

## Settings

### I. All settings.

Our population of interest is adults 18 years of age or older with depression who have not responded to treatment(s). The depressive illness can be part of either major depressive disorder or a bipolar disorder, but one of these diagnoses must be a primary diagnosis. For example, schizophrenia with a secondary diagnosis of MDD, or dysthymia, would not be eligible for this report. If a study involves both eligible and ineligible patients and does not report data separately, that whole study will be excluded. Populations with no evidence of treatment nonresponse (*e.g.*, a study in which the absence of treatment response is not part of the selection criteria) will not be eligible.

Eligible interventions include those that have both been tested as a treatment targeting TRD in adults and been identified by guidelines, consensus statements, the MEDCAC panel, or systematic reviews as alternatives for TRD treatment. These criteria ensure consideration of interventions with a minimum threshold amount of data addressing its effectiveness in TRD populations. Comparison groups include concurrent control groups (*e.g.*, active, sham, or placebo) and a control group from an interrupted time series.

We will require outcomes to have been identified previously as the most meaningful to depression management decision making. In our earlier comparative effectiveness work on depression, we asked our Technical Expert Panel and Key Informants to rank the relative importance of these outcomes following a process proposed by the GRADE Working Group.<sup>30</sup> We used SurveyMonkey<sup>®</sup> for an anonymous ranking of the relative importance of outcomes. Participants used a 9-point Likert scale to rank outcomes into three categories: (1) Critical for decision making, (2) important but not critical for decision making, and (3) of low importance for decision making. They identified six outcomes as critical and five as important, and they supported the inclusion of an additional depressive outcome (change in depressive severity). For one of the adverse events outcomes, serious adverse events, we will use the FDA definition and will consider physical, psychological, and cognitive events. We will require relevant studies for the current project to report on at least 1 of these 12 outcomes.

All study durations and all settings are eligible. Pre/post studies that do not use interrupted time series analyses will be excluded, because potential

confounding from multiple sources renders questionable the ability of these study designs to support causal inferences. We will include English-language articles and exclude studies that are not published fully in English.

**Sharon B. Arnold,**

*Acting Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our Web site at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to

HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register.**” Set forth below is a list of petitions received by HRSA on December 1, 2016, through December 31, 2016. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and
2. Any allegation in a petition that the petitioner either:
  - a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or
  - b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the

onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading "For Further Information Contact"), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: February 6, 2017.

**James Macrae,**

*Acting Administrator.*

#### List of Petitions Filed

1. George J. Stippich, III, Milwaukee, Wisconsin, Court of Federal Claims No: 16-1595V
2. Donna J. Madej, Jackson, New Jersey, Court of Federal Claims No: 16-1596V
3. Julia Franklin, Boston, Massachusetts, Court of Federal Claims No: 16-1598V
4. Marie Scutt, Brooklyn, New York, Court of Federal Claims No: 16-1599V
5. Samantha Cantu, Chicago, Illinois, Court of Federal Claims No: 16-1600V
6. Albert Cestaro, Westlake, Ohio, Court of Federal Claims No: 16-1601V
7. Tacoma C. Lewis on behalf of C.A.I., Charlotte, North Carolina, Court of Federal Claims No: 16-1604V
8. Helen McElroy, Sarasota, Florida, Court of Federal Claims No: 16-1605V
9. Carol Lifton, Lakeland, Florida, Court of Federal Claims No: 16-1606V
10. Corinne Williamson, Meadowbrook, Pennsylvania, Court of Federal Claims No: 16-1607V
11. Amber Peterson, Las Vegas, Nevada, Court of Federal Claims No: 16-1608V
12. Tracy Goodspeed, Laramie, Wyoming, Court of Federal Claims No: 16-1609V
13. Rodney Blankenship, Stockton, California, Court of Federal Claims No: 16-1610V
14. Mary Mancina, Mandeville, Louisiana, Court of Federal Claims No: 16-1612V
15. Steven Jenkins, Bend, Oregon, Court of Federal Claims No: 16-1614V
16. Mary Bond, Jackson, Mississippi, Court of Federal Claims No: 16-1615V
17. Aurelia Gilbert, Boston, Massachusetts, Court of Federal Claims No: 16-1617V
18. Daniele Strawmyre Butler on behalf of C.B., Philadelphia, Pennsylvania, Court of Federal Claims No: 16-1620V
19. James Gilmer, Fort Meade, Maryland, Court of Federal Claims No: 16-1623V
20. Janine Fonfara, Norwich, Connecticut, Court of Federal Claims No: 16-1625V
21. Joseph C. Webb, III, Virginia Beach, Virginia, Court of Federal Claims No: 16-1627V
22. Armand Thomas, Las Vegas, Nevada, Court of Federal Claims No: 16-1628V
23. Matthew J. Johnson, Lincoln, Nebraska, Court of Federal Claims No: 16-1630V
24. Edward A. Sokol, Pittsburgh, Pennsylvania, Court of Federal Claims No: 16-1631V
25. Robert Stockdale, Wellesley Hills, Massachusetts, Court of Federal Claims No: 16-1632V
26. Kristin Dawn Bardon, Ventura, California, Court of Federal Claims No: 16-1634V
27. Travis Lee and Nicole Bailey on behalf of E.L., Loma Linda, California, Court of Federal Claims No: 16-1635V
28. Kara Evans, Baltimore, Maryland, Court of Federal Claims No: 16-1638V
29. Doreen Dileo, Greensboro, North Carolina, Court of Federal Claims No: 16-1639V
30. Donna Worcester, Melrose, Massachusetts, Court of Federal Claims No: 16-1641V
31. Robert L. Goewey, Winsted, Connecticut, Court of Federal Claims No: 16-1644V
32. Virven Warren, Greensboro, North Carolina, Court of Federal Claims No: 16-1645V
33. Doris Handler, Baraboo, Wisconsin, Court of Federal Claims No: 16-1649V
34. Emilia Silva, Reno, Nevada, Court of Federal Claims No: 16-1652V
35. Shelly A. Chmielewski, Burlington, Vermont, Court of Federal Claims No: 16-1653V
36. Kerri Hall, Mountain Home, Arkansas, Court of Federal Claims No: 16-1654V
37. Carol T. Nosches, Rancho Santa Margarita, California, Court of Federal Claims No: 16-1657V
38. George Kos, Woodland Hills, California, Court of Federal Claims No: 16-1658V
39. Kelli Tenneson, Boston, Massachusetts, Court of Federal Claims No: 16-1664V
40. Gabor Meszaros, Maywood, Illinois, Court of Federal Claims No: 16-1665V
41. Dawn Andrews, Bryn Mawr, Pennsylvania, Court of Federal Claims No: 16-1666V
42. Staceann Thomas, Stuart, Florida, Court of Federal Claims No: 16-1667V
43. Jennifer Reed, Washington, District of Columbia, Court of Federal Claims No: 16-1670V
44. Helene Frost, Manhattan Beach, California, Court of Federal Claims No: 16-1671V
45. Johnny Sturdivant, Hartsville, South Carolina, Court of Federal Claims No: 16-1672V
46. Raymond Johnson and Sasha Hall on behalf of Antonio Rocha, Deceased, Moreno Valley, California, Court of Federal Claims No: 16-1674V
47. David Goodwin, Dresher, Pennsylvania, Court of Federal Claims No: 16-1676V
48. Vilai Thomas, Las Vegas, Nevada, Court of Federal Claims No: 16-1677V
49. Ann Woo and David Sievertson on behalf of B.W.S., Washington, District of Columbia, Court of Federal Claims No: 16-1679V
50. David Bogdan on behalf of Michael Grant, Deceased, Philadelphia, Pennsylvania, Court of Federal Claims No: 16-1681V
51. Patrick McAleese, Alvin, Texas, Court of Federal Claims No: 16-1683V
52. Gloria Boeske, Grand Rapids, Michigan, Court of Federal Claims No: 16-1685V
53. Catherine Miriani, Bellaire, Michigan, Court of Federal Claims No: 16-1686V
54. Luis Garcia, Beverly Hills, California, Court of Federal Claims No: 16-1687V
55. David Byrd, Beverly Hills, California, Court of Federal Claims No: 16-1688V
56. Joseph Zumbrun, Cheyenne, Wyoming, Court of Federal Claims No: 16-1689V
57. James Dwyer, San Antonio, Texas, Court of Federal Claims No: 16-1690V
58. Scott Proper, Novi, Michigan, Court of Federal Claims No: 16-1692V
59. Shannon Frogge, Dresher, Pennsylvania, Court of Federal Claims No: 16-1693V
60. Deborah Franklin, Duluth, Georgia, Court of Federal Claims No: 16-1698V
61. William T Smith, Washington, District of Columbia, Court of Federal Claims No: 16-1699V
62. Thomas Casey, Hickory, North Carolina, Court of Federal Claims No: 16-1700V
63. Heather O'Keefe, Spokane, Washington, Court of Federal Claims No: 16-1705V
64. Kaylan Brodnax, Baton Rouge, Louisiana, Court of Federal Claims No: 16-1706V
65. Lee R. Campbell, M.D., Indianapolis, Indiana, Court of Federal Claims No: 16-1707V
66. Alceo Lucarelli, Boston, Massachusetts, Court of Federal Claims No: 16-1712V
67. Marcel Pelletier and Sarah Pelletier on behalf of B.P., Boston, Massachusetts, Court of Federal Claims No: 16-1713V
68. Regina Foster on behalf of H.G., Chattanooga, Tennessee, Court of Federal Claims No: 16-1714V
69. Margaret Albers, Buffalo, New York, Court of Federal Claims No: 16-1715V
70. Jeanette Kuhl on behalf of E.K., Detroit, Michigan, Court of Federal Claims No: 16-1716V
71. Ju Won Lee, Los Angeles, California, Court of Federal Claims No: 16-1719V
72. Andrea Owens-Bachmann, Vero Beach, Florida, Court of Federal Claims No: 16-1720V
73. Merrill Schumacher, Carson City, Nevada, Court of Federal Claims No: 16-1721V

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