

order the TRI-toxin and substitute it for BOTOX, and the proposal to debar specifically finds that another physician authorized a nurse to place that order. However, Dr. Lynch, as a principal of TPSG, was responsible for failing to ensure that there were controls and procedures in place to prevent other physicians or a nurse from ordering unapproved drugs for administration to patients. His own admitted inaction on that front warrants treating his management participation as an unfavorable factor.¹

Consistent with the proposal to debar, the record establishes that the medical practice of which Dr. Lynch was a part ultimately took voluntary steps to mitigate the effect on the public health from its unlawful conduct (see section 306(c)(3)(C) of the FD&C Act). Furthermore, it is undisputed that Dr. Lynch had no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F) of the FD&C Act). Therefore, these will be treated as favorable factors. In light of the foregoing four considerations, one of which weighs against Dr. Lynch, debarment for 2 years is appropriate.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to him, finds that Dr. Lynch has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 2 years is appropriate.

As a result of the foregoing findings, Dr. Lynch is debarred for 2 years 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) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved, or pending, drug product application, who knowingly uses the services of Dr. Lynch, in any capacity during his

period of debarment, will be subject to civil money penalties. If Dr. Lynch, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Lynch during his period of debarment.

Any application by Dr. Lynch for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0301 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov/>.

Dated: February 24, 2015.

Stephen Ostroff,

Director, Office of the 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, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services 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 11C-26, Rockville, MD 20857; (301) 443-6593.

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 of Health and Human Services, 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 Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which 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 January 1, 2015, through January 31, 2015. 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.

¹ See *United States v. Park*, 421 U.S. 658, 673-74 (1975) (holding that a high-level manager within a business entity bears a responsibility to prevent and correct violations of the FD&C Act).

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. “Sustained, 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. “Sustained, 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, Room 11C-26, 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 25, 2015.

Mary K. Wakefield,
Administrator.

List of Petitions Filed

1. Jason Chevalier, Wakefield, Rhode Island, Court of Federal Claims No: 15-0001V
2. Juan Alvarado, Rockaway Park, New York, Court of Federal Claims No: 15-0002V
3. Kimberly Durgala, Johnson City, New York, Court of Federal Claims No: 15-0003V
4. Leanell Jones, Fairfield, California, Court of Federal Claims No: 15-0004V
5. Marion Eugene Hayward, Wellesley Hills, Massachusetts, Court of Federal Claims No: 15-0005V
6. Kathleen Konen on behalf of Joseph Konen, Lexington, Michigan, Court of Federal Claims No: 15-0006V
7. Deborah Valles, Oak Lawn, Illinois, Court of Federal Claims No: 15-0007V
8. William Davis and Nicole Davis on behalf of Z.D., Lexington, North Carolina, Court of Federal Claims No: 15-0008V
9. Wyatt Tanner, Columbus, Ohio, Court of Federal Claims No: 15-0011V
10. John Ford, Charleston, South Carolina, Court of Federal Claims No: 15-0012V
11. Martin Crowley, Parris Island, North Carolina, Court of Federal Claims No: 15-0015V
12. Candie Decker on behalf of A.D., Great Neck, New York, Court of Federal Claims No: 15-0017V
13. Norman Reed, Bridgewater, Massachusetts, Court of Federal Claims No: 15-0018V
14. Erica Vancleave, Mill Creek, Washington, Court of Federal Claims No: 15-0019V
15. Linda Schorel, Hudson, Florida, Court of Federal Claims No: 15-0021V
16. Oscar A. Dighero, Garden Grove, California, Court of Federal Claims No: 15-0022V
17. Brandie Terry, Brazoria, Texas, Court of Federal Claims No: 15-0023V
18. Randall Ho, Chicago, Illinois, Court of Federal Claims No: 15-0025V
19. Elaine Stout, Centreville, Virginia, Court of Federal Claims No: 15-0026V
20. Rachael Hanna, Boston, Massachusetts, Court of Federal Claims No: 15-0031V
21. Julie Reiling, Phoenix, Arizona, Court of Federal Claims No: 15-0032V
22. Sherry Smith, Sarasota, Florida, Court of Federal Claims No: 15-0033V
23. Rachel Faucher, Berlin, New Hampshire, Court of Federal Claims No: 15-0034V
24. Cynthia Kuhn, Boston, Massachusetts, Court of Federal Claims No: 15-0035V
25. Wahib Mashini, Irvine, California, Court of Federal Claims No: 15-0036V
26. Patricia Lynne Spilman, Towson, Maryland, Court of Federal Claims No: 15-0037V
27. Linda Roche, Boston, Massachusetts, Court of Federal Claims No: 15-0038V
28. Audra Najera, San Diego, California, Court of Federal Claims No: 15-0039V
29. Jamie Emerson, Boston, Massachusetts, Court of Federal Claims No: 15-0042V
30. Todd Carlson and Carrie Carlson on behalf of E.C., Vienna, Virginia, Court of Federal Claims No: 15-0043V
31. Willard First, Langhorne, Pennsylvania, Court of Federal Claims No: 15-0047V
32. Louis Danni, Niagara Falls, New York, Court of Federal Claims No: 15-0048V
33. Violet Wilson, Auburn, California, Court of Federal Claims No: 15-0049V
34. Douglas Tullio, Washington, District of Columbia, Court of Federal Claims No: 15-0051V
35. Timothy Kelly, Jackson, Michigan, Court of Federal Claims No: 15-0052V
36. Craig Richardson, Princeton, New Jersey, Court of Federal Claims No: 15-0053V
37. Thomas Steffens on behalf of William K. Woll, Deceased, Venice, Florida, Court of Federal Claims No: 15-0059V
38. Rebeca Vega Henchys, Aguadilla, Puerto Rico, Court of Federal Claims No: 15-0060V
39. Finnettia Garner, Houston, Texas, Court of Federal Claims No: 15-0063V
40. Margaret Carpenter, Easton, Pennsylvania, Court of Federal Claims No: 15-0064V
41. Leah Hawkins Bennett on behalf of Varnadora McNeal Hawkins, Deceased, Winter Haven, Florida, Court of Federal Claims No: 15-0065V
42. Jillaine Burghardt, Lake Success, New York, Court of Federal Claims No: 15-0067V
43. David Hoskins, Jr. on behalf of Annabelle Hoskins, Deceased, Huber Heights, Ohio, Court of Federal Claims No: 15-0071V
44. Leslie Hammond, Ephraim, Utah, Court of Federal Claims No: 15-0072V
45. Jose De La Cruz Herrera, Birmingham, Alabama, Court of Federal Claims No: 15-0076V
46. Laura Williams, Farmville, Virginia, Court of Federal Claims No: 15-0080V
47. Phyllis Webb, Millsboro, Delaware, Court of Federal Claims No: 15-0081V
48. Gail A. Clements on behalf of Ronald Clements, Deceased, Murrieta, California, Court of Federal Claims No: 15-0083V
49. Angelika Belgrade, Wilmington, Delaware, Court of Federal Claims No: 15-0084V
50. Sevela DePlush and Mykelle D’Tiole on behalf of M.J.D., Bayside, California, Court of Federal Claims No: 15-0085V
51. Michelle Schneider on behalf of R.S., Leander, Texas, Court of Federal Claims No: 15-0086V
52. Jacqueline Haim, Weston, Florida, Court of Federal Claims No: 15-0089V
53. James Moore, Weston, Florida, Court of Federal Claims No: 15-0090V
54. James Bojan on behalf of J.D.B., Baraboo, Wisconsin, Court of Federal Claims No: 15-0091V
55. Laurie Dart, St. Petersburg, Florida, Court of Federal Claims No: 15-0092V
56. Colleen Dotson, El Cajon, California, Court of Federal Claims No: 15-0093V
57. Gloria Massey Chinae, Irvine, California, Court of Federal Claims No: 15-0095V
58. Anthony Forziati, Belmont, Massachusetts, Court of Federal Claims No: 15-0096V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering (NIBIB) Announcement of Requirements and Registration for the 2015 Design by Biomedical Undergraduate Teams (DEBUT) Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The National Institute of Biomedical Imaging and Bioengineering