

In the United States Court of Federal Claims

No. [Redacted] V
(Filed December 16, 2008)¹

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JANE DOE/17,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

* * * * *

*
* National Childhood Vaccine
* Injury Act of 1986, 42 U.S.C.
* §§ 300aa-1 to -34 (2000); Proof
* of Causation; Review of Factual
* Findings and Discretionary Acts
* of Special Master; Expert and
* Witness Credibility.
*
*

Jane Doe/17, pro se.

Heather L. Pearlman, United States Department of Justice, with whom were *Gregory G. Katsas*, Assistant Attorney General, *Timothy P. Garren*, Director, *Vincent J. Matanoski*, Acting Deputy Director, *Gabrielle M. Fielding*, Assistant Director, Washington, D.C., for respondent.

OPINION AND ORDER

Bush, *Judge.*

^{1/} This opinion was filed under seal on November 20, 2008, in accordance with Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims (Appendix B to the Rules of the United States Court of Federal Claims). Petitioner has moved to have her name redacted from the opinion. That request is granted, substituting Jane Doe/17 for petitioner’s name in this public version of the opinion. Pursuant to Vaccine Rule 18(a), no vaccine filings other than opinions are made available to the public.

Before the court is petitioner Jane Doe/17's motion to review the Chief Special Master's May 30, 2008 decision (Opin.) denying her request for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2000) (the Act). In her Vaccine Act petition (Pet.) filed March 31, 2004, Jane Doe/17 alleged that a varicella vaccine administered to her at age forty-seven "significantly aggravat[ed] a pre-existing condition."² Pet. at 1. The Chief Special Master denied relief to Jane Doe/17, finding that she had not "established by a preponderance of the evidence that the varicella vaccinations petitioner received on March 7, 2001 and June 4, 2001, more likely than not significantly aggravated a pre-existing condition." Opin. at 18. For the reasons stated below, the court upholds the Chief Special Master's decision.

BACKGROUND

I. Factual Disputes Summary

Jane Doe/17 participated in a clinical research trial (the study) as a healthy control when she was forty-seven years old. There are many disputes of fact as to petitioner's health both before and after she received varicella vaccinations through the study in 2001. The court begins by addressing the most significant of these disputes, briefly presenting petitioner's relevant allegations of fact and the Chief Special Master's findings of fact.

The first dispute is whether Jane Doe/17 suffered from an immune deficiency before getting the varicella vaccinations. The particular immune deficiency alleged by petitioner is Common Variable Immunodeficiency (CVID). Pet.'s 3d Sub. at 1.³ This disorder is "characterized by low levels of serum immunoglobulins (antibodies) and increased susceptibility to infections." Pet.'s

^{2/} Varicella is "[a]n acute contagious disease . . . caused by the Varicella-Zoster virus genus" and is also known as chicken pox. Stedman's Medical Dictionary 2090 (28th ed. (Illustrated) 2006). The research study in which Jane Doe/17 participated identified itself as a "clinical study of a chicken pox vaccine, which we hope will prevent shingles in HIV-infected adults." Pet. Ex. at 3.

^{3/} Petitioner submitted records and other documents on August 11, 2005 (Pet.'s 2d Sub.), October 21, 2005 (Pet.'s 3d Sub.), and, subsequently, on other dates. *See infra* note 8.

4th Sub. at 12. CVID is the pre-existing condition alleged by petitioner to have been aggravated by her varicella vaccinations. The Chief Special Master found that petitioner had not shown by a preponderance of the evidence that she had CVID prior to receiving the vaccinations. Opin. at 13.

Another factual dispute concerns Jane Doe/17's history of irritable bowel syndrome (IBS).⁴ According to petitioner, she had one bout of severe IBS in 1978, which responded to treatment and was resolved no later than 1979. Pet. at 2. Jane Doe/17 alleges that diarrhea symptoms reappeared approximately two weeks after she received her second varicella vaccination on June 4, 2001, beginning with severe flu-like symptoms, evolving into chronic mild diarrhea, then worsening into severe diarrhea. *Id.* The Chief Special Master found, instead, that Jane Doe/17 suffered from chronic IBS prior to receiving the varicella vaccinations. Opin. at 15-16.

There is also a dispute as to whether petitioner, or other members of her family, had severe immune responses to vaccinations in their medical histories. Jane Doe/17 alleges that two of her immediate family members experienced anaphylactic reactions to either smallpox or tetanus immunizations.⁵ Pet.'s 3d Sub. at 5. Petitioner also alleges that she fell ill with pneumonia each time she received oral polio vaccine, in 1960 and in 1962. *Id.* at 4-5. In addition, Jane Doe/17 claims to have had serum sickness after receiving a rabies antitoxin in 1967.⁶ *Id.* at 4. The Chief Special Master noted that these allegations were not supported by any direct, contemporaneous proof, such as medical records discussing severe reactions to vaccinations. Opin. at 14. Therefore, the Chief Special Master, negatively assessing the credibility of petitioner, found no basis for concluding that Jane Doe/17's family had a history of autoimmune problems.

Finally, a dispute exists as to whether Jane Doe/17 reported adverse gastrointestinal reactions to the study staff within weeks after receiving the two

⁴/ Irritable bowel syndrome is "characterized by gastrointestinal signs and symptoms including constipation, diarrhea, gas, and bloating." Stedman's Medical Dictionary 1902.

⁵/ Anaphylactic means "manifesting extremely great sensitivity to foreign protein or other material." Stedman's Medical Dictionary 73.

⁶/ Serum sickness, according to petitioner's expert, is triggered by a hypersensitivity reaction related to the injection of an antitoxin, such as rabies antitoxin. Pet.'s 5th Sub. at 1, 7.

varicella vaccinations, one on March 7, 2001 and the other on June 4, 2001. Petitioner alleges that she had “severe flu like symptoms 2 weeks post [second] injection, . . . includ[ing] severe nausea, vomiting and diarrhea.” Pet. at 2. Petitioner also alleges that she “continued to experience worsening diarrhea, nausea, abdominal pain and retching through the summer and fall of 2001.” *Id.* Jane Doe/17 testified that she reported these symptoms to study staff. Hearing Transcript (Tr.) at 23, 66.

The most nearly contemporaneous documentation of petitioner’s post-vaccination gastrointestinal symptoms is not in records from the study, but in a treating gastroenterologist’s letter written March 11, 2002, noting that petitioner had reported on March 8, 2002 that her chronic IBS had been worsening for the “past eight months,” or from July 2001 to March 2002. Pet. Ex. at 94. The principal investigator conducting the study logged an adverse event report in 2003 which stated that Jane Doe/17 reported her chronic diarrhea symptoms to study staff in 2003. *See* Pet.’s 2d Sub. at 4 (report of chronic diarrhea and collagenous colitis diagnosis recorded in June 2003); *see also id.* at 11 (report of collagenous bowel disorder and anti-diarrheal medications use recorded March 20, 2003).⁷ The contemporaneous records from 2001 maintained by the vaccine study are silent as to petitioner’s alleged gastrointestinal symptoms, although other complaints from Jane Doe/17 are documented. *Id.* at 5, 8. The Chief Special Master, again negatively assessing the credibility of petitioner and relying more on the study records, was not persuaded that Jane Doe/17 had reported diarrhea symptoms to the study staff in the weeks immediately following her second inoculation.

II. Overview of Procedural History and Certain Relevant Facts

Jane Doe/17 filed her petition for compensation under the Act on March 31, 2004, originally proceeding *pro se*. Accompanying her petition were one hundred pages of supporting medical records and other documents. One of these documents, the consent form for the study, describes the procedures for collecting health information from study participants after they received vaccinations:

Study personnel will talk to you by telephone from the

⁷/ Collagenous colitis is “characterized by persistent watery diarrhea and a deposit of a band of collagen beneath the basement membrane of colon surface epithelium.” Stedman’s Medical Dictionary 408.

clinic every week for three weeks after each dose of vaccine. You will be asked about any symptoms you may have experienced between visits to the clinic. In addition to these phone calls, for 42 days (6 weeks) after each injection you will record any symptoms you may have in a diary given to you at the clinic.

Six weeks after each dose of vaccine, you will come to the clinic. You will be expected to return your diary at these visits, answer questions about side effects to the vaccine, and have a physical exam performed.

....

You will go to the clinic for a total of 8 visits during the study. These visits will be scheduled weeks 0 (when you receive the initial dose of vaccine), 6, 12, 18, 24, 52 and months 24 and 36. At each visit you will have a physical exam, and blood tests

Pet. Ex. at 5.

Petitioner also attached correspondence from various treating physicians to her petition. Three letters from Dr. Victor M. Fishman, her gastroenterologist, are of interest here. The first, written on March 11, 2002, apparently records his first work-up of Jane Doe/17 for chronic diarrhea symptoms:

[She has] a chronic history of irritable bowel syndrome. Her first symptoms were at age 24 . . . [but] over a couple of years her symptoms improved until they reached her baseline which has been more intermittent and mild. However, over the past eight months her symptoms have been worsening again.

Pet. Ex. at 94. Two weeks later, Dr. Fishman again described his patient as having chronic diarrhea, and more specifically, “chronic severe irritable bowel syndrome, which has been worsening recently.” *Id.* at 91. After treating Jane Doe/17 for IBS for one year, Dr. Fishman gave an overview of her condition in a referral letter:

She is 49 years old who [sic] has had difficulty with abdominal pain and diarrhea since approximately the age of 24. . . . Her symptoms improved to a moderate extent until about a year before she saw me.

Id. at 100. Dr. Fishman also opined that “[t]here is obviously [a] fair amount of psychological components to her disease process,” and reported that Jane Doe/17 has a history of depression. *Id.* at 101; *see also* Pet.’s 2d Sub. at 10 (adverse event report noting a diagnosis of depression predating vaccinations in 2001).

In 2005, petitioner obtained counsel, an attorney with approximately fifteen years of experience with vaccine cases in this court. On March 15, 2005, the special master assigned to the case set a schedule for the filing of additional medical records. This schedule was greatly enlarged, and petitioner’s filings of medical and other records, and medical literature, extended into December 2007.⁸ Petitioner’s expert report was filed on May 25, 2006. Respondent also filed an expert report, on September 28, 2006, medical literature on December 19, 2006 and documents related to the 2001 vaccine study on October 22, 2007. The court has reviewed this evidentiary record, but given the mass of information presented to the Chief Special Master, will only discuss the most relevant documents in its review of his decision.

Some of these records indicate that Jane Doe/17 had a pre-existing condition of irritable bowel syndrome at the time of her varicella vaccinations. Dr. Kathleen Brady noted in an adverse event report for the vaccine study that petitioner “has a pre-existing condition of irritable bowel syndrome.” Pet.’s 2d Sub. at 4. Jane Doe/17 testified that she saw Dr. Brady about once a week, because they worked in the same clinic. Tr. at 76. A counselor took Jane Doe/17’s medical history in April 2000 and noted that “[s]he claims to have what is called an atonic colon, which she claims is a form of GI disorder.”⁹ Pet.’s 11th Sub. at 450. Petitioner applied for Social Security disability benefits in 2000 and noted among her

⁸/ Petitioner’s numbered submissions of documents, beyond those mentioned *supra* in note 3, were filed on March 21, 2006, May 25, 2006, November 7, 2006, December 27, 2006, September 17, 2007, September 19, 2007, December 17, 2007, and December 26, 2007.

⁹/ The adjective “atonic” means “without normal tone or tension.” Stedman’s Medical Dictionary 176.

conditions “chronic, uncontrolled diarrhea from spastic colon.”¹⁰ *Id.* at 463. She also noted on one form that Celexa, a medication she was taking, had a side-effect of diarrhea. *Id.* at 468.

Petitioner stopped working in late 2002, over a year after getting her second varicella vaccination. She recited her medical history to physicians when she was documenting her health problems in order to obtain disability benefits from an insurer. In two such interviews in 2003, she reported that her diarrhea symptoms began in January 2002. *See* Pet.’s 10th Sub. at 107 (psychiatric evaluation of April 29, 2003) (“According to [Jane Doe/17] and the above records, she was in her usual state of good physical and emotional health . . . until January 2002, when she developed symptoms including persistent diarrhea and abdominal pain.”), 131 (gastroenterological evaluation of April 29, 2003) (“[Jane Doe/17] reports that she was well until approximately January 2002 when she noted the diarrhea.”). In contrast, on a Social Security disability reporting form submitted in 2005, Jane Doe/17 described the onset of her pain symptoms as “slowly to really awful – started midsummer 2001, horrible by Dec[.] 2002.” Pet.’s 11th Sub. at 134. On the same topic on a reporting form sent by facsimile in 2003, Jane Doe/17 gave a similar chronology: “pain as diarrhea started mild 5/01 bad by 12/01, dx [diagnosis] 3/02, debilitated 12/02.” *Id.* at 168.

In addition to the documentary evidence filed by the parties throughout the course of this litigation, the Chief Special Master had before him pre- and post-hearing briefs from the parties, a post-hearing response brief from petitioner, and live hearing testimony from the parties’ experts and Jane Doe/17. The Chief Special Master rendered his decision on May 30, 2008. Petitioner’s attorney was granted permission to withdraw from representation on June 10, 2008. The Chief Special Master denied petitioner’s *pro se* motion for reconsideration on June 26, 2008. Petitioner filed a motion for review of the Chief Special Master’s decision on June 30, 2008, which has been fully briefed.¹¹

III. The Chief Special Master’s Consideration of Petitioner’s Theory that

^{10/} The “nonspecific” term “spastic colon” describes “symptoms such as abdominal pain, flatulence, and alternating diarrhea with constipation.” Stedman’s Medical Dictionary 411.

^{11/} The court permitted petitioner to file a supplemental brief (Pet.’s Supp. Br.), at her request, and afforded respondent an opportunity to respond to petitioner’s supplemental brief.

the Varicella Vaccinations Significantly Aggravated Her Pre-existing CVID

A. Testimony Relevant to Causation

According to Jane Doe/17's hearing testimony, her problems with diarrhea started "within a week to 10 days [after her second inoculation with the varicella vaccine] to the best of [her] recollection." Tr. at 18. She also recalled getting a "very severe upper respiratory tract infection" two weeks after the second vaccination, and reporting her symptoms to study staff. *Id.* at 19-20. She remembered getting severe fever blisters at the same time. *Id.* at 20. Jane Doe/17 specifically recalls reporting her various symptoms to Dr. Kathleen Brady at the study. *Id.* at 23. Dr. Brady could not recall whether such a conversation had occurred, and did not have documents confirming Jane Doe/17's communications with study staff. Status Report of Nov. 13, 2007.

Jane Doe/17's testimony regarding her post-vaccination symptoms and her communications with study staff was quite vivid. When answering questions about the onset of her health problems, she described her symptoms as including "a very severe upper respiratory tract infection," and "a terrible outbreak of fever blisters." Tr. at 19-20. Similarly, in her affidavit, petitioner reported that she "suffered severe flu like symptoms 2 weeks post [second] injection, this included severe nausea, vomiting and diarrhea." Pet.'s 3d Sub. at 8. On cross-examination as to why the study staff had recorded none of these symptoms, despite their protocol to specifically solicit reports of adverse symptoms, she suggested that her reports were not recorded because she worked at the site and spoke to the study staff informally. Tr. at 67-68. At a scheduled interview twenty-four weeks after receiving the second vaccination there were no adverse effects of the vaccine recorded. Tr. at 71. Jane Doe/17 explains that she did not tell study staff about the diarrhea at that time because she did not yet think her problem was related to the vaccination. *Id.*

When Jane Doe/17 was asked to identify the first contemporaneous medical record indicating her diarrhea symptoms, she pointed to her colonoscopy in March 2002. Tr. at 34. When asked whether her primary care physician had been consulted about her gastrointestinal problems before then, Jane Doe/17 stated that she had called him for a referral to a gastroenterologist, but had not had an office visit. *Id.* at 35. No medical records from her primary physician for 2001 or 2002

were submitted by petitioner. Her pharmacy records, however, showed multiple medications prescribed by her primary physician during the last three months of 2001. Tr. at 74. Petitioner first denied seeing her primary care physician in late 2001, and then conceded that she might have visited him. Tr. at 73-75.

During the hearing, Jane Doe/17 denied having irritable bowel syndrome before her vaccinations in 2001, other than during the late 1970s. Tr. at 39, 43. She stated that she believed Dr. Fishman, who took her medical history and stated that she had chronic IBS, had misunderstood her complaints of mild diarrhea during menstruation. Tr. at 63-64. Jane Doe/17 testified that she did not recall seeing her primary physician for perhaps two years before the vaccinations, because she was very healthy. Tr. at 59-60. Records for those two years were not submitted by petitioner. When questioned as to other medical treatments she was receiving in 2001, petitioner at first remembered none, but conceded, when confronted with records of treatment, that she had seen a podiatrist, a chiropractor and a dermatologist that year. Tr. at 65, 70-71.

B. Causation Argued

Petitioner argued before the Chief Special Master that the lab tests she took before and after the vaccinations show that her immune system was compromised and that she should not have taken the vaccines. Pet.'s Post-Hearing Br. at 4-5. In addition, petitioner contended that her worsening immune deficiency and related symptoms were caused by the vaccinations. *Id.* at 15. Respondent, on the other hand, argued that neither the facts of this case, nor the theory relied upon by petitioner's expert, supported the allegation that Jane Doe/17's vaccinations significantly aggravated a pre-existing condition of CVID. Resp.'s Post-Hearing Br. at 21. Petitioner responded that her "collagen[ous] colitis was a by-product caused by the immune deficiency that was significantly aggravated by the Varicella vaccine." Pet.'s Post-Hearing Resp. Br. at 10.

C. Petitioner Failed to Prove Causation by a Preponderance of the Evidence

The Chief Special Master weighed the evidence before him and found that the record did not support the causation theory advanced by petitioner. In doing so, he noted that the lack of credibility of petitioner as a witness was damaging to her case. Opin. at 2. He also described petitioner's case as suffering from a

number of “medical and factual deficiencies.” *Id.* at 9. In some detail, the Chief Special Master noted the considerable inconsistencies between the contemporaneous documents in the record, and the factual allegations and testimony of Jane Doe/17. *Id.* at 15-18.

The Chief Special Master also determined that Dr. Brian K. Adler, petitioner’s expert, was “not credible,” *Opin.* at 9, for many reasons. First, he found that Dr. Adler’s training and experience in immunology were insufficient, and that his theory of causation was not supported by the literature discussing CVID. The Chief Special Master found, furthermore, that Dr. Adler placed too much credence in petitioner’s undocumented allegations of her family’s immunological problems, suggesting that such reliance was unwarranted “in the absence of supporting clinical or laboratory data.” *Id.* at 10. Even if in some circumstances a medical expert could rely on a patient’s uncorroborated description of her medical and family history, petitioner’s lack of credibility undermined her expert’s theory of causation because so much of his theory depended on the accuracy of her reports of immunological problems. *Id.* at 15. In essence, the Chief Special Master found that Dr. Adler’s theory of causation had “no factual predicate.” *Id.*

The Chief Special Master also rejected petitioner’s theory of causation because he found respondent’s expert, Dr. Stephen J. McGeady, “extremely well-qualified,” “knowledgeable,” more credible, convincing and persuasive. *Id.* at 10. Dr. McGeady opined that Jane Doe/17 had not shown that she had CVID prior to receiving the vaccinations, because neither her laboratory test results nor her descriptions of her health were typical for CVID patients. *Id.* at 12. Because the linchpin of petitioner’s theory was a pre-existing case of CVID, later significantly aggravated by two varicella vaccinations in 2001, failing to prove by a preponderance of the evidence that she had CVID before receiving the vaccinations was fatal to her claim.¹² *Id.*

^{12/} Petitioner does not allege that the Chief Special Master applied an incorrect legal standard when rejecting her theory of causation for her post-vaccination health problems. The court sees no error in the Chief Special Master’s causation analysis. The preponderance of the evidence did not show that Jane Doe/17 had a pre-existing condition of CVID, which could have been significantly aggravated by the varicella vaccinations. The evidence thus did not satisfy the second of the *Althen* factors, requiring that a vaccination and an alleged vaccine injury exhibit a
(continued...)

D. Motion for Reconsideration

Petitioner requested reconsideration of the denial of her claim. She offered to obtain additional evidence supporting her version of her medical and family history, Pet.'s Recon. Mot. at 2, and stated her reasons for believing her claim was valid. Her motion for reconsideration explores her health issues at length and adds new allegations of fact in narrative form. In her motion, Jane Doe/17 suggests that the Chief Special Master should have allowed her to refute the contents of her Social Security application records. *Id.* at 9. In addition, she alleges that any diarrhea symptoms she had in the years immediately preceding the vaccinations were short-term and temporary side-effects of a high dose of the medication Effexor. *Id.* at 16. Jane Doe/17 also suggests that she had occasional constipation and diarrhea associated with menstruation. *Id.* at 18. In sum, she contends that the “atonic colon and spastic colon noted in the 2000 [Social Security] records are nothing but the history given by [petitioner] of her diagnosis in 1978,” and are not evidence of a history of irritable bowel syndrome in the years preceding the vaccinations. *Id.* at 19. Attached to the motion were over one hundred unnumbered pages of unindexed exhibits, including a document entitled “Rebuttal to Doctor McGeady’s opinion,” as well as a lengthy transcript of a sentencing hearing in 2000. The Chief Special Master concluded that petitioner had presented “no compelling information requiring reconsideration” and denied petitioner’s motion. Order of June 26, 2008.

DISCUSSION

I. Standard of Review

The United States Court of Federal Claims has jurisdiction to review a decision by a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). “Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *de Bazan v. Sec’y of Health and Human Servs.*, 539 F.3d 1347, 1350 (Fed. Cir. 2008) (citing 42 U.S.C. § 300aa-12(e)(2)(B) and *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1277 (Fed. Cir.

¹²(...continued)

“logical sequence of cause and effect.” *See Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

2005)); *see also Hanlon v. Sec’y of Dep’t of Health & Human Servs.*, 191 F.3d 1344, 1348 (Fed. Cir. 1999) (“Under the Vaccine Act, the Court of Federal Claims may not disturb the factual findings of the special master unless they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” (quoting 42 U.S.C. § 300aa-12(e)(2)(B))). This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master’s decision is under scrutiny:

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the “not in accordance with law” standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec’y of Dep’t of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The arbitrary and capricious standard of review is used to consider factual findings by the special master. *Id.* The scope of this review is limited, and highly deferential. *Lampe v. Sec’y of Dep’t of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Burns by Burns v. Sec’y of Dep’t of Health & Human Servs.*, 3 F.3d 415, 416 (Fed. Cir. 1993). “If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Hines ex rel. Sevier v. Sec’y of Dep’t of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see also Burns*, 3 F.3d at 416. The special master likewise has broad discretion to determine the credibility of witnesses. *Bradley v. Sec’y of Dep’t of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (“The fact-finder has broad discretion in determining credibility because he saw the witnesses and heard the testimony.”) (citation omitted). This court’s arbitrary and capricious review of the fact findings of a special master is “well understood to be the most deferential possible.” *Munn*, 970 F.2d at 870 (citations omitted).

The other standard of review relevant to this case, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he relies. *See id.*, 970 F.2d at 870 n.10.

II. Burden of Proof in an Off-Table Vaccine Injury Case

There are two distinct avenues for recovery under the Vaccine Act. *See* 42 U.S.C. § 300aa-11(c). First, a petitioner who has received a vaccination listed on the Act's Vaccine Injury Table may recover for any resulting illness, disability, injury or condition which is also listed on that Table, or a significant aggravation thereof. *Id.* § 300aa-11(c)(1)(C)(i); *see also id.* § 300aa-14(a); 42 C.F.R. § 100.3 (2007) (current version of the Vaccine Injury Table). Second, a petitioner who has received a vaccination listed on the Table, but whose vaccine-related injuries do not meet Table requirements, may recover under the "off-Table" theory of recovery. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A). Under this theory, a petitioner may make out a prima facie case of entitlement to compensation by showing, by a preponderance of the evidence, that a Table vaccine actually caused the petitioner to sustain an illness, disability, injury or condition which is not listed on the Table, or that first appeared outside the time limits set by the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *Pafford v. Sec'y of Dep't of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner's burden of proof in an off-Table case is to show "a medical theory causally connecting the vaccination and the injury." *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citation omitted).

A petitioner who hopes to recover for an off-Table claim must establish causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1); *Pafford*, 451 F.3d at 1355. This requires "preponderant evidence both that [the] vaccination[] [was] a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford*, 451 F.3d at 1355 (citing *Shyface v. Sec'y of Dep't of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccination "must be a 'substantial factor'" in bringing about the injury, but "it need not be the sole factor or even the predominant factor." *Id.* at 1357 (quoting *Shyface*, 165 F.3d at 1352-53).

The Federal Circuit recently addressed the evidentiary burden associated with causation in off-Table cases. That court explained that a petitioner who wishes to demonstrate that a vaccination brought about his or her injury must present:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278 (explaining that “[a] persuasive medical theory is demonstrated by ‘proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]’ the logical sequence being supported by ‘reputable medical or scientific explanation[,]’ *i.e.*, ‘evidence in the form of scientific studies or expert medical testimony’” (quoting *Grant*, 956 F.2d at 1148)); *see also Pafford*, 451 F.3d at 1355; *Capizzano v. Sec’y of Dep’t of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006).

As to the evidence related to the three factors, “these prongs must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford*, 451 F.3d at 1355. Further, “[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.” *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149). It is likewise critical to recognize that the special master may not make a finding of causation which is based on the claims of a petitioner alone, that is not substantiated by medical records or by medical opinion. *See* 42 U.S.C. § 300aa-13(a)(1). Thus, the presentation of medical records or medical opinion supporting a claim is a prerequisite to recovery. *Id.* Only if a petitioner presents adequate evidence on the three essential aspects of causation, and thus makes a prima facie case for liability, does the burden shift to the Secretary to prove, also by a preponderance of the evidence, an alternate cause of the alleged injury.¹³ *Id.*; *de Bazan*, 539 F.3d at 1352 (citations omitted).

^{13/} There has been some discussion in non-precedential caselaw as to whether the causation-in-fact burden of proof applicable to the significant aggravation of an off-Table illness should be different than the causation-in-fact burden of proof applicable to a new off-Table illness. *See Loving v. Sec’y of Health and Human Servs.*, No. 02-469V, 2008 WL 4692376, at *2 (Fed. Cl. Spec. Mstr. Oct. 6, 2008); *DeRoche v. Sec’y of Health and Human Servs.*, No. 97-643V, 2002 WL 603087, at *33-34 (Fed. Cl. Spec. Mstr. Mar. 28, 2002). The court agrees with
(continued...)

III. Analysis of Petitioner’s Allegations of Error

In the initial paragraph of Jane Doe/17’s motion for review now before the court, petitioner discusses gaps in the evidentiary record in her case and posits that mistakes on the part of her counsel were largely responsible for the denial of her claim.¹⁴ Pet.’s Mot. at 2.¹⁵ Her first substantial argument is that the Chief Special Master erred in selectively focusing on portions of the record, and not “mak[ing] reference to the entire body of material presented.” *Id.* at 4. Her second argument is that the Chief Special Master ignored additional evidence attached to her motion for reconsideration. *Id.* Her third argument is that Dr. McGeady was found to be more persuasive than her treating physicians or Dr. Adler, and that this was error. *Id.* at 4-5. Her fourth argument is that Dr. McGeady’s description of a plausible time-frame for the onset of autoimmune problems fits the facts of her case. *Id.* at 6. Her fifth argument is that the Chief Special Master incorrectly assessed her credibility based on a record of inconsistent descriptions of her irritable bowel symptoms in the years preceding the vaccinations. *Id.* Attached to petitioner’s motion are numerous exhibits, some of which had also been attached to her motion

¹³(...continued)

the special master in *Loving*, who found the *Althen* analysis and other precedent related to new off-Table illnesses to be applicable to cases involving the significant aggravation of an existing off-Table illness. *See* 2008 WL 4692376, at *3. Even if a different formulation of the *Althen* test of causation were devised for the significant aggravation of off-Table illnesses, here the court cannot imagine how the failure of proof of a pre-existing condition of CVID could support a theory that the varicella vaccinations significantly aggravated petitioner’s CVID.

^{14/} This allegation is without merit. It is clear from the record that it was the credibility of petitioner’s expert, the implausibility of his theory of causation, and petitioner’s lack of credibility that undermined her claim. And although petitioner faults her counsel for the tardy filing of her 2000 Social Security application records, Pet.’s Mot. at 1-2, it was the content of those records, not the timing of their filing, that was relied upon by the Chief Special Master for his decision, *see* Opin. at 16-17.

^{15/} Petitioner’s motion and the accompanying exhibits are not paginated or otherwise clearly organized or indexed. Some leniency is afforded *pro se* litigants, *Kelley v. Sec’y, U.S. Dept. of Labor*, 812 F.2d 1378, 1380 (Fed. Cir. 1987); thus, the court has attempted to discern in these materials all of petitioner’s arguments and contentions. Page numbers have been attributed to the seven-page narrative portion of the motion. To the extent that petitioner presented additional comments or arguments in her motion that are not discussed here, the court has considered them and found them to be unpersuasive.

for reconsideration. These exhibits include affidavits concerning her childhood serum sickness in response to a rabies vaccination, medical records from 2005-06, medical article excerpts, and various letters of support referencing Jane Doe/17's professional activities.

After receiving respondent's response to petitioner's motion for review, petitioner filed a supplemental brief by leave of the court. In this brief, petitioner argues that it was procedural error to allow petitioner's counsel to submit her Social Security application records after her evidentiary hearing, thus denying petitioner a chance to rebut that documentary evidence with live hearing testimony. Pet.'s Supp. Br. at 4, 12. Petitioner discusses at length her understanding of her immunological problems and the significantly aggravating effect of the varicella vaccines she received in 2001. *Id.* at 5-11. Petitioner also discusses and comments on the evidence relied on by the Chief Special Master to conclude that she suffered from chronic irritable bowel syndrome in the years preceding the vaccinations, and that she was not a credible witness. *Id.* at 12-15.

Petitioner presents additional arguments which, in her opinion, invalidate the decision of the Chief Special Master. For example, she suggests that her expert never claimed it was CVID that was significantly aggravated by the varicella vaccine, just a "genetic permissiveness" for CVID.¹⁶ Pet.'s Supp. Br. at 15. Petitioner also asserts that the Chief Special Master was not qualified to review her medical records unassisted by expert testimony. *Id.* at 20. In her supplemental brief, petitioner elaborates on her argument that Dr. McGeady's opinion concerning her health should not have been believed, when her treating physicians have diagnosed her as suffering from CVID. *Id.* at 20-23. Petitioner also describes various sources of corroboration that she could have drawn upon had she known that her credibility regarding her medical and family history would have been questioned. *Id.* at 23-24. Finally, petitioner asserts that she would not have lied to receive benefits from the vaccine program. *Id.* at 27.

Thus, to summarize and categorize the contentions presented in petitioner's

^{16/} On the contrary, Dr. Adler's written report states that "[i]t is my opinion that the administration of the [varicella] vaccine aggravated [Jane Doe/17]'s then unknown and asymptomatic preexisting condition of Common variable Immune deficiency (CVID)." Pet.'s 5th Sub. at 4. Dr. Adler also testified that Jane Doe/17 had CVID prior to the vaccinations, and that his theory of causation for her vaccine injury depended on that diagnosis. Tr. at 86, 131-32.

motion for review and supplemental brief, Jane Doe/17 offers seven principal legal arguments for overturning the Chief Special Master's decision. Three of petitioner's arguments suggest that the Chief Special Master mismanaged this case, and are reviewed under the abuse of discretion standard:

- A. The Chief Special Master interpreted medical records without the assistance of expert opinion, and should have solicited expert review of certain documents.
- B. The Chief Special Master ignored evidence attached to petitioner's motion for reconsideration, and this was prejudicial error.
- C. The Chief Special Master should have allowed petitioner an occasion to rebut, through live testimony, information included in her 2000 Social Security application.

Four arguments attack fact findings by the Chief Special Master, and are reviewed under the arbitrary and capricious standard:

- D. Had the Chief Special Master not focused excessively on petitioner's 2000 Social Security application and properly evaluated the preponderance of the evidence, he would have concluded that petitioner's pre-existing immunological problems were significantly aggravated by the vaccinations she received in 2001.
- E. The Chief Special Master irrationally favored the opinion of Dr. McGeady over those of her treating physicians and Dr. Adler.
- F. Petitioner's collagenous colitis diagnosis conforms to the time-frame for the onset of vaccine-related immunological problems described by Dr.

McGeady and, thus, was more likely than not to have been caused by the vaccinations.

- G. The Chief Special Master arbitrarily found petitioner to lack credibility based on nonexistent or insignificant conflicts between her testimony and documentary evidence.

Both of these standards of review are “highly deferential.” *Burns*, 3 F.3d at 416 (quoting *Hines*, 940 F.2d at 1528). The court’s limited, narrow task, as defined by the governing statute and controlling precedent, is to review the decision rendered by the special master with deference. The court turns first to petitioner’s allegations that the Chief Special Master mismanaged this case.

A. Did the Chief Special Master Neglect to Obtain the Assistance of Expert Opinion in Order to Interpret Medical Records?

Petitioner points to the fact that her 2000 Social Security application records were filed after the parties’ medical experts had submitted their written reports and testified. Jane Doe/17 asserts that the Chief Special Master impermissibly relied on his reading of the Social Security records, not on a professional evaluation of those records by a doctor. Pet.’s Supp. Br. at 20. The Chief Special Master, however, in consulting those records, was not interpreting lab results or x-rays. He was seeking, as trier of fact, to resolve the conflict between testimony from petitioner, asserting that she had been free of irritable bowel symptoms since age twenty-four, and records from her gastroenterologist and the study staff, which reported that she had chronic irritable bowel syndrome. *See* Opin. at 15-16. In the Social Security records, the Chief Special Master found documentation that petitioner was reporting in 2000 that she had “chronic, uncontrolled diarrhea from spastic colon” and “an atonic colon, which is a form of GI disorder.” Pet.’s 11th Sub. at 450, 463.

Inquiry into conflicts between the live testimony of a witness and documentary records of statements from the same witness are appropriate for a trier of fact, and a medical degree is not required to discern obvious contradictions. *See Burns*, 3 F.3d at 417 (approving of a special master’s perusal of medical records to determine that the petitioner’s live testimony was not credible). A special master has wide discretion in conducting proceedings that help him

determine the credibility of witnesses. *Id.* (citations omitted). The Chief Special Master did not abuse his discretion in reviewing evidence from petitioner's 2000 Social Security application.

B. Did the Chief Special Master Ignore Additional Evidence Attached to Petitioner's Motion for Reconsideration?

Petitioner faults the Chief Special Master for allegedly ignoring the attachments to her motion for reconsideration, consisting of well over one hundred unnumbered and unindexed pages. Pet.'s Mot. at 4. In particular, Jane Doe/17 references the affidavits from family members, and a 2007 lab result showing a positive rabies titer, documents she provided to support her allegations of post-rabies vaccination serum sickness at age thirteen. *Id.* at 3-4. The Chief Special Master stated in his denial of her motion for reconsideration that he "reviewed the submitted materials and determined that the materials contained no compelling information requiring reconsideration of [his] Decision." Order of June 26, 2008.

The court does not view the cursory denial of petitioner's motion for reconsideration as an abuse of discretion, for two reasons. First, it would have been an arduous task to discuss each of the numerous attachments to Jane Doe/17's motion for reconsideration, and to show how all of these exhibits, when taken as a whole, were not compelling. Petitioner, herself, made this task almost impossible by inserting fleeting and cryptic references to the attachments to her motion for reconsideration in a lengthy, rambling narrative. Second, the attachments to petitioner's motion for reconsideration serve only to shore up her version of her medical and family history, and her credibility, in a general way. Nothing in the attached documents refutes key findings of the Chief Special Master.

Dr. Adler, as an expert, was found to be not credible, largely based on his lack of accreditation in immunology, lack of pertinent experience, and his faulty interpretation of the literature on CVID. Opin. at 10-11. He was also discredited for relying too much on petitioner's self-reported medical and family history. *Id.* The affidavits submitted by petitioner were dated November 2006, six months after Dr. Adler's expert report was written. When he testified in 2007, Dr. Adler conceded that he continued to rely, for his opinion, on petitioner's version of her medical history, and on school absence records, and had not consulted any other sources of corroborating information. Tr. at 100-01. Thus, the Chief Special Master's negative credibility determination regarding Dr. Adler and his rejection of

Dr. Adler's theory of causation, in this case, would necessarily be unaffected by the affidavits presented by Jane Doe/17. *See* Opin. at 10 (noting that the difference in "expert credibility [was] in and of itself sufficient to support a finding against petitioner").

As to Jane Doe/17's attempts to improve her own credibility as a witness, the attachments to her motion for reconsideration miss the mark. The Chief Special Master was especially concerned about the accuracy of her testimony and her allegations of fact, on the subject of Jane Doe/17's health immediately before and after she was vaccinated in 2001. As the Chief Special Master stated:

There are two primary reasons for finding Jane Doe/17's testimony not credible: (1) her testimony regarding her IBS is either evidence of such a poor memory that nothing she said can be taken as accurate or, quite simply, she lied; and, (2) her testimony conflicts with information contained in the contemporaneous medical records.

Opin. at 15. The Chief Special Master then proceeded to point out inconsistencies and contradictions in her testimony, and conflicts between her testimony and contemporaneous records. *Id.* at 15-17. None of the attachments provided by petitioner along with her motion for reconsideration are contemporaneous medical records supporting her version(s) of her health problems, or lack thereof, in 2000 or 2001.¹⁷ Thus, although petitioner's motion for reconsideration provided additional support for some of her allegations, particularly as to her childhood rabies vaccine reaction, the conflicts between her description of her health and contemporaneous documents from 2000 and 2001 remain unaffected by the attachments to her motion.

For these reasons, the court does not find that the Chief Special Master abused his discretion in denying petitioner's motion for reconsideration without discussing the significance of each of the attachments thereto. Nothing in those documents was compelling evidence that would warrant reconsideration of his key

^{17/} Petitioner submitted pharmaceutical records for October through December 2001, but these records were already before the Chief Special Master when he made his entitlement decision. *See* Pet.'s 6th Sub. Ex. 4.

findings of fact. If there was error here, and the court sees none, such error was harmless, because petitioner was in no way prejudiced by the terse denial of her motion for reconsideration.¹⁸

C. Did the Chief Special Master Abuse His Discretion when He Did Not Re-open the Record for Additional Live Testimony after Receiving the 2000 Social Security Application Records?

In his role as trier of fact, the Chief Special Master is required to balance his responsibilities for obtaining relevant evidence and for efficiently resolving the claim before him. Vaccine Rule 3(b) (“The special master shall determine the nature of the proceedings with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master’s decision.”). In the years before the Chief Special Master rendered his decision, petitioner in this case was allowed to submit documentary evidence on eleven occasions, from March 31, 2004 through December 26, 2007. Enlargements of time were repeatedly granted petitioner for the purpose of completing the record. Hearing dates were proposed for May, June and July, 2007, although the hearing was eventually pushed back until October 19, 2007. Approximately two months later, petitioner’s Social Security disability records were finally filed. Absent an urgent need for live testimony to explain the information contained in those records, the Chief Special Master was within his discretion to render his decision without re-opening the evidentiary hearing.¹⁹ *See Burns*, 3 F.3d at 417 (upholding a special master’s decision not to hold an additional hearing because it was “within her discretion to determine that an additional hearing . . . was not necessary”).

Even if the parties had requested that the Chief Special Master hold an

^{18/} The Vaccine Rules of this court do not require a detailed order denying every argument for reconsideration. *See* Vaccine Rule 10(c). Even a special master’s ruling on entitlement may be delivered from the bench, with no written opinion. *See Bradley*, 991 F.2d at 1576. The Chief Special Master’s order denying reconsideration falls within the acceptable bounds of the streamlined procedures provided for vaccine cases.

^{19/} According to the docket, a status conference was held after the Social Security records were filed and “the parties agreed that at this time no re-examination [of petitioner] was necessary.” Jan. 23, 2008 docket entry.

additional evidentiary hearing, the court believes such a hearing would have been futile. The 2000 Social Security application documents speak for themselves. Petitioner's live testimony could not offer anything more than contradictory versions of her medical history, or background context for her records, which are unambiguous. Furthermore, petitioner has had ample time to rebut the statements contained in those records. *See* Pet.'s Post-Hearing Br. at 2; Pet.'s Recon. Mot. at 10-11, 16-20. The Chief Special Master did not find these arguments compelling, and there is no reason to think that live testimony from Jane Doe/17 presenting similar justifications would have altered his view of her credibility. *See Campbell ex rel. Campbell v. Sec'y of Dept. of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("It is, of course, true that where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight.") (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395-96 (1948); *Montgomery Coca-Cola Bottling Co. v. United States*, 615 F.2d 1318, 1328 (Ct. Cl. 1980)). For these reasons, the court does not find that the Chief Special Master abused his discretion by ruling on petitioner's claim without offering her another chance to testify. *See* Vaccine Rule 8(d) ("The special master may decide a case on the basis of written filings without an evidentiary hearing."); *Hale v. Sec'y of Dept. of Health & Human Servs.*, 22 Cl. Ct. 403, 409 (1991) ("A special master has discretion to determine whether testimonial evidence, in addition[] to written statements[,] is necessary.").

D. Was the Chief Special Master's Reliance on Petitioner's 2000 Social Security Records to Support His Denial of Petitioner's Claim Arbitrary or Capricious?

Petitioner's challenge to the Chief Special Master's weighing of facts regarding causation of her post-vaccination health problems is many-faceted. First, Jane Doe/17 apparently believes the Chief Special Master gave too much weight to her 2000 Social Security file. *See* Pet.'s Mot. at 4 ("While a judge may rule on the credibility of a witness and their evidence, to not . . . make reference to the entire body of material presented and only reference the 2000 Social security information finding should fall within a standard of arbitrary and capricious determination warranting judicial review."). Second, Jane Doe/17 also apparently believes that the Chief Special Master did not give enough weight to evidence which corroborates her allegations of fact concerning her health problems in 2002 and 2003. *See id.* (noting that the Chief Special Master did not discuss her 2003 Social Security application). Third, Jane Doe/17 argues that the Chief Special Master did

not properly give weight to various documents, which in her opinion, support petitioner's "theory of a hypersensitivity/automimmune reaction to the varicella vaccine due to having a low contraindicated Igg level and a high immunity titer to chickenpox as being a rational[] theory and biologically plausible." *Id.* at 5-6.

The court will address each of these contentions in turn. It is important to note, however, that the Chief Special Master is charged under the Vaccine Act with "weighing the testimony and other evidence and drawing reasonable inferences" therefrom. *Tebcherani ex rel. Tebcherani v. Sec'y of Dep't of Health & Human Servs.*, 55 Fed. Cl. 460, 480 (2003). This court may not second guess the evaluation of the evidence, or substitute its own judgment for that of a special master, when he has weighed and considered the evidence of record. *Id.* (citation omitted). As the Federal Circuit has stated,

Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.

Munn, 970 F.2d at 871.

1. The 2000 Social Security Application

As to the Chief Special Master's reliance on petitioner's 2000 Social Security application records, the court does not find that he was arbitrary or capricious in giving these records substantial weight. Petitioner's theory of causation posited that she had a pre-existing condition of CVID, which was significantly aggravated by her varicella vaccinations, as evidenced, in part, by the onset of diarrhea and other flu-like symptoms approximately two weeks after receiving the second varicella vaccination on June 4, 2001. Pet. at 2; Pet.'s 3d Sub. at 8; Tr. at 18. Petitioner alleged repeatedly that she had been relatively healthy in the years immediately preceding 2001, Pet.'s 3d Sub. at 7, and specifically, that she had not suffered from IBS since an episode at age twenty-four, many years earlier, Tr. at 43, 62-63. As the Chief Special Master noted, if petitioner suffered from IBS as a chronic condition before 2001, this fact would discredit both the factual underpinnings of her vaccine injury theory, and her credibility. Opin. at 15.

The Chief Special Master reasonably relied on the 2000 Social Security records, in part, to decide that the weight of the evidence before him showed that petitioner suffered from chronic IBS before receiving the varicella vaccinations in 2001.²⁰ Opin. at 16 (“Thus, petitioner’s testimony that prior to vaccination she did not suffer from bowel problems, other than a bout of IBS at age 24 is directly contradicted by Dr. Fishman’s history taken in 2002, the history recorded in the [study’s] research log taken in 2003, and the information petitioner gave to [the Social Security Administration] in 2000.”). All of these records contained contemporaneous documentation of petitioner’s gastrointestinal problems, directly contradicting her hearing testimony. Indeed, as the Federal Circuit has stated, “oral testimony in conflict with contemporaneous documentary evidence deserves little weight.” *Cucuras v. Sec’y of Dep’t of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993)) (citations omitted).

The 2000 Social Security application records undermined petitioner’s theory of causation of her vaccine injury, and her credibility. The Chief Special Master made no clear error in judgment in relying on Jane Doe/17’s 2000 Social Security records in denying her claim, and his findings of fact cannot be disturbed under the substantially deferential standard of review applicable here. *See Hines*, 940 F.2d at 1528 (noting that when the consideration of relevant evidence leads to plausible inferences and a rational conclusion, a special master’s decision will not generally be overturned).

^{20/} In one instance of little importance, the Chief Special Master may have read more into the 2000 Social Security application than was warranted. The onset date for symptoms listed in Jane Doe/17’s disability benefits application may indeed show that petitioner was claiming an onset date of 1995 for her chronic IBS. Opin. at 3, 16; Pet.’s 11th Sub. at 463. However, four disabling conditions are listed on her application: “severe mental depression, anxiety, post-traumatic stress, and chronic, uncontrolled diarrhea from spastic colon.” Pet.’s 11th Sub. at 463. Petitioner now argues, and her ambiguous listing of one onset date for four disabling conditions may support, that 1995 was the onset date she was claiming only for certain mental health conditions, not for IBS. *See* Pet.’s Mot. at 2 (stating that “[t]he 2000 Social security application was made as a result of the psychological stress from [her] claim that she was convicted wrongly and pursued for 6 years as if an animal by the Pennsylvania Attorney general’s office”); *id.* at 3 (alleging that her 2000 application “was for treatment of Post traumatic Stress disorder and Depression primarily”); Pet.’s Supp. Br. at 13 (alleging that her 2000 application “had nothing to do with permanently disabling diarrhea”). Even if the Chief Special Master accorded more weight to the onset date reported in Jane Doe/17’s 2000 Social Security file than it deserves, his most significant finding was that the 2000 Social Security application provides evidence of Jane Doe/17’s chronic IBS, and that finding is fully supported by the record.

2. The 2003 Social Security Application

Jane Doe/17 apparently does not believe that the Chief Special Master properly weighed evidence of her health problems that developed in the years following her vaccinations. She argues, in particular, that her 2003 Social Security application records “clearly show the long term and pronounced effects the vaccine plausibly had on [her].” Pet.’s Mot. at 4. Unfortunately for petitioner, the evidence of her illness in recent years is not, by itself, sufficient to show a vaccine injury. Her burden of proof, in part, is to show, by a preponderance of the evidence, a logical sequence of cause and effect linking the varicella vaccinations she received in 2001 to a significant aggravation of her alleged pre-existing condition of CVID. *Althen*, 418 F.3d at 1278. The Chief Special Master’s inquiry began, quite reasonably, with a review of the evidence of her pre-existing CVID. Opin. at 10 (noting this “primary issue[]: . . . whether petitioner had an ‘unknown’ pre-existing condition that the vaccine could aggravate”).

Petitioner did not meet that initial burden. Her expert was not credible on the topic of her pre-existing CVID, and respondent’s expert persuasively testified that petitioner did not have CVID at the time of her vaccinations. The Chief Special Master concluded that “in accordance with petitioner’s theory of her case, the vaccine could not have aggravated a pre-existing condition, because there is no persuasive evidence of an underlying condition.” Opin. at 13. Whether or not petitioner developed CVID in recent years is irrelevant, because her theory of causation was that of significant aggravation of a pre-existing condition, and she presented no alternative vaccine injury argument with adequate support, such as reputable expert opinion or persuasive scientific literature.²¹ *Althen*, 418 F.3d at 1278. Once petitioner’s theory of causation unraveled, the Chief Special Master was not required to examine or give weight to evidence going to the precise definition and diagnosis of Jane Doe/17’s health problems. Because the Chief Special Master considered relevant evidence that was sufficient to rationally decide petitioner’s claim, his decision not to discuss her 2003 Social Security records was neither arbitrary nor capricious, particularly in view of the fact that these records

^{21/} The Chief Special Master questioned respondent’s expert in an effort to gauge the plausibility of any alternate theories of causation that might fit the facts of this case. Tr. at 191-98. Dr. McGeady did not believe that the vaccines were causally connected to petitioner’s collagenous colitis, under any likely theory of causation.

do not provide proof that Jane Doe/17 had CVID prior to 2001.

3. Weight Not Given to Other Documents

Similarly, Jane Doe/17 suggests that not enough weight was given to other documentary evidence which, in her opinion, supports the theory that the varicella vaccinations significantly aggravated her CVID. Pet.'s Mot. at 5-6. In particular, she mentions a short email she received from the Centers for Disease Control (CDC) in 2007. This CDC email responds to an email from Jane Doe/17, which mentioned her correspondence with a CDC physician two years earlier, and which presented this question: "Because I was immune to varicella, would not the autoimmune problem be more the probable cause [of my generalized autoimmune disease] as an adverse reaction [to the vaccine?]" Pet.'s 9th Sub. Ex. 20. The CDC response petitioner received noted that the physician she was trying to reach was not in the office that day, that she acted correctly in reporting the adverse event, that her email would be forwarded to other staffers, and that no action would be taken by the CDC at that time "unless the vaccine safety or varicella experts want to know more." *Id.* The author of the email, a public health educator and not a physician, also stated that "[y]our rationale seems reasonable and biologically plausible." *Id.* This emailed comment does not qualify as expert opinion, medical record of a diagnosis, or scientific literature. The Chief Special Master was not arbitrary or capricious when he gave this email little or no weight, because it is not relevant evidence.

Another document given no weight by the Chief Special Master, according to petitioner, is a Vaccine Adverse Event Reporting System (VAERS) report. Pet.'s Mot. at 6. "The Special master ignores the written VAERS report done by Dr[.] Rob Mac[G]regor, the head of the study the [petitioner] was in indicating the plausibility of a hypersensitivity/autoimmune reaction in September 2007." *Id.* The document in question was filed on September 17, 2007, one month before the evidentiary hearing, and was not relied upon by the parties' experts, or by counsel in their post-hearing briefs. Pet.'s 8th Sub. Ex. 17 at 3. Unlike the records from the study submitted by petitioner and certified by her counsel to have been provided by the University of Pennsylvania School of Medicine, this VAERS report was supplied by Jane Doe/17 to her counsel. *Compare* Pet.'s 2d Sub. Atty. Cert. *with* Pet.'s 8th Sub. Atty. Cert. The VAERS report is undated and has the names "Rob MacGregor, MD and [Jane Doe/17]" in the "Form completed by (Name)" block. Pet.'s 8th Sub. Ex. 17 at 3. At the evidentiary hearing, Jane

Doe/17 noted that there were “three VAERS reports. I filled out one myself.” Tr. at 69. It is impossible to tell from the VAERS form referenced by petitioner whether the comments on the form reflect the thoughts of Dr. MacGregor or the thoughts of Jane Doe/17. For this reason, the Chief Special Master’s rational decision to accord this document little or no weight was not arbitrary or capricious.

Petitioner’s challenge to the weight given to various documentary pieces of evidence fails, because nothing in the Chief Special Master’s weighing of the evidence has been shown to be arbitrary or capricious. The Chief Special Master considered the relevant, credible evidence pertinent to Jane Doe/17’s claim, and his decision shows rational analysis and no clear error in judgment. For these reasons, the court must reject petitioner’s challenge to the Chief Special Master’s weighing of the evidence before him.

E. Did the Chief Special Master Irrationally Favor the Opinion of Dr. McGeady?

1. Dr. Adler and Dr. McGeady

As previously stated, the Chief Special Master did not find Dr. Adler to be a credible expert, based on his lack of accreditation in immunology, his lack of pertinent experience, his faulty view or interpretation of the literature on COVID and his over-reliance on petitioner’s self-reported medical and family history. Opin. at 6, 10. The Chief Special Master found Dr. McGeady to be extremely well-qualified, credible, and persuasive, based on his impressive teaching career, publications, clinical experience and accreditation, as well as his thorough preparation for the evidentiary hearing. *Id.* at 7, 10. The Chief Special Master described Dr. McGeady’s testimony in detail, and judged it to be consistent with relevant literature and thoroughly grounded in extensive experience with immunological diseases. *Id.* at 11-12. Dr. McGeady was found to be “far more convincing” and “vastly more persuasive” than Dr. Adler. *Id.* at 13.

It is well-settled that conclusions regarding the persuasiveness of particular medical experts and their theories are “virtually unchallengeable on appeal.” *Lampe*, 219 F.3d at 1362; *Hanlon*, 191 F.3d at 1349 (stating that such findings are “virtually unreviewable” (quoting *Bradley*, 991 F.2d at 1575)). Indeed, the applicable standard of review is “uniquely deferential . . . in a case in which the

medical evidence of causation is in dispute.’” *Lampe*, 219 F.3d at 1362 (quoting *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). Here, there is more than enough evidence to support the Chief Special Master’s conclusion that the theory of causation presented by Dr. Adler was less persuasive than that of Dr. McGeady, who testified that the varicella vaccine would not significantly aggravate a pre-existing condition of COVID.²² The expert reports and hearing testimony fully support the Chief Special Master’s conclusion.

Moreover, even if this court had been more impressed by Dr. Adler’s theory of causation, there is no question that the court lacks authority to re-weigh the evidence of causation presented to the Chief Special Master. *See Munn*, 970 F.2d at 871; *Tebcherani*, 55 Fed. Cl. at 479 (“[T]his Court does not generally have authority to re-weigh evidence presented and ruled upon by the Special Master, even if this court might have considered the significance of the expert testimony differently.”) (citations omitted). Substantial deference must be afforded to the Chief Special Master’s evaluation of expert opinion. *Lampe*, 219 F.3d at 1362. On this record, the court concludes that the Chief Special Master acted neither arbitrarily nor capriciously when he accepted Dr. McGeady’s opinion and rejected Dr. Adler’s theory of causation.

2. Dr. McGeady and Jane Doe/17’s Treating Physicians

Petitioner argues that the Chief Special Master incorrectly favored Dr. McGeady’s diagnosis of her health over that given by her treating physicians. *See* Pet.’s Mot. at 5 (“Dr. McGeady in his testimony disagrees with his two respected colleagues . . . , who had multiple hands on examination of the [petitioner]. . . . The Special master ignores the diagnosis of the two well respected adult immunologist physicians . . .”). It is true that opinions of treating physicians as to the causes of a particular vaccine injury should be considered by a special master. *See Cappizzano*, 440 F.3d at 1326. But here petitioner’s argument focuses on perceived differences between the diagnostic approaches of Dr. McGeady and her

^{22/} Petitioner relies on the difference in clinical experience between the two experts to support her argument that Dr. Adler was the more persuasive expert. Pet.’s Mot. at 5. There was extensive testimony describing Dr. McGeady’s clinical experience, which includes twenty-five years of practice seeing adults and children. Tr. at 137. The court finds no error in the Chief Special Master’s assessment of the qualifications of Dr. McGeady and the persuasiveness of his opinions.

treating immunologists. Petitioner's argument is not persuasive, for two reasons.

First, the disagreements between Dr. McGeady and Jane Doe/17's treating physicians largely reflect his reluctance to confirm certain diagnoses without more data. Dr. McGeady testified at length about how a physician may diagnose CVID, and stated that his approach was not evidenced in Jane Doe/17's medical records. *See* Tr. at 147-48 (noting that he could find no evidence that Jane Doe/17's physicians had conducted certain tests that he would have thought appropriate for establishing a CVID diagnosis), 166 (testifying that "on the basis of the information we have [from Jane Doe/17's medical records], [her immunological deficiencies are] incompletely explored"). The hearing transcript also shows that Dr. McGeady was not sure whether Jane Doe/17 had CVID in 2007, despite records that she was receiving treatment to address CVID in that year. *Compare* Tr. at 175 (stating that "even now [2007], I would be very hesitant to call her [condition] common variable immunodeficiency") *with* Pet.'s 8th Sub. Ex. 13 at 2. Dr. McGeady also was not sure what caused Jane Doe/17's collagenous colitis. Tr. at 186. Thus, rather than directly disagreeing with Jane Doe/17's treating physicians as to petitioner's theory of vaccine injury causation, Dr. McGeady expressed unwillingness, on the record presented by the parties, to confirm a 2007 CVID diagnosis or a causal link between her CVID and her collagenous colitis.

Second, the Chief Special Master did not rely on Dr. McGeady for a current diagnosis of Jane Doe/17's bowel problems. The Chief Special Master's initial task was to determine whether or not Jane Doe/17 had a pre-existing condition of CVID at the time of her vaccinations in 2001. The Chief Special Master agreed with Dr. McGeady's opinion that Jane Doe/17 did not have CVID in early 2001, because her lab results from that time did not meet the criteria for CVID, and she had reported none of the typical medical problems of CVID patients. *Opin.* at 12-13. There are no contemporaneous medical records from Jane Doe/17's treating physicians that discuss CVID before she received the varicella vaccinations in 2001, and petitioner has not pointed to more recent records where a treating physician has suggested that she had CVID before 2001. Because there is no contrary opinion from a treating physician, the Chief Special Master did not illogically favor the opinion of respondent's expert over that of a treating physician. The only relevant conflict in opinion resolved by the Chief Special Master was the conflict between Dr. Adler and Dr. McGeady, discussed *supra*. For these reasons, the court finds nothing arbitrary or capricious in the credence given Dr. McGeady's opinions by the Chief Special Master.

F. Did Respondent’s Expert Support a Finding that Petitioner’s Collagenous Colitis Was a Vaccine-related Immunological Problem?

During his testimony, Dr. McGeady discussed some of the flaws in Dr. Adler’s theory of causation. Tr. at 188-89. For example, Dr. Adler opined that an autoimmune response had occurred within fourteen days of the varicella vaccinations, yet such a response would normally take months, according to Dr. McGeady. *Id.* at 189. Petitioner now argues that her collagenous colitis symptoms fit Dr. McGeady’s description of an appropriate time-frame for autoimmune disorders caused by a vaccine. *See* Pet.’s Mot. at 6 (noting that her “entire description of her condition plays out as Dr. Mc[G]eady indicates”).

The court cannot take the isolated comment from Dr. McGeady regarding an appropriate time-frame for autoimmune reactions to a vaccine as an endorsement of petitioner’s theory of causation. Dr. McGeady consistently testified that Jane Doe/17’s varicella vaccinations had no plausible causal relationship with her collagenous colitis or CVID. Tr. at 161, 186, 192. Dr. McGeady rejected Dr. Adler’s theory of causation, and rejected alternate, unargued theories that might have been presented to link the varicella vaccinations with Jane Doe/17’s health problems in recent years. *Id.* at 158-62, 189, 191-92. His testimony cannot be construed to support petitioner’s theory of causation, and petitioner has offered no reputable medical opinion or scientific studies supporting her alternate theory of a more gradual onset of vaccine-related aggravation of her CVID. *See Althen*, 418 F.3d at 1278 (requiring expert medical testimony or scientific studies to support a persuasive medical theory). An out-of-context comment from Dr. McGeady’s testimony does not constitute proof of causation under *Althen*.

Evidence of an appropriate temporal relationship between the varicella vaccinations and Jane Doe/17’s autoimmune problems is not enough to meet petitioner’s burden here. *See id.* (citing *Grant*, 956 F.2d at 1149). The Chief Special Master found that petitioner’s theory of causation, alleging the significant aggravation of a pre-existing condition, had not been proved by a preponderance of the evidence, because the evidence did not show that she had CVID before getting the varicella vaccinations in 2001. Opin. at 13. That finding was supported by the evidence before him, and cannot be disturbed absent a clear error in judgment. His assessment of Dr. McGeady’s testimony and opinions was reasonable and

thorough, and his denial of petitioner's claim is perfectly in tune with Dr. McGeady's expert opinion. Even if the court were allowed to re-weigh Dr. McGeady's testimony and come to a new conclusion about petitioner's theory of causation, it sees no reason to do so here.

G. Did the Chief Special Master Err in Finding Petitioner to be Not Credible?

Finally, petitioner attacks the Chief Special Master's finding that her testimony and allegations of fact are not credible. Jane Doe/17 argues that the Chief Special Master misconstrued the differences between her testimony about her IBS and Dr. Fishman's records. Pet.'s Mot. at 6. She also represents that the 2000 Social Security "application [only] indicates she had a diagnosis of Irritable Bowel and an Atonic colon, in 1978, that was quite severe and caused the premature birth [of] her son." *Id.* at 3. Jane Doe/17 asserts that her work history contradicts any inference that she had chronic IBS prior to 2001. Pet.'s Supp. Br. at 13-14.

As previously stated, "oral testimony in conflict with the contemporaneous documentary evidence deserves little weight." *Cucuras*, 993 F.2d at 1528 (citations omitted). In vaccine cases,

[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id. Here, two medical records contradict petitioner's oral testimony and allegations of fact. In 2002 and 2003, Dr. Fishman consistently described Jane Doe/17 as suffering from chronic IBS, less problematic over the years than her first bout at age 24. Pet. Ex. at 91, 94, 100. A mental health counselor in 2000 noted that petitioner "claim[ed] to have what is called an atonic colon, which is a form of GI disorder." Pet.'s 11th Sub. at 450.

Additional records contradict Jane Doe/17's testimony and allegations of

fact regarding her history of IBS. In petitioner's 2000 Social Security application, "chronic, uncontrolled diarrhea from spastic colon" is among her answers to the question "What are the illnesses, injuries or conditions that limit your ability to work?" Pet.'s 11th Sub. at 463. Her disabling diarrhea is not mentioned as a historical incident taking place in 1978, but as a current condition limiting her ability to work in 2000. In 2003, Dr. Brady noted in the log notes of the study that Jane Doe/17 "has a pre-existing condition of irritable bowel syndrome." Pet.'s 2d Sub. at 4. These records establish a history of reports from petitioner that she had chronic IBS before receiving the varicella vaccinations in 2001, and this history stretches from 2000 to 2003. The court does not find that the Chief Special Master erred in finding these records more credible than Jane Doe/17's version of her medical history.

The Chief Special Master noted additional discrepancies between Jane Doe/17's testimony and records of medical visits in 2001. Opin. at 17. He was also troubled by the lack of any mention in the study records of petitioner's gastrointestinal symptoms, which she claims to have reported at the time of their occurrence. *Id.* at 17-18; *see also* Tr. at 23, 66. This court has held that a lack of contemporaneous evidence to corroborate a petitioner's allegations of symptoms can justify a finding that those allegations are not credible. *See Snyder by Snyder v. Sec'y of Dep't of Health & Human Servs.*, 36 Fed. Cl. 461, 465-66 (1996) (citing *Bradley v. Sec'y of Dep't of Health & Human Servs.*, 24 Cl. Ct. 641, 644-45 (1991), *aff'd*, 991 F.2d 1570 (Fed. Cir. 1993)), *aff'd*, 117 F.3d 545 (Fed. Cir. 1997). Here, petitioner was in regular contact with study staff who were following a protocol for collecting information about vaccine side-effects, and there is no contemporaneous record of the symptoms she now reports. She also was in regular contact with her primary physician, and had other medical treatments in 2001, yet none of the contemporaneous records before the Chief Special Master mentions the severe post-vaccination symptoms that are now alleged by Jane Doe/17 to have occurred in 2001. The Chief Special Master also had the opportunity to examine Jane Doe/17 under oath. The court finds no error in the Chief Special Master's determination that petitioner was not credible.

It is critical to recognize that the credibility findings of a special master are afforded great deference. *See Munn*, 970 F.2d at 871 (stating that "of course we do not examine the . . . credibility of the witnesses," as this is a matter "within the purview of the fact finder"). This is so because the special master "saw the witnesses and heard the testimony." *Bradley*, 991 F.2d at 1575 (citation omitted).

For that reason, credibility findings are rarely disturbed by this court. In this instance, it was the Chief Special Master who heard testimony from Jane Doe/17, and, absent clear error, he must therefore be the final arbiter of her credibility. Finding no such error here, the Chief Special Master's finding that Jane Doe/17's testimony and allegations of fact were not credible shall not be disturbed.

CONCLUSION

For all of the above reasons, the court holds that the Chief Special Master's decision in this case was not arbitrary, capricious, an abuse of discretion, or otherwise contrary to law.

Accordingly, it is hereby **ORDERED** that

- (1) Petitioner's Motion for Review, filed on June 30, 2008, is **DENIED**;
- (2) The decision of the Chief Special Master is **SUSTAINED**;
- (3) The Clerk's office is directed to **ENTER** judgment dismissing the petition; and
- (4) Petitioner's motion to redact her name from this opinion, filed by leave of the court on December 12, 2008, is **GRANTED**; redactions are not required of other filings in this case to which access is restricted by the court's rules.

LYNN J. BUSH
JUDGE