACCV on or about February 15, 2020.

<sup>8</sup> National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 FR 43794 (July 20, 2020).

<sup>9</sup> <https://www.regulations.gov/document?D=HRS-2020-0002-0373>.

National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–1 *et seq.*) (Vaccine Act), which established the National Vaccine Injury Compensation Program (VICP). The objectives of the VICP are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be federally compensated.

While the federal government recommends that individuals be vaccinated against a wide range of illnesses and diseases, it does not mandate them. Each state decides which vaccines are required for child's enrollment and attendance at a childcare facility or school in that state. Vaccination requirements and allowable exemptions vary by state.<sup>13</sup>

*Comment:* Commenters believe that there should be no vaccines that contain metals, formaldehyde, preservatives, fetal tissue, and other potentially harmful ingredients to humans.

*Response:* That is beyond the scope of this final rule. For more information on the contents of vaccines and their safety, please see <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines>.

*Comment:* Some commenters believe that vaccines are an attempt to supersede their rights as parents, and this regulation should be abandoned.

*Response:* The federal government is not trying to supersede parent's rights. The purpose of vaccines are to eradicate diseases and to reduce the number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough. This regulation does not address parents' rights with respect to their children.

*Comment:* A commenter expressed anger about the Gardasil HPV vaccine causing injury and death.

*Response:* There is a safe and effective HPV vaccine that can prevent the infections that most commonly cause cancer. Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant; 9vHPV) was approved by the FDA for use in 2014. The safety of Gardasil 9 was studied in clinical trials

that individuals be vaccinated against a wide range of illnesses and diseases. See Recommended Vaccines by Age. Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> (last reviewed Jan. 2021).

<sup>13</sup> More information about state vaccination requirements for daycare and school entry can be found at <https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html> (last reviewed Jan. 2021).

with more than 15,000 participants before it was licensed and continues to be monitored. Gardasil 9 protects against 9 types of cancer-causing HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. For more information on the HPV vaccine, side effects, and who should and should not receive this vaccine, see <https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html>.

*Comment:* Some commenters asked to make vaccines optional. They believe that vaccines should not be mandated. Commenters believe that all vaccines should be voluntary. Many commenters contended that they are not. Many expressed a strong desire against being forced to get any vaccine, specifically the COVID–19 vaccine.

*Response:* State laws establish vaccination requirements for school children and some state healthcare workers. Revision of state laws and requirements are not within the scope of this final rule.

*Comment:* Some commenters expressed concern that their jobs made it mandatory to have vaccines. They believe that since their jobs make it mandatory, all related injuries should be compensated by the government.

*Response:* Employment requirements are beyond the scope of this final rule.

*Comment:* Some commenters believe that all of the studies supporting vaccines are biased and created out of fear of the “vaccine lobby.”

*Response:* Vaccines are one of the greatest success stories in public health. Through use of vaccines, we have eradicated smallpox and nearly eliminated wild polio virus. The number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough is at an all-time low. The United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.<sup>14</sup> Also, regulating clinical research and reviewing the safety of

<sup>14</sup> <http://www.cdc.gov/vaccin19esafety/ensuringsafety/history/index.html>.

vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

## Section II: COVID–19 Vaccine Comments

*Comment:* Some commenters expressed concern that the proposed rule did not add the COVID–19 vaccine to the Table. Some commenters believe that the Notice of Proposed Rulemaking would stop the automatic addition of the COVID–19 vaccine to the Vaccine Injury Table. Some believe the COVID–19 vaccine should be added to the Table to make the general public feel better about taking the vaccine; they believe that the change in the Table will increase fear of vaccination. Some commenters believe that since the COVID–19 vaccine is not included on the Table, it is unsafe. Others are concerned that the Government will mandate the COVID–19 vaccine, and that the changes to the Table are an attempt by the government to shield itself from any responsibility to compensate for COVID–19 vaccine related injuries. Other commenters asked if someone was injured by the COVID–19 vaccine, how would they be compensated.

*Response:* This final rule has zero impact on inclusion of the COVID–19 vaccine on the Table. The COVID–19 vaccine can separately be added to the Table, but the Department needs to follow the process specified in 42 U.S.C. 300aa–14(c)–(d) to do so. This includes that the ACCV recommend that the COVID–19 vaccine be added, or opine on the Department's recommendation to add the COVID–19 vaccine to the Table. Prior to COVID–19 vaccines being added to the Table, injuries resulting from these vaccines can be compensated under the Countermeasures Injury Compensation Program (CICP).

The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP and filing a claim are available at the toll-free number 1–855–266–2427 or the CICP's website, <https://www.hrsa.gov/cicp/>.

*Comment:* Commenters believe that it is suspicious that the Administration is trying to remove injuries from the Table “secretly” during the COVID–19 pandemic. Other commenters suggested that the Department should not remove SIRVA from the Table at a time when millions more vaccines are being administered against COVID–19.

*Response:* The Department respectfully disagrees that injuries are

being removed from the Table “secretly.” The ACCV publicly discussed the proposal on March 6, 2020 and May 18, 2020. Recordings of both discussions are publicly available at <https://www.hrsa.gov/advisory-committees/vaccines/meetings.html>. The Department subsequently published the Notice of Proposed Rulemaking in the **Federal Register** and provided a 180-day public comment period. It also held a public hearing on the proposed rule on November 9, 2020. The fact that the commenters were able to comment on the proposed rule indicates that SIRVA and vasovagal syncope are not being removed “secretly.” This final rule has zero impact on the COVID–19 vaccine, which is not currently on the Table. Those injured by the COVID–19 vaccine can recover from the VICP if they satisfy the statutory and regulatory prerequisites.

*Comment:* A commenter expressed anger about the COVID–19 vaccine altering the very DNA of its recipient.

*Response:* This comment is outside the scope of this rulemaking. The Department notes, though, that COVID–19 mRNA vaccines do not affect or interact with DNA in any way.<sup>15</sup>

*Comment:* Some commenters asked the Department to consider giving people stimulus checks in exchange for receiving the COVID–19 vaccine.

*Response:* Whether to provide stimulus checks for receiving the COVID–19 vaccine is outside the scope of this final rule.

*Comment:* One commenter asked the Department to reconsider removing SIRVA and vasovagal syncope from the Table because nurses, and those on the medical front line, need protection from liability, especially considering the overwhelming year they have had due to the COVID–19 pandemic.

*Response:* The Department thanks front-line workers for the tremendous work they have done over the past year. This final rule does not impact PREP Act immunity for Covered Persons (as defined in the PREP Act) who manufacture, distribute, order, or administer COVID–19 vaccines. Under the PREP Act and the Secretary’s March 10, 2020 PREP Act declaration, as amended, during the effective period of the declaration, Covered Persons are immune from suit and liability (absent willful misconduct) 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.<sup>16</sup>

### *Section III: General Support for the Proposed Rule*

*Comment:* Some commenters believe that there is no good rationale to include adverse events that are due to the physical administration of the vaccine rather than the effects of the contents. Commenters believe keeping those events covered by the program actually waters down the intent of the program and pulls away resources from the people who were actually affected by the vaccines themselves.

*Response:* The Department agrees.

*Comment:* Some commenters believe that the high number of SIRVA and vasovagal syncope cases submitted to the VICP has led to a falsely elevated number of reported side effects and reinforcing the “fear” of receiving vaccines by those who may be uninformed.

*Response:* The Department agrees. Since the scientific literature indicates that SIRVA and vasovagal syncope results from poor vaccination technique and the act of injection, rather than the vaccine components, removing SIRVA and vasovagal syncope from the Table would more accurately reflect the number of reported side effects actually caused by vaccine components. Such claims, which are not associated with vaccines or their components, therefore erroneously suggest that vaccines are less safe than they in fact are.

*Comment:* Some commenters believe that SIRVA and vasovagal syncope cases submitted to the VICP has also contributed to a delayed process in awarding monies to those with valid claims related to the vaccine itself.

*Response:* The Department agrees.

*Comment:* Some commenters believe the federal government is not the place to lodge a complaint related to the administration of a vaccine. The appropriate place to do this is through the traditional court system or through practitioner licensing boards. They believe that current use and the number of claims for shoulder injury in adults are against the intent and spirit of the original law.

*Response:* The Department thanks the commenters for these comments. It is the Department’s belief that Congress intended for the Vaccine Act’s compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA and

vasovagal syncope are generally not those types of injuries or illnesses. With proper injection technique, SIRVA is likely preventable. The scientific literature also suggests that those administering vaccines can take steps to significantly reduce the likelihood of vasovagal syncope.

### *Section IV: General Concerns*

*Comment:* Many commenters believed that vaccine or pharmaceutical companies should be solely liable for all negative side effects caused by their vaccines. They called for the repeal of the laws which grant vaccine manufacturers immunity.

*Response:* The National Childhood Vaccine Injury Act of 1986 was passed by Congress. To repeal the Act would require a statutory amendment and thus is not within the scope of this final rule.

*Comment:* Some commenters fear that the proposed rule will disband the entire VICP.

*Response:* This final rule is not disbanding the VICP. For the most part, this final rule reverts to the status quo as of January 2017. The one additional change, removing Item XVII, is being done because the Secretary has serious concerns that Item XVII does not comport with applicable law. All vaccines currently on the Table, and the vast majority of injuries currently on the Table, will remain on the Table after this final rule becomes effective.

*Comment:* Many commenters stated that the National Vaccine Injury Compensation Program covers injuries caused not only by the contents of the vaccine, but also the administration of the vaccine. They stated that but for the vaccine, there would not be a faulty administration, and there would not be a SIRVA injury. Many other commenters stated that all injuries, whether caused by the contents of the vaccine or by faulty administration of the vaccine, should be covered by the VICP. Commenters stated that HHS incorrectly interpreted the Vaccine Act to preclude claims involving “negligence by the vaccine administrator.” This commenter stated that contrary to the HHS interpretation of the Act, legislative history shows that Congress expressly indicated that it sought to broadly cover all injuries or death associated with vaccine administrations.

*Response:* The Secretary respectfully disagrees with the comment that whether or not SIRVA is caused by faulty administration the VICP should cover the injuries. The Department has concluded that the Vaccine Act should be read as not applying to cover injuries, like SIRVA and vasovagal syncope, which involve negligence by the vaccine

<sup>15</sup> More information about how COVID–19 mRNA vaccines work can be found at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>.

<sup>16</sup> 42 U.S.C. 247d–6d; see also Fourth Amendment to the Secretary’s PREP Act Declaration, 85 FR79,190, 79,195 (Dec. 9, 2020).

administrator. The Vaccine Act is ambiguous in how it handles such injuries, and in the Department's view there are strong reasons to exclude them from coverage under the Act's compensation scheme.

The Act creates a compensation program "for a vaccine-related injury or death." 42 U.S.C. 300aa-11(a)(1). Under the Act, "only . . . a person who has sustained a vaccine-related injury or death" can recover. 42 U.S.C. 300aa-11(a)(9). The Act defines "[v]accine-related injury or death" as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. 300aa-33(5) (emphasis added); see also *Dean v. HHS*, No. 16-1245V, 2018 WL 3104388, at \*9 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining "vaccine" as "any substance designed to be administered to a human being for the prevention of 1 or more diseases") (quoting 26 U.S.C. 4132(a)(2)). Thus, the compensation program covers injuries "associated with" the vaccine itself.

SIRVA is not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term "associated with" was meant to sweep in injuries caused by negligent administration of the vaccine. Although the Act permits petitioners to recover for Vaccine Table injuries without demonstrating causation in individual cases, the term "associated with" nevertheless requires that the injury, in general, be causally related to the vaccine itself. This is clear both from dictionary definitions of "associated," which means "related, connected, or combined together" (Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/associated>. Accessed 10 Jul. 2020), and from the text of the Act itself, see, e.g., 42 U.S.C. 300aa-22(b)(1) (focusing on injuries that "resulted" from vaccine side effects); 42 U.S.C. 300aa-13(a)(1)(B) & (2)(B) (excluding "trauma" that has "no known relation to the vaccine involved").

Importantly, in the key operative provisions discussed above, the phrase "associated with" is linked to the vaccine itself, not to the technique in administering the vaccine. See *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 611 (2013) (in interpreting phrase "associated with industrial activity,"

the key consideration is the scope of "industrial activity"; the "statute does not foreclose a more specific definition by the agency" and "a reasonable interpretation . . . could . . . require the discharges to be related in a direct way to operations at 'an industrial plant'"); *Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 861 (1984) ("[T]he meaning of a word must be ascertained in the context of achieving particular objectives, and the words associated with it may indicate that the true meaning of the series is to convey a common idea.").

That basic requirement is not met with SIRVA and vasovagal syncope. While the act of being vaccinated may be a but-for cause of those injuries, the injury is not associated with the vaccine itself because, with proper administration technique, those injuries will not result from the vaccine. Rather, SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique.

There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.

First, as the Federal Circuit has explained, troubling issues arise if the Act were to apply to "negligence facially unrelated to the vaccine's effects." *Amendola v. Sec., Dept. of Health & Human Servs.*, 989 F.2d 1180, 1187 (Fed. Cir. 1993). It could include, for example, "the doctor's negligent dropping of an infant patient" or use of contaminated equipment. *Id.* at 1186-87. The better reading of the statute is that it does not reach this far.

Second, the definition of vaccine-related injury carves out "an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. 300aa-33(5) (emphasis added). By excluding from the definition those injuries associated with an adulterant or contaminant intentionally added to the vaccine, Congress indicated its intent to permit suit only where the injury was caused by the components of the vaccine itself, not individual fault. Relatedly, in the provisions setting forth the standard for awarding compensation, Congress specified that an award is not appropriate when injury was "due to factors unrelated to the administration of the vaccine," and further defined that phrase to include "trauma . . . which have no known relation to the vaccine involved." 42 U.S.C. 300aa-13(a)(1)(B) & (2)(B). In other words, Congress excluded compensation for injuries that were not related "to the vaccine involved."

Third, the statutory scheme requires that the patient "received a vaccine set

forth in the Vaccine Injury Table," 42 U.S.C. 300aa-11(c)(1)(A), tying compensation to the receipt of a specific listed vaccine. See 42 U.S.C. 300aa-11(c)(1)(C)(i) (speaking to an injury aggravated "in association with the vaccine referred to" on the Vaccine Injury Table); 42 U.S.C. 300aa-11(c)(1)(C)(ii)(I) (for conditions not on the Vaccine Injury Table, allowing proof that the condition "was caused by a vaccine" on the Table); 42 U.S.C. 300aa-11(c)(1)(C)(ii)(II) (same). But negligent administration can occur without regard to the specific vaccine and, as noted above, can encompass anything from negligent needle placement to "the doctor's negligent dropping of an infant patient." *Amendola*, 989 F.2d at 1186-87. Congress strongly signaled that it was focused on compensation for harm caused by the vaccine by requiring that the Table list the vaccines themselves and the types of injuries the vaccines themselves would cause.

Fourth, in the provision preempting state tort liability, Congress protected manufacturers from liability when the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared . . ." 42 U.S.C. 300aa-22(b)(1). This language shows Congress wanted to preserve a state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration. Given that the Vaccine Act seeks to replace state tort remedies for the injuries it covers, this reinforces the conclusion that the Act does not reach SIRVA and vasovagal syncope.

Fifth, Congress provided for health care providers who administer vaccines to record detailed information about the vaccination, including the date of administration; the manufacturer; the name of the provider; and other identifying information. 42 U.S.C. 300aa-25. This information is well suited to a program designed to compensate for injuries associated with the vaccine itself, since it provides the key details about the vaccine provided and when. But this reporting requirement is woefully inadequate if the Program was designed to compensate for negligence by the provider, which would require maintaining careful records regarding the actual administration of the vaccine.

In setting up the original Vaccine Injury Table, Congress referenced conditions "resulting from the administration of such vaccines." 42 U.S.C. 300a-14(a). But this phrase was not designed to define the scope of the program or the Table; instead, Congress directed the Secretary to add conditions

to the Table if they were “associated with such vaccines.” 42 U.S.C. 300aa–14(e)(1)(B) & (2)(B). And it is telling that Congress included nothing similar to SIRVA or other injuries caused by negligent vaccine administration in the original Table, rather than injuries associated with the vaccine components themselves. Finally, that Congress asked the Secretary to “make or assure improvements” in the “administration” of vaccines, 42 U.S.C. 300aa–27(a)(2), among many areas of improvement in the vaccination process, does not imply that the compensation program covers negligent administration.

Perhaps for some or all of these reasons, state courts have found that injuries arising from negligent administration of a vaccine are not “vaccine-related injuries” under 42 U.S.C. 300aa–33(5), and therefore are not preempted by the Vaccine Act. *See, e.g., Neddeau v. Rite Aid of Conn.*, 2015 WL 5133151, at \*3 (Super. Ct. Conn. July 28, 2015) (state court action did not allege a “vaccine-related” injury and therefore was not barred by the Vaccine Act, because plaintiff’s allegation that the administrator struck the needle too high was an allegation that her injuries “were caused by negligence in the physical process of injecting the vaccine, not by the effects of the vaccine”); *Nwosu ex rel. Ibrahim v. Adler*, 969 So. 2d 516, 519 (Ct. App. Fla. 2007) (claim arising from a physician’s negligent injection of a vaccine was not a “vaccine-related injury,” and adding that “[i]t is true that had the child not been vaccinated, she would not have been injured. However, her injury as alleged, does not flow from the inoculant injected into her body [so] it is not the type of injury covered under the Act”).

The Table should only include injuries caused by a vaccine or its components, not the manner in which the vaccine was administered. Thus, a petitioner must have an injury or death “associated” with the vaccine, not one resulting from poor injection technique or other improper administration of the vaccine. The Department believes SIRVA and vasovagal claims should not be included on the Table and cannot be based on causation in fact, because they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault.

*Comment:* Some commenters asked that this final rule be postponed until the new administration enters office, arguing that it is unfair to change the VICP in the final days of President Trump’s administration.

*Response:* Past practice has often been to finalize rules that are ready for finalization without waiting for the incoming Administration to take office.<sup>17</sup> This is consistent with the Department’s desire to as expeditiously as possible ensure the Table complies with applicable law.

*Comment:* Many commenters took issue with the Department’s assertion in the proposed rule that retaining SIRVA and vasovagal syncope injuries on the Table will encourage frivolous petitions for compensation and add to DOJ’s caseload.

*Response:* The proposed rule explained in detail how DOJ’s caseload has increased since SIRVA and vasovagal syncope were added to the Table. DOJ had informed the Department that, out of 2,214 SIRVA claims filed since 2017, DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination.

#### Section V: SIRVA-Specific Comments

*Comment:* Many commenters stated that according to medical literature, not all SIRVA is related to improper injection technique, and some or all cases of SIRVA result from the antigen itself, not just the needle placement in the bursa. These commenters stated that this undermines the Department’s justification for removing SIRVA from the Vaccine Injury Table. They also state that HHS was incorrect to suggest that “there is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.” Other commenters stated that since medical literature is split on the cause of SIRVA, it should be left on the table until further research can be done.

*Response:* There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.<sup>18</sup> Since the 2017 Final Rule was promulgated, additional

<sup>17</sup> For example, fifty-six (56) new rules were finalized in the final two (2) full days of the previous Administration. *See Federal Register*, [https://www.federalregister.gov/documents/search?conditions%5Bpublication\\_date%5D%5Bgte%5D=1%2F18%2F2017&conditions%5Bpublication\\_date%5D%5Blte%5D=1%2F20%2F2017&conditions%5Btype%5D%5B%5D=RULE](https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=1%2F18%2F2017&conditions%5Bpublication_date%5D%5Blte%5D=1%2F20%2F2017&conditions%5Btype%5D%5B%5D=RULE).

<sup>18</sup> *See* Barnes MG, Ledford C, Hogan K. A “needling” problem: shoulder injury related to vaccine administration. *J Am Board Fam Med*. 2012 Nov-Dec;25(6):919–22; Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don’t aim too high: Avoiding shoulder injury related to vaccine administration. *Aust Fam Physician*. 2016 May;45(5):303–6.

scientific research concluded that subdeltoid or subacromial bursitis and other shoulder lesions are “more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account [a] patient’s characteristics, *i.e.*, sex, body weight, and physical constitution),” rather than “antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response.”<sup>19</sup> The Department has not seen compelling peer-reviewed publications, submitted either by the commenters or otherwise, that calls into question this conclusion. Indeed, SIRVA stands for shoulder injury *related to vaccine administration*.

*Comment:* Many commenters wrote about their SIRVA injuries and experiences with treatment and therapy. Many received or were in the process of receiving compensation through the VICP. They stressed the pain and suffering they went through due to a badly administered vaccine and asked for SIRVA to remain on the Table. They believe they deserve just compensation

<sup>19</sup> Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine*, 2017;35:4870–4876. *See also* Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician*. 2019 Jan;65(1):40–42 (explaining that SIRVA “is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle”); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. *Mil Med*. 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule). Another recent study reviewed the Vaccine Adverse Event Reporting System (VAERS) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction following injection of inactivated influenza vaccine (IIV). *See* B.F. Hibbs, C.S. Ng, O. Museru *et al.*, Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010–2017, *Vaccine*. The review found that, of the 266 reports where contributing factors for the injury were reported, 216 (81.2%) described the vaccination as being given “too high” on the arm. Other reports described improper or poor administration technique (*e.g.*, bone strikes, “administered in tendon”), uneven position between vaccinator and the patient (*e.g.*, vaccinator standing while patient sitting), vaccination needle too long, and others (*e.g.*, difficulty injecting vaccine). A small minority of reports also indicated the patient had a history of thyroid dysfunction or diabetes. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.*, the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.*, the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.*, the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

for their SIRVA injury through the VICP. These commenters stressed that the compensation is needed for treatments, pain and suffering, lost wages, and to help cover expenses while they are unable to work. They stressed that their SIRVA injuries make employment or career advancement extremely difficult, and many could no longer work in their chosen fields.

*Response:* The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA is generally not that type of injury or illness. Moreover, under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court. Those injured still have an opportunity to be compensated by the faulty party.

*Comment:* Many commenters asked what their recourse for SIRVA injuries would be if it is removed from the Table. Many other commenters believe that removal of SIRVA from the Table will eliminate any recourse for patients of improperly administered vaccines.

*Response:* Under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court (or in federal court if the requirements for diversity jurisdiction under 28 U.S.C. 1332 are satisfied).

*Comment:* Many commenters believe that vaccine administration by poorly trained and minimally qualified staff is what leads to a high number of SIRVA cases, so the Government should provide more training, guidelines, and supervision of medical staff and companies that administer vaccines. These commenters suggest mandating more vaccine administration training and certification. Some suggested that funds from the VICP should be set aside to train providers with the proper technique of vaccine administration. They believe that unless there is more regulation for continuous training on injection administration, SIRVA should not be removed from the table.

*Response:* The Department agrees that SIRVA is caused by improper vaccine administration. The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly. Doing so will improve public confidence in

vaccinations. Removing SIRVA from the Table further incentivizes learning proper administration technique. The Department agrees that proper vaccine administration is critical to ensure that vaccination is safe and effective. CDC provides recommendations on vaccine administration technique, many of which can be found at <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>.

*Comment:* Some commenters opposed removing SIRVA from the Table, but stress that since the injury is caused by faulty administration, the person administering the vaccine and causing the injury should be held accountable.

*Response:* While the Department disagrees with the suggestion to keep SIRVA on the Table, the Department understands the desire to hold accountable those who cause injury by using faulty administration. If those who administer vaccines can be held liable when a patient suffers from SIRVA as a result of the administration of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but awarding no-fault compensation from the VICP to those with SIRVA and vasovagal syncope claims lessens the incentive to take appropriate precautions. Since Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators may be left unaware that they used an improper technique. If SIRVA and vasovagal syncope are included in the Table, petitioners will continue to seek to recover from the VICP, where they can recover more easily because they need not prove causation, rather than from those who failed to properly administer the vaccine.

*Comment:* A commenter suggested increasing the VICP tax to help cover all SIRVA injuries and support more administration training.

*Response:* The Department lacks the authority to increase the VICP tax, and this is beyond the scope of this final rule.

*Comment:* Some commenters threatened that if SIRVA is removed from the Table, they will wage a campaign to discourage the public at large from receiving flu vaccines.

*Response:* Flu vaccines have a good safety record. Hundreds of millions of Americans have safely received flu vaccines over the past 50 years, and

there has been extensive research supporting the safety of flu vaccines. A flu vaccine is the first and best way to reduce your chances of getting the flu and spreading it to others. CDC recommends that everyone 6 months of age and older receive a flu vaccine every year. More information on the safety of flu vaccines can be found at <https://www.cdc.gov/flu/prevent/general.htm>. The Department anticipates that this final rule may result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better incentivize those administering vaccines to use proper injection technique.

*Comment:* Commenters believe the general public should be better informed about the risk of SIRVA. Some suggestions included an ad campaign, or informational pamphlets handed out before vaccine injection. One commenter suggested that all patients should receive the entire list of ingredients of all vaccines before they consent to the vaccine.

*Response:* All healthcare providers (as defined in the Vaccine Act) are required by the Vaccine Act (42 U.S.C. 300aa–26) to give the appropriate VIS or Vaccine Information Statement to the patient (or parent or legal representative) prior to every administration of specific vaccines. A VIS or Vaccine Information Statement is a document, produced by CDC, that informs vaccine recipients—or their parents or legal representatives—about the benefits and risks of a vaccine they are receiving. Such materials shall be revised “(1) after notice to the public and 60 days of comment thereon, and (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.” 42 U.S.C. 300aa–26(b). Since the aforementioned statutory required steps were not taken prior to the proposed rule, the commenter's suggestions are outside the scope of this final rule. Further information about vaccine ingredients can be found at <https://www.cdc.gov/vaccines/vac-gen/additives.htm>.

*Comment:* Many commenters stress that HHS has drastically changed its position since March 21, 2017 when it adopted the Final Rule adding SIRVA to the Vaccine Injury Table. Commenters point to past Departmental interpretations of SIRVA and vasovagal syncope, and the inclusion of these injuries as covered under the VICP. They argue that the Department does not have an adequate bases for changing

its interpretation of these injuries. Moreover, the Department has concluded that there are strong policy reasons for now removing SIRVA from the Table.

*Response:* As discussed above, it is the Department's belief that vasovagal syncope is not a "vaccine-related injury" and therefore should not be included on the Table or compensable under the VICP. 42 U.S.C. 300aa-11, 300aa-14(e), and the inclusion of the injury in 2017 was incorrect.

*Comment:* Many commenters believe that SIRVA should remain on the table because "No evidence has been presented by DHHS justifying the removal of these injuries."

*Response:* The scientific literature indicates that SIRVA likely results from poor vaccination technique, rather than the vaccine or its components alone. The notice of proposed rulemaking that preceded the Final Rule characterized SIRVA as an "adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection (the procedure where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder."<sup>20</sup> The IOM similarly concluded that "the injection, and not the contents of the vaccine, contributed to the development of deltoid bursitis."<sup>21</sup> Indeed, the primary case series relied upon by the Department in promulgating the proposed rule and Final Rule found that the medical literature supports the possibility that SIRVA may result from inappropriate needle length and/or injection technique.<sup>22</sup> There is nearly uniform agreement in the scientific community that SIRVA is caused by improper vaccine administration, rather than by the vaccine itself.<sup>23</sup> Since the

Final Rule was promulgated, additional scientific research concluded that subdeltoid or subacromial bursitis and other shoulder lesions are "more likely to be the consequence of a poor injection technique (site, angle, needle size, and failure to take into account [a] patient's characteristics, *i.e.*, sex, body weight, and physical constitution)," rather than "antigens or adjuvants contained in the vaccines that would trigger an immune or inflammatory response."<sup>24</sup>

*Comment:* Some commenters stated that HHS's justification for removing SIRVA from the VICP does not comport with best available science, because, although HHS correctly states that SIRVA and syncope are considered to be adverse injuries following direct trauma from an injection point, "negligent administration" and "poor vaccination technique" are not exclusively connected with the onset of SIRVA and

Nov-Dec; 25(6):919-22; Cross GB, Moghaddas J, Buttery J, Ayoub S, Korman TM. Don't aim too high: Avoiding shoulder injury related to vaccine administration. *Aust Fam Physician*. 2016 May; 45(5):303-6.

<sup>24</sup> Martín Arias, K.H., Fadrique, R., Sáinz Gil, M., and Salgueiro-Vazquez, M.E., Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations, *Vaccine*, 2017; 35: 4870-4876. See also Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can. Fam. Physician*. 2019 Jan; 65(1): 40-42 (explaining that SIRVA "is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle"); Macomb CV, Evans MO, Dockstater JE, Montgomery JR, Beakes DE. Treating SIRVA Early With Corticosteroid Injections: A Case Series. *Mil Med*. 2019 Oct 17 (noting that SIRVA does not occur unless the vaccine is mistakenly given in the shoulder capsule). Another recent study reviewed the Vaccine Adverse Event Reporting System (VAERS) database from July 2010 to June 2017 for reports of atypical shoulder pain and dysfunction following injection of inactivated influenza vaccine (IV). See B.F. Hibbs, C.S. Ng, O. Museru *et al.*, Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2017, *Vaccine*. The review found that, of the 266 reports where contributing factors for the injury were reported, 216 (81.2%) described the vaccination as being given "too high" on the arm. Other reports described improper or poor administration technique (*e.g.*, bone strikes, "administered in tendon"), uneven position between vaccinator and the patient (*e.g.*, vaccinator standing while patient sitting), vaccination needle too long, and others (*e.g.*, difficulty injecting vaccine). A small minority of reports also indicated the patient had a history of thyroid dysfunction or diabetes. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.*, the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.*, the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.*, the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

syncope-related injuries. Commenters stated that the agency did not consider that serious injuries may occur following the onset of SIRVA or a syncope-related event.

*Response:* It is possible that serious injuries may occur following the onset of SIRVA or a syncope-related event, but the scientific literature suggests such injuries generally result from the act of injection, rather than the vaccine or its components. That negligent administration or poor vaccination technique may also be connected with other injuries does not change the Department's conclusions.

*Comment:* Some commenters stated that SIRVA injuries are not as rare as the Department states. They state that due to lack of information, many SIRVA injuries are not recognized or reported.

*Response:* The Department did not state that SIRVA injuries are rare.

*Comment:* Some commenters argue that medical literature supports that SIRVA alone cannot result from negligent administration of a vaccine, because these injuries are a combination of both (1) the needle placed into the subacromial bursa and (2) the vaccine components that are needed to cause the immune response, resulting in SIRVA.

*Response:* It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.*, the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.*, the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.*, the deltoid muscle). Such injuries are fairly characterized as resulting from the vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

#### Section VI: Vasovagal Syncope Specific Concerns

*Comment:* Some commenters shared their negative experiences with vasovagal syncope. One commenter said he was left alone after receiving a vaccine, which resulted in severe injuries to his face and causing him to need extensive medical treatment. He stated that the VICP is the only recourse to financial compensation for pain and suffering, since Texas malpractice laws make it difficult to obtain compensation.

*Response:* The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses

<sup>20</sup> National Vaccine Injury Compensation: Revision to the Vaccine Injury Table ("2015 Proposed Rule"), 80 FR 45132, 45136 (July 29, 2015) (emphasis supplied); see also Adverse Effects of Vaccines: Evidence and Causality ("IOM Report"), at 620, available at <https://www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality>.

<sup>21</sup> IOM Report at 620. SIRVA is a medicolegal term, not a medical diagnosis, that is meant to capture a broad array of potential shoulder injuries. However the IOM only made findings concerning deltoid bursitis.

<sup>22</sup> Atanasoff S, Ryan T, Lightfoot R, and Johann Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), *Vaccine* 28(51): 8049-52 (recommending that injections avoid the top third of the deltoid muscle to avoid shoulder injury).

<sup>23</sup> See Barnes MG, Ledford C, Hogan K. A "needling" problem: Shoulder injury related to vaccine administration. *J Am Board Fam Med*. 2012



that cannot be predicted in advance and can occur without fault. Vasovagal syncope is generally not that type of injury or illness. Scientific and medical literature support the conclusion that syncope may be caused by the act of vaccination, but not its contents.<sup>25</sup> Texas state malpractice laws are beyond the scope of this final rule.

*Comment:* Some commenters stated that contrary to the Department's position that vasovagal syncope is not a vaccine-related injury, the IOM found "sufficient mechanistic evidence supporting the conclusion that syncope is 'directly related to vaccine administration,'" and that the CDC has reported people fainting after receiving nearly all vaccines. While the commenters agree that steps can be taken to reduce the risk of syncope, they state that it should remain on the Injury Table.

*Response:* The IOM found insufficient epidemiologic evidence of an association between the injection of a vaccine and syncope, but it found sufficient mechanistic evidence supporting the conclusion that syncope is "directly related to vaccine administration."<sup>26</sup> The IOM explained that evidence it examined as part of its review suggested "that the injection, and not the contents of the vaccine, contributed to the development of syncope."<sup>27</sup> In addition, because syncope is an injury related *solely* to the injection of a vaccine, the Department did not add syncope to the 2017 revisions to the Table as an injury for vaccines that are not administered by injection, such as oral polio and rotavirus vaccine.

*Comment:* One commenter stated that removing syncope from the table would go against three decades of precedent and the weight of the medical evidence.

*Response:* The Department respectfully disagrees. Vasovagal syncope was not added to the Table until 2017. From the inception of the Table until 2017, vasovagal syncope is not included.

#### Section VII: Comments Regarding Item VII

*Comment:* Some commenters are concerned that removing Item XVII from

the Table will remove an avenue to add new vaccines to the Table.

*Response:* The Department is removing Item XVII from the table because it has serious concerns that Item XVII is contrary to law, including the procedures described in the Vaccine Act for amending the Table. Specifically, to the extent that Item XVII provides a unilateral mechanism for adding injuries and vaccines to the Table, it may be inconsistent with the Vaccine Act. The Vaccine Act provides a method for adding new vaccines to the Table, and it is far from clear that the approach in Item XVII complies with that method. The Vaccine Act provides that the Secretary may promulgate regulations to modify the Table, but in doing so, he "shall provide for notice and opportunity for a public hearing and at least 180 days of public comment."<sup>28</sup> Moreover, the Table cannot be revised unless "the Secretary has first provided to the [ACCV] a copy of the proposed regulation or revision, requested recommendations and comments by the [ACCV], and afforded the [ACCV] at least 90 days to make such recommendations."<sup>29</sup> Item XVII, by contrast, suggests that vaccines are added to the Table once the CDC recommends them for routine administration to children and an excise tax is imposed, even prior to notice and public comment or comments from the ACCV.<sup>30</sup> This may be inconsistent with the rulemaking requirements of the Administrative Procedure Act 5 U.S.C. 553, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, various Executive Orders that cabin rulemaking (see, *e.g.*, Executive Order 12866), and the Vaccine Act.

Moreover, even with the removal of Item XVII, new vaccines may be added to the Table under 42 U.S.C. 300aa-14(d), when appropriate.

*Comment:* One commenter stated that HHS's argument that Item XVII is unlawful is without merit. Article I of the Constitution provides Congress the authority to delegate responsibilities to

<sup>28</sup> 42 U.S.C. 300aa-14(c)(1).

<sup>29</sup> 42 U.S.C. 300aa-14(d).

<sup>30</sup> The language in Item XVII also raises Constitutional concerns. Item XVII in effect allows CDC to add vaccines to the Table so long as the Secretary publishes notice of coverage. The Office of Legal Counsel has previously opined that a statute that sought to authorize the CDC director to take certain action unilaterally was inconsistent with the Executive Powers Clause. (Statute Limiting The President's Authority To Supervise The Director Of The Centers For Disease Control In The Distribution Of An AIDS Pamphlet, 12 U.S. Op. Off. Legal Counsel 47, 48, 1988 WL 390999, at \* 1). For the same reasons, it is not clear that the CDC director, as an inferior officer, has the authority to unilaterally add vaccines to the Table without the approval of the Secretary.

independent agencies, and the Vaccine Act expressly provides that HHS shall amend the Vaccine Injury Table to include any CDC vaccine recommended for routine childhood use within two years. According to this commenter, Congress provided the CDC with an autonomous role in the VICP process, and its recommendations are separate from administrative action by HHS. Therefore, commenters stated that Item XVII is lawful.

*Response:* The Vaccine Act provides that the Secretary may promulgate regulations to modify the Table, but in doing so, he "shall provide for notice and opportunity for a public hearing and at least 180 days of public comment."<sup>31</sup> Moreover, the Table cannot be revised unless "the Secretary has first provided to the [ACCV] a copy of the proposed regulation or revision, requested recommendations and comments by the [ACCV], and afforded the [ACCV] at least 90 days to make such recommendations."<sup>32</sup> Item XVII, by contrast, suggests that vaccines are added to the Table once the CDC recommends them for routine administration to children and an excise tax is imposed, even prior to notice and public comment or comments from the ACCV.

*Comment:* One commenter stated that Item XVII does have merit, especially because it streamlines the process to allow for quicker inclusions of important vaccines. This commenter stated that this is especially important and timely due to the impact of the COVID-19 pandemic and the need to provide quick compensation for COVID-19 vaccine-related injuries or deaths. Removing Item XVII would just frustrate the stated purpose of the Vaccine Act.

*Response:* The Department appreciates the desire to quickly add vaccines to the Table. However Congress in 42 U.S.C. 300aa-14 specified the procedures that must be followed to amend the Table. In addition, an excise tax would have to be imposed.

*Comment:* A few commenters opposed the removal of the mechanism to add vaccines to the Table under item XVII. According to the commenters, the proposed rule would stop the automatic addition of COVID-19 and other new vaccines to the VICP, which could potentially delay or permanently prevent the COVID-19 vaccine from being covered under the VICP, and subjecting administrators to lawsuits in the future. Commenters suggested that

<sup>31</sup> 42 U.S.C. 300aa-14(c)(1).

<sup>32</sup> 42 U.S.C. 300aa-14(d).

<sup>25</sup> 80 FR 45,137 (The IOM found that one case report suggested that "the injection, and not the contents of the vaccine, contributed to the development of syncope"). See also IOM Report at 18 ("injection of vaccine, independent of the antigen involved, can lead to" syncope); Miller, E. and Woo, E.J. Time to prevent injuries from postimmunization syncope, *Nursing*, 2006 36 (12): 20.

<sup>26</sup> 80 FR 45137.

<sup>27</sup> 80 FR 45137. See also IOM Report.

this policy change is seemingly at odds with the actions undertaken by HHS to expand liability protections for administrators under authorities granted in the PREP Act.

*Response:* The Department appreciates the desire to quickly add vaccines to the Table. However Congress in 42 U.S.C. 300aa–14 specified the procedures that must be followed to amend the Table. In addition, an excise tax would have to be imposed. During the effective period of the Secretary’s COVID–19 PREP Act declaration, Covered Persons are already immune 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 FDA-approved or FDA-licensed COVID–19 vaccines (unless they engage in willful misconduct that causes death or serious physical injury). See 42 U.S.C. 247d–6d.

#### Section VIII: Miscellaneous Comments

*Comment:* A commenter asked that the license for the Hepatitis B Vaccine be revoked until further safety studies are done.

*Response:* This is beyond the scope of this final rule. For more information on the safety of this vaccine, see <https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQd04>; <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.html>.

*Comment:* Some commenters believe that all vaccines should be automatically added to the VICP. Other commenters asked for specific vaccines to be added to the Table immediately.

*Response:* In 42 U.S.C. 300aa–14(c)–(d), Congress specified procedures that the Department must follow to add vaccines to the Table. In revising the Table, the Department must follow these procedures. The Department notes, though, that if a vaccine is in a category of vaccines that is already covered by the VICP, then the new vaccine product is already covered even before the date of licensure. For example, hepatitis B vaccines are covered under the Program under Category VIII of the Vaccine Injury Table. If a new hepatitis B vaccine is licensed in the U.S., it is already automatically covered under the VICP. Adding specific vaccines to the Table in this final rule is likely impermissible under the Administrative Procedure Act and the logical outgrowth doctrine. Such vaccines could be added in a separate rulemaking.

*Comment:* Many commenters stressed that vaccines should be changed so they do not need to be administered with a shot.

*Response:* This is beyond the scope of this final rule.

*Comment:* Some commenters believed that any and all mandatory vaccines should be covered. Specifically, a commenter expressed her anger over a “mandatory” TD shot to travel out of the country.

*Response:* There are no vaccination requirements for visitors to the United States, and U.S. residents traveling abroad do not need any vaccines to reenter the United States. Many vaccines are recommended by the CDC and primary care doctors when travelling outside the United States, but they are not mandatory under federal law.<sup>33</sup>

*Comment:* One commenter said it was unfair that the Table does not include heart conditions, because they were diagnosed with Pericarditis 24 hours after receiving the DMMR vaccine.

*Response:* To gain entitlement to compensation under the VICP, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating what is referred to as a “Table injury.” That is, a petitioner may show that the vaccine recipient (1) received a vaccine covered under the Act; (2) suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the “Table”—corresponding to the vaccination in question; and (3) that the onset of such injury took place within the time period specified in the Table. If so, the injury is presumed to have been caused by the vaccine, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor unrelated to the vaccination (see 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B), and 300aa–14(a)). Whether to add heart conditions to the Table is beyond the scope of this final rule.

*Comment:* A commenter expressed concern that CDC guidelines for vaccine administration are not followed, which is leading to SIRVA and vasovagal syncope. Some commenters believe that pharmacies should not be allowed to administer vaccines if injuries such as SIRVA and Vasovagal Syncope are occurring.

<sup>33</sup> For more information on Vaccines recommended for international travel: <https://wwwnc.cdc.gov/travel/destinations/traveler/none/united-states#:~:text=There%20are%20no%20vaccination%20requirements,reater%20the%20United%20States>. (last viewed Jan. 2021).

*Response:* The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly. Doing so will improve public confidence in vaccinations. Removing SIRVA from the Table further incentivizes learning proper administration technique. The Department agrees that proper vaccine administration is critical to ensure that vaccination is safe and effective. CDC provides recommendations on vaccine administration technique, many of which can be found at <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>. Whether pharmacists should be allowed to vaccinate is beyond the scope of this final rule.

*Comment:* One commenter believed that instead of removing SIRVA and vasovagal syncope from the Table, a new department should be created to deal exclusively with injuries caused by vaccine administration.

*Response:* Only Congress, not the Department, has the authority to create a new department to deal exclusively with injuries caused by vaccine administration.

*Comment:* One commenter suggested that vaccine companies should be mandated to set apart part of their profits to help fund the National Vaccine Injury Compensation Program (VICP).

*Response:* The source of funding for the VICP is the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund is already funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

*Comment:* Some commenters believed that all those injured should be able to go to their local court and file claims.

*Response:* Under 42 U.S.C. 300aa–11(a)(2), no person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or

death, unless the person has first filed a petition in the Court. This is mandated by statute, and the Department does not have the authority to change this.

*Comment:* Some commenters believe that removing SIRVA and Vasovagal syncope will result in burdensome and time consuming litigation that is unfair to those injured since they would have to provide evidentiary support in state court. They also believe that the claims will clog up federal, state, and local courts. Other commenters suggested that removing these injuries from the VICP will lead to claim suppression because many individuals will not have the resources to pursue their claims in court.

*Response:* It is the Department's position that if SIRVA and vasovagal syncope were removed from the Table, individuals could still file SIRVA and vasovagal syncope claims in state court, or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367. Once in those court, petitioners would be required to prove causation between the manner of administration and the claimed injury.

Further, this final rule is unlikely to unduly burden the civil tort system. The Department conducted a search in the WestLaw legal database for cases in state court that contained both the terms "SIRVA" and "vaccine," and found only 20 hits, at least two of which were cases involving an entity named SIRVA and not the injury. It is possible that some additional cases were filed in federal district court. Nonetheless, the Department believes based on this data that any additional burden on the civil tort system, which would be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.

*Comment:* Some commenters worry that removing SIRVA and vasovagal syncope from the Table will result in doctors and pharmacists being unwilling to administer vaccines because they fear personal liability.

*Response:* The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner, but the Department also wants to incentivize those who administer vaccines to do so properly.<sup>34</sup>

<sup>34</sup> See Frakes, M., & Jena, A.B. (2016). Does Medical Malpractice Law Improve Health Care Quality?. *Journal of public economics*, 143, 142–158. <https://doi.org/10.1016/j.jpubeco.2016.09.002> (Finding "evidence suggesting that treatment quality may improve upon reforms that expect

Doing so will improve public confidence in vaccinations. Many physicians and pharmacists were willing to administer vaccines prior to SIRVA and vasovagal syncope's addition to the Table in 2017. In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.<sup>35</sup>

*Comment:* Commenters suggest that the tax on flu vaccines that sustain the VICP fund should be returned to the doctors, pharmacists, and other vaccine administrators so that individuals injured by administration can sue the provider directly.

*Response:* The source of funding for the VICP is the Trust Fund. The Trust Fund is funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

*Comment:* Some commenters asked that all time limits for injuries be removed from the VICP.

*Response:* Revision of the statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

*Comment:* Many commenters wrote about their personal negative reactions to vaccine components.

*Response:* These comments are outside the scope of this rulemaking, since the scientific literature indicates that SIRVA and vasovagal syncope results from poor vaccination technique and the act of injection, rather than the vaccine components.

*Comment:* Some commenters asked that vaccine injury reporting be significantly improved to reflect all injuries caused by vaccine components. Some asked that reporting to the Vaccine Adverse Event Reporting System (VAERS) be mandatory. A commenter referenced the Harvard Pilgrim Health Care report which found that less than 1 percent of vaccine adverse events are reported.

*Response:* This final rule concerns the VICP, which is distinct from the Vaccine Adverse Event Reporting

physicians to adhere to higher quality clinical standard").

<sup>35</sup> See 85 FR 52,136, 52140 (Aug. 24, 2020).

System. As such, these comments are outside the scope of this final rule.

*Comment:* Two commenters opposed removing SIRVA from the Table because they stated that they have seen compensation greatly help those injured by providing resources for rehab treatment.

*Response:* The Department sympathizes with those who suffered an injury, but it is the Department's belief that Congress intended for the Vaccine Act's compensation system to be used for unavoidable injuries and illnesses that cannot be predicted in advance and can occur without fault. SIRVA is generally not that type of injury or illness. Moreover, under this final rule, those with SIRVA injuries are not barred from suing those who injured them in state court. Those injured still have an opportunity to be compensated.

*Comment:* Many commenters believe that the proposed rule changes are contrary to the legislative intent behind the creation of the vaccine injury compensation program, namely providing fair and prompt compensation to those individuals that have suffered well recognized injuries related to certain vaccines whilst shielding the pharmaceutical and medical industries from significant exposure.

*Response:* The Department explained in the proposed rule<sup>36</sup> and elsewhere herein why this final rule is consistent with Congressional intent.

*Comment:* Some commenters stated that it was the intention of Congress to centralize claims for compensation out of hundreds of tort venues to a centralized administrative compensation system, and removing SIRVA and vasovagal syncope is contrary to that congressional intent.

*Response:* The Department explained in the proposed rule<sup>37</sup> and elsewhere herein why this final rule is consistent with Congressional intent. SIRVA and vasovagal syncope are not the sorts of injuries that Congress intended for inclusion in the Table.

*Comment:* Many commenters believe that the proposed rule change will result in exposing pharmaceutical companies to liability and will inadvertently "chill" vaccine production.

*Response:* For the most part, this final rule merely reverts to the status quo as of January 2017. In fact, the vaccination rate has gone down slightly since SIRVA and vasovagal syncope were added to

<sup>36</sup> See 85 FR 43,796–43,797.

<sup>37</sup> See 85 FR 43,796–43,797.

the Table,<sup>38</sup> so it seems unlikely that this final rule will “chill” vaccine production.

*Comment:* Many commenters stated that there is no data supporting the Department’s position that the trust fund is running out of money. These commenters state that without this data, HHS should not change the Vaccine Injury Table.

*Response:* SIRVA claims are diminishing the Trust Fund.<sup>39</sup> The Department did not state that the Trust Fund is running out of money. The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

*Comment:* Many commenters do not believe that reducing the caseload of the VICP is a plausible justification to change the Injury Table. Others believe that the VICP should just hire more people to help process the caseload.

*Response:* The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because of caseload concerns.

*Comment:* Some commenters stated that limiting VICP claims would be harmful to families because if individuals and their families are inadequately compensated for injuries or death, they can be economically harmed. These costs could also be passed on to taxpayers when injured individuals and their families are forced to resort to extreme measures such as filing for bankruptcy.

*Response:* If SIRVA and vasovagal syncope were removed from the Table, individuals could still file SIRVA and vasovagal syncope claims in state court.<sup>40</sup>

*Comment:* Some commenters stated that HHS’s interpretation of Section 300aa–11(a)(2)(A) of the Vaccine Act is flawed because it interprets “associated with the vaccine” to mean that the injury must come from the vaccine itself instead of from the administration of the vaccine. The Department relies on a dictionary definition of “associated with” to conclude that it means “related, connected, or combined together,” but does not explain why this definition forecloses cases in which the vaccine “combine[s] together” with its administration to bring about the

illness. Furthermore, the phrase “associated with the administration of the vaccine” is not qualified. Congress could have said “associated with the *non-negligent* administration of the vaccine” or “associated with the *proper* administration of the vaccine.” Commenters suggested that if (as HHS states in the proposed rule) Congress intended to cover only those injuries associated with some “antigen,” then lawmakers would have used that word somewhere in the Act.

Commenters stated that according to the tort law principles in which the Vaccine Act is grounded, “legal cause” often implicates the combined effects of two or more forces, each constituting a substantial factor in bringing about the harm, and imposes liability upon each person or thing responsible for those forces. Therefore, consistent with tort law principles, a SIRVA claimant can be found to have “sustained a vaccine-related injury” when a third party’s negligent administration of the vaccine acts concurrently with the contents of needle, *i.e.*, the vaccine, which combined effect is in turn a substantial factor in bringing about the petitioner’s harm. The commenter stated that this is consistent with the definition of “associated with.”

*Response:* Cases where the vaccine “combine[s] together” with its administration to bring about the illness are fairly characterized as resulting from the administration technique, since they would not have occurred if the administration were proper. The fact that Congress could have said “non-negligent” administration of the vaccine or “associated with the “proper” administration of the vaccine” does not call into question the Department’s careful examination of, and analysis of, the relevant statutory terms, which is informed by the Department’s expertise in this subject matter.

*Comment:* Some commenters disagree with the Department’s reasoning that “associated with” does not include injuries caused by negligent administration of the vaccine. They point to 42 U.S.C. 300aa–11 which they contend specifically provides for “administration” of the vaccine. They state that the Act refers to “administration of the vaccine” 17 times. Other commenters list prior interpretation of the act to be inconsistent with the Department’s “new” interpretation.

*Response:* The Vaccine Act does in certain places refer to “administration of” or the “administrator” of the vaccine. But the Department thinks that those usages were not meant to suggest the Program covers negligence in the

administration of the vaccine, but served other purposes. At most, these usages render the statute ambiguous with respect to needle injuries. In Section 300aa–11(a)(2)(A), the statute precludes suits against “a vaccine administrator,” but this reference does not define the scope of the compensation program—instead, it protects administrators from suits “arising from a vaccine-related injury or death associated with the administration of a vaccine.” This language is not entirely clear, as it appears to impose two distinct qualifications that both must be met but are worded slightly differently. It may be a belt and suspenders approach to ensure that vaccine administrators are protected from tort claims like in *Amendola*, where the vaccine itself was properly administered and caused the injury, but the petitioner alleged the administrator was negligent in deciding to give the vaccine. *See* 989 F.2d at 1186 (holding Vaccine Program does not exclude cases of “negligence in deciding, for example, whether to administer an otherwise satisfactory vaccine”). The important point is that the first qualification—“arising from a vaccine-related injury”—is also included here and, Congress defined this requirement to include only injuries associated with the vaccine itself. *See also* 42 U.S.C. 300aa–11(b)(1)(A) (referencing individuals who “died as the result of the administration of a vaccine” but only if the individual sustained a “vaccine-related injury”). In setting up the original Vaccine Injury Table, Congress referenced conditions “resulting from the administration of such vaccines.” 42 U.S.C. 300a–14(a). But this phrase was not designed to define the scope of the program or the Table; instead, Congress directed the Secretary to add conditions to the Table if they were “associated with such vaccines.” 42 U.S.C. 300aa–14(e)(1)(B) & (2)(B). And it is telling that Congress included nothing similar to SIRVA or other injuries caused by negligent vaccine administration in the original Table, rather than injuries associated with the vaccine components themselves. Finally, that Congress asked the Secretary to “make or assure improvements” in the “administration” of vaccines, 42 U.S.C. 300aa–27(a)(2), among many areas of improvement in the vaccination process, does not imply that the compensation program covers negligent administration.

Furthermore, state courts have found that injuries arising from negligent administration of a vaccine are not “vaccine-related injuries” under 42

<sup>38</sup> *See, e.g.*, <https://www.cdc.gov/flu/fluview/coverage-1718estimates.htm>; <https://www.cdc.gov/nchs/data/hsr/2018/031.pdf>.

<sup>39</sup> 85 FR 43,798.

<sup>40</sup> Or Federal district court if they satisfy the requirements of 28 U.S.C. 1332 or 28 U.S.C. 1367.

U.S.C. 300aa–33(5), and therefore are not preempted by the Vaccine Act. *See, e.g., Neddeau v. Rite Aid of Conn.*, 2015 WL 5133151, at \*3 (Super. Ct. Conn. July 28, 2015) (state court action did not allege a “vaccine-related” injury and therefore was not barred by the Vaccine Act, because plaintiff’s allegation that the administrator struck the needle too high was an allegation that her injuries “were caused by negligence in the physical process of injecting the vaccine, not by the effects of the vaccine”); *Nwosu ex rel. Ibrahim v. Adler*, 969 So. 2d 516, 519 (Ct. App. Fla. 2007) (claim arising from a physician’s negligent injection of a vaccine was not a “vaccine-related injury,” and adding that “[i]t is true that had the child not been vaccinated, she would not have been injured. However, her injury as alleged, does not flow from the inoculant injected into her body [so] it is not the type of injury covered under the Act”).

The Table should only include injuries caused by a vaccine or its components, not the manner in which the vaccine was administered. Thus, a petitioner must have an injury or death “associated” with the vaccine, not one resulting from poor injection technique or other improper administration of the vaccine.

*Comment:* One commenter stated that to the extent that negligence may well be a component of some SIRVA injuries, categorically excluding these as vaccine-related injuries would make sense only if one could show that negligence alone causes SIRVA. The commenter asserts that medical literature shows that all SIRVA injuries necessarily involve an inflammatory, immune reaction in the deltoid/bursa region. (*See Vaccine-related Shoulder Discomfort*, M. Bordor & E. Montalvo; *Shoulder injury related to vaccine administration*, S. Atanasoff, et al.)

*Response:* SIRVA stands for shoulder injury related to vaccine administration. The Department does not necessarily agree that the scientific literature shows that all SIRVA injuries necessarily involve an inflammatory, immune reaction in the deltoid/bursa region. It is possible that certain injuries characterized as SIRVA occur when an immunologically active substance designed to trigger an inflammatory response (*i.e.*, the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (*i.e.*, the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (*i.e.*, the deltoid muscle). Such injuries are fairly characterized as resulting from the

vaccination technique, since they would not have occurred if the injection occurred in the proper part of the body.

*Comment:* Some commenters provided critical reviews of the research cited by HHS in the proposed rule. One commenter stated that the medical and scientific literature cited by the Department is contrary to (or at best inconclusive of) the proposition that SIRVA is caused solely by the physical conduct attributable to the person administering the vaccine.

*Response:* The Department respectfully disagrees, and maintains the view espoused in the proposed rule. The Department correctly characterized the literature in the proposed rule.

*Comment:* One commenter stated that HHS wrongfully stated that the standard of proof for establishing entitlement of a SIRVA claim is too low or lenient, leading to the filing of dubious or frivolous claims without providing any evidence of this in the proposed rule.

This commenter stated that the suspicion of activity is not proper justification for the Department’s proposed policy change. The commenter also stated that the Department’s claim that there has been a dramatic increase in SIRVA claims is meaningless without context, such as an increase in the number of flu vaccines administered from the 2016/2017 flu season to the 2018/2019 flu season. This commenter also pointed out that there is no evidence that SIRVA claims are diminishing the Trust Fund, because according to the US Treasury Bulletin for March 2020, the balance of the Trust Fund at the end of FY 2019 was \$3.95 billion, up from \$3.85 billion at the end of FY 2018.

*Response:* DOJ informs the Department that, as of the time of the proposed rule, out of 2,214 SIRVA claims filed since 2017, DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination. The proposed rule noted that the vaccination rate had decreased slightly since SIRVA was added to the Table,<sup>41</sup> yet SIRVA claims have risen dramatically in recent years. The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

*Comment:* Some commenters stated that if SIRVA is removed from the Vaccine Injury Table, it will have to be covered by malpractice insurance, which could unnecessarily drive up the

costs of delivering vaccines and reduce the number of people willing to administer them.

*Response:* It is not clear this was problematic in the United States before SIRVA and vasovagal syncope were added to the Table in 2017, and the Department has been unable to locate any evidence that insurance has materially declined due to the addition of SIRVA and vasovagal syncope to the Table. Moreover, the vaccination rate has gone down slightly between when SIRVA and vasovagal syncope were added to the Table and the time of the proposed rule.<sup>42</sup>

*Comment:* A commenter asked that if SIRVA and vasovagal syncope are removed from the Table, all claims filed before the Final Rule be allowed to continue through the National Vaccine Injury Compensation Program.

*Response:* This final rule applies to claims filed after the effective date of this final rule.

*Comment:* A commenter stated that in the 34 years since the Vaccine Act was passed by Congress, HHS has only ever added to the Injury Table, and that it is deeply troubling and potentially against the intent of the Act to remove injuries from the Table.

*Response:* The Vaccine Act explicitly provides that the Secretary can “delete from” the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided. 42 U.S.C. 300aa–14(c)(3). Therefore, this final rule is consistent with the statutory text and Congressional intent.

*Comment:* Some commenters stated that the Department’s contention that SIRVA should be removed, in part, because patient records were altered in 27 out of 2,214 cases is unsupported. They state that the average fraudulent health care claims, according to the National Health Care Anti-Fraud Association, is 3%, which is higher than the reported fraud in the SIRVA records, which is 1.2%. One commenter points out that, as of January 1, 2020, the Court requires that all medical records be certified under the Pre-Assignment Review Order, which greatly reduces the chance of fraudulent records.

*Response:* DOJ had identified 27 cases in which altered medical records have been filed, some of which involved changes to the site of vaccination. However, it is possible there were additional instances that DOJ did not uncover. The Department is finalizing this final rule because of a combination of legal and policy reasons stated herein and in the proposed rule, not solely because of fraud.

<sup>41</sup> 85 FR 43,801 n.33.

<sup>42</sup> 85 FR 43,801.

*Comment:* Some commenters stated that removing coverage for SIRVA and syncope is inconsistent with the Program's twin purposes of creating a simplified means of recovery for those injured by the administration of vaccines and providing liability protection to vaccine administrators and manufacturers. Commenters state that the policy objective is triggered by the immunization and does not vary with whether the claimed injury is a consequence of the contents versus the administration process.

*Response:* The Department agrees that the VICP seeks to create a simplified means of recovery and provide certain liability protection to vaccine administrators and manufacturers. But it only seeks to do so for injuries encompassed by the Vaccine Act. The Act creates a compensation program "for a vaccine-related injury or death." 42 U.S.C. 300aa-11(a)(1). Under the Act, "only . . . a person who has sustained a vaccine-related injury or death" can recover. 42 U.S.C. 300aa-11(a)(9). The Act defines "[v]accine-related injury or death" as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. 300aa-33(5) (emphasis added); see also *Dean v. HHS*, No. 16-1245V, 2018 WL 3104388, at \*9 (Fed. Cl. Spec. Mstr. May 29, 2018) (defining "vaccine" as "any substance designed to be administered to a human being for the prevention of 1 or more diseases") (quoting 26 U.S.C. 4132(a)(2)). Thus, the compensation program covers injuries "associated with" the vaccine itself.

SIRVA is not a vaccine, and it is not an injury caused by a vaccine antigen, but by administration of the vaccine by the health care provider. The Department does not think the term "associated with" was meant to sweep in injuries caused by negligent administration of the vaccine. Although the Act permits petitioners to recover for Vaccine Table injuries without demonstrating causation in individual cases, the term "associated with" nevertheless requires that the injury, in general, be causally related to the vaccine itself. This is clear both from dictionary definitions of "associated," which means "related, connected, or combined together" (Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/associated>. Accessed 10 Jul. 2020), and from the text of the Act itself, see, e.g., 42 U.S.C.

300aa-22(b)(1) (focusing on injuries that "resulted" from vaccine side effects); 42 U.S.C. 300aa-13(a)(1)(B) & (2)(B) (excluding "trauma" that has "no known relation to the vaccine involved").

Importantly, in the key operative provisions discussed above, the phrase "associated with" is linked to the vaccine itself, not to the technique in administering the vaccine. See *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 611 (2013) (in interpreting phrase "associated with industrial activity," the key consideration is the scope of "industrial activity"; the "statute does not foreclose a more specific definition by the agency" and "a reasonable interpretation . . . could . . . require the discharges to be related in a direct way to operations at 'an industrial plant'"); *Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 861 (1984) ("[T]he meaning of a word must be ascertained in the context of achieving particular objectives, and the words associated with it may indicate that the true meaning of the series is to convey a common idea.").

That basic requirement is not met with SIRVA and vasovagal syncope. While the act of being vaccinated may be a but-for cause of those injuries, the injury is not associated with the vaccine itself because, with proper administration technique, those injuries will not result from the vaccine. Rather, SIRVA and vasovagal syncope result from the use of improper—that is, negligent—administration technique.

There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.<sup>43</sup>

*Comment:* Many commenters stated that the proposed rule is not supported by the cited financial concerns; that SIRVA payouts in the last three years only account for 1% of the \$4 billion life-to-date total that the program has paid for claims for all injuries. They contend that the fund has enough money to support SIRVA claims. Other commenters pointed out that the awards paid out on an annual basis has substantially decreased, while the fund has increased in size. Some commenters contend that financial concerns is not a proper basis to remove an injury from the Table.

*Response:* The Department is finalizing this final rule for a combination of legal and policy reasons explained herein and in the proposed rule, not solely because any particular claims are diminishing the Trust Fund.

<sup>43</sup> See 85 FR 43,796, 43,797.

*Comment:* Many commenters stated that the Department should not move forward with this final rule since the ACCV voted against the rule changes.

*Response:* The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments. However, the Department found the ACCV's comments not adequately persuasive.<sup>44</sup> For reasons stated herein and in the proposed rule, the Department believes that credible scientific and medical evidence supports this final rule.

*Comment:* Some commenters stated that removing SIRVA and vasovagal syncope from the Table will have the negative effective of reducing the amount of providers who are willing to administer vaccinations, thereby lowering the overall number of people vaccinated. A few commenters also stated that the legislative history of the Vaccine Act shows that Congress took steps to provide protections for healthcare providers. These commenters suggest that removing SIRVA from the Vaccine Injury Table would be contrary to Congressional intent and undercut key purposes of the Vaccine Act.

*Response:* The Department respectfully disagrees. The Department has been unable to locate any evidence that premiums have materially declined due to the addition of SIRVA and vasovagal syncope to the Table. Moreover, the vaccination rate has gone down slightly since SIRVA and vasovagal syncope were added to the Table.<sup>45</sup> In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.<sup>46</sup>

*Comment:* Some commenters disagree with the Department's statement that the present regime lessens the incentive of vaccine administrators to take appropriate precautions during administration. They state that that health care providers, including pharmacists, are highly trained, skilled professionals that seek to provide high quality care to their patients, and are not likely to be negligent in the care they provide because of their knowledge of

<sup>44</sup> See 85 FR 43,801-43,802 for a detailed discussion of why the Department did not find the ACCV's comments to be adequately persuasive.

<sup>45</sup> See, e.g., <https://www.cdc.gov/flu/fluview/coverage1718estimates.htm>; <https://www.cdc.gov/nchs/data/hsr/2018/031.pdf>.

<sup>46</sup> See 85 FR 52,136, 52140 (Aug. 24, 2020).

liability protection. Further they list several instances where civil action can be filed under the Act (under 42 U.S.C. 300aa–21(a), the patient/petitioner may reject the Federal Claims judgment and pursue a civil action; the vaccine administered is not listed in the Table; the injury sustained is not listed in the Table; the injury/illness did not last 6 months). Commenters argue that health care providers are bound by their ethical, moral, and legal duties to protect public health and no other consideration eliminates or lessens that commitment.

*Response:* The Department is grateful for the many health care professionals and pharmacists who improve public health by vaccinating the American public, and does not believe they would intentionally administer a vaccine in an improper manner. The Department has taken many steps during the COVID–19 pandemic to increase the universe of individuals who can safely vaccinate. Ensuring vaccines are administered safely will increase public confidence in vaccinations. Since Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators may be left unaware that they used an improper technique.<sup>47</sup> 42 U.S.C. 300aa–21(a) does not materially change the analysis, because there are not many instances where an individual would go through the VICP process, fail to recover, and then be able to recover in state court. There are also not many instances where a petitioner would elect to forgo his or her recovery from the VICP to sue in state court, since it is not often that an individual could recover more in state court, and there are risks inherent in state court litigation.

*Comment:* One commenter who serves on the Advisory Commission on Childhood Vaccines stated that a representative from HHS should have come to talk to the Commission about the proposed rule. This commenter stated that additional evidence should have been provided by HHS at the May 2020 meeting of the Commission, but HHS was not involved in the meeting. The commenter stated that it was the responsibility of HHS to provide sufficient evidence to justify its recommendation, not the job of the Commission to provide sufficient evidence to support its rejection. Another commenter stated that by not adopting the recommendation of the Commission, HHS risks undermining the integrity of the Federal Advisory Committee Act (FACA) process and the willingness of qualified experts to serve on such committees.

*Response:* The proposal provided to the ACCV before the May 2020 meeting, which synthesized the views of many within the Department, was the Department's best explanation for why it was proposing the changes to the Table. The Department's proposed regulation provided to the ACCV provided ample scientific and legal justification. The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments, but it would raise constitutional concerns if a federal Agency had to accept the recommendations of a FACA.

*Comment:* A few commenters stated that there is no evidence to support that the Department's position that "SIRVA petitions are likely to unnecessarily risk reductions in the funding available for children and others who sustain unavoidable vaccine-related injury or death" because the taxes collected by vaccine manufacturers and paid into the Trust Fund have exceeded outflows for every year except Fiscal Year 2013. Commenters also stated that this reasoning ignores the fact that some SIRVA claims involve children.

*Response:* It stands to reason that if large sums are paid to SIRVA petitioners, that risks reducing funding available for others who sustain unavoidable vaccine-related injuries or deaths. At the time of the proposed rule, over 99.2% of SIRVA cases (3,034 out of 3,057) filed since FY 2010 were filed by adults.<sup>48</sup>

*Comment:* Some commenters urge the VICP and the CACP to merge together to promote unity and clarity.

*Response:* Revision of the formation and organization of the VICP and the CACP would require a statutory amendment and thus is not within the scope of this final rule.

*Comment:* Many commenters stated that patients, healthcare providers, vaccine administrators, and vaccine manufacturers do not support the Notice of Proposed Rulemaking.

*Response:* For the legal and policy reasons stated herein and in the proposed rule, the Department is finalizing this final rule. The Department notes, in addition, that non-SIRVA cases, including those filed on behalf of children, are adversely affected as resources are stretched or diverted to litigate SIRVA cases.

*Comment:* Many commenters state that even before SIRVA was added to the Table in 2017, individuals were able to receive compensation from the VICP for their SIRVA related injuries. Commenters point to VICP cases in

which the Vaccine Court held that a causal connection between the administration of the vaccine and the consequential injury is sufficient proof for an award under the Vaccine Act. Comments stated that the Department's change in policy is contrary to the Congressional Intent of the Act and would have a devastating effect upon parties' ability to recover for their injuries.

*Response:* Prior to SIRVA's addition to the Table, SIRVA claims were sometimes awarded due to a combination of the government resolving the claims without litigating them to conclusion, and public statements by the Department suggesting SIRVA was a cognizable injury. The proposal to add SIRVA to the Table was in the works for several years before the 2015 notice of proposed rulemaking was published, and there was a great deal of public discussion about it at the ACCV and at the Court of Federal Claims' annual judicial conference. The Department has in the past not always contested cases alleging injuries that have been proposed for addition to the Table if the case as pleaded fulfilled the criteria for entitlement to compensation. However, for the reasons discussed in the proposed rule and this final rule, including the Department's review of the statute and more recent scientific literature, the Department no longer believes such claims should be included on the Table or can be based on causation in fact, because they are not injuries associated with vaccines or their components, nor are they unavoidable injuries or illnesses that cannot be predicted in advance, or that can occur without fault.

*Comment:* Several commenters stated that HHS switched its position in this rulemaking without adequately considering the input of the Advisory Commission on Childhood Vaccines which unanimously rejected the rule change, and without discussing the change with the CDC's Advisory Committee for Immunization Practices (ACIP), HHS's own National Vaccine Advisory Committee (NVAC), the National Foundation for Infectious Disease (NFID), and the Institute of Vaccine Safety at Johns Hopkins whose epidemiologists have consulted closely with the Program since its inception.

*Response:* The Department is grateful to the ACCV for its time spent considering the proposed changes and for providing its comments. The Department considered the ACCV's

<sup>47</sup> 85 FR 43,802.

<sup>48</sup> 85 FR 43,798.

comments.<sup>49</sup> However, the Department found the ACCV's comments not adequately persuasive. The Department has also considered public comments from a wide variety of perspectives during the two public hearings and 180-day public comment period on the proposed rule.

*Comment:* A few commenters stated that they believe the reason for HHS's policy change is to reduce the Department's workload, which has increased due to the large number of SIRVA cases. Commenters stated that workload concerns are not a valid reason for making a policy change. Some commenters added that the change would not actually make the system more efficient, but would rather shift the burden of SIRVA cases to the civil tort system.

*Response:* The Department has set forth herein and in the proposed rule a series of legal and policy reasons for finalizing this final rule. The Department believes based on the examined data that any additional burden on the civil tort system, which would be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.<sup>50</sup>

*Comment:* One commenter warned that this rule could result in the increase in the cost of vaccines, as more medical providers are exposed to liability.

*Response:* With respect to SIRVA and vasovagal syncope, this final rule will revert to the status quo as of January 2017. In addition, certain pharmacists are already immune from suit and liability for claims for loss caused by, arising out of, relating to, or resulting from the administration of certain childhood vaccines to individuals ages three through 18 for the duration of the Secretary's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.<sup>51</sup>

*Comment:* One commenter disagreed with the Department's contention that by excluding from the definition those injuries associated with an adulterant or contaminant intentionally added to the vaccine, Congress intended to permit suit only where the injury was caused by the components of the vaccine itself. The commenter states that the Department is applying the doctrine of *ejusdem generis* (i.e., where general words follow an enumeration of two or

more things, they apply only to persons or things of the same general kind or class specifically mentioned). However, here, an adulterant and contaminant are *exceptions* instead of enumerations. Therefore, the commenter contends that the Department's interpretation of Congress' intent is not supported.

*Response:* The Department respectfully disagrees. There are several indicators in the language and structure of the Vaccine Act that show it was not meant to cover negligent administration of the vaccine.<sup>52</sup>

*Comment:* One commenter stated that the Department mischaracterized current SIRVA cases when it said "petitioners in such cases often prevail because of the low burden of proof and because it is not necessary to prove causation." The commenter said that litigation records show complex cases in which the Department of Justice "vigorously" advocated for the DHHS.

*Response:* The Department agrees that the Department of Justice generally vigorously advocates for the Department. But the burden of proof on petitioners is low, and petitioners generally need not prove causation.

*Comment:* One commenter stated that the proposed rule change may disproportionately and severely affect minority communities, since many do not have the same access to quality care; the time, energy, and know-how to navigate a complex legal system; and the resources to access compensation.

*Response:* Aiding minority communities was not posited as a reason to add SIRVA or vasovagal syncope to the Table when they were added in 2017.<sup>53</sup> In any event, this final rule will alleviate the Department's significant legal concerns about whether the current Table comports with applicable law.

*Comment:* Some commenters stated that HRSA is attempting to undo the lengthy and thorough legal and medical analysis it performed when it promulgated the Rule that put both vasovagal syncope and SIRVA on the Vaccine Injury Table in 2017.

*Response:* This final rule is the product of a lengthy and thorough legal and scientific analysis, including an analysis of scientific literature published after finalization of the 2017 Final Rule.

*Comment:* One commenter argued that the Vaccine Act has a subrogation clause which permits the Federal government to seek recompense if the VICP compensates a claim, but determines later that a health care

professional was negligent in administering a vaccine. Thus, injury claims resulting from the administration of vaccines should still be eligible for VICP compensation.

*Response:* This subrogation provision does not properly incentivize the vaccine administrator, since it is unlikely that the Federal government would assert many claims against administrators, given the burden and expense compared to the relatively small potential recovery for the Federal government. Individuals would have a greater incentive to assert such claims if the administrator were negligent.

*Comment:* Some commenters stated that the Department incorrectly relies on *Amendola v. Sec., Dept. of Health & Human Servs.*, 989 F.2d 1180 (Fed. Cir. 1993) to say that issues would arise if the Vaccine Act were interpreted to cover injuries caused by negligent administration. Commenters contend that the Federal Circuit Judge stated "Congress clearly intended by the amendment to apply the Act to pediatricians who administered a vaccine as well as to the manufacture who made it," and "[w]e see no basis for drawing a bright line that excludes erroneous judgment calls by the administrator, as well as negligent contamination." One commenter concludes that *Amendola*, in fact, confirms that the Vaccine Act protects both vaccine administrators and manufactures.

*Response:* The Department respectfully disagrees with this characterization of *Amendola*. As the Federal Circuit has explained, troubling issues arise if the Act were to apply to "negligence facially unrelated to the vaccine's effects." *Amendola v. Sec., Dept. of Health & Human Servs.*, 989 F.2d 1180, 1187 (Fed. Cir. 1993). It could include, for example, "the doctor's negligent dropping of an infant patient" or use of contaminated equipment. *Id.* at 1186-87. The better reading of the statute is that it does not reach this far.

*Comment:* One commenter argued that the state tort liability preemption in Subpart B merely covers the remedies available to patients after they have gone through the VICP, not that Congress intended to "preserve a state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration."

*Response:* Congress protected manufacturers from liability when the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared. . ." 42 U.S.C. 300aa-22(b)(1). This language shows Congress wanted to preserve a

<sup>49</sup> See 85 FR 43,801-02 (discussing the ACCV's comments in depth).

<sup>50</sup> 85 FR 43,804.

<sup>51</sup> See 85 FR 52,136, 52140 (Aug. 24, 2020).

<sup>52</sup> See 85 FR 43,796-97.

<sup>53</sup> See 85 FR 6294.



state tort remedy for certain avoidable injuries, such as those caused by negligent vaccine administration. Given that the Vaccine Act seeks to replace state tort remedies for the injuries it covers, this reinforces the conclusion that the Act does not reach SIRVA and vasovagal syncope.

*Comment:* One commenter disagreed with the Department's position that recordkeeping and reporting requirements are "woefully inadequate if the Program was designed to compensate for negligence by the provider," since physicians are subject to myriad state laws and regulations governing medical records. The commenter stated that Congress authorized HHS to promulgate additional recordkeeping requirements if need be.

*Response:* The text and structure of the Vaccine Act show that it was not meant to cover negligent administration of the vaccine. That some state laws and regulations govern medical records is besides the point.

*Comment:* Many commenters argued that this rule is an unconscionable attempt to alleviate HHS's backlog of pending cases, and that the public would be better served if the Department was to hire additional personal to handle case management.

*Response:* The Department respectfully disagrees. The Department has set forth a series of legal and policy reasons for this final rule both herein and in the proposed rule.

### III. Statutory Authority

The primary statutory authority for this rulemaking is 42 U.S.C. 300aa-14. 42 U.S.C 300aa-14(c)(1) provides that the "Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, he shall provide for notice and opportunity for a public hearing and at least 180 days of public comment." 42 U.S.C. 300aa-14(c)(3), in turn, provides: "A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death."

### IV. Statutory and Regulatory Requirements

#### A. Executive Orders 12866, 13563, and 13771: Regulatory Planning and Review

E.O. 12866 and E.O. 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 supplements and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866, which emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues require special analysis. The Department anticipates that the final rule will save limited compensation funds under the National Vaccine Injury Compensation Program. Specifically, it will reduce the amount of program funds spent on program administration, reduce the amount of funds paid out to those with SIRVA or vasovagal syncope claims, and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the original intent of the VICP. Moreover, the Department anticipates that the final rule may result in fewer individuals suffering from SIRVA or vasovagal syncope, because it will better incentivize those administering vaccines to use proper injection technique. If those who administer vaccines can be held liable when a patient suffers from SIRVA or vasovagal syncope as a result of the administration of the vaccine, those who administer vaccines will have greater incentive to use proper injection technique. In addition, the final rule may also limit the ability of those opposed to vaccinations to cite to the high number of SIRVA awards to misleadingly suggest that vaccines are less safe than they truly are.

The Department considered, as an alternative to the proposed rule and this final rule, issuing a notice of proposed

rulemaking that would revise the definition of SIRVA so that those with true shoulder injuries were able to recover while reducing the number of less appropriate claims. However, the Department concluded that removing SIRVA from the Table is preferable. If SIRVA is removed from the Table, those with actual SIRVA injuries would still be able to recover in state court. Removal is preferable to redefining SIRVA, because it better addresses the vaccine hesitancy concern, is more in line with the Vaccine Act and Congressional intent, and incentivizes learning and utilizing proper administration technique. Indeed, because Vaccine Act proceedings are generally sealed and not made available to the public, vaccine administrators often are left unaware that they used an improper technique.

The Department also considered, as alternatives to this final rule, not removing one or more of (1) SIRVA, (2) vasovagal syncope, or (3) Item XVII from the Table. For the reasons discussed herein and in the proposed rule, the Department rejected these alternatives.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely or materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a "significant" regulatory action is subject to Office of Management and Budget (OMB) review. As discussed below regarding the anticipated effects, these changes are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. OMB has waived review over this final rule.

### B. Economic and Regulatory Impact

In accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities. Between FY 2017 and FY 2019, the VICP on average paid out \$30,893,481.90 per year to petitioners alleging SIRVA claims. The VICP on average paid out \$124,489.56 per year to petitioners alleging vasovagal syncope claims. When this final rule goes into effect, the Department anticipates that small entities will not actually pay these amounts, because fewer SIRVA and vasovagal syncope claims would be filed if petitioners had to prove causation. In addition, vaccines are often administered by non-small entities, so even if total amounts paid approximated the amounts paid on average between FY 2017 and FY 2019, claims against small entities would be less. It is the Department's belief that should the amounts paid equal the amounts annually paid out of the VICP between FY 2017 and FY 2019, and such claims are paid in full by small entities, these amounts will not constitute a significant impact on a substantial number of small entities for purposes of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has determined that this final rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of \$154 million or more in any one year. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

The provisions of this rule will also not negatively affect family well-being or the following family elements: family safety; family stability; marital commitment; parental rights in the

education, nurture and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

On January 30, 2017, the White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This final rule partially repeals prior regulations and is not expected to increase incremental costs, so it is not anticipated to be a regulatory or deregulatory action under Executive Order 13771.

As stated above, this final rule modifies the Vaccine Injury Table to ensure that the Table complies with applicable law, the Table is consistent with medical and scientific literature, those administering vaccines have additional incentive to use proper injection technique, and the VICP has sufficient funds to adequately compensate those injured by vaccines listed in the Table.

### C. Executive Order 12988: Civil Justice Reform

The agency has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this final rule complies with this Executive Order.

### V. Summary of Impacts

This final rule has the effect of removing injuries from the Table that are not encompassed by the provisions of the Vaccine Act and that are reducing the pool of funds available to those injured by vaccines or vaccine components. It therefore aligns the Table with the Department's understanding of Congress' intent and public policy in favor of compensating those harmed by injuries associated with the vaccine or vaccine components, and particularly children who have suffered such harm. The rule also has the effect of ensuring that the limited compensation resources available under the National Vaccine

Injury Compensation Program are provided to those with vaccine-related injuries or deaths. In addition, because of the large volume of SIRVA claims, removing SIRVA from the Table will reduce the amount of program funds spent on program administration and ensure that funds awarded from the VICP are awarded to individuals whose claims arise from vaccine-related injuries, which is consistent with the Department's interpretation of the original intent of the VICP.

The final rule also better incentivizes those who administer vaccines to use proper injection technique. It may also help correct misleading and erroneous suggestions that vaccines are not safe. Because COVID-19 and the COVID-19 vaccines are not currently on the Table, the Department does not believe this rule will have an impact on patients with COVID-19 or the COVID-19 vaccines.

Moreover, the rule is unlikely to unduly burden the civil tort system. The Department conducted a search in the WestLaw legal database for cases in state court that contained both the terms "SIRVA" and "vaccine," and found only 20 hits, at least two of which were cases involving an entity named SIRVA and not the injury.<sup>54</sup> It is possible that some additional cases were filed in federal district court. Nonetheless, the Department believes based on this data that any additional burden on the civil tort system, which will be dispersed across States and not concentrated in any one or few States, from removing SIRVA and vasovagal syncope from the Table and reverting to the status quo as of January 2017 will be minimal.

### A. Executive Order 13132—Federalism

HHS has reviewed this final rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have "federalism implications." This final rule will not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and

<sup>54</sup> <https://1.next.westlaw.com/Search/Results.html?query=%22sirva%22%20%26%20%22vaccine%22&jurisdiction=ALLSTATES&saveJuris=False&contentType=CASE&querySubmissionGuid=i0ad6ad3f000001733a44933a7bf4372d&startIndex=1&searchId=i0ad6ad3f000001733a44933a7bf4372d&kmSearchIdRequested=False&simpleSearch=False&isAdvancedSearchTemplatePage=False&skipSpellCheck=False&isTrDiscoverSearch=False&thesaurusSearch=False&thesaurusTermsApplied=False&ancillaryChargesAccepted=False&proviewEligible=False&eventingTypeOfSearch=FRM&transitionType=Search&contextData=%28sc.Search%29>

responsibilities among the various levels of government.”

**B. Collection of Information**

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This final rule is projected to have no impact on current reporting and recordkeeping burden, as the amendments finalized in this rule will not impose any data collection requirements under the PRA.

**List of Subjects in 42 CFR Part 100**

Biologics, Health insurance, Immunization.

Accordingly, 42 CFR part 100 is amended as set forth below:

**PART 100—VACCINE INJURY COMPENSATION**

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

**Authority:** Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8). The revision reads as follows:

**§ 100.3 Vaccine injury table.**

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses,

conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the Qualifications and Aids to Interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the Qualifications and Aids to Interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

TABLE 1 TO PARAGRAPH (a)—VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis .....	≤4 hours.
	B. Brachial Neuritis .....	2–28 days (not less than 2 days and not more than 28 days).
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib).	A. Anaphylaxis .....	≤4 hours.
	B. Encephalopathy or encephalitis .....	≤72 hours.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV).	A. Anaphylaxis .....	≤4 hours.
	B. Encephalopathy or encephalitis .....	5–15 days (not less than 5 days and not more than 15 days).
IV. Vaccines containing rubella virus (e.g., MMR, MMRV).	A. Chronic arthritis .....	7–42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (e.g., MMR, MM, MMRV).	A. Thrombocytopenic purpura .....	7–30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient.	
	—Vaccine-strain virus identified .....	Not applicable.
VI. Vaccines containing polio live virus (OPV).	—If strain determination is not done or if laboratory testing is inconclusive.	≤12 months.
	A. Paralytic Polio.	
	—in a non-immunodeficient recipient .....	≤30 days.
	—in an immunodeficient recipient .....	≤6 months.
	—in a vaccine associated community case .....	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient .....	≤30 days.
—in an immunodeficient recipient .....	≤6 months.	
—in a vaccine associated community case .....	Not applicable.	
VII. Vaccines containing polio inactivated virus (e.g., IPV).	A. Anaphylaxis .....	≤4 hours.
VIII. Hepatitis B vaccines .....	A. Anaphylaxis .....	≤4 hours.
IX. Haemophilus influenzae type b (Hib) vaccines.	No Condition Specified. ....	Not applicable.
X. Varicella vaccines .....	A. Anaphylaxis .....	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease.	
	—Vaccine-strain virus identified .....	Not applicable.

TABLE 1 TO PARAGRAPH (a)—VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XI. Rotavirus vaccines .....	—If strain determination is not done or if laboratory testing is inconclusive. C. Varicella vaccine-strain viral reactivation .....	7–42 days (not less than 7 days and not more than 42 days). Not applicable.
XII. Pneumococcal conjugate vaccines.	A. Intussusception .....	1–21 days (not less than 1 day and not more than 21 days). Not applicable.
XIII. Hepatitis A vaccines .....	No Condition Specified. ....	Not applicable.
XIV. Seasonal influenza vaccines ...	A. Anaphylaxis .....	≤4 hours.
	B. Guillain-Barré Syndrome .....	3–42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines .....	A. Anaphylaxis .....	≤4 hours.
XVI. Human papillomavirus (HPV) vaccines.	A. Anaphylaxis .....	≤4 hours.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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