

the above information, ORA found that the felony convictions were for conduct relating to the regulation of drug products. The product testing at issue included drug products, specifically sunscreens.¹

On March 14, 2023, Winne submitted a request for a hearing. Winne's request for a hearing does not provide any information or factual analysis rebutting the findings in ORA's proposal to debar him. Instead, Winne's request for a hearing raises three policy considerations. First, Winne admits his wrongdoing and confirms the appropriateness of debarment but asks FDA to consider a "reduced decision" due to his ability to "make a significant difference in the industry by offering my unique perspective on clinical studies and clinical data." Second, Winne mentions the debarment of another individual linked to the same investigation and states that his actions stemmed from that individual's direction. Third, Winne asserts that he cooperated with Federal investigators throughout the investigation process.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Winne's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). Winne has not raised a genuine and substantial issue of fact regarding whether he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Rather, Winne affirms that he engaged in fraudulent conduct regarding the product testing that this conduct formed the factual basis of the felony convictions. Insofar as Winne intends to argue that he provided "substantial assistance" in the investigation or prosecution of qualifying offenses under section 306(d)(4)(C) of the FD&C Act, he

may apply for special termination of his debarment. While the statute does not define substantial assistance, FDA "considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases."²

II. Findings and Order

The Chief Scientist, under section 306(a)(2) of the FD&C Act and under the authority delegated to her, finds that David Roy Winne has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. As a result of the foregoing findings, Winne is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Winne, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Winne, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Winne during his period of debarment.

Dated: August 14, 2023.

Namandjé N. Bumpus,
Chief Scientist.

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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 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

¹ See section 201(g) of the FD&C Act (21 U.S.C. 321(g)) (defining drugs, *inter alia*, to include products for use in preventing disease in man or intended to affect the structure or function of the body); "Sunscreen Drug Products for Over-the-Counter Human Use," 43 FR 38206 at 38209 (August 25, 1978) (stating an FDA-convened panel's conclusion that "products intended to be used for prevention of sunburn or any other such similar condition should be regarded as drugs"); see also 21 CFR 201.327 (2011) (outlining certain testing requirements for certain over-the-counter sunscreen drug products and declaring such products to be misbranded if SPF labeling claims not supported by adequate testing).

² "Baldev Raj Bhutani; Denial of Hearing on Application for Special Termination of Debarment," 77 FR 75636 at 75638 (December 12, 2012) (citing "Amirul Islam; Grant of Special Termination; Final Order Terminating Debarment," 68 FR 58352 (October 9, 2003)).

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 June 1, 2023, through June 30, 2023. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the 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, Health 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.

Carole Johnson,
Administrator.

List of Petitions Filed

1. Nancy Wessel, Topeka, Kansas, Court of Federal Claims No: 23-0797V
2. Alfred Englert, Jr., Fort Worth, Texas, Court of Federal Claims No: 23-0798V
3. Valentina Mudrenco on behalf of T. M., Carmichael, California, Court of Federal Claims No: 23-0799V
4. Nikkia Martin on behalf of C. K., Oxon Hill, Maryland, Court of Federal Claims No: 23-0801V
5. Juli Shimp on behalf of Taryn Starck, Deceased, Phoenix, Arizona, Court of Federal Claims No: 23-0802V
6. Patricia West, Chapel Hill, North Carolina, Court of Federal Claims No: 23-0803V
7. Trennese Howard-Lucas, Southfield, Michigan, Court of Federal Claims No: 23-0804V
8. Sarah Pittenger, Lake Ariel, Pennsylvania, Court of Federal Claims No: 23-0807V
9. Jacqueline Grutsch McKinney, Muncie, Indiana, Court of Federal Claims No: 23-0812V
10. Carla Thomas, Columbus, Ohio, Court of Federal Claims No: 23-0814V
11. Valeri Cowart, Birmingham, Alabama, Court of Federal Claims No: 23-0816V
12. Emily Beck, Racine, Wisconsin, Court of Federal Claims No: 23-0817V
13. Danielle Kellogg, Golden, Colorado, Court of Federal Claims No: 23-0819V
14. Zayne Wodzinski, Coraopolis, Pennsylvania, Court of Federal Claims No: 23-0823V
15. Alicia Sawyer on behalf of T. S., Woodstock, Georgia, Court of Federal Claims No: 23-0825V
16. Cara Barger, Dresher, Pennsylvania, Court of Federal Claims No: 23-0826V
17. Neyton Colindres, Los Angeles, California, Court of Federal Claims No: 23-0827V
18. Steven Rios, Ronkonkoma, New York, Court of Federal Claims No: 23-0830V
19. William Wotawa, Boston, Massachusetts, Court of Federal Claims No: 23-0831V
20. Luke Laporta, Phoenix, Arizona, Court of Federal Claims No: 23-0842V
21. Andrea Lynette Ortiz, Belen, New Mexico, Court of Federal Claims No: 23-0845V
22. Juha Oh, Portland, Oregon, Court of Federal Claims No: 23-0847V
23. Barbara Powers, Prescott, Arizona, Court of Federal Claims No: 23-0848V
24. Sharon Engel, Washington, District of Columbia, Court of Federal Claims No: 23-0850V
25. Sean Patrick Regan, Smithtown, New York, Court of Federal Claims No: 23-0851V
26. Amanda Sutton, Phoenix, Arizona, Court of Federal Claims No: 23-0852V
27. John Gautier, Wilmington, North Carolina, Court of Federal Claims No: 23-0860V
28. Sharon Beasley, Dallas, Georgia, Court of Federal Claims No: 23-0861V
29. Marisa Brienza, Toledo, Ohio, Court of Federal Claims No: 23-0863V
30. Judy McMahon, Campbell, California, Court of Federal Claims No: 23-0864V
31. Kristen McKiernan, Boston, Massachusetts, Court of Federal Claims No: 23-0865V
32. Nancy Prante, Olmsted, Ohio, Court of Federal Claims No: 23-0869V
33. Christopher Gorkinski, Salem, Wisconsin, Court of Federal Claims No: 23-0870V
34. Ashley Langelier, Phoenix, Arizona, Court of Federal Claims No: 23-0871V
35. Denise M. Hocht, Fruita, Colorado, Court of Federal Claims No: 23-0874V
36. Pamela Browning, Easley, South Carolina, Court of Federal Claims No: 23-0875V
37. Iris Rosario, Hartford, Connecticut, Court of Federal Claims No: 23-0876V
38. Deborah Ellison, Clarksville, Tennessee, Court of Federal Claims No: 23-0877V
39. Anna Thompson, Notre Dame, Indiana, Court of Federal Claims No: 23-0881V
40. Rod Senior on behalf of the Estate of Susan Senior, Deceased, Fort Myers, Florida, Court of Federal Claims No: 23-0882V
41. Margaret Hand, Las Vegas, Nevada, Court of Federal Claims No: 23-0883V
42. Mary Levy, North Riverside, Illinois, Court of Federal Claims No: 23-0884V
43. Claudia Thompson, Jacksonville, Florida, Court of Federal Claims No: 23-0885V
44. Giovannina Delli Compagni, Edgewater, New Jersey, Court of Federal Claims No: 23-0886V
45. Jo Hahn, Port St. Lucie, Florida, Court of Federal Claims No: 23-0888V
46. Shelli Getz, Boston, Massachusetts, Court of Federal Claims No: 23-0890V
47. Noelani Bailey, Sacramento, California, Court of Federal Claims No: 23-0892V
48. Gail Cope, Grove City, Ohio, Court of Federal Claims No: 23-0893V
49. Morgan Kirby, Phoenix, Arizona, Court of Federal Claims No: 23-0895V
50. James Rudolph, Washington, District of Columbia, Court of Federal Claims No: 23-0898V
51. Lisa Taylor, Berkeley, California, Court of Federal Claims No: 23-0899V
52. Alisa Inahara, San Diego, California, Court of Federal Claims No: 23-0900V
53. Donna Losago, Washington, District of Columbia, Court of Federal Claims No: 23-0902V
54. Winifred Elbertson, White House, Tennessee, Court of Federal Claims No: 23-0903V
55. Gary Kafer, Gatesville, Texas, Court of Federal Claims No: 23-0905V
56. Melissa Malloy, Phoenix, Arizona, Court of Federal Claims No: 23-0907V
57. Dena Long, South Jordan, Utah, Court of Federal Claims No: 23-0912V
58. Valerie Amundsen, Fridley, Minnesota, Court of Federal Claims No: 23-0914V
59. Jennifer Capobianco-Petras, Danvers, Massachusetts, Court of Federal Claims No: 23-0915V
60. Cheeranjiva Dhanraj, Killeen, Texas, Court of Federal Claims No: 23-0916V
61. Susan Hubbard, Wauwatosa, Wisconsin, Court of Federal Claims No: 23-0917V
62. Cassandra Gibbs, Cincinnati, Ohio, Court of Federal Claims No: 23-0923V

63. Emory Garrett, Duarte, California, Court of Federal Claims No: 23–0924V
 64. Jay M. Burrows, Clayton, New York, Court of Federal Claims No: 23–0925V
 65. Teresa Jupiter, Florence, South Carolina, Court of Federal Claims No: 23–0927V
 66. Jacqueline London, Morris Plains, New Jersey, Court of Federal Claims No: 23–0929V
 67. Mary Mahoney, Ellston, Iowa, Court of Federal Claims No: 23–0932V
 68. Alexandra Cumming, Phoenix, Arizona, Court of Federal Claims No: 23–0937V
 69. Rebecca J. Barger, Honolulu, Hawaii, Court of Federal Claims No: 23–0939V
 70. Vicki Mullin, Paso Robles, California, Court of Federal Claims No: 23–0940V
 71. Lisa Bakke, Seattle, Washington, Court of Federal Claims No: 23–0941V
 72. Nancy Ann Buccigrossi, Wellesley, Massachusetts, Court of Federal Claims No: 23–0943V
 73. Elizabeth Pomales-Rodriguez, Wellington, Florida, Court of Federal Claims No: 23–0945V
 74. Daniel Alam, Boston, Massachusetts, Court of Federal Claims No: 23–0947V
 75. Sharon Kawashiri, Torrance, California, Court of Federal Claims No: 23–0949V
 76. Hannah Ellis, Fort Wayne, Indiana, Court of Federal Claims No: 23–0962V
 77. Sylvester Barnes, III, Orange, Ohio, Court of Federal Claims No: 23–0963V
 78. Nicole Scammell on behalf of V. S., Commack, New York, Court of Federal Claims No: 23–0974V
 79. Renae Walker, Atlanta, Georgia, Court of Federal Claims No: 23–0978V
 80. Sheryl Leturgey on behalf of B. L., Oswego, Illinois, Court of Federal Claims No: 23–0979V
 81. Christine Avery, Seattle, Washington, Court of Federal Claims No: 23–0984V
 82. Michael Goncalves, Sacramento, California, Court of Federal Claims No: 23–0985V
 83. Garrett Dolling, Reno, Nevada, Court of Federal Claims No: 23–0986V
 84. Ainsley McLaughlin, Phoenix, Arizona, Court of Federal Claims No: 23–0987V
 85. Robert Wilson, Houston, Texas, Court of Federal Claims No: 23–0988V
 86. Avery Carter, Harlan, Iowa, Court of Federal Claims No: 23–0989V
 87. Linda McCurdy, Lancaster, Pennsylvania, Court of Federal Claims No: 23–0990V
 88. Brenda Coles-Jacobs, Feasterville, Pennsylvania, Court of Federal Claims No: 23–0991V
 89. Alexis Rodriguez, Phoenix, Arizona, Court of Federal Claims No: 23–0992V
 90. Darlene Roberts, Boston, Massachusetts, Court of Federal Claims No: 23–0993V
 91. Kathy Sanders, Newnan, Georgia, Court of Federal Claims No: 23–0996V
 92. Joanne Doherty, Boston, Massachusetts, Court of Federal Claims No: 23–0998V
 93. Leysa Stotemyer, Harrisburg, Pennsylvania, Court of Federal Claims No: 23–1001V
 94. Gisella Vargas, Neptune, New Jersey, Court of Federal Claims No: 23–1010V
 95. Terrill O'Brien, Glassboro, New Jersey, Court of Federal Claims No: 23–1011V
 96. Louis Massa, Akron, Ohio, Court of Federal Claims No: 23–1012V
 97. Daisy Jutting, Hayti, South Dakota, Court of Federal Claims No: 23–1014V
 98. Amanda Rivera on behalf of A. R., Phoenix, Arizona, Court of Federal Claims No: 23–1017V
 99. Kelly Joynier, Columbia, South Carolina, Court of Federal Claims No: 23–1020V

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BILLING CODE 4165–15–P

TABLE 1—WPSI AWARD RECIPIENT
[2021–2026]

Grant No.	Award recipient name	City, state	Award amount
UH0MC29440	American College of Obstetricians and Gynecologists	Washington, DC	\$449,000

Justification: Supplemental funding under this award will enhance HRSA's efforts to disseminate the Women's Preventive Service Guidelines and increase knowledge of the guidelines in standard clinical practice. The planned supplemental award to ACOG is within the scope of the most recent funding opportunity's (HRSA–21–045) program purpose, which aims to improve women's health across the lifespan. The supplemental funding, not to exceed \$449,000, will support the

implementation and expansion of program education and outreach.

Carole Johnson,
Administrator.

[FR Doc. 2023–17808 Filed 8–17–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award;
Women's Preventive Services Initiative

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

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing supplemental funds not to exceed \$449,000 to the Women's Preventive Services Initiative (WPSI) in fiscal year 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, Chief, Maternal and Women's Health Branch, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, at ksherman@hrsa.gov and 301–443–1702.

SUPPLEMENTARY INFORMATION: *Intended Recipient of the Award:* One award to American College of Obstetricians and Gynecologists (ACOG), the current recipient under WPSI, as listed in Table 1.

Amount of Non-Competitive Award: One award up to \$449,000.

Project Period: March 1, 2021, to February 28, 2026.

CFDA Number: 93.110.

Award Instrument: Supplement.

Authority: 42 U.S.C. 701(a)(2) (title V, section 501(a)(2) of the Social Security Act).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supplements to Sickle Cell Disease
Newborn Screening Follow-up
Program Recipients (HRSA–21–036)

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

ACTION: Notice of supplemental awards.

SUMMARY: HRSA will provide supplemental award funds to all 25 Sickle Cell Disease (SCD) Newborn Screening (NBS) Follow-up Program