In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 10-771V
Filed: May 16, 2016

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OLIVIA MEYLOR,	* TO BE PUBLISHED
	*
Petitioner,	* Special Master Hamilton-Fieldman
v.	*
	*
SECRETARY OF HEALTH	* Gardasil; Human Papillomavirus (HPV)
AND HUMAN SERVICES,	* Vaccine; Statute of Limitations; First
	* Symptom or Manifestation of Onset;
	* Premature Ovarian Failure (POF);
	* Primary Ovarian Insufficiency (POI);
Respondent.	* Dismissal.
* * * * * * * * * * * * * * * * *	

Mark Krueger, Krueger & Hernandez, SC, Baraboo, WI, for Petitioner.
Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION[1]

This is an action by Olivia Meylor ("Petitioner")[2] seeking an award under the National Vaccine Injury Compensation Program (hereinafter "Program").[3] Respondent contends that the

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[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] Petitioner was a minor at the outset of litigation; thus, until she reached her eighteenth birthday, the petitioners were her parents. Once she turned eighteen, the case caption was changed. But for ease of reference, the undersigned disregards this distinction in the present decision.

[3] The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (hereinafter "Vaccine Act"), provides the statutory provisions governing the Program.

petition was untimely filed, and as such should be dismissed. For the reasons set forth below, the undersigned concludes that the petition was untimely filed, and it is therefore hereby dismissed.

I. FACTUAL BACKGROUND

Petitioner was born on May 8, 1994, without complications. Pet'r's Ex. 3 at 5-22, ECF No. 8-4.[4] Other than allergies, frequent ear infections, and asthma, her early medical history appears uneventful. At her twelve-year-old well child visit on June 7, 2006, Petitioner's pubertal development was documented at Tanner Stages I and I.[5] Pet'r's Ex. 4a at 92, ECF No. 8-5. By age 13, she was at Tanner Stages III and III, but had not yet experienced menarche.[6] *Id.* at 73, 78. She received her first HPV vaccination at her well child visit on July 6, 2007. *Id.* at 72.

Following the first vaccination, Petitioner experienced headaches, cramping, and joint pain. Tr. at 36, *Madelyn Meylor v. Sec'y of HHS*, No. 10-770V, ECF No. 60, 62, 66 (hereinafter "*Meylor* Tr."). Additionally, she complained "of general symptoms such as depression and sleep disturbances" and had "episodes of lightheadedness and tremulousness, anxiety, panic attacks, and difficulties in focusing/concentrating in her school work." Pet'r's Ex. 31 at 2, ECF No. 50-3 (Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian Failure:*

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[4] Unless explicitly provided otherwise, all citations refer to the exhibits in *Meylor*, not *Culligan v. Sec'y of HHS*, No. 14-318V.

[5] Pubertal development is measured by assessing an individual's stages of puberty using the Tanner growth chart, which is "based on pubic hair growth, development of genitalia in boys, and breast development in girls." Tanner stage, *Stedman's Medical Dictionary* (28th Ed. 2013) (hereinafter "*Stedman's*"). The undersigned considers Tanner stages I (child) and II (prepubertal) as showing "no signs of pubertal development," and Tanner stages III (early pubescent) and IV (late pubescent) as showing such signs. Dr. Frankfurter testified that a young woman who has never menstruated and who has no signs of secondary sexual development by age 13 should be evaluated. Tr. at 377, *Culligan,* ECF Nos. 81, 83 (unlike with exhibits, citations are to the transcript in *Culligan* unless provided otherwise).

[6] Menarche is "the establishment or beginning of menstruation." Menarche, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*"). Menstruation is "the cyclic, physiologic discharge through the vagina of blood and mucosal tissues from the nonpregnant uterus; it is under hormonal control and normally recurs, usually at approximately four-week intervals, in the absence of pregnancy during the reproductive period (puberty through menopause) of the female of the human." Menstruation, *Dorland's*.

Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants, Am. J. Reproductive Immunology (2013)).[7]

Petitioner received the second dose of the HPV vaccine on November 15, 2007, Pet'r's Ex. 4a at 71, and the third dose on August 1, 2008, *id.* at 62. On September 28, 2009, Mrs. Meylor telephoned the office of Petitioner's gynecologist to inquire about testing for menstrual problems, since Petitioner's older sister was undergoing such testing. *Id.* at 44. Mrs. Meylor was advised to contact Petitioner's primary provider if she was "not getting periods." *Id.*

On October 8, 2009, Mrs. Meylor called the office of Petitioner's pediatrician to express her concern that Petitioner might be depressed. *Id.* at 43. She described Petitioner as "tearful, withdrawn, not motivated, and [unable to] sleep." *Id.* She was referred to make an appointment for behavioral counseling. *Id.*

On November 27, 2009, Petitioner presented to her pediatrician for an evaluation of swelling around her eyes and hives on her abdomen. *Id.* at 38. Following an examination, she was diagnosed with acute urticaria of likely viral etiology and advised to treat with an anti-inflammatory and an antihistamine. *Id.* at 39. There was no discussion of her lack of menses noted, nor any mention of the behavioral issues.

On January 29, 2010, Petitioner was evaluated for an upper respiratory infection ("URI"). *Id.* at 34. She reported symptoms of cough, chest tightness, and intermittent fever. *Id.* The physician diagnosed viral URI with bronchospasm, and prescribed Prednisone (an albuterol inhaler) and cough syrup with codeine. *Id.*

On February 10, 2010, Petitioner saw her primary physician for fever, cough, and body aches, including some headaches, and lethargy, all of which had been ongoing for two months. *Id.* at 29. Physical examination was "basically normal." *Id.* at 30. She was diagnosed with sinusitis and prescribed a high-dose of amoxicillin. Pet'r's Ex. 4a at 30. The physician noted

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[7] Petitioner's medical history is presented as a case study in this article co-authored by her medical expert, Dr. Yehuda Shoenfeld. *See Meylor* Tr. at 148 (affirming that "Case 2" is Petitioner). The article discloses that Petitioner complained of these symptoms "10 days after the first injection." Pet'r's Ex. 31 at 2. Dr. Schoenfeld confirmed that this medical history was obtained from Petitioner's mother, and not from Petitioner's medical records. *Meylor* Tr. at 235. When asked by the undersigned whether he thought it was strange that this history was not reflected in the medical records, he replied in the negative, explaining that physicians vary in what they choose to write in a clinical chart, and that subjective complaints such as sleep disturbances are often not noted. *Id.* at 233-34. Petitioner's mother also testified that, as teenagers, her daughters were not very forthcoming with their doctors. *Id*. at 232-33, 37-38.

that he was "not sure" all of Petitioner's symptoms were due to the sinusitis and suspected possible anxiety or depression. *Id.*

On March 30, 2010, Petitioner returned for an evaluation of cold symptoms. *Id.* at 24. She was diagnosed with chronic sinusitis and prescribed another course of amoxicillin. *Id.*

On April 28, 2010, Petitioner's mother called the primary care physician's after-hours service to report that Petitioner had a fever and was vomiting. *Id.* at 20. Based on the symptoms, the nurse assessed probable viral gastritis and provided instructions on proper care. *Id.* In response to a question asked during the call, Petitioner's mother stated that Petitioner's menses were irregular, with her only menstrual period occurring in December 2009. *Id.*

In early May 2010, Petitioner's mother telephoned the primary care physician's office to express concern about Petitioner having had only one period to date and to request an evaluation for possible primary ovarian insufficiency ("POI").[8] *Id.* at 18-19. She was especially concerned because Petitioner's sister had been diagnosed with that condition. *Id.* Petitioner was referred to a physician assistant in endocrinology, Kathleen Gamoke, for consultation. *Id.*

On July 6, 2010, Petitioner presented for her evaluation with Ms. Gamoke. Petitioner reported that she had had only two menstrual periods—the first in November 2009 and a second in December—and was thereafter amenorrheic. *Id.* at 13-17. Physical examination was unremarkable and she appeared to be in good health. *Id.* Blood was drawn for testing, and depending on the results, a pelvic ultrasound and additional screening would be ordered. *Id.*

On July 8, 2010, Ms. Gamoke left a message for Petitioner's mother to call regarding Petitioner's results. *Id.* at 11. The following day, Petitioner's mother was informed that the testing showed Petitioner had "high FSH and LH with undetectable estradiol," results that were consistent with ovarian failure. *Id.* On July 12, 2010, Petitioner underwent a pelvic ultrasound, which reflected a normal appearing uterus, but did not convincingly identify her ovaries. *Id.* at 136. Subsequent genetic testing was negative for Fragile-X syndrome. *Id.* at 126.

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[8] Although the parties and the undersigned initially used the term, "premature ovarian failure" or "POF" to define Petitioner's injury— it became clear from the literature filed by the experts that POI "is the preferred term for the condition that was previously referred to as [POF]. . . . The condition is considered to be present when a woman who is less than 40 years old has had amenorrhea for 4 months or more, with two serum FSH levels (obtained at least 1 month apart) in the menopausal range." *See* Pet'r's Ex. 15, Tab 1 at 1, *Culligan*, ECF No. 53-2 (Lawrence Nelson, *Primary Ovarian Insufficiency*, 360 New Eng. J. Med. 606, 606 (2009)) (hereinafter "Nelson" with pincites to Petitioner's pagination). Therefore, the undersigned will refer to the condition as POI.

On July 28, 2010, Ms. Gamoke confirmed that Petitioner suffered from POI and recommended that she receive hormone replacement therapy and maintain adequate calcium intake for bone health. Pet'r's Ex. 4a at 9. She also recommended yearly screening for other autoimmune disorders. *Id.* She counseled that if Petitioner wished to conceive, she would need to see a reproductive endocrinologist. *Id.* However, the likelihood of a pregnancy was low. *Id.* Petitioner received a prescription for Ortho-Cept (desogestrel and ethinyl estradiol). *Id.*

On October 5, 2010, Petitioner's mother telephoned Ms. Gamoke's office to report that Petitioner was experiencing breakthrough bleeding and to request that a higher dose of hormones be prescribed. *Id.* at 8. A prescription for TriNessa (norgestimate and ethinyl estradiol), a different hormone medication, was provided. *Id.* On October 14, 2010, Petitioner's mother called to report that Petitioner continued to bleed heavily. *Id.* at 7. Ms. Gamoke advised that Petitioner stop the hormone treatment and retry the new pill after two months. *Id.* At a follow-up appointment on December 1, 2010, Petitioner was prescribed a new hormone therapy regimen consisting of Vivelle-Dot (estradiol) and Prometrium (progesterone). *Id.* at 2.

II. PROCEDURAL BACKGROUND

On November 8, 2010, Petitioner filed the present action, alleging that the Human Papillomavirus vaccinations ("Gardasil" or "HPV" vaccines) administered to her July 6 and November 15, 2007, and August 1, 2008 caused her to suffer from POI. Pet., ECF No. 1.

On December 15, 2010, the special master to whom the case was assigned held the initial status conference with the parties' counsel. *See* Minute Entry (Dec. 17, 2010). Thereafter, on December 23, 2010, Petitioner filed the required medical records and a statement of completion. *See* Statement of Completion, ECF No. 9.[9]

On March 18, 2011, Respondent filed her Rule 4(c) Report, wherein she argued both that the claim was untimely filed and that Petitioner had failed to carry her burden of proof under *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Resp't's Report at 4-8, ECF No. 11. Specifically, Respondent argued that Petitioner had not submitted an expert report or medical literature to support the assertion that the HPV vaccine caused Petitioner's POI, and "[n]one of her treating physicians attributed her problem to the vaccine." *Id.* at 6. Furthermore, "although Petitioner stopped menstruating after she had received three HPV vaccinations, her last menstrual period was in December 2009, two and a half years after the first vaccination and more than a year after the third." *Id.* Respondent asserted that there was "no basis" in the record

[9] Additional medical records were filed on December 21, 2011, and March 27 and August 13, 2012. *See* Pet'r's Exs. 5, 6, 19, 20, ECF Nos. 18-2 to 18-4, 25-2, 30-2. These records were reviewed by the undersigned, but will not be discussed here as they are not pertinent to the issue being decided.

to establish this as a temporally appropriate time frame to associate Petitioner's vaccinations and her illness. Resp't's Report at 6. Respondent additionally noted that Petitioner's sister suffered from the same condition, which "strongly suggests that there may be a genetic cause." *Id.* In Respondent's view, Petitioner's claim was "based entirely on a '*post hoc ergo propter hoc*' line of reasoning (*i.e.*, her symptoms started after the vaccinations, therefore they were caused by the vaccinations)." *Id.*

Following a status conference on April 28, 2011, Petitioner was ordered to file a medical expert report. *See* Scheduling Order (Apr. 29, 2011), ECF No. 12. On February, 13, 2012, Petitioner filed the expert report of Dr. Shoenfeld, along with his CV and relevant medical literature. *See* Pet'r's Exs. 7-16, ECF Nos. 23-2 to 24-3. The report and CV of a second expert, Dr. Orit Pinhas-Hamiel ("Dr. Hamiel"), were filed on March 22, 2012. Pet'r's Exs. 17-18, ECF Nos. 24-2 to 24-3.

On March 28, 2012, the special master convened a status conference to discuss Petitioner's expert reports. *See* Minute Entry (Mar. 28, 2012). Due to certain deficiencies in the reports, Petitioner was ordered to file a supplemental report from Dr. Shoenfeld, and was given the option of filing a supplemental report from Dr. Hamiel. *See* Scheduling Order (Mar. 30, 2012) at 1-3, ECF No. 26.

On August 15, 2012, Petitioner filed Dr. Shoenfeld's supplemental report, along with supporting medical literature. *See* Pet'r's Exs. 21-26, ECF No. 31-2 to 31-7.

On October 22, 2012, Respondent filed responsive expert reports and CVs from Drs. Barry Bercu and Arnold Levinson. Resp't's Exs. A-D, ECF Nos. 32-1 to 32-4.[10] Respondent filed relevant supporting medical literature on October 31, 2012. Resp't Exs. A1-A48, C1-C3.[11]

On February 20, 2013, the special master convened a status conference to discuss the parties' respective expert reports and to set deadlines. *See* Scheduling Order (Feb. 21, 2013), ECF No. 38. Among other things, the parties were ordered to identify dates for a two-day Entitlement Hearing. *Id.* at 3.

On February 21, 2013, Petitioner submitted a second supplemental expert report from Dr. Shoenfeld addressing the opinions of Drs. Bercu and Levinson. Pet'r's Ex. 27, ECF No. 36-2.

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[10] Respondent filed an updated CV for Dr. Levinson on November 20, 2013. Resp't's Ex. I, ECF No. 59-1.

[11] Where no ECF citation is provided, the exhibit(s) was/were filed via compact disc.

Respondent's experts declined to respond to Dr. Shoenfeld's second supplemental report. *See* Resp't's Status Report (Mar. 8, 2013) at 1, ECF No. 42.

In response to the parties' input, an Entitlement Hearing was scheduled for November 7-8, 2013, in Washington, D.C., before the undersigned. *See* Hearing Order (Apr. 8, 2013); *see also* Order Reassigning Case, ECF No. 39. A status conference was held on May 2, 2013, to discuss the pending hearing and to set additional deadlines. *See* Scheduling Order (May 23, 2013), ECF No. 45. Another status conference was held on September 17, 2013, to further discuss the hearing and to establish a schedule for pre-hearing submissions.[12] *See* Scheduling Order (Sept. 20, 2013). Petitioner and Respondent filed pre-hearing briefs on September 26, 2013, and October 24, 2013, respectively. Pet'r's Prehearing Submissions, ECF No. 52; Resp't's Prehearing Submissions, ECF No. 55.

The Entitlement Hearing was held as scheduled, *see* Minute Entry (Nov. 8, 2013), with additional testimony heard on February 6, 2014, *see* Minute Entry (Feb. 6, 2014). Petitioner filed her post-hearing brief on March 14, 2014, and Respondent filed hers on April 4, 2014. Pet'r's Post Hr'g Br., ECF No. 64; Resp't's Post Hr'g Br., ECF No. 70.

In November 2014, this case was identified for inclusion with other POI cases in an "omnibus proceeding" established to address the question of what constitutes the first symptom or manifestation of POI. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*, ECF No. 23. The answer to this question is integral to the undersigned's determination of whether each petitioner had filed her claim within the statute of limitations. *See* 42 U.S.C. § 300aa-16(a)(2) (2012) (requiring that petitions be filed prior to "the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of injury").

[12] The hearing was planned as a "dual hearing" in which the claims of Petitioner and her sister, Madelyne, would be heard together. Scheduling Order (Sept. 20, 2013) at 1, ECF No. 51. During this status conference, the undersigned emphasized that despite being heard together, the claims "involve[d] two separate and unique individuals" who must be treated distinctly "even if there is great similarity between [their] cases." *Id.* The undersigned still felt that it was appropriate to have one hearing for both girls, but underscored that "the hearing would have to be conducted carefully." *Id.* For example, "Petitioners' experts could use the same theory of how the vaccines caused the injuries claimed for both girls"; however, "the experts for both sides would need to treat the girls as separate and distinct individuals" when offering their opinions. *Id.*

The lead case in the proceeding was *Culligan.*[13] In *Culligan*, Respondent opposed entitlement to compensation because the first symptom of the petitioner's POI was oligomenorrhea,[14] which she had experienced more than three years prior to the filing of her claim, making it untimely under 42 U.S.C. § 300aa-16(a)(2). *See* Resp't's Rule 4(c) Report at 3-4, *Culligan*, ECF No. 20.

At a *Culligan* status conference held on September 23, 2014, the undersigned discussed with the parties the necessity of establishing the date that the statute of limitations began to run in *Culligan* and other cases alleging an injury of POI caused by Gardasil in order to assess the timeliness of the claims. *See* Scheduling Order (Sept. 25, 2014) at 1, *Culligan*, ECF No. 22. The undersigned directed the petitioner in *Culligan*'s counsel, Mark Krueger, who is also counsel in the instant case, to begin the process of identifying other POI claimants for inclusion in an omnibus proceeding focused on the question of timeliness.[15] *Id*.

On October 1, 2014, Mr. Krueger filed a status report in which he identified eight POI cases[16] to be included in the undersigned's assessment of timeliness. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*. Petitioner subsequently named *Culligan* as the "test case" for timeliness. *See* Pet'r's Status Report (Nov. 5, 2014) at 1, *Culligan*, ECF No. 25.

Another status conference was held on November 20, 2014, during which the parties agreed that "in all pending [POI] cases . . . an expert hearing [would] be held to address the question of what constitutes 'the first symptom or manifestation of [POI] onset recognized as such by the medical profession at large.'" Scheduling Order (Nov. 24, 2014) at 1, *Culligan*, ECF No. 26 (citing *Cloer v. Sec'y of HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc)). The undersigned explained that a timeliness determination would be made on the basis of the

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[13] Once *Culligan* had been designated as the lead case, all of the filings for the onset proceedings were completed in the *Culligan* case, and not in the trailing cases. This section of the procedural history is therefore derived from the *Culligan* case. Citations to the *Culligan* record are so noted.

[14] Oligomenorrhea is defined as "menstrual flow happening less often than normal, defined as at intervals of 35 days to 6 months; called also *infrequent menstruation*." Oligomenorrhea, *Dorland's*.

[15] Mr. Krueger represents all but one of the petitioners in the omnibus proceeding.

[16] Petitioner identified *Culligan*; *Alexander v. Sec'y of HHS*, 14-868V; *Tilley v. Sec'y of HHS*, 14-818V; *Fishkis v. Sec'y of HHS*, 14-527V; *Lee v. Sec'y of HHS*, 14-258V; *Lydia McSherry v. Sec'y of HHS*, 14-154V; *Meghan McSherry v. Sec'y of HHS*, 14-153V; and *Stone v. Sec'y of HHS*, 13-289V. Pet'r's Status Report (Oct. 1, 2014) at 1, ECF No. 23.

evidence presented at the *Culligan* hearing; similar hearings would *not* be conducted in the other POI cases, all of which would trail *Culligan* for purposes of timeliness determinations. *Id*. The undersigned added four additional POI cases[17] to the list of cases set to trail *Culligan*. *Id*. The undersigned also ordered that all parties seeking to be joined in the omnibus proceeding consent to share their medical records, *see* Scheduling Order (Nov. 24, 2014) at 2, *Culligan*, and all parties later obliged.

The parties and the undersigned proceeded to identify questions for the experts (to be researched and answered before the hearing) regarding the nature and timing of the first symptom or manifestation of onset of POI in the aforementioned cases. *See, e.g.*, Order (Feb. 18, 2015) at 1, *Culligan*, ECF No. 37; Scheduling Order (Jan. 30, 2015) at 1, *Culligan*, ECF No. 36; Pet'r's Status Report (Dec. 29, 2014) at 1, *Culligan*, ECF No. 31; Scheduling Order (Nov. 24, 2014) at 2, *Culligan*; Resp't's Status Report (Oct. 28, 2014) at 1, *Culligan,* ECF No. 24. The parties and their experts ultimately agreed that, except in *Culligan*, in which the entire medical record would be considered by the experts, the experts would "offer opinions regarding the onset issues in the trailing cases by considering the facts of those cases as hypotheticals." Joint Status Report (Jan. 20, 2015) at 1, *Culligan*, ECF No. 33. To facilitate this process, Petitioner filed summaries of the facts of all twelve POI cases. *See* Pet'r's Ex. 9, *Culligan*, ECF No. 34-2.[18] Except in *Culligan*, the experts were to rely on the factual summaries, in lieu of the medical records themselves, to articulate their opinions regarding timeliness. *See* Joint Status Report (Jan. 20, 2015) at 1, *Culligan*.

At a status conference held on January 28, 2015, the undersigned set deadlines for the parties' expert reports regarding timeliness. *See* Order (Jan. 30, 2015) at 2, *Culligan*. The experts were directed to address all of the identified timeliness questions separately, "on a question-by-question basis." *Id*. at 1.

On February 19 and March 3, 2015, three additional cases,[19] all filed by Mr. Krueger, were added to the list of POI trailing cases. *See* Scheduling Order (Mar. 3, 2015) at 1, *Culligan*,

[17] The four added cases were *Chenowith v. Sec'y of HHS*, 14-996V; *Bello v. Sec'y of HHS*, 13-349V; *Madelyne Meylor v. Sec'y of HHS*, 10-770V; and the instant case. *Id.* The petitioners in these cases were all represented by Mr. Krueger.

[18] A factual summary for another trailing POF case–*Smith v. Sec'y of HHS*, 14-1107V–was also filed in *Culligan*. *See* Order Appendix (Feb. 23, 2015) at 2-3, *Culligan*, ECF No. 39-1; *see also* Order (Jan. 30, 2015) at 1-2, *Culligan*, ECF No. 36; Order (Jan. 26, 2015), *Culligan*, ECF No. 35. The petitioner in *Smith* was represented by different counsel.

[19] The cases were *Brayboy v. Sec'y of HHS*, 15-183V; *Garner v. Sec'y of HHS*, 15-143V; and *Vakalis v. Sec'y of HHS*, 15-134V.

ECF No. 45; Scheduling Order (Feb. 19, 2015) at 1, *Culligan*, ECF No. 38. Mr. Krueger subsequently filed factual summaries of the three new cases. *See* Pet'r's Exs. 10, 11, 12, *Culligan*, ECF Nos. 40-2, 41-2, 44-2.

On March 12, March 13, and April 29, 2015, Petitioner filed expert reports and supporting medical literature, all of which were purportedly limited to the issue of timeliness. *See* Pet'r's Ex. 13, *Culligan*, ECF Nos. 47-2 to 51-6; Pet'r's Ex. 15, *Culligan*, ECF Nos. 53-1 to 54-3; Pet'r's Ex. 17, *Culligan*, ECF Nos. 76-78. The expert reports were authored by Dr. Felice Gersh and Dr. Hamiel. *See* Pet'r's Ex. 13, Tab 1, *Culligan*; Pet'r's Ex. 15, Tab 1, *Culligan*. The reports filed by Drs. Gersh and Hamiel reflected that they had reviewed the medical records underlying all of the POI cases. *See* Pet'r's Ex. 13, Tab 1 at 12-13, *Culligan*; Pet'r's Ex. 15, Tab 1 at 17, *Culligan*.

The undersigned convened a status conference on April 1, 2015, after having reviewed Petitioner's expert reports. *See* Scheduling Order (Apr. 2, 2015) at 1, *Culligan,* ECF No. 55. The undersigned noted that, "notwithstanding the fact that Petitioner's onset experts have now reviewed the medical records associated with every [POI] case, Respondent's onset expert(s) will review only the cases' factual summaries, the *Culligan* record, and Respondent's list of hypothetical questions." *Id*. Also, having expressed some concern about the extent to which Petitioner's expert reports reflected an understanding of the relevant question regarding timeliness, the undersigned reiterated the following:

> [T]he relevant date, for purposes of assessing onset under *Cloer*, is *not* the first point in time at which a definitive diagnosis could have been made; rather, it is the time at which the first symptom or manifestation of the allegedly vaccine-caused injury occurred. The onset experts must make this assessment with the benefit of hindsight, rather than placing themselves in the shoes of the treating, diagnosing physicians. The parties are directed to address this issue as specifically as possible in their pre-hearing briefs.

Id. (full citation omitted).

Respondent then filed an expert report regarding timeliness, as well as relevant medical literature, on May 8, May 28, and June 1, 2015. Resp't's Ex. A to A.32, *Culligan,* ECF Nos. 57-1 to 59-6, 63-1 to 63-3, 66-1 to 67-4. Respondent's expert report was authored by Dr. David Frankfurter. Resp't's Ex. A at 6, *Culligan*.

At a status conference held on May 14, 2015, Respondent confirmed that, in preparing his expert report, Dr. Frankfurter had reviewed only the factual summaries submitted by Petitioner (and the medical record from *Culligan*). *See* Order (May 15, 2015) at 1, *Culligan,*

ECF No. 61. Mr. Krueger agreed that, notwithstanding the fact that his experts had reviewed all of the medical records in all of the POI cases, "his experts would be referring to the factual summaries rather than to the medical records themselves" at the timeliness hearing. *Id*.

The parties filed their pre-hearing briefs simultaneously on June 1, 2015, *see* Pet'r's Prehearing Submissions, *Culligan,* ECF No. 65; Resp't's Prehearing Submissions, *Culligan,* ECF No. 69; and the hearing took place on June 16 and 17, 2015, *see* Minute Entry (June 18, 2015), *Culligan*. Petitioner's experts, Drs. Gersh and Hamiel, and Respondent's expert, Dr. Frankfurter, testified. Tr. at 4, 255.

On July 1, 2015, the undersigned issued an order identifying nine POI cases[20] "as presumptively precluded under the applicable statute of limitations." Order (July 1, 2015) at 1, *Culligan,* ECF No. 79. *Culligan* was included among the presumptively precluded cases. *Id*. The undersigned also identified six cases[21] that appeared to have been timely filed. *Id*. Having apprised the parties of these preliminary conclusions, the undersigned granted them additional time to file status reports identifying the cases in which they intended to contest this determination and explaining what they had identified as the first symptom or manifestation of onset in each of those cases. *Id*. at 2.

On August 28, 2015, Respondent filed a status report in which she stated that she did not intend to contest the undersigned's preliminary findings in any of the presumptively timely cases filed by Mr. Krueger. Resp't's Status Report (Aug. 28, 2015) at 1, *Culligan,* ECF No. 84. In status reports filed on September 2 and 30, 2015, Petitioner argued that all of the preliminarily precluded cases were, in fact, timely. *See* Pet'r's Status Report (Sept. 2, 2015) at 2-7, *Culligan*, ECF No. 85 (addressing *Culligan*, *Chenowith*, *Garner*, *Lee*, *Lydia McSherry*, and *Madelyne Meylor*); Pet'r's Status Report (Sept. 30, 2015) at 1-2, *Culligan,* ECF No. 87 (addressing *Fishkis*, *Meghan McSherry*, *Stone*).

At a status conference held on October 13, 2015, the undersigned "informed the parties that, for purposes of an onset determination, the [POI] cases [would] be divided [into] two groups: petitioners who never menstruated . . . and the rest of the [POI] petitioners." *See* Scheduling Order (Oct. 14, 2015) at 1, *Culligan,* ECF No. 88.

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[20] *Culligan*, *Chenowith*, *Fishkis*, *Garner*, *Lee*, *Lydia McSherry*, *Madelyne Meylor*, *Meghan McSherry*, and *Laughlin*. Order (July 1, 2015) at 1.

[21] The instant case, as well as *Alexander*, *Bello*, *Brayboy*, and *Vakalis*. *Id.* The undersigned also identified as timely *Smith*, a trailing POF case that had been filed by a different attorney, s*upra* n. 7. *Id.* In *Tilley*, the undersigned directed the parties to file additional briefs regarding timeliness. *Id.*

Relevant post-hearing briefing[22] concluded on January 20, 2016. *See* Pet'r's Post Hr'g Br., *Culligan,* ECF No. 91; Resp't's Post Hr'g Brs., *Culligan,* ECF No. 94; Pet'r's Post Hr'g Reply Br., *Culligan,* ECF No. 95. Petitioner's claim is now ready for a determination of the first symptom or manifestation of onset of the alleged vaccine-related injury; and, relatedly, whether the Vaccine Act's statute of limitations bars the claim.

III. ANALYSIS

A. Applicable Legal Standard

Section 300aa-16(a)(2) of the Vaccine Act provides that, regarding

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1998], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.

42 U.S.C. § 300aa-16(a)(2).

This statute of limitations is not triggered by the administration of the vaccine, but "begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought." *Cloer*, 654 F.3d at 1335. "[E]ither a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first." *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

"[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations." *Carson ex rel. Carson v. Sec'y of HHS*, 727 F.3d 1365, 1369 (Fed. Cir. 2013), *reh'g & reh'g en banc denied*, 2013 WL 4528833 at *1. "A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." *Markovich*, 477 F.3d at 1357. While the symptom of an injury must be recognized as such "by the medical profession at large," *Cloer*, 654 F.3d at 1335, even subtle symptoms that a petitioner would recognize "'only with the benefit of hindsight, after a doctor makes a definitive diagnosis of injury,'" trigger the running of the statute of limitations, whether or not the petitioner or even multiple medical providers understood their significance *at the time*. *Carson*, 727 F.3d at 1369-70 (quoting *Markovich*,

[22] Briefing addressing Petitioner's request for interim attorneys' fees is not relevant to the timeliness issue and is therefore not included in this discussion.

477 F.3d at 1358).[23]

There is no explicit or implied discovery rule under the Vaccine Act. *Cloer,* 654 F.3d at 1337. The date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine-related injury "does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Id.* at 1339. Nor does it depend on when a petitioner knew or should have known of a potential connection between an injury and a vaccine. *Id.* at 1338 ("Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury."); *see Markovich*, 477 F.3d at 1358 ("Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." (internal quotation marks omitted)).[24]

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[23] Petitioner argues that "POI is a latent injury" and that "the first symptom of onset, in terms of the applications [sic] of the statute of limitations, can be subtle and can precede manifestation of onset by months or even years." Pet'r's Post Hr'g. Br. at 9. This argument has been made before: the Court of Federal Claims, in *Setnes v. United States*, 57 Fed. Cl. 175 (2003), "was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms 'symptom' and 'manifestation.'" *Markovitch*, 477 F.3d at 1357-58. The *Setnes* court's interpretation of the "first symptom or manifestation of onset" language of the statute was rejected by *Markovich*, a ruling that has since been reaffirmed by the Federal Circuit en banc in *Cloer*. 654 F.3d at 1334-1335.

[24] To the extent Petitioner argues that this interpretation of the Vaccine Act's statute of limitations violates the Fifth Amendment on Equal Protection and Due Process Grounds, *see* Pet'r's Post Hr'g Br. at 11-13, the undersigned concurs with the reasoning articulated in numerous decisions to the contrary, all of which hold that the Act's statute of limitations does not violate the Constitution merely because it bars certain petitioners from bringing a claim before they knew, or even could have known, that their injuries were vaccine-related. *See, e.g.*, *Cloer v. Sec'y of HHS*, 85 Fed. Cl. 141, 150-51 (2008), *rev'd on other grounds*, 603 F.3d 1341, *aff'd en banc*, 654 F.3d 1322 (Fed. Cir. 2011); *Leuz v. Sec'y of HHS*, 63 Fed. Cl. 602, 607-12 (2005); *Wax v. Sec'y of HHS*, No. 03-2830V, 2012 WL 3867161, at *6-8 (Fed. Cl. Spec. Mstr. Aug. 7, 2012); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004); *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 753-54 (Ill. App. Ct. 2007).

B. Symptoms of POI Onset, Including Criteria for Distinguishing "Symptom" from "Normal"

Primary ovarian insufficiency can begin abruptly, *see* Tr. at 69; *see also* Nelson at 2-3; but it may also develop over several years, *see* Tr. at 70, 198-99, 398; *Meylor* Tr. at 447; *see also* Nelson at 2-3; Pet'r's Ex. 17, Tab 50 at 2 (Paolo Beck-Peccaz & Luca Persam, *Premature Ovarian Failure*, 1 Orphanet J. Rare Diseases, at 2 (Apr. 2006)) (hereinafter "Beck-Peccaz"). Thus, a woman could have symptoms of POI for several years before actually ceasing menstruation or being diagnosed with POI. *See* Tr. at 70, 198-99, 398*; see also* Tr. at 319; Nelson at 2-3; Beck-Peccaz at 2. The experts agreed that the symptoms of primary ovarian insufficiency include menstrual irregularities, including primary and secondary amenorrhea, cycle and frequency irregularity, and excessive or prolonged bleeding; delayed menarche; lack of breast development and poor growth velocity; night sweats; hot flashes; sleep disturbances; mood changes; joint pain; recurring ovarian cysts; arrested puberty; and marked hirsutism. Tr. at 38, 57, 68, 319, 366; *Meylor* Tr. at 59-60, 68-70, 77, 410. Most of these symptoms are not "normal" for a woman under the age of 40. Petitioner therefore does not dispute that they can constitute the "first symptom or manifestation of onset" of POI for purposes of the Act's statute of limitations.

In fact, both Petitioner's experts and the medical literature *emphasize* the degree to which symptoms other than menstrual irregularity signify POI. In her expert report, Dr. Hamiel called hot flashes and night sweats the "hallmarks of the menopausal transition." Pet'r's Ex. 15 at 5, *Culligan*. At the *Meylor* hearing, both Dr. Hamiel and Dr. Shoenfeld testified, on multiple occasions, that sleep disturbances constituted a symptom of POI, *Meylor* Tr. at 47, 53, 60, 68, 77, 126, 130, 233, as are joint pains and emotional problems such as anxiety and depression, *Meylor* Tr. at 68-70. Of particular note, Dr. Shoenfeld attested that sleep disturbances are a "major criteria" for diagnosing the autoimmune disorder, POI, and explicitly clarified that sleep disturbances are "symptoms, . . . not signs." *Id.* at 233. Furthermore, Dr. Bercu, Respondent's expert, testified that sleep disturbance and night sweats were "more typical of premature menopause" than they were of normal pubertal development. *Id.* at 381-82. And the medical literature supports the attestations of Drs. Hamiel and Shoenfeld. *See* Nelson at 4; Pet'r's Ex. 15, Tab 6 at 2, ECF No. 53-7 (Vincent T. Martin, *Migraine and the menopausal transition*, 35 Neurological Scis. S65, S66 (2014)); Resp't's Ex. A.1 at 6, ECF No. 57-3 (Corrine K. Welt, *Primary ovarian insufficiency: a more accurate term for premature ovarian failure*, 68 Clinical Endocrinology 499, 504 (2008)). Given this (and Petitioner's failure to argue otherwise), the undersigned now concludes that the aforementioned symptoms (beyond menstrual irregularities and delayed menarche), constitute symptoms of POI.

At this point, the undersigned notes that the parties engaged in a lengthy dispute in this case and the related cases regarding whether and when menstrual irregularity and delayed

menarche constitute symptoms of POI. Although an extensive discussion of the parties' positions and the undersigned's conclusion was warranted in the related cases, it is ultimately not dispositive of this case. Therefore, the undersigned merely reiterates her conclusion that menstrual irregularity constitutes a symptom when it meets the criteria specified in the ACOG Opinion. *See* Resp't's Ex. A.2, *Culligan*, ECF No. 57-4 (Comm. on Adolescent Health Care, Am. Coll. of Obstetricians & Gynecologists, *Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign*, Comm. Op. No. 349 (Nov. 2006)) (hereinafter "ACOG Opinion" or "ACOG Op."). The ACOG Opinion provides the following specific conditions under which menstrual irregularity is sufficiently abnormal so as to constitute a symptom of POI[25]:

Menstrual Conditions That May Require Evaluation

Menstrual periods that:

- Have not started within 3 years of thelarche[26]
- Have not started by 13 years of age with no signs of pubertal development
- Have not started by 14 years of age with signs of hirsutism[27]
- Have not started by 14 years of age with a history or examination suggestive of excessive exercise or eating disorder
- Have not started by 14 years of age with concerns about genital outflow tract obstruction or anomaly
- Have not started by 15 years of age[28]

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[25] Petitioner also argues that irregular menstruation should not be considered the first symptom of POI because it "can be explained by other causes." Pet'r's Post Hr'g Reply Br. at 2-3. This argument has been repeatedly rejected by the Federal Circuit, and is equally as unpersuasive here. A symptom need not be exclusive to the particular injury alleged in order to be "the first symptom" of that injury for purposes of the Act. *See Markovich*, 477 F.3d at 1357 ("A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the significance of a symptom with regard to a particular injury."); *see also Carson*, 727 F.3d at 1370 (holding that even where "[t]here is no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal . . . it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism, the alleged vaccine injury.").

[26] Thelarche is "the beginning of development of breasts in the female." Thelarche, *Stedman's*.

[27] Hirsutism is the "presence of excessive bodily and facial hair, usually in a male pattern, especially in women." Hirsutism, *Stedman's.*

- Are regular, occurring monthly, and then become markedly irregular[29]
- Occur more frequently than every 21 days or less frequently than every 45 days[30]
- Occur 90 days apart even for one cycle[31]
- Last more than 7 days
- Require frequent pad or tampon changes (soaking more than one every 1-2 hours)

Id. at 5. But again, the undersigned repeats that the ACOG Opinion is only reproduced herein to provide context; unlike many of the related cases, it does not play a dispositive role in Petitioner's case.[32]

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[28] At the hearing, Doctors Hamiel and Gersh opined that an adolescent who has not reached menarche by age 16 should be evaluated for primary amenorrhea. Tr. at 92, 238. Dr. Frankfurter opined that the age of evaluation should be 15 years. Tr. at 365. Both the ACOG Opinion and Dr. Hillard, author of medical literature introduced by Petitioner, acknowledge that the traditional definition of primary amenorrhea has been no menarche by age 16. ACOG Op. at 2; Pet'r's Ex. 15, Tab 4, at 5, ECF No. 53-5 (Hillard, Paula, *Menstruation in Adolescents: What Do We Know? and What Do We Do with the Information?*, 27 J. Pediatric Adolescent Gynecology 309 (2014)) (hereinafter "Hillard" with pincites to Petitioner's pagination). However, both articles note that 95-98% of females will have experienced menarche by age 15, and that delays in evaluating these young women can result in delays in detection and treatment of significant disorders, including POI. ACOG Op. at 2; Hillard at 6.

[29] At the hearing, Dr. Hamiel testified that she would recommend further evaluation of a non-adolescent woman whose cycle had been regular (21-35 days) and then became irregular (less frequent than every 35 days). Tr. at 67.

[30] For women over the age of 18, this criterion is more frequently than every 21 days or less frequently than every 35 days. *See* ACOG Op. at 3; *see also* Tr. at 39 (documenting Dr. Hamiel's testimony normal menstrual frequency for a woman in her twenties is 21-35 days). The undersigned interprets this criterion to apply to frequency over two or more cycles.

[31] At the hearing, Dr. Hamiel testified that no menstruation for 90 days is not "normal." Tr. at 79.

[32] Because Petitioner has no record of contraceptive use relevant to this case, the undersigned has entirely omitted any discussion of contraceptive use that, although dispositive in at least one of the related cases, would be wholly superfluous in this opinion.

C. Application of the Onset Symptom Criteria to the Present Case

Petitioner filed her petition on November 8, 2010, *see* Pet.; her petition is therefore time-barred if "the first symptom or manifestation of onset" of her alleged vaccine-related injury, POI, occurred before November 8, 2007. *See* 42 U.S.C. § 300aa-16(a)(2). All of the parties agree that Petitioner had not manifested any symptoms of POI before her first HPV vaccination on July 6, 2007. *See*, *e.g.*, *Meylor* Tr. at 59, 410; Resp't's Ex. C at 7. The undersigned agrees: Petitioner was at Tanner Stages I and I at age 12, Pet'r's Ex. 4b at 92, then III and III at age 13, Pet'r's Ex. 4a at 73, 78, which appears to be normal pubertal development (according to the ACOG Opinion).

However, the testimony of Petitioner's mother and of Drs. Hamiel and Schoenfeld all place the first symptom of POI long before the actual diagnosis. Dr. Hamiel testified that "[t]he decrease in estrogen [from POI] is gradual. It takes as long as a female in menopause. It may take years." *Meylor* Tr. at 71. Dr. Hamiel also testified that the fact that Petitioner was depressed, tearful, unmotivated, and suffered from sleep disturbances "could be signs [of POI] even before somebody has the first menses," *Meylor* Tr. at 60; "fatigue, sleeplessness, mood changes . . . were already signs that she's developing some sort of decreased estrogen level," continued Dr. Hamiel, *Meylor* Tr. at 77. Finally, Dr. Hamiel testified of Petitioner, "[t]he fact that she got [menarche] in the edge of the normal age of onset of the first menses could suggest that she already had the signs [of POI] even before that." *Id.* at 60.

In his article in the American Journal of Reproductive Immunology documenting the POI cases of Petitioner (Case 2) and her sister (Case 1), Dr. Shoenfeld wrote that Petitioner "complained, 10 days after the first injection, of general symptoms such as depression and sleep disturbances. She also experienced episodes of lightheadedness and tremulousness, anxiety, panic attacks, and difficulties in focusing/concentrating in her school work." Pet'r's Ex. 31 at 2. Dr. Shoenfeld confirmed at hearing that he had obtained this medical history from Petitioner's mother. *Id*. at 235. Petitioner did not testify at either hearing, and the majority of the factual testimony at both focused on the more complicated and somewhat confused medical history of Petitioner's sister.[33] However, Petitioner's mother did testify that both Petitioner and her sister experienced headaches, cramping, and joint pain "right after the first shot." *Meylor* Tr. at 36.

Based on this testimony, along with the testimony of all of the experts cited above, providing that depression, mood changes, sleeplessness, and joint pain are symptoms of POI, the undersigned finds that the first symptom of POI experienced by Petitioner occurred approximately ten days after she received the first Gardasil injection on July 6, 2007.

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[33] Indeed, this confusion formed the basis of why the undersigned preliminarily judged Petitioner's claim to survive the statute of limitations.

IV. CONCLUSION

Based on the foregoing analysis, the undersigned finds that the first symptom of Petitioner's injury occurred in July 2007. Because that date precedes the statute of limitations deadline by four months, the undersigned concludes that Petitioner's claim is time-barred. Her petition therefore must be, and is hereby, **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment herewith.[34]

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

[34] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.