

information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 15, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## 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 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 Lisa L. Reyes, Clerk of Court, 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, Maryland 20857; (301) 443–6593, or visit our website 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 United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, 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 May 1, 2021, through May 31, 2021. 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 United States 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, Maryland 20857. The Court's caption (Petitioner's Name v. Secretary of HHS) 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.

**Diana Espinosa,**

*Acting Administrator.*

#### List of Petitions Filed

1. Kelly Hannon, Washington, District of Columbia, Court of Federal Claims No: 21–1304V
2. Margaret Hoyt, Washington, District of Columbia, Court of Federal Claims No: 21–1305V
3. Sarah Lopez, Washington, District of Columbia, Court of Federal Claims No: 21–1306V
4. Lydia M. Goode, Greensboro, North Carolina, Court of Federal Claims No: 21–1307V
5. Jonathan Jarog, Chicago, Illinois, Court of Federal Claims No: 21–1308V

6. Chad Adaway, Birmingham, Alabama, Court of Federal Claims No: 21-1311V
7. John Buen, Boston, Massachusetts, Court of Federal Claims No: 21-1314V
8. Robert Ben, Colorado Springs, Colorado, Court of Federal Claims No: 21-1315V
9. David Plaut, Fort Collins, Colorado, Court of Federal Claims No: 21-1316V
10. Ciara Johnson, Durango, Colorado, Court of Federal Claims No: 21-1317V
11. Lindsay Walker on behalf of R.W., Aurora, Colorado, Court of Federal Claims No: 21-1318V
12. Dana Hilden, Phoenix, Arizona, Court of Federal Claims No: 21-1321V
13. Debbie L. Tice, Jackson, Mississippi, Court of Federal Claims No: 21-1322V
14. Rhonda Boyd, Huntsville, Alabama, Court of Federal Claims No: 21-1323V
15. Janice Walker, Ventura, California, Court of Federal Claims No: 21-1325V
16. Mary Patricia Turner, Washington, District of Columbia, Court of Federal Claims No: 21-1327V
17. Kara Mahuron, Washington, District of Columbia, Court of Federal Claims No: 21-1328V
18. Estate of James Leroy Doeblor, Deceased, Pascagoula, Mississippi, Court of Federal Claims No: 21-1331V
19. Marlena Lloyd and Jeffrey Lloyd on behalf of C.L., Boston, Massachusetts, Court of Federal Claims No: 21-1332V
20. Keith Montague, Boston, Massachusetts, Court of Federal Claims No: 21-1333V
21. Daniel Murphy, Philadelphia, Pennsylvania, Court of Federal Claims No: 21-1334V
22. Jennifer Huch and Lucas Huch on behalf of L.L.L.H., Bedford, Texas, Court of Federal Claims No: 21-1335V
23. Michelle Gill on behalf of A.G., Phoenix, Arizona, Court of Federal Claims No: 21-1336V
24. Thomas Burbank, Plainville, Connecticut, Court of Federal Claims No: 21-1337V
25. Clifton Foley and Kelli Foley on behalf of N.F., Deceased, Burlington, North Carolina, Court of Federal Claims No: 21-1338V
26. Juanita Artman, Washington, District of Columbia, Court of Federal Claims No: 21-1340V
27. Ramon K. Jusino and Ann M. Jusino on behalf of W.J. Staten Island, New York, Court of Federal Claims No: 21-1342V
28. Nardia Thompson Harris, Nanuet, New York, Court of Federal Claims No: 21-1345V
29. Michael Williamson, Murfreesboro, Tennessee, Court of Federal Claims No: 21-1346V
30. John Allain, Sulphur, Louisiana, Court of Federal Claims No: 21-1349V
31. Jennifer Clark, Chattanooga, Tennessee, Court of Federal Claims No: 21-1350V
32. Robert Silver, Shelby, North Carolina, Court of Federal Claims No: 21-1351V
33. Kelsey Hamonds, Edgewood, Kentucky, Court of Federal Claims No: 21-1352V
34. Mindy Schuehrer, Marie, Michigan, Court of Federal Claims No: 21-1353V
35. Hortencia Torres, Annandale, Virginia, Court of Federal Claims No: 21-1356V
36. Laurel Bennett, Washington, District of Columbia, Court of Federal Claims No: 21-1357V
37. Marie Tully, Washington, District of Columbia, Court of Federal Claims No: 21-1358V
38. Donna Fulbright, Washington, District of Columbia, Court of Federal Claims No: 21-1359V
39. Jovonna Beyer, New York, New York, Court of Federal Claims No: 21-1362V
40. Richard Munoz, Plant City, Florida, Court of Federal Claims No: 21-1369V
41. Josephine Feitel, Georgetown, Texas, Court of Federal Claims No: 21-1370V
42. Austin Reid, Louisville, Kentucky, Court of Federal Claims No: 21-1374V
43. Elizabeth Fellows, Kansas City, Missouri, Court of Federal Claims No: 21-1378V
44. Stephen R. Hunt, Athens, Ohio, Court of Federal Claims No: 21-1379V
45. Raymond Milligan, Jr., Sulphur Springs, Texas, Court of Federal Claims No: 21-1382V
46. Tina Paxson, Bloomington, Indiana, Court of Federal Claims No: 21-1383V
47. Rashawnda L. Benton, Greensboro, North Carolina, Court of Federal Claims No: 21-1384V
48. Jerome Dacurawat, Alexandria, Virginia, Court of Federal Claims No: 21-1389V
49. Krystal Kilgore, Morristown, Tennessee, Court of Federal Claims No: 21-1390V
50. Jeffrey A. Ridenour, Lima, Ohio, Court of Federal Claims No: 21-1392V
51. Lori Kathleen Ogden Erickson, Milton, Washington, Court of Federal Claims No: 21-1395V
52. Angela Saporito, Nutley, New Jersey, Court of Federal Claims No: 21-1398V
53. Shawn Wilson-Blount, White Plains, New York, Court of Federal Claims No: 21-1400V
54. Geeta Karra, Philadelphia, Pennsylvania, Court of Federal Claims No: 21-1402V
55. Jonathan Charter, Manchester, Connecticut, Court of Federal Claims No: 21-1404V
56. Tammy Walden on behalf of J.F., Phoenix, Arizona, Court of Federal Claims No: 21-1406V
57. Bruce A. Ades, Denver, Colorado, Court of Federal Claims No: 21-1407V
58. Wendy O'Neil, Englewood, New Jersey, Court of Federal Claims No: 21-1410V

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research

Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**DATES:** The meeting will be held on Wednesday, July 21, from 11:00 a.m. until 4:30 p.m., and Thursday, July 22, 2021, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website when this information becomes available.

**ADDRESSES:** This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, July 21, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with presentation of recommendations on justice as an ethical concept in 45