In the United States Court of Federal Claims

No. 17-259
Filed: July 9, 2025
Reissued: July 24, 2025[1]

HEATHER GOFF,	)
Petitioner,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

Courtney Jorgenson, Siri & Glimstad LLP, Phoenix, Arizona, for Petitioner.

Michael S. Bliley, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for Respondent, *with whom were Yaakov M. Roth*, Acting Assistant Attorney General, *C. Salvatore D'Alessio*, Director, Torts Branch, Civil Division, *Heather L. Pearlman*, Deputy Director, Torts Branch, Civil Division, and *Lara A. Englund*, Assistant Director, Torts Branch, Civil Division.

OPINION AND ORDER

MEYERS, Judge.

In her petition, Heather Goff contends that the influenza vaccinations she received during the 2015–16 flu season caused her to suffer two strokes.[2] After considering the petition, the expert reports, medical records, and witness testimony, the Special Master concluded that Ms. Goff failed to carry her burden of establishing by a preponderance of the evidence that the

[1] The court issued this Opinion and Order to the parties on July 9, 2025, and, pursuant to Vaccine Rule 18(b), gave them an opportunity to propose redactions. Because they did not propose any, the court reissues this Opinion and Order in its entirety.

[2] The term "stroke" refers to various medical conditions involving "local damage to the brain in a particular area related to the blood flow and the vascular structures of the brain." Hr'g Tr. 31:21–24 (ECF Nos. 59–60) (testimony of Dr. Laura S. Boylan); *accord id.* at 145:25–146:4 (testimony of Dr. Steven Messé).

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influenza vaccines she received caused her to suffer her stroke.[3] The Special Master found Ms. Goff's expert's causation theory unpersuasive, that another condition was more likely the cause of the stroke than the vaccine, and that the stroke did not occur within a medically appropriate timeframe after the vaccination. In other words, the Special Master concluded that Ms. Goff failed to establish any of the three things that she must prove to prevail on her claim. Because the Special Master considered all the evidence under the proper legal framework, explained her weighing of that evidence and testimony, and provided a reasoned explanation for her decision that is supported by the record, her decision was neither arbitrary nor capricious. As a result, the court sustains the Special Master's decision.

I. Background

A. Factual Background

Ms. Goff received the influenza vaccine on September 14, 2015. Pet'r's Ex. 1 ¶ 3 (ECF No. 6-1); Pet'r's Ex. 14 (ECF No. 8-6).[4] This was the first time in about 18 years she got vaccinated for influenza, and she did so because her employer at the time required it. Pet'r's Ex. 1 ¶ 3. Following the vaccine, Ms. Goff experienced "shoulder pain, which lasted a few days," but otherwise had no "lingering effects." *Id.*

On March 22, 2016, Ms. Goff received a second influenza vaccine in her left arm. *Id.* ¶ 4; Pet'r's Ex. 2 (ECF No. 6-2). She got this second influenza vaccine as a requirement of her new employer, Banner University Medical Center ("Banner"). Pet'r's Ex. 1 ¶ 4. At the time of the March influenza vaccine, Ms. Goff was 43 years old and in good health. Pet'r's Ex. 2 (indicating Ms. Goff was not sick); Hr'g Tr. 6:25–7:7 (ECF Nos. 59–60) (testimony of Ms. Goff) (testifying she was "feeling just fine"). Based on Ms. Goff's statement from 2017, after the March 2016 influenza vaccine her left arm was "sore and pink" for the "following few days . . . but [that] seemed to lessen over the next week." Pet'r's Ex. 1 ¶ 5. Ms. Goff testified in 2021 that she "was red, swollen all the way down [her] arm and into [her] forearm for a couple months" after the March 2016 influenza vaccine. Hr'g Tr. 7:20–22. The record does not include any medical records for Ms. Goff between March 22, 2016, and March 30, 2016. *Goff v. Sec'y*

[3] Because both experts agreed that Ms. Goff's second stroke was likely caused by a cerebral angiogram that she underwent because of the first stroke, the Special Master focused on the potential connection between her influenza vaccinations, particularly the second vaccination, and the first stroke. *Goff v. Sec'y of Health & Hum. Servs.*, No. 17-259V, 2025 WL 431582, at *20 (Fed. Cl. Spec. Mstr. Jan. 13, 2025) (ECF No. 85). Similarly, the parties' arguments (with one exception regarding a claimed "booster effect" of the combination of the two vaccinations) focused on the connection between the second influenza vaccination and the first stroke, particularly with respect to *Althen* prong three's timing requirement. Therefore, the court's analysis is similarly focused on the vaccine's potential connection to the first stroke.

[4] Because the parties' exhibits span multiple CM/ECF entries, the court cites the parties' exhibit numbers rather than their CM/ECF numbers.

of Health & Hum. Servs., No. 17-259V, 2025 WL 431582, at *3 (Fed. Cl. Spec. Mstr. Jan. 13, 2025) (ECF No. 85).[5]

Then on March 30, 2016, Ms. Goff woke up lacking "feeling or control of [her] right arm," babbling, experiencing "drooping on the right side of [her] face," and "feeling progressively weaker." Pet'r's Ex. 1 ¶ 6; *see* Pet'r's Ex. 6 at 12, 14 (ECF Nos. 6-6 to 6-8); Hr'g Tr. 8:2–12. She was taken to the Abrazo West Campus Emergency Room ("Abrazo ER") and treated for an acute ischemic stroke.[6] Pet'r's Ex. 6 at 12–13. Her admission records reveal that Ms. Goff had no prior history of stroke and had been in "good chronic health" other than having hypothyroidism. *Id.* at 220. The records also indicate that she did not have a fever, rash, or swelling at the time of admission, although she had elevated blood pressure. *Id.* at 222, 280–81. Her lab results reflect that her C-reactive protein ("CRP")[7] level, erythrocyte sedimentation rate ("ESR")[8] level, complete blood count, and hypercoagulable[9] workup were normal. *Id.* at 342, 344–50.

Ms. Goff underwent additional medical testing while at the Abrazo ER. *Id.* at 331–37. Magnetic resonance imaging ("MRI") without contrast of the brain revealed a "left middle

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[5] The court cites the Special Master's public decision filed on February 6, 2025, throughout this Opinion and Order because all the information pertinent to the present motion for review appears in the public decision.

[6] An ischemic stroke occurs when a part of the brain does not receive sufficient blood flow because a blood vessel is blocked. Pet'r's Ex. 39 (ECF No. 57-1); *accord* Hr'g Tr. 32:1–33:12 (testimony of Dr. Boylan); *id.* at 146:8–11 (testimony of Dr. Messé).

[7] CRP is "a globulin that forms a precipitate with the somatic C-polysaccharide of the pneumococcus in vitro; it is the most predominant of the acute-phase proteins." *Goff*, 2025 WL 431582, at *4 n.3 (citing Dorland's Medical Dictionary Online).

[8] The erythrocyte sedimentation rate is:

> [T]he rate at which erythrocytes precipitate out from a well-mixed specimen of venous blood, measured by the distance the top of the column of erythrocytes falls in a given time interval under specified conditions; an increase in rate is usually due to elevated levels of plasma proteins, especially fibrinogen and immunoglobulins, which decrease the zeta potential on erythrocytes by dielectric shielding and thus promote rouleau formation. It is increased in monoclonal gammopathy, hypergammaglobulinemia due to inflammatory disease, hyperfibrinogenemia, active inflammatory disease, and anemia.

Goff, 2025 WL 431582, at *4 n.4 (citing Dorland's Medical Dictionary Online).

[9] Hypercoagulability is "the state of being more readily coagulated than normal." *Goff*, 2025 WL 431582, at *4 n.5 (citing Dorland's Medical Dictionary Online).

cerebral artery territory 5 x 25 mm acute infarct."[10] *Id.* at 5, 230, 232, 274, 278, 336–37. Magnetic resonance angiography ("MRA") without contrast of the neck revealed a potential "filling defect" in her left internal carotid artery. *Id.* at 230, 274, 278, 336. A computed tomography ("CT") angiogram[11] of her neck revealed "mild" atherosclerotic plaque causing 30–40% narrowing of her left internal carotid artery. *Id.* at 5, 230, 232, 274, 277, 331–32. Ms. Goff was discharged from the Abrazo ER on April 2, 2016, with a diagnosis of an acute cerebrovascular accident.[12] *Id.* at 5.

On April 5, 2016, Ms. Goff reported left arm pain that started that morning during a follow-up appointment. Pet'r's Ex. 8 at 7, 10 (ECF No. 6-10). Her follow-up appointment records reflect that she had elevated blood pressure, but report an otherwise normal physical examination. *Id.* at 7–10.

Ms. Goff completed a Vaccine Adverse Event Reporting System ("VAERS") report on April 15, 2016. Pet'r's Ex. 3 (ECF No. 6-3). In it, she noted her influenza vaccine on March 22, 2016, subsequent facial numbness and droop, difficulty speaking, arm and hand numbness, and reduced sensation processing on March 30, 2016. *Id.* Ms. Goff testified that she completed the VAERS report because she felt "very strongly that [her stroke] had everything to do with this flu shot." Hr'g Tr. 11:19–21.

On April 20, 2016, Ms. Goff returned to the Abrazo ER because she had "high blood pressure and continued to have left [arm] soreness extending to [her] scapular area, shoulder and jaw," and she feared she was having another stroke. Pet'r's Ex. 1 ¶ 10; Pet'r's Ex. 6 at 494. Her admission records note Ms. Goff complained of "left arm pain/burning for 2 weeks following flu shot," and that she felt "her symptoms [we]re [an] adverse reaction to the flu shot and no one is listening [to] her." Pet'r's Ex. 6 at 494; *see also id.* at 503. Her physical examination records indicate Ms. Goff did not have a fever or rash, her neurological examination was normal, and her lab results were normal. Pet'r's Ex. 6 at 494–97; Pet'r's Ex. 4 at 10–16, 19 (ECF No. 6-4). Her diagnosis upon discharge was left arm pain. Pet'r's Ex. 6 at 503.

Ms. Goff also had a follow-up appointment at Neuropro, Inc., on April 20, 2016. Pet'r's Ex. 10 at 9–10 (ECF No. 8-2). On the Neuropro new patient evaluation form, Ms. Goff reported that she experienced "[f]ever" in her "shoulder, neck, chest and scapular region" since her influenza vaccine. *Id.* at 5. She reported that she suffered a transient ischemic attack[13] on March

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[10] An infarct "is when the nervous tissue actually dies and [is] irreversibly injured as a result of that reduced flow of blood." Hr'g Tr. 146:14–16 (testimony of Dr. Messé). An infarct is evidence that a stroke occurred. *Id.* at 146:24–147:1.

[11] "A CT angiogram is "a noninvasive procedure[] . . . [where the physician] inject[s] contrast, and as the contrast is filling up the blood vessels in the neck and the head, . . . [t]he patient is moving through the CT scanner," which "take[s] pictures." Hr'g Tr. 157:12–17 (testimony of Dr. Messé).

[12] A cerebrovascular accident is another term for an "ischemic stroke." Hr'g Tr. 147:10, 147:15 (testimony of Dr. Messé).

[13] Transient ischemic attacks "are transient neurological symptoms, typically focal neurologic systems, that are attributed to reduced blood flow in a particular blood vessel . . . . The

22, 2016, the same day that she received the influenza vaccine. *Id.* Her Neuropro appointment records indicate Ms. Goff did not have a rash. *Id.* at 6, 9. The Neuropro physician ordered that Ms. Goff undergo a cerebral angiogram[14] to "rule out vasculitis." *Id.* at 10; *see* Pet'r's Ex. 1 ¶ 11.

Ms. Goff had another follow-up appointment on May 9, 2016. Pet'r's Ex. 8 at 1. Her records indicate her left arm pain was "resolved" at the time of that appointment. *Id.* at 1, 4.

On June 24, 2016, Ms. Goff underwent a cerebral angiogram. Pet'r's Ex. 1 ¶ 12; Pet'r's Ex. 38 at 679–82 (ECF Nos. 49-3 to 49-5). The cerebral angiogram discovered atherosclerotic plaque in her left internal carotid artery causing about 35–40% narrowing, consistent with her testing at the Abrazo ER. Pet'r's Ex. 38 at 681–82.

Then, while at work on June 30, 2016, Ms. Goff's "boss noticed an obvious change in [her] speech . . . and immediately took [Ms. Goff] to the emergency room at Banner." Pet'r's Ex. 1 ¶ 13; *cf.* Hr'g Tr. 12:20–13:2 (testimony of Ms. Goff) (stating she "ask[ed] a colleague to take [her] to [her] boss' office because [she was not] talking straight"). Upon admission to the Banner emergency room ("Banner ER"), Ms. Goff was aphasic. Pet'r's Ex. 38 at 9, 544–46, 567, 570, 897, 900. Her treating physicians assessed her to be at a 1 or 2 on the National Institutes of Health stroke scale.[15] *Id.* at 247–52.

At the Banner ER, Ms. Goff underwent another CT angiogram, and its results indicate that she "has . . . small linear filling defect[s], most consistent with . . . carotid web[s]"[16] in her left and right internal carotid arteries. Pet'r's Ex. 37 at 36–37 (ECF No. 49-2); Pet'r's Ex. 38 at

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symptoms would last less than 24 hours and be without any evidence of injury on neuro-imaging." Hr'g Tr. 146:17–23 (testimony of Dr. Messé).

[14] A cerebral angiogram "is an invasive procedure where a radiologist or interventional neurologist or neurosurgeon will insert a catheter . . . into an artery in the groin, called the femoral artery, and then move that catheter up into the blood vessels in the neck and in the aortic arch." Hr'g Tr. 156:4–11 (testimony of Dr. Messé).

[15] The National Institutes of Health stroke scale is used by health care providers to "assess the severity of a stroke. Health care providers use it to measure neurological function and deficits by asking the person to answer questions and perform several physical and mental test[s]." *Goff*, 2025 WL 431582, at *5 n.7 (quoting Nat'l Inst. Neurological Disorders & Stroke, *NIH Stroke Scale*, Nat'l Insts. Health, https://www.ninds.nih.gov/health-information/stroke/assess-and-treat/nih-stroke-scale). "A score of 1 is defined as . . . 'Not alert; but arousable by minor stimulation to obey, answer, or respond.'" *Id.* (quoting Nat'l Inst. Neurological Disorders & Stroke, *supra*). A score of 2 is defined as "Not alert; requires repeated stimulation to attend or is obtunded and requires strong or painful stimulation to make movements." Nat'l Inst. Neurological Disorders & Stroke, *supra*.

[16] A carotid web "is a[n] abnormal growth in the lining of the blood vessel. [T]here's three layers to the arteries, and with a carotid web, the intimal layer, which is the innermost layer, has collagen deposited abnormally, and so there is this outgrowth that occurs." Hr'g Tr. 160:22–161:3 (testimony of Dr. Messé); *accord id.* at 56:9–12, 56:19–57:1 (testimony of Dr. Boylan).

34, 473–74, 508. The "more prominent" web appeared to be in her left internal carotid artery. Pet'r's Ex. 37 at 37; Pet'r's Ex. 38 at 34, 474, 508.

She had another MRI that showed an approximately 2 cm left thalamic lesion. Pet'r's Ex. 37 at 24; Pet'r's Ex. 38 at 9, 521, 550. The lesion raised concerns of a brain tumor. Pet'r's Ex. 37 at 24; Pet'r's Ex. 38 at 9, 521, 550–51. Accordingly, Ms. Goff underwent a brain biopsy to determine whether she had a brain tumor. Pet'r's Ex. 38 at 9, 591–94. Her treating physician initially determined her biopsy results were "more suggestive of stroke than tumor." *Id.* at 594; *see* Pet'r's Ex. 9 at 7 (ECF No. 8-1). Upon review of her results after Ms. Goff's discharge from the Banner ER, a Mayo Clinic physician explained the biopsy tissue results showed "an inflammatory-reactive process" that was "consistent with a subacute ischemic infarct." Pet'r's Ex. 38 at 785.

Ms. Goff's subsequent medical records describe her March 30, 2016, and June 30, 2016, medical events as strokes. Pet'r's Ex. 36 at 1 (ECF No. 49-1); Pet'r's Ex. 37 at 1; *see* Pet'r's Ex. 40 at 1 (ECF No. 63-1). Those records indicate her March 30, 2016, stroke was possibly related to the carotid webs, and her June 30, 2016, stroke was possibly related to the June 24, 2016, cerebral angiogram. Pet'r's Ex. 37 at 2, 4. Her subsequent medical records clarify that the 35% narrowing of her left internal carotid artery "looks like a typical carotid web." *Id.* at 7. Those records also explain that her "second stroke involved [a] significant portion of her left thalamus, which is in a different circulation in the carotid artery." *Id.* at 7, 14. One of her subsequent treating physicians described her two strokes as cryptogenic.[17] *Id.* at 1. As recently as 2020, Ms. Goff reported to a treating physician that she "felt like" her strokes resulted from "a flu shot." Pet'r's Ex. 40 at 1.

In her testimony, Ms. Goff mentioned that she has "trouble remembering things" because of her strokes. Hr'g Tr. 12:7–11, 12:14–15. She also testified to the continuing impact of the strokes on her life. *Id.* at 10:11–21, 13:17–18:4.

B. Procedural History

Ms. Goff filed her petition for compensation in 2017. ECF No. 1. She claimed that the influenza vaccine she received on March 22, 2016, caused her strokes. *Id.* ¶¶ 1, 6, 12, 17. She filed her medical records and two expert reports in support of her petition.

1. Dr. Boylan's First Report

Ms. Goff filed an expert report from Dr. Laura S. Boylan and supporting medical literature. Dr. Boylan has worked as an attending neurologist and neuro-hospitalist. Pet'r's Ex. 18 at 1 (ECF No. 24-1); Pet'r's Ex. 16 at 1 (ECF No. 23-1). She also has taught neurology, is a member of neurology-related professional groups, has served as a reviewer for medical

[17] "A cryptogenic stroke is a stroke with no clear etiology following a thorough workup . . . ." Hr'g Tr. 147:20–21 (testimony of Dr. Messé).

publications, and has authored peer-reviewed papers. Pet'r's Ex. 18 at 2–5, 8–11. Dr. Boylan estimated that she has diagnosed and treated over 1,000 stroke patients. Pet'r's Ex. 16 at 2.[18]

In her expert report, Dr. Boylan reviewed Ms. Goff's medical history and relevant medical literature. *Id.* at 2–11. Dr. Boylan opined that Ms. Goff's two influenza vaccines "caused or contributed to the occurrence and severity of" Ms. Goff's two strokes in 2016. *Id.* at 11.

Dr. Boylan's opinion focused on immune and inflammatory responses. She explained that "[i]mmune and inflammatory responses are key components of the body's defense system," but "provocations" of the immune system "can cause neurologic illness." *Id.* at 3. She cited medical literature showing "substantial evidence that inflammation plays a role in stroke." *Id.* (first citing Liam Smeeth et al., *Risk of Myocardial Infarction and Stroke after Acute Infection or Vaccination*, 351 New England J. Med. 2611 (2004), filed as Pet'r's Ex. 31 (ECF No. 25-4); then citing Armin J. Grau et al., *Influenza Vaccination is Associated with a Reduced Risk of Stroke*, 36 Stroke 1501 (2005), filed as Pet'r's Ex. 23 (ECF No. 24-6); then citing B.W. McColl et al., *Systemic Infection, Inflammation and Acute Ischemic Stroke*, 158 Neuroscience 1049 (2009), filed as Pet'r's Ex. 27 (ECF No. 24-10); then citing Katie N. Murray et al., *Systemic Immune Activation Shapes Stroke Outcome*, 53 Molecular & Cellular Neuroscience 14 (2013), filed as Pet'r's Ex. 28 (ECF No. 25-1); then citing A. Niroshan Siriwardena et al., *Influenza and Pneumococcal Vaccination and Risk of Stroke or Transient Ischaemic Attack*, 32 Vaccine 1354 (2014), filed as Pet'r's Ex. 30 (ECF No. 25-3); and then citing Heather J. Fullerton et al., *Infection, Vaccination, and Childhood Arterial Ischemic Stroke*, 85 Neurology 1459 (2015), filed as Pet'r's Ex. 22 (ECF No. 24-5)). According to Dr. Boylan, "[i]nflammation promotes blood clotting . . . and hence a state of inflammation promotes stroke." *Id.* at 10. Thus, she opined that provocations of inflammation, including "infection, trauma, surgery, and, rarely, vaccination," can cause neurologic illness, including strokes. *Id.* at 3.

Dr. Boylan explained that infections, including influenza infections, "have been associated with an increased risk of vascular events." *Id.* Specifically, "medical literature supports a relationship between influenza *infection* and stroke." *Id.* at 11 (citing Pet'r's Ex. 22). She also cited medical literature to support that "[p]ost infectious neurological syndromes typically start within 2-6 weeks following exposure." *Id.* at 3 (citing Enrico Marchioni, et al., *Postinfectious Neurologic Syndromes*, 80 Neurology 882 (2013), filed as Pet'r's Ex. 32 (ECF No. 25-5)). Dr. Boylan acknowledged that "[i]nfections cause immune provoked neurological illness much more frequently than do vaccines." *Id.* at 11.

Even so, Dr. Boylan explained there is "concern that vaccination itself could be associated with increased short term stroke risk." *Id.* at 3, 11. This is because vaccines can also provoke the inflammatory system. *Id.* at 3. Such provocation is "protective" for most people, but "[i]n rare cases, it is harmful." *Id.* (citing Ctrs. for Disease Control & Prevention, *Prevention and Control of Seasonal Influenza with Vaccines Recommendations of the Advisory Committee on Immunization Practices —United States, 2016–17 Influenza Season*, 65 Morbidity &

[18] The Special Master detailed far more of Dr. Boylan's qualifications than the court does. *Goff*, 2025 WL 431582, at *7. Because the Government does not challenge the Special Master's qualification of Dr. Boylan as an expert, the court provides only a limited summary.

Mortality Wkly. Rep. (2016), filed as Pet'r's Ex. 20 (ECF No. 24-3)). With respect to the influenza vaccine, she acknowledged it "has been shown to decrease cardiovascular risk at the population level." *Id.* (citing Pet'r's Exs. 23, 30–31). But "in rare individuals," she opined that a neurological illness "will occur as a post-vaccine phenomenon even though vaccination reduces overall risk in the population." *Id.* at 11. As further support, Dr. Boylan cited medical literature that reported "[c]ases of strokes thought to possibly have been caused by vaccines." *Id.* (first citing Yi-Pin Lin et al., *Ischaemic Stroke and Influenza A H1N1 Vaccination: A Case Report*, 7 Archives Med. Sci. 345 (2011), filed as Pet'r's Ex. 26 (ECF No. 24-9); then citing Graciela Cárdenas et al., *Neurological Events Related to Influenza A (H1N1) pdm09*, 8 Influenza & Other Respiratory Viruses 339 (2014), filed as Pet'r's Ex. 19 (ECF No. 24-2); and then citing Elaine Wirrell et al., *Stroke After Varicella Vaccination*, 145 J. Pediatrics 845 (2004), filed as Pet'r's Ex. 33 (ECF No. 25-6)).

Dr. Boylan also explained that when someone gets two vaccines in a single season, the second vaccine is called a "booster," and "clinical responses" from a booster vaccine "may be adverse as well as beneficial." *Id.* at 3–4. She explained that children receive influenza vaccine boosters, so the response to the vaccine may be affected by the frequency of and total dose of vaccination. *Id.* (citing Pet'r's Ex. 20). She noted that Ms. Goff received the influenza vaccine and a booster during the 2015–16 influenza season. *Id.* at 4.

Dr. Boylan characterized the March 30, 2016, event as a stroke, and the June 30, 2016, event as "most likely a second stroke." *Id.* at 5, 10. Upon review of Ms. Goff's medical records, Dr. Boylan concluded that "[i]t is clear that Ms. Goff's treating physicians considered her stroke to be unusual from the outset" because her initial evaluation "went beyond the usual evaluation in a search for the many rare conditions which can cause or be associated with stroke in a relatively young adult." *Id.* at 6. She explained that "[s]trokes at age 43, even in the presence of one or several risk factors . . . are rare." *Id.* Based on the National Stroke Association Stroke Risk Calculator, Ms. Goff, when treated as if she were 45 years old at the time of her stroke (because the calculator does not accept ages below 45) and with her history of smoking, would be predicted to have "a 0.4% risk of having a stroke over the course of ten years." *Id.* at 10.

Dr. Boylan found Ms. Goff's medical test results "unusual" because "inflammation sufficient to light up on an MRI and produce suspicion of tumor or infection is rare." *Id.* at 9–10. Ms. Goff's tissue taken for the biopsy "provided definitive diagnosis of an active inflammatory process and did not show changes associated with tumors or infections." *Id.* at 10. Ms. Goff's inflammation appeared "particularly strong" to Dr. Boylan. *Id.* at 11. Dr. Boylan further opined that Ms. Goff's "history of allergic sensitivity, recurrent shingles and thyroid disease . . . are associated with abnormalities in the immune/inflammatory system and may have predisposed her to stroke." *Id.* at 10.

Additionally, Dr. Boylan agreed with Ms. Goff's treating physician that Ms. Goff had carotid webs. *Id.* at 4, 9. She opined that Ms. Goff "was likely predisposed to having a stroke . . . because she has bilateral carotid webs." *Id.* at 10–11. Dr. Boylan identified a carotid web as an "abnormalit[y that] predispose[s] to stroke." *Id.* at 4. Carotid webs are associated with stroke, "particularly among young women," because "abnormal blood flow through the vessels causes clots to form[, and t]he clots then are prone to dislodge and clog arteries downstream, starving parts of the brain of oxygen and glucose." *Id.* (first citing P.M.C. Choi et al., *Carotid*

Webs and Recurrent Ischemic Strokes in the Era of CT Angiography, 36 Am. J. Neuroradiology 2134 (2015), filed as Pet'r's Ex. 21 (ECF No. 24-4); then citing Diogo C. Haussen et al., *Carotid Web (Intimal Fibromuscular Dyplasia) Has High Stroke Recurrence Risk and Is Amenable to Stenting*, 48 Stroke 1 (2017), filed as Pet'r's Ex. 24 (ECF No. 24-7); and then citing P.I. Sajedi et al., *Carotid Bulb Webs as a Cause of "Cryptogenic" Ischemic Stroke*, 38 Am. J. Neuroradiology 1399 (2017), filed as Pet'r's Ex. 29 (ECF No. 25-2)). Because Ms. Goff has carotid webs, Dr. Boylan considered Ms. Goff "prone to have strokes." *Id.* at 4, 10. She observed that "Ms. Goff's extensive stroke evaluation did not reveal any apparent cause of stroke other than the carotid webs." *Id.* at 10.

Based on her analysis, Dr. Boylan opined Ms. Goff's carotid webs predisposed her to stroke before vaccination, and "[v]accines activate the immune/inflammatory system," which also "predisposes an individual to the formation of clots." *Id.* at 11. Dr. Boylan concluded that "within a reasonable degree of medical certainty," Ms. Goff's influenza vaccines "most likely provoked an immune/inflammatory response which caused or contributed to the occurrence and severity of" Ms. Goff's strokes. *Id.*

With respect to Ms. Goff's second stroke, Dr. Boylan concluded that the location of the lesion "suggested it might not be able to be attributed to the carotid web." *Id.* at 9. That lesion could be "due to late changes from the first stroke, a new stroke and/or possible inflammation of cerebral blood vessels." *Id.* at 10. Nonetheless, she concluded that Ms. Goff's influenza vaccines "caused and/or contributed to the occurrence and severity of Ms. Goff's subsequent strokes occurring March 30, 2016, and June 30, 2016 and subsequent neurologic deficit." *Id.* at 12.

2. Dr. Messé's Report

The Government filed an expert report and supporting medical literature from Dr. Steven Messé. Dr. Messé is a professor of neurology and the director of the vascular neurology fellowship at the University of Pennsylvania. Resp't's Ex. A at 1 (ECF No. 32-1); Resp't's Ex. B at 1 (ECF No. 32-7). He has also served as a reviewer of medical publications, is a member of several professional groups, and has authored peer-reviewed papers. Resp't's Ex. B at 2–3, 6–13. Dr. Messé estimated that he has treated thousands of stroke patients. Resp't's Ex. A at 1.[19]

Based on his review of the medical literature and Ms. Goff's medical records, Dr. Messé opined Ms. Goff's strokes "were not related to the influenza vaccination." *Id.* at 3. Dr. Messé emphasized that medical literature supports that the "influenza vaccination is associated with a *reduced*, not *increased*, risk of stroke." *Id.* He explained that several studies Dr. Boylan relied upon indicate the influenza vaccine is "protective." *Id.* (referring to Pet'r's Ex. 31). And he clarified that the case studies Dr. Boylan cited include one study of a different vaccine and two studies of "a series of patients with a broad array of neurologic events peri-vaccination or

[19] The Special Master detailed far more of Dr. Messé's qualifications than the court does. *Goff*, 2025 WL 431582, at *12. Because Ms. Goff does not challenge the Special Master's qualification of Dr. Messé as an expert, the court provides only a limited summary.

infection, yet with no control group to determine whether these events were more, or less, likely to occur during this time." *Id.* at 3–4 (referring to Pet'r's Exs. 19, 26, 33).

Dr. Messé then discussed how ulcerated plaque could have caused Ms. Goff's stroke. *Id.* at 4. Upon his review of Ms. Goff's records, Dr. Messé determined she had "ulcerated plaque in the internal carotid artery, resulting in 30-40% stenosis," and "carotid plaque with <50% stenosis has . . . been associated with increased stroke risk." *Id.* (citing Jonathan M. Coutinho et al., *Nonstenotic Carotid Plaque on CT Angiography in Patients with Cryptogenic Stroke*, 87 Neurology 665 (2016), filed as Resp't's Ex. A, Tab 1 (ECF No. 32-2)). He observed that "ulcerated plaque is associated with an even higher risk for stroke." *Id.* (citing A.C. van Dijk et al., *Intraplaque Hemorrhage and the Plaque Surface in Carotid Atherosclerosis: The Plaque At RISK Study (PARISK)*, 36 Am. J. Neuroradiology 2127 (2015), filed as Resp't's Ex. A, Tab 2 (ECF No. 32-3)). To explain how plaque leads to stroke, Dr. Messé discussed how the "rupture or endothelial erosion" of plaque may cause a clot to form, which may then dislodge in the artery and block the blood flow. *Id.* (citing G. Alistair Lammie, *Recently Occluded Intracranial and Extracranial Carotid Arteries*, 30 Stroke 1319 (1999), filed as Resp't's Ex. A, Tab 3 (ECF No. 32-4)). Dr. Messé concluded that Ms. Goff's atherosclerotic plaque was more likely the cause of her stroke. *Id.*

In his report, Dr. Messé disagreed with Dr. Boylan that Ms. Goff had a carotid web because the cerebral angiogram indicated Ms. Goff had atherosclerotic plaque. *Id.* He reasoned that the cerebral angiogram is the "gold standard to assess blood vessel abnormalities," so its finding of plaque instead of a carotid web was compelling to Dr. Messé. *Id.* Regardless, Dr. Messé concluded that, if Ms. Goff has carotid webs, the carotid web could be a "plausible mechanism for the stroke." *Id.* at 5. Because Ms. Goff either had ulcerated plaque or a carotid web, Dr. Messé viewed it "unnecessary to blame" the influenza vaccine as the cause of the stroke. *Id.* at 4.

Dr. Messé also disagreed with Dr. Boylan that the inflammation on Ms. Goff's MRI was abnormal. *Id.* He explained that inflammation "after stroke is very common after the first day or two, and typically persists for weeks." *Id.* (citing Martin Bendszus & Guido Stoll, *Silent Cerebral Ischaemia: Hidden Fingerprints of Invasive Medical Procedures*, 5 Neurology 364 (2006), filed as Resp't's Ex. A, Tab 4 (ECF No. 32-5)). Further, Ms. Goff's biopsy results were consistent with a stroke, and "there was no suggestion from the pathologists that there was abnormal inflammation present." *Id.*

As for the second stroke, Dr. Messé explained that the cerebral angiogram likely caused it. *Id.* at 4–5. He relied medical literature finding that strokes "are common after cerebral angiogram[s]." *Id.* at 4 (citing Resp't's Ex. A, Tab 4).

Finally, Dr. Messé explained that cryptogenic strokes are common, especially among "young stroke patients." *Id.* at 5 (citing Robert G. Hart, *Embolic Strokes of Undetermined Source: The Case for a New Clinical Construct*, 13 Neurology 429 (2014), filed as Resp't's Ex. A, Tab 5 (ECF No. 32-6)). The lack of a clear explanation of Ms. Goff's strokes should not mean that the influenza vaccine, which is generally "protective," caused her strokes. *Id.*

In sum, Dr. Messé did not "believe that the influenza vaccination played any significant role in" Ms. Goff's strokes. *Id.* Rather, the medical literature supports that the influenza vaccine reduces the risk of stroke, and Ms. Goff "was actively using tobacco and had mild hyperlipidemia, with an ulcerated atherosclerotic plaque in the left internal carotid artery . . . strongly suggesting that this was likely the cause of her stroke." *Id.*

3. Dr. Boylan's Rebuttal Report

Ms. Goff submitted a second report from Dr. Boylan in response to Dr. Messé's report. In her rebuttal report, Dr. Boylan agreed with Dr. Messé and the medical literature that vaccines reduce strokes at the population level, but countered that vaccines could still cause strokes in some people. Pet'r's Ex. 35 (ECF No. 43-1). She reiterated that Ms. Goff's MRI results were abnormal, and that Ms. Goff has carotid webs. *Id.* Dr. Boylan's "conclusion remain[ed] unchanged." *Id.*

4. The Entitlement Hearing

Special Master Oler held an entitlement hearing from April 6–7, 2021.

a) Dr. Boylan's Testimony

Dr. Boylan was recognized as an expert in neurology at the entitlement hearing. Hr'g Tr. 31:7–9, 31:15. She summarized her opinion as follows: "[T]he vaccine induced a pro-inflammatory state which promoted the formation of a clot in Ms. Goff's preexisting carotid web and that there was a subsequent breakup of that clot, and it went downstream and caused her stroke." *Id.* at 129:10–14.

Dr. Boylan concluded that inflammation "plays a major role in stroke" because inflammation promotes clotting. *Id.* at 34:11–15, 54:18–20. The mechanism by which inflammation promotes clotting, according to Dr. Boylan, involves the endothelium, or the "innermost lining of the vessels." *Id.* at 39:23–40:3. The endothelium in blood vessels pulsates to send blood into the brain and then relaxes to allow the blood to flow away from the brain, so endothelium-dependent relaxation causes "poor circulation . . . that can predispose to stroke." *Id.* at 53:2–13. Dr. Boylan admitted this mechanism of stroke is not specific to the influenza vaccine. *Id.* at 104:16–19.

Dr. Boylan acknowledged a range of provocations can cause inflammation. *Id.* at 36:6–19. Given that range, Dr. Boylan testified that "not every inflammation will provoke a stroke, and not every stroke will be caused by inflammation by any means. . . . [And] stroke itself causes an inflammatory response." *Id.* at 39:17–22, 101:5–20. She explained Katie N. Murray et al., *Systemic Immune Activation Shapes Stroke Outcome*, 53 Molecular & Cellular Neuroscience 14 (2013) (the "Murray study") provides that "the insult of stroke itself will provoke an immune response, and . . . you can have a worse outcome from stroke if you have a lot of inflammation." Hr'g Tr. 49:24–50:5 (discussing Pet'r's Ex. 28).

And infections, including the influenza infection, "are . . . associated with stroke." Hr'g Tr. 35:10–11. Although recognizing that a natural infection "produces more of an inflammatory

response than a vaccine," *id.* at 103:6–8, Dr. Boylan testified that vaccines generally produce "very dramatic inflammatory responses," *id.* at 42:1–9.

Dr. Boylan relied on the "concern" in Liam Smeeth et al., *Risk of Myocardial Infarction and Stroke after Acute Infection or Vaccination*, 351 New England J. Med. 2611 (2004) (the "Smeeth study") about "the well established association between vaccines and inflammation." Hr'g Tr. 38:7–13 (discussing Pet'r's Ex. 31). Although the Smeeth study "is not about the influenza vaccine," it "used the flu vaccine to promote an inflammatory response." Hr'g Tr. 53:22–54:6 (discussing Pet'r's Ex. 31). The study's authors found "certain markers and changes in vascular reactivity . . . were evident two weeks after the vaccination." *Id.* at 54:6–10 (discussing Pet'r's Ex. 31). Dr. Boylan explained that the Smeeth study sought to discern whether "vaccines could cause strokes to such a degree that . . . it was not a good idea to give them at least to some people in the population." *Id.* at 38:11–13 (discussing Pet'r's Ex. 31). Given that the Smeeth study "found that in their population, the vaccine prevented stroke," Dr. Boylan agreed that "at the population level, . . . vaccination for influenza reduces rates of influenza." *Id.* at 38:15–21 (discussing Pet'r's Ex. 31).

Regardless, Dr. Boylan testified the Smeeth study does not mean "that in rare individuals there [will not] be adverse effects" from the influenza vaccine. *Id.* at 38:15–21. People may have "idiosyncratic responses[that] . . . depend on genetic factors, epigenetic factors, hormonal status, age, a whole range of environmental and individual risk factors." *Id.* at 42:10–13. She testified the potential for idiosyncratic responses concurred with the results of Graciela Cárdenas et al., *Neurological Events Related to Influenza A (H1N1) pdm09*, 8 Influenza and Other Respiratory Viruses 339 (2014) (the "Cárdenas study"). Hr'g Tr. 43:5–12 (discussing Pet'r's Ex. 19).

Dr. Boylan then explained that a person has an increased risk of stroke during an inflammatory response, such as an inflammatory response to the influenza vaccine, if the person has a vascular abnormality that promotes clotting. Hr'g Tr. 55:12–56:2, 79:2–12. She pointed to Yi-Pin Lin et al., *Ischaemic Stroke and Influenza A H1N1 Vaccination: A Case Report*, 7 Archives Med. Sci. 345 (2011) (the "Lin study"), which observed that the influenza vaccine may trigger clotting "if you have anything [that is] going to make you likely to form clots . . . something systemic, like a cancer, or it could be something anatomic, like an abnormal carotid web or atherosclerosis." Hr'g Tr. 78:6–79:12 (discussing Pet'r's Ex. 26).

Dr. Boylan identified carotid webs as a cause of stroke, but also recognized they are a rare condition. Hr'g Tr. 57:13–18. Dr. Boylan testified that Ms. Goff had a carotid web in her left internal carotid artery, and that her first stroke occurred downstream from the web. *Id.* at 64:16–65:2, 71:18–72:20. As Dr. Boylan explained, carotid webs can create an irregular turbulence in blood flow that produces a "stasis" (i.e., a stoppage or slowdown) of blood. *Id.* at 61:5–24. That stasis of blood can then become a clot that can dislodge and flow downstream in the blood vessel to cause damage. *Id.* at 62:21–63:17. The clot may block blood flow to the brain and thus cause an ischemic stroke. *Id.* at 64:6–15. Dr. Boylan acknowledged that the studies she cited discussing carotid webs do not mention that an inflammatory trigger is necessary to cause a stroke in a person with carotid webs, and that those studies involved younger patients like Ms. Goff. *Id.* at 106:20–108:7 (reviewing Pet'r's Exs. 21, 24).

Dr. Boylan opined Ms. Goff suffered a thromboembolic ischemic stroke. *Id.* at 33:17–21. Dr. Boylan explained that having a stroke at age 43 is "highly unusual." *Id.* at 70:25–71:9. She discussed the stroke calculator results from her expert report and Ms. Goff's low risk of stroke at her age. *Id.* at 89:4–90:22. And Dr. Boylan acknowledged that Ms. Goff "fit[s] more of a profile of someone who might have a carotid web, and . . . that would increase your risk of having a stroke, but it [does not] mean [you are] predetermined to have a stroke." *Id.* at 70:25–71:9. Rather, Dr. Boylan testified that Ms. Goff's stroke was "much more likely to have been the reaction to the flu shot" than the carotid web because "the underlying carotid web alone has not been sufficient, in the absence of an angiogram, for any prior or subsequent events." *Id.* at 91:4–9. Dr. Boylan believed the influenza vaccine, "a known pro-inflammatory, prothrombotic stimulus," and Ms. Goff's stroke were "related" because the stroke occurred "shortly" after the vaccine. *Id.* at 81:3–6.

To explain Ms. Goff's reaction to the influenza vaccine before her first stroke, Dr. Boylan testified Ms. Goff was "feeling ill before she had the stroke, and she had local pain in the arm before she had the stroke[, s]o she was having an inflammatory reaction." *Id.* at 47:20–24, 68:15–16, 68:23–69:16. Dr. Boylan saw no other potential triggers for Ms. Goff's inflammatory response around March 22, 2016, in Ms. Goff's records other than the influenza vaccine. *Id.* at 69:17–22. But the only record citation Dr. Boylan identified to support her conclusion that Ms. Goff experienced inflammatory symptoms was Ms. Goff's report of "fever" on her April 20, 2016, new patient form. *Id.* at 121:8–18, 121:22–122:4, 122:22–123:15 (discussing Pet'r's Ex. 10). Dr. Boylan also pointed to Ms. Goff's right arm weakness at the time of admission at the Abrazo ER on March 30, 2016, but Ms. Goff received the influenza vaccine in her left arm. *Id.* at 121:22–123:15.

Dr. Boylan testified that the timing of Ms. Goff's influenza vaccine, inflammatory reaction, illness, and stroke eight days later was "the timing that you would expect." *Id.* at 48:13–21. In support, Dr. Boylan discussed B.W. McColl et al., *Systemic Infection, Inflammation and Acute Ischemic Stroke*, 158 Neuroscience 1049 (2009) (the "McColl study") that observed the risk of stroke is the highest within a week of the onset of the inflammatory response. Hr'g Tr. 130:1–132:24 (discussing Pet'r's Ex. 27). Dr. Boylan acknowledged that she did not know how long the immune system response to the influenza vaccine lasts. Hr'g Tr. 119:18–25. Yet she is "confident" the immune response lasts "at least as long as the time period from the [March 22, 2016] vaccine to the first stroke. [That is] not unusual to [Dr. Boylan]. To [her], [that is] not a stretch." *Id.* at 120:3–6. She explained the Vaccine Injury Table provides guidance on timing. *Id.* at 116:9. She also stated that "conventionally" six to eight weeks is "an operational way to define what might be autoimmune," but after six months, Dr. Boylan would not attribute any reaction to the inflammation. *Id.* at 115:23–116:25. She agreed that someone having a stroke after a vaccine could be a coincidence, but did not think that was the case for Ms. Goff. *Id.* at 105:20–106:8. In addition, Ms. Goff's lack of recurrent strokes, setting aside the June 30, 2016, stroke, also indicated to Dr. Boylan that "the vaccine triggered the stroke" because the carotid web on its own has not caused other strokes. *Id.* at 84:14–23.

Turning to Ms. Goff's second stroke, Dr. Boylan testified that stroke did not occur downstream from the carotid web. *Id.* at 76:21–22. Dr. Boylan was "not sure" about the cause of the second stroke and explained Ms. Goff "had an angiogram the week prior, . . . and an angiogram is itself associated with a risk of stroke." *Id.* at 85:24–86:15. Dr. Boylan explained

that Ms. Goff got the cerebral angiogram because of the first stroke, so "the angiogram was a consequence of the first stroke, but that second stroke may well have been a consequence of the angiogram." *Id.* at 86:17–22, 87:9–18.

When asked about her booster effect theory, Dr. Boylan explained that her opinion does not "depend or hinge on" Ms. Goff's September 2015 influenza vaccine, but that the September vaccine "makes [her] feel more confident . . . because [it is] yet another thing that is pro-inflammatory." *Id.* at 91:15–18. Dr. Boylan testified that the first influenza vaccine may have enhanced Ms. Goff's reaction to the second vaccine, but she admitted she did not file any medical literature about the booster effect of receiving two influenza vaccines. *Id.* at 92:6–21.

In brief, Dr. Boylan summarized her opinion as follows:

> I believe that [the March 22, 2016, influenza] vaccine, through a direct effect or through its pro-inflammatory stimulation possibly, and also with the booster effect, adduced an acute inflammatory response, which, in turn, triggered an inflammatory cascade, which includes a prothrombotic state, and that triggered abnormal blood flow over her preexisting carotid webs, formed a thrombus, which flew downstream and caused a stroke.

Id. at 94:7–14; *see also id.* at 129:10–14. As a result, Dr. Boylan would not recommend that Ms. Goff receive future influenza vaccines. *Id.* at 84:24–85:18. Dr. Boylan also did not view Ms. Goff's history of smoking as the likely cause of the strokes. *Id.* at 88:19–24.

b) Dr. Messé's Testimony

Dr. Messé was recognized as an expert in neurology and vascular neurology at the entitlement hearing. *Id.* at 145:8–13. He did not believe the influenza vaccine caused Ms. Goff's strokes. *Id.* at 154:20–155:1.

Dr. Messé admitted that "there is some evidence that inflammation can contribute to stroke risk." *Id.* at 180:17–18. And he acknowledged that the Smeeth study noticed an increase in stroke risk after an influenza infection. *Id.* at 170:3–173:7 (discussing Pet'r's Ex. 31). He disagreed with Dr. Boylan's conclusion that the response to an influenza vaccine could produce the same harm as the response to an influenza infection because he saw no support for that equivalence. *Id.* at 189:7–190:9. He testified that "there is no evidence whatsoever that . . . [the] influenza vaccine can cause a stroke." *Id.* at 169:11–13.

To the contrary, Dr. Messé explained that the Smeeth study does not indicate an increased risk of stroke after the influenza vaccine. *Id.* at 172:6–173:2, 222:9–223:4 (discussing Pet'r's Ex. 31). He clarified that the Smeeth study does not suggest that the vaccine helps reduce stroke risk by "thin[ning] the blood or something that would prevent stroke." *Id.* at 222:9–14 (discussing Pet'r's Ex. 31). For the individuals reported in the Smeeth study who had strokes within a week of their influenza vaccines, Dr. Messé explained those cases as "coincidental," and the incidence rate was "much lower than you would expect in that time period," supporting that stroke is not caused by the vaccine. *Id.* at 181:24–182:8 (discussing Pet'r's Ex. 31). He

admitted the Smeeth study would not detect "if something happens [in] one in 10 million people." *Id.* at 192:20–193:1 (discussing Pet'r's Ex. 31).

Dr. Messé also explained that two other studies Dr. Boylan relied upon—A. Niroshan Siriwardena et al., *Influenza and Pneumococcal Vaccination and Risk of Stroke or Transient Ischaemic Attack*, 32 Vaccine 1354 (2014) (the "Siriwardena study") and Armin J. Grau et al., *Influenza Vaccination is Associated with a Reduced Risk of Stroke*, 36 Stroke 1501 (2005) (the "Grau study")—also indicated a reduced risk of stroke after influenza vaccination. Hr'g Tr. 173:18–175:5 (discussing Pet'r's Exs. 23, 30). The Siriwardena study identified a "24 percent reduction in stroke risk" after the influenza vaccine. Hr'g Tr. 174:10–18 (discussing Pet'r's Ex. 30). And the Grau study reflected a reduction of stroke risk in around half of the patients. *Id.* at 175:1–4 (discussing Pet'r's Ex. 23).

Dr. Messé criticized Ms. Goff's reliance on the Cárdenas study because it pertained to "autoimmune responses in general" and "provides no evidence that the vaccinations are actually causing these disorders." *Id.* at 176:18–22 (discussing Pet'r's Ex. 19). He explained the only support in the Cárdenas study for its theory that the influenza vaccine causes neurological disorders were "observational case reports." *Id.* at 177:2–4 (discussing Pet'r's Ex. 19). And neither of the two case reports highlighted in the study involved a stroke patient. *Id.* at 177:5–10 (discussing Pet'r's Ex. 19).

Based on Ms. Goff's medical records, Dr. Messé opined that her first stroke was a "left middle cerebral artery stroke." *Id.* at 155:2–7. Dr. Messé did not view Ms. Goff's stroke at 43 years old as unusual. *Id.* at 167:3–23. He recognized that strokes among 43-year-olds are less common than 83-year-olds, but that does not make them abnormal in younger people. *Id.* at 166:23–23, 180:9–14. "[L]ots of younger people . . . are having strokes," and their "mechanisms of stroke tend to be different than they are for older people." *Id.* at 167:3–9.

Dr. Messé testified that Ms. Goff had three risk factors for stroke: her smoking, "elevated LDL, which is cholesterol," and an "abnormality in her carotid artery, which is either a web or atherosclerosis." *Id.* at 155:8–14. Dr. Messé "favor[ed]" that Ms. Goff had a carotid web in her left internal carotid artery based on her CT angiogram performed on June 30, 2016. *Id.* at 158:11–159:17. He also considered it possible that Ms. Goff had ulcerated plaque causing a 30–40% narrowing of her artery because that was the conclusion of her cerebral angiogram performed on June 24, 2016. *Id.* at 157:6–8, 159:3–17. Because Ms. Goff had no significant amount of other plaque throughout her body, Dr. Messé still favored that she had a carotid web over plaque. *Id.* at 159:3–17. Dr. Messé explained that the carotid web is a "condition[] that would predispose to stroke in a younger person." *Id.* at 167:10–12. Given the presence of the carotid web, Dr. Messé opined it is a "very plausible mechanism for her stroke, and [it is] the best . . . explanation that we have." *Id.* at 160:7–9. Regardless, Dr. Messé testified that if Ms. Goff had atherosclerotic plaque with a 30–40% narrowing of her artery or a carotid web, both are "extremely plausible mechanism[s] for a stroke." *Id.* at 160:14–20.

Given the presence of the carotid web, Dr. Messé also did not believe that Ms. Goff would need a catalyst to cause a stroke because the web itself "would be a very plausible mechanism to have a stroke." *Id.* at 161:14–20. He did not view the Lin study as providing support that a catalyst was needed to trigger a stroke in a person with a preexisting prothrombotic

state. *Id.* at 175:17–25 (discussing Pet'r's Ex. 26). The Lin study involved a 75-year-old man, and Dr. Messé explained a stroke at that age is unsurprising. *Id.* at 175:14–16, 208:24, 223:23–224:17 (discussing Pet'r's Ex. 26). And the Lin study discusses prothrombotic hypercoagulable states, which increase the risk of producing clots throughout the body, while a carotid web is a preexisting prothrombotic risk factor for stroke that can only cause clots in the vicinity of the web. *Id.* at 206:10–19, 207:9–20 (discussing Pet'r's Ex. 26). To the extent the Lin study supports that an influenza vaccine can trigger a stroke in a person with a hypercoagulable state like the man reported in that study, Dr. Messé distinguished it from Ms. Goff's case involving a carotid web. *Id.* at 208:2–20, 223:23–224:21.

Dr. Messé testified that he saw "no evidence [in Ms. Goff's medical records] that there was a systemic inflammatory state that was going on when she had her stroke." *Id.* at 162:13–15. Rather, some of Ms. Goff's medical records indicated no redness or swelling of her arms. *Id.* at 164:12–16. Dr. Messé observed that Ms. Goff's records reflected that she did not have a fever upon admission to the ER, and her lab results did not provide evidence of inflammation. *Id.* at 165:17–166:10. He also recognized that Ms. Goff's treating physicians "checked her coagulation studies . . . to see whether she had any relatively rare conditions that can predispose to form clots, and those were all normal." *Id.* at 166:13–16. Dr. Messé acknowledged that not all testing is perfect and may not catch all symptoms of inflammation, but for a "systemic inflammatory state [that is] bad enough to cause a stroke, [he] would expect to see something." *Id.* at 219:5–8, 219:12–220:13. Dr. Messé also addressed the inflammation found in Ms. Goff's biopsy by explaining that inflammation "is the natural response to a stroke, not the cause of the stroke." *Id.* at 169:2–5. He testified that the biopsy of Ms. Goff's thalamus was "completely consistent with subacute stroke." *Id.* at 168:23–169:1.

With respect to timing, Dr. Messé admitted Ms. Goff's first stroke occurred during the inflammatory period after the influenza vaccine. *Id.* at 212:19–22. He explained, however, that the stroke also occurred when studies show a reduced stroke risk in people who are vaccinated. *Id.* at 212:24–213:2.

Turning to Ms. Goff's second stroke, Dr. Messé "favor[ed]" that Ms. Goff's cerebral angiogram was the cause, but he did not want to "rule out that the web caused that second stroke." *Id.* at 195:20–196:7. Dr. Messé explained that the cerebral angiogram requires a catheter to travel "through the aortic arch and all those blood vessels that go up to the head, [and] it is not uncommon for a little blood clot or plaque to be knocked off and cause additional brain injury at that time." *Id.* at 156:12–16. Thus, he believed it more likely than not that the cerebral angiogram caused Ms. Goff's second stroke. *Id.* at 195:20–196:7. But he was uncertain about the cause of the second stroke and considered it possible that it was caused by the carotid web. *Id.* at 203:2–204:4.

c) Post-Hearing Exhibits

Following the entitlement hearing, Ms. Goff filed two more articles. ECF No. 65; *Children, the Flu, and the Flu Vaccine*, Ctrs. for Disease Control & Prevention, filed as Pet'r's Ex. 41 (ECF No. 65-1); Charles C. Eswena & Mitchell S. Elkind, *Inflammatory Risk Factors, Biomarkers and Associated Therapy in Ischaemic Stroke*, 12 Neurology 594 (2016), filed as Pet'r's Ex. 42 (ECF No. 65-2). The first is a copy of a Centers for Disease Control and

Prevention webpage discussing guidance on influenza for children, including the need for "[s]ome children 6 months through 8 years of age" to get "two doses of influenza vaccine." Pet'r's Ex. 41 at 1. The second is a study that discusses the risk of stroke increasing following inflammation from infections, including the influenza infection. Pet'r's Ex. 42.

The Government also filed additional medical literature. ECF No. 69. It filed Aroon D. Hingorani et al., *Acute Inflammation Impairs Endothelium-Dependent Dilation in Humans*, 102 Circulation 994 (2000) (the "Hingorani study") that examined responses to the *Salmonella typhi* vaccine and noted endothelium-dependent relaxation in response to that vaccine. Resp't's Ex. C (ECF No. 69-1). The Smeeth study cites the Hingorani study. Pet'r's Ex. 31 at 2 n.15. The Government also filed the tables that accompany the Cárdenas study. Resp't's Ex. D (ECF No. 69-2). Finally, the Government filed a study on the causation of serious neurologic events after the 2009 H1N1 influenza vaccine. Resp't's Ex. E (ECF No. 69-3).

5. The Special Master's Decision

After Special Master Oler's appointment to the D.C. Superior Court, this case was reassigned to Special Master Shah on August 13, 2024. ECF No. 78. Special Master Shah issued her decision on January 13, 2025. ECF No. 83; *Goff*, 2025 WL 431582. The Special Master explained that "[n]either expert felt that the June 2016 stroke was a direct result of the March 22, 2016 flu vaccination," so "[t]he operative question to resolve, then, is whether [Ms. Goff]'s first stroke on March 30, 2016, was caused by the subject flu vaccination." *Goff*, 2025 WL 431582, at *20. The Special Master decided Ms. Goff had not met her burden to prove the influenza vaccine caused her March 2016 stroke under any of the *Althen* prongs and denied her petition. *Id.* at *1.

Ms. Goff now moves for review of the Special Master's decision. ECF No. 86.

II. Standard of Review

The National Childhood Vaccine Injury Act of 1986 created the National Vaccine Injury Compensation Program to provide compensation for "a vaccine-related injury or death." 42 U.S.C. § 300aa-10(a). To receive compensation under the Program, the person "who has sustained a vaccine-related injury" files a petition, naming the Secretary of Health and Human Services as the respondent, with the United States Court of Federal Claims Office of Special Masters. *See* 42 U.S.C. § 300aa-11(a)(1), (b)(1)(A).

A petitioner seeking compensation under the Vaccine Act must have suffered an injury from a vaccine either listed on the Vaccine Injury Table or "not set forth in the Vaccine Injury Table but which was caused by a vaccine." *Id.* § 300aa-11(c)(1)(C). Ms. Goff did not seek compensation for an injury listed on the Vaccine Injury Table. *See* ECF No. 67 at 15; 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3. The Vaccine Act "does not relax proof of causation in fact for non-Table Injuries." *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner alleging a non-table injury must prove by a preponderance of the evidence that "the vaccine more likely than not caused the condition alleged." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014).

To prove causation in a non-table injury case, a petitioner 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 a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). A theory of causation cannot be proven through "a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury . . . without more." *Id.* at 1278. The petitioner must prove each of the *Althen* prongs by a preponderance of the evidence to satisfy the petitioner's prima facie case that the vaccine was the "but-for" cause of the injury. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008) ("[T]he petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor."); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (explaining that the *Althen* "prongs must cumulatively show that the vaccination was a 'but-for' cause of the harm"); *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (adopting the tort theory of causation for vaccine cases).

The preponderance of the evidence standard does not require "scientific certainty" to establish causation. *LaLonde*, 746 F.3d at 1338; *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). "[S]uccessfully proving the elements of the *Althen* test establishes that the medical evidence indicating that the vaccine may have caused the petitioner's injury is strong enough to infer causation-in-fact absent proof that some other factor was the actual cause." *de Bazan*, 539 F.3d at 1354 (emphasis omitted); *see Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1342 (Fed. Cir. 2010) ("Once the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine.").

After the special master renders a decision, a party may seek review in this court. 42 U.S.C. § 300aa-12(e)(1). The filing of a motion for review gives this court jurisdiction "to undertake a review of the record of the proceedings." *Id.* § 300aa-12(e)(2). The Act allows the court to do one of the following:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. This court reviews the decisions of the special masters to determine whether "any findings of fact and conclusion of law . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 300aa-12(e)(2)(B).

The arbitrary or capricious review of a special master's findings of fact is a "highly deferential standard of review." *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993); *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 889 (Fed. Cir. 1992); *see Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (explaining the court must "uphold a special master's findings unless the court concludes that those findings are arbitrary or capricious"). Under that standard, this court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses" because "these are all matters within the purview of" the special master as the fact finder. *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *Munn*, 970 F.2d at 871. In other words, this court does not "second guess the Special Masters fact-intensive conclusions." *Hodges*, 9 F.3d at 961. "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 Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see Lampe*, 219 F.3d at 1362 (describing a special master's evaluations of credibility and persuasiveness to be "virtually unchallengeable on appeal").

III. Discussion

Ms. Goff moves the court to set aside the Special Master's decision because the Special Master's findings on each prong of *Althen* were arbitrary or capricious. ECF No. 86 at 1–2. She seeks a remand to the Special Master "with instructions to enter a finding that [Ms. Goff] should be entitled to compensation and instructing the Special Master to conduct further proceedings consistent with [that] determination." *Id.* at 2. But Ms. Goff's motion asks the court to reweigh the evidence considered by the Special Master. *See* ECF No. 88 at 3, 15–18. The court is not permitted to do so. Because the Special Master considered all the relevant evidence, drew plausible inferences from the evidence, and provided a rational explanation for her decision, *see Hines*, 940 F.2d at 1527, the court denies the motion for review.

A. The Special Master rationally explained that Ms. Goff failed to meet her burden under *Althen* prong one.

Althen prong one requires proof by the preponderance of the evidence of a "medical theory causally connecting the vaccination and the injury." 418 F.3d at 1278. The petitioner "must provide a 'reputable medical or scientific explanation' for [the] theory." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). Although the theory must be "sound and reliable," the petitioner need not prove it with "medical or scientific certainty." *Id.* (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). "The assessment of whether a proffered theory of causation is 'reputable' can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard[.]" *Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009).

To satisfy prong one, Ms. Goff's expert, Dr. Boylan, presented a theory that "carotid webs are a pre-existing condition that, when coupled with an inflammatory response to

vaccination, can cause an ischemic stroke." ECF No. 88 at 15. In other words, her causation theory has four components: (1) Ms. Goff had a preexisting prothrombotic condition, the carotid web, that had not caused a stroke on its own, (2) she received the influenza vaccine, (3) the vaccine triggered an inflammatory response, and (4) the inflammatory effects paired with the prothrombotic condition caused a stroke. The Special Master found Ms. Goff did not prove her prong one theory by the preponderance of the evidence because Ms. Goff did not provide sufficient evidence to support that (1) a carotid web needs a catalyst to cause a stroke, and (2) the influenza vaccine produces the inflammatory effects associated with strokes. *Goff*, 2025 WL 431582, at *21–24. Ms. Goff contends she proved that the influenza vaccine can cause strokes by a preponderance of the evidence through Dr. Boylan's expert reports, testimony, and supporting medical literature. ECF No. 88 at 5.

1. The record adequately supports the Special Master's conclusion that Ms. Goff did not prove by a preponderance of the evidence that an inflammatory trigger is necessary to cause a stroke in a person with carotid webs.

The Special Master found "both parties' experts agreed [Ms. Goff] had a carotid web, a conclusion that is supported by the medical records." *Goff*, 2025 WL 431582, at *22. That said, she also found that "Dr. Boylan failed to submit any supportive evidence illustrating how the flu vaccine could produce a stroke in a person with this condition." *Id.*

Dr. Boylan's theory provides in part that Ms. Goff's carotid webs needed an inflammatory trigger to cause a stroke. The Special Master found none of the supporting medical literature in the record indicated an inflammatory trigger is needed to cause a stroke in someone with a carotid web. *Id.* at *22–23. To the contrary, she surveyed the literature and found that none "hypothesized that any type of vaccination could exacerbate the risk" of a stroke in a person with carotid webs. *Id*. at *22. And the "literature she submitted identified carotid web as an independent risk factor for stroke in [Ms. Goff]'s age group." *Id*. at *23. In fact, the Special Master identified several studies discussed the high stroke risk of carotid webs and that doctors should suspect them to be the cause of a stroke in people with no other risk factors. *Id.* (discussing Pet'r's Exs. 21, 24, 29). Based on the lack of support in medical literature, the Special Master did not credit Dr. Boylan's theory that an inflammatory trigger was necessary to cause Ms. Goff's stroke. *Id.* at *22–23.

Ms. Goff does not argue that she provided medical literature on the relationship between carotid webs, influenza vaccines, and strokes. Rather, she contends the rarity of carotid webs justifies the lack of supporting literature on the relationship between influenza vaccines and carotid webs in causing strokes. ECF No. 88 at 15. The absence of medical literature to support Dr. Boylan's theory does not establish the Special Master reached an arbitrary or capricious finding. Quite the opposite. *Althen* prong one requires some evidence that the theory proposed actually applies to the vaccine and injury at issue. *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 135 (2011), *aff'd per curiam*, 463 F. App'x 932 (Fed. Cir. 2012). The absence of support for Dr. Boylan's theory reflects that the Special Master properly reviewed the record and rationally determined Ms. Goff did not meet her burden.

Dr. Boylan's testimony is the only support that Ms. Goff presents to support that carotid webs cause strokes when paired with an inflammatory trigger. ECF No. 88 at 15. Dr. Boylan

testified that a "vascular abnormality," like a carotid web, "increase[s] your risk of having a stroke" during an inflammatory response. Hr'g Tr. 55:14–57:21. But the Special Master found no support for Dr. Boylan's testimony in the medical literature. *Goff*, 2025 WL 431582, at *23. Again, the medical literature indicates carotid webs are risk factors for strokes, and it does not suggest that an additional trigger is necessary to cause strokes in a patient with carotid webs. *See* Pet'r's Ex. 21 at 1, 5–6; Pet'r's Ex. 24 at 1, 4; Pet'r's Ex. 29 at 1, 5. The Special Master found this literature, if anything, runs contrary to Dr. Boylan's testimony because the medical literature "identifie[s] [a] carotid web as an independent risk factor for stroke in [Ms. Goff]'s age group." *Goff*, 2025 WL 431582, at *23. Given the medical literature, the Special Master did not reach an arbitrary or capricious finding that Dr. Boylan's testimony standing alone failed to carry Ms. Goff's burden to prove an inflammatory trigger is needed to cause a stroke in a person with carotid webs. It was rational to conclude that it was more likely than not that the carotid webs caused Ms. Goff's stroke and that the influenza vaccine had nothing to do with it.

> 2. Based on the record below, the Special Master rationally concluded that Ms. Goff did not prove by a preponderance of the evidence the inflammatory effects of the influenza vaccine.

The Special Master considered all the evidence in the record and acknowledged that Ms. Goff "provided some support for the proposition that inflammation . . . can play a role in stroke." *Goff*, 2025 WL 431582, at *21. Even so, the Special Master decided Ms. Goff did not meet her burden on prong one because "[i]t is not enough . . . to point to an association between stroke and inflammation without providing some evidence characterizing the inflammatory properties of the [influenza] vaccine." *Id.* Ms. Goff disagrees with the Special Master's characterization of her evidence on the role of inflammation in causing strokes. ECF No. 88 at 6–7. Upon its review, the court finds no arbitrary or capricious error in the Special Master's consideration of Ms. Goff's evidence on inflammation and stroke.

a) Inflammation and Stroke

The Special Master reviewed Ms. Goff's evidence to support that some kinds of inflammation are associated with stroke. *Goff*, 2025 WL 431582, at *21. But she recognized that not all kinds of inflammation are associated with stroke, so she sought evidence that the influenza vaccine produced the kinds of inflammatory effects associated with causing strokes. *Id.* at *21–22. Ms. Goff, however, did not provide "any evidence of the type, quantity, or duration of the inflammatory products of the flu vaccine." *Id.* at *22. Thus, the Special Master found Ms. Goff did not meet her burden to prove her causation theory.

Ms. Goff contends the Special Master went to "great lengths to minimize the strength of Dr. Boylan's argument regarding inflammation and stroke." ECF No. 88 at 7. Ms. Goff also argues that the Special Master heightened her burden on prong one to require proof "that every possible immune provocation . . . can lead to a stroke." *Id.*

As Ms. Goff highlights in her motion, Dr. Boylan's first expert report stated that "[p]rovocations which cause a surge in the body's auto-immune response can cause neurologic illness. Such provocations include infection, trauma, surgery and, rarely, vaccination." *Id.* at 6 (quoting Pet'r's Ex. 16 at 3). Dr. Boylan cited six studies in support of her statement that

"[t]here is substantial evidence that inflammation plays a role in stroke." Pet'r's Ex. 16 at 3 (citing Pet'r's Ex. 31; then citing Pet'r's Ex. 23; then citing Pet'r's Ex. 27; then citing Pet'r's Ex. 28; then citing Pet'r's Ex. 30; and then citing Pet'r's Ex. 22). Although those studies indicate certain inflammatory triggers are associated with strokes, they do not prove all inflammatory triggers are associated with strokes. *See* Pet'r's Ex. 22 at 1, 6–7 (concluding infections may trigger strokes in children, but "routine vaccinations appear protective"); Pet'r's Ex. 23 at 1, 5–6 (acknowledging studies that found infections may affect stroke risk and concluding the "influenza vaccination may be associated with reduced stroke risk"); Pet'r's Ex. 27 at 1, 9 (recognizing that inflammation is known to have a significant impact on stroke risk and that the influenza vaccine may reduce stroke risk); Pet'r's Ex. 28 at 1, 9 (explaining that stroke risk may increase in light of inflammation from "chronic disease or acute infection"); Pet'r's Ex. 30 at 1, 5–7 (mentioning studies finding an increased stroke risk after respiratory infections, and observing a reduced risk of stroke after influenza vaccination); Pet'r's Ex. 31 at 1, 5–8 (concluding "acute infections are associated with a transient increase in the risk of vascular events[, but b]y contrast, influenza, tetanus, and pneumococcal vaccinations do not produce a detectable increase in the risk of vascular events"); *see also infra* Sections III.A.2.b–c (discussing Pet'r's Exs. 23, 30–31). Consistent with those studies, Dr. Boylan testified that inflammation "plays a major role in stroke," and infections are associated with stroke. Hr'g Tr. 34:11–35:25. Dr. Boylan also testified that not all inflammatory triggers are associated with stroke. *Id.* at 39:17–22, 101:5–20. Further, Dr. Boylan acknowledged that infections are more inflammatory than vaccines. *Id.* at 42:1–9, 103:6–8.

But the Special Master sought evidence that described the inflammatory effects of the influenza vaccine to determine whether the vaccine Ms. Goff received could cause the kind of inflammatory effects associated with strokes. This does not heighten Ms. Goff's burden to prove that all inflammation causes stroke. To the contrary, it narrows the scope by focusing on influenza-vaccine-specific evidence. And Ms. Goff does not, and cannot, assert that the submitted medical literature speaks to the inflammatory effects of the influenza vaccine. *See* ECF No. 92 at 8. Dr. Boylan did not report or testify that the influenza vaccine was associated with stroke. Nor does the medical literature cited in her report indicate such an association. Indeed, the literature found that the data indicated a reduction in stroke risk rather than increasing that risk. *See Goff*, 2025 WL 431582, at *23; Pet'r's Ex. 23 at 5–6; Pet'r's Ex. 27 at 9; Pet'r's Ex. 30 at 5–7; *infra* Sections III.A.2.b–c. As this court has observed, "the first prong of *Althen* would be rendered meaningless" if petitioners can meet their burden "[w]ithout any empirical evidence that the theory actually applies" to the vaccine and injury at issue. *Caves*, 100 Fed. Cl. at 135. Here, the record reflects that Ms. Goff and her expert Dr. Boylan provided no evidence that the influenza vaccine provokes the kind of inflammation needed to cause a stroke. The Special Master did not arbitrarily or capriciously require evidence of the inflammatory effects of the influenza vaccine, nor did Ms. Goff meet that requirement.

b) Endothelium-Dependent Relaxation Theory

The Special Master also found unpersuasive Dr. Boylan's theory that inflammation from the influenza vaccine impairs endothelium-dependent relaxation that in turn causes stroke. *Goff*, 2025 WL 431582, at *22 & n.13. Ms. Goff contends that she satisfied *Althen* prong one with Dr. Boylan's testimony on how inflammation can impair endothelium-dependent relaxation in the blood vessels leading to the brain. ECF No. 88 at 7–8. Dr. Boylan explained that the

endothelium is the innermost lining of the blood vessels, and the endothelium pulses and relaxes to send blood into the brain and allow blood to flow away from the brain. Hr'g Tr. 51:20–52:10, 53:2–14. When the blood vessels undergo impaired endothelium-dependent relaxation, Dr. Boylan testified the blood does not properly flow to the brain and may lead to stroke. *Id.* at 53:2–14. Dr. Boylan posited that inflammation can impair endothelium-dependent relaxation that in turn causes stroke. *Id.* at 51:15–54:10. The Special Master specifically acknowledged Dr. Boylan's testimony on this possible mechanism of stroke. *Goff*, 2025 WL 431582, at *22. Yet the Special Master found that Dr. Boylan's "attempt[] to tie" her theory involving inflammation causing impaired endothelium-dependent relaxation to the influenza vaccine was "unpersuasive." *Id.*

Dr. Boylan discussed the Smeeth and Hingorani[20] studies to tie the influenza vaccine to impaired endothelium-dependent relaxation. *See* Hr'g Tr. 53:2–54:10. The Smeeth study cites the Hingorani study as indicative that "vaccination . . . induced a short-lived inflammation that was associated with profound suppression of the endothelium-dependent relaxation." Pet'r's Ex. 31 at 2 & n.15 (citing Resp't's Ex. C). The Hingorani study measured the effects of the *Salmonella typhi* vaccination on endothelium-dependent relaxation. Resp't's Ex. C. Notably, the Smeeth study "accept[ed] that the Hingorani study did show a transient effect of vaccination on endothelium-dependent relaxation of the vessels." *Goff*, 2025 WL 431582, at *22 n.13; Pet'r's Ex. 31 at 2, 7–8. Thus, the Smeeth study itself assumed that proposition. Pet'r's Ex. 31 at 7–8 ("We do not know whether the transient increase in [vascular event] risk is due to a short-term alteration of endothelial function or to other mechanisms . . . ."). The Smeeth study reviewed the United Kingdom's national healthcare database for patients who had an influenza infection or vaccine and then suffered a heart attack or stroke within a year of the infection or vaccine.[21] *Id.* at 2–4. The study categorized the resulting data to determine whether the patients had a heart attack or a stroke during the first 90 days after the infection or vaccine, which was treated as the "risk period." *Id.* at 4–6. The Smeeth study did not measure markers for endothelium-dependent relaxation.

In her discussion of the Smeeth and Hingorani studies, Dr. Boylan stated the Hingorani study measured biomarkers in the blood after administering the influenza vaccine as an inflammatory trigger to determine the effects of inflammation on the endothelium. Hr'g Tr. 53:22–24. The Special Master found that testimony to be "incorrect[]," which "weaken[ed]" the strength of Dr. Boylan's opinion testimony tying the endothelium-dependent relaxation theory to the influenza vaccine. *Goff*, 2025 WL 431582, at *22. Ms. Goff does not argue in her motion that Dr. Boylan's testimony was correct. *See* ECF No. 92 at 9. And upon the court's review, the

[20] Dr. Boylan did not name the Hingorani study in her testimony, but she discussed "the experiment [the Smeeth study authors are] referencing" that involves an experimental model testing endothelium-dependent relaxation, which is the Hingorani study. Hr'g Tr. 51:9–13, 52:22–53:17 (describing the Smeeth study "referencing" a study "where they were trying to study the effects of inflammation and measure them"); Pet'r's Ex. 31 at 2 & n.15 (citing Resp't's Ex. C).

[21] The Smeeth study also included patients who had acute urinary tract infections, acute bronchitis, chest infections, pneumonia, pneumococcal vaccinations, or tetanus vaccinations. Pet'r's Ex. 31 at 2, 5–6.

record adequately supports the Special Master's conclusion that her testimony was incorrect. Neither study tested the effects of the influenza vaccine on endothelium-dependent relaxation as Dr. Boylan's testimony suggested. The court will not disturb the Special Master's well-reasoned determination that Dr. Boylan's endothelium-dependent relaxation theory lacked credibility because of her incorrect testimony.

c) Epidemiological Studies

The Special Master further found that the epidemiological studies were "reassuring" about the properties of the influenza vaccine, and if anything, they indicate the vaccine "is associated with a reduced, not increased, risk of stroke." *Goff*, 2025 WL 431582, at *23–24. Ms. Goff argues that the influenza vaccine's protective effect against stroke at the population level, shown in epidemiological studies, does not preclude the possibility that the vaccine will cause stroke in some individuals. *See* ECF No. 88 at 6 n.1. Here, Dr. Boylan testified about "idiosyncratic" responses to vaccines that depend on individual risk factors, *id.* at 10 (quoting Hr'g Tr. 42:1–13), and Dr. Messé agreed that population-level studies do not consider the cause of every individual's case, *id.* at 12 (quoting Hr'g Tr. 192:24–193:1). The Government contends the Special Master's finding on prong one was based on "reasonably weigh[ing] the epidemiological evidence as part of the record as a whole." ECF No. 92 at 12. On the court's review, the Special Master appropriately considered the epidemiological studies in the record.

While epidemiological studies are not required evidence in vaccine cases, special masters do not need to "ignore probative epidemiological evidence that undermines [a] petitioner's theory." *D'Tiole v. Sec'y of Health & Hum. Servs.*, 726 F. App'x 809, 811 (Fed. Cir. 2018); *Grant*, 956 F.2d at 1149 (describing epidemiological studies as "probative medical evidence relevant to causation"). The Federal Circuit has also recognized the limitations of epidemiological studies: "[E]pidemiological studies are designed to reveal statistical trends only for a carefully constructed test group[, so s]uch studies provide no evidence pertinent to persons not within the parameters of the test group." *Moberly*, 592 F.3d at 1324. Most importantly for this court's review, the Special Master recognized these limits as well. *Goff*, 2025 WL 431582, at *23–24. It was not arbitrary or capricious for the Special Master to consider the epidemiological studies in this case.

Three epidemiological studies in the record reflect that the influenza vaccine does not increase the risk of stroke:

- The Grau study found the influenza vaccine "is associated with reduced risk of stroke." Pet'r's Ex. 23 at 5.
- The Siriwardena study observed that the influenza vaccine "was associated with [a] 24% reduction in stroke risk." Pet'r's Ex. 30 at 5.
- The Smeeth study discovered the influenza vaccine does not increase the risk of stroke. Pet'r's Ex. 31 at 6–8; *see also* ECF No. 88 at 12.

The Special Master found these epidemiological studies did not support that the influenza vaccine causes sufficient inflammation to lead to a stroke; if anything, they were "reassuring"

about the effect of the influenza vaccine on stroke risk. *Goff*, 2025 WL 431582, at *22–24 & n.13.

The Special Master did not construe these studies to preclude a theory the influenza vaccine could not cause a stroke in rare cases, only that the data showed that the vaccine correlated to a lower stroke risk in the general population. *See id.* at *23–24. Although these studies would not reveal if the influenza vaccine may cause a stroke in an incredibly rare instance, it was not arbitrary or capricious for the Special Master to find they complement the lack of evidence that the influenza vaccine causes stroke. These studies do not provide the support that Ms. Goff needed—they do not indicate that the influenza vaccine causes strokes. And the Special Master distinguished the case reports where strokes occurred after vaccines from Ms. Goff's case because one case report involved a "substantially older" patient with a history of stroke and other comorbidities and the other involved the varicella vaccine, not the influenza vaccine. *Id.* at *24. Thus, it was not arbitrary or capricious for the Special Master to conclude these case reports did not outweigh the epidemiological evidence that the influenza vaccine is not associated with an increased stroke risk at the population level. *See id.* The possibility that the influenza vaccine caused a stroke in a patient beyond the scope of these epidemiological studies is not sufficient for the court to set aside the Special Master's well-reasoned decision.

d) The Cárdenas Study

Ms. Goff next contends that the Cárdenas study provided preponderant evidence that her vaccination caused her stroke. The Cárdenas study reviewed existing medical literature reporting neurological illnesses following the H1N1 influenza vaccine. Pet'r's Ex. 19 at 1–2. Of the reported patients, seven suffered strokes after their influenza vaccinations. *Id.* at 2. The study also provided thorough case studies of two patients who experienced neurological illness following their vaccinations; neither of whom suffered a stroke. *Id.* at 3–4. Based on its findings, the Cárdenas study observed the H1N1 influenza vaccine "may promote an exacerbated peripheral inflammatory response," and a "peripheral inflammatory response may promote neuroinflammation, which may underlie the neurological symptoms observed in the two cases reported herein, and in those published elsewhere." *Id.* at 4–5; *see also* ECF No. 88 at 9 (quoting Pet'r's Ex. 19 at 4).

The Special Master acknowledged that the Cárdenas study "proposed that neuroinflammation could result from vaccination" and "identified seven cases of stroke following H1N1 flu vaccination." *Goff*, 2025 WL 431582, at *21. Still, the Special Master found this study did not supply "evidence characterizing the inflammatory properties of the subject vaccine." *Id.* As the Government explains, the Cárdenas study "couche[s]" potential effects of the influenza vaccine "in terms of possibilities and effects that 'may' occur," and therefore "does not offer any evidence regarding the inflammatory effects of the flu vaccine." ECF No. 92 at 8. And the study identifies patients who received a vaccine and then experienced neurologic illnesses without a clear explanation of the mechanism by which the vaccine caused the neurologic illness, if the vaccine caused the illness at all. The Cárdenas study's theories of causation, including neuroinflammation from the vaccine, are inconclusive. As a result, the Special Master did not reach an arbitrary or capricious finding that the Cárdenas study did not prove that the influenza vaccine produces inflammatory effects that cause strokes.

e) Booster Effect Theory

The Special Master also found that Ms. Goff did not present sufficient evidence to support the "booster effect" theory. *Goff*, 2025 WL 431582, at *22. Ms. Goff challenges that finding. ECF No. 88 at 13–14. Recall that receiving multiple vaccines in one flu season is "often referred to as giving a 'booster,'" and a booster influenza vaccine is recommended for children. Pet'r's Ex. 16 at 3–4 (citing Pet'r's Ex. 20). Dr. Boylan theorized that the "frequency and total dose of vaccine administered are considered to be relevant to clinical response. Theoretically, such clinical responses may be adverse as well as beneficial. An enhanced immune provocation may result in higher risk of adverse events." *Id.* at 4. At the entitlement hearing, Dr. Boylan testified that Ms. Goff's September 2015 and March 2016 influenza vaccines combined might have produced a greater inflammatory response. Hr'g Tr. 91:15–92:21. After the hearing, Ms. Goff submitted a copy of a Centers for Disease Control and Prevention webpage that recommends children up to 8 years old receive two influenza vaccines per season. Pet'r's Ex. 41 at 1. The webpage further explains "[t]he first dose 'primes' the immune system; the second dose provides immune protection." *Id.* Additionally, the webpage mentions that different influenza vaccines "are approved for different age groups." *Id.*

The Special Master discussed Dr. Boylan's booster effect theory, but she found Dr. Boylan's testimony "unpersuasive" and that her supporting medical literature did not support the booster effect theory. *Goff*, 2025 WL 431582, at *22. As the Special Master explained, Dr. Boylan did not point to any supporting medical literature at the entitlement hearing for her theory that Ms. Goff's September 14, 2015, influenza vaccine "primed" her to have a response to her second influenza vaccine on March 22, 2016. *Id.* And the evidence that Ms. Goff produced after the entitlement hearing pertained to the effect of two influenza vaccines on children, which "are typically formulated differently from those for adults." *Id.* The Special Master's view of the evidence is consistent with the record, so the court sees nothing arbitrary or capricious in the Special Master's finding that no evidence corroborates Dr. Boylan's booster effect theory testimony.

3. The Special Master did not require that Ms. Goff prove her causation theory with scientific certainty.

As a general matter for prong one, Ms. Goff contends that the "preponderance of the evidence standard does not require scientific certainty," so her theory need not rely on "epidemiological studies or 'general acceptance in the scientific or medical communities.'" ECF No. 88 at 4 (quoting *Moberly*, 592 F.3d at 1325). She also cites *Cloer v. Secretary of Health and Human Services*, 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), to support that a petitioner may prevail on *Althen* prong one by providing sufficient circumstantial evidence of a link between the vaccine and the injury before a theory receives objective recognition in the medical community. ECF No. 88 at 5.

While Ms. Goff is correct that she need not "present proof of causation to the level of scientific certainty," the Special Master was "entitled to require some indicia of reliability to support" Dr. Boylan's theory. *Moberly*, 592 F.3d at 1324; *see LaLonde*, 746 F.3d at 1341 ("[P]etitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence

standard."); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) ("By inclusion of the terms 'relevant and reliable,' Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters."). The Special Master weighed Ms. Goff's evidence against the Government's, and ultimately found Ms. Goff "failed to produce preponderant evidence of a sound, reliable theory demonstrating how the flu vaccine is capable of causing stroke." *Goff*, 2025 WL 431582, at *21–24.

This finding "does not mean that the Special Master was demanding scientific certainty; [s]he might simply have been demanding some degree of acceptable scientific support when concluding" that Ms. Goff's claim "was not supported by a preponderance of the evidence." *Hodges*, 9 F.3d at 962. The record makes clear that the Special Master did not require scientific certainty; she sought *some* evidence that Dr. Boylan's theory actually applied to patients with carotid webs and actually applied to the influenza vaccine. Ms. Goff presented no such evidence. As a result, the Special Master's finding that Ms. Goff did not meet her burden on *Althen* prong one by a preponderance of the evidence was not arbitrary or capricious.

B. The Special Master rationally found Ms. Goff's medical records and supporting medical literature did not support her causation theory on *Althen* prong two.

Because the Special Master found Ms. Goff did not meet her burden on *Althen* prong one, the Special Master did not have to discuss *Althen* prong two. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1358 (Fed. Cir. 2013) (explaining that the failure to satisfy one of the *Althen* prongs renders the rest of the prongs unnecessary to address); *DePena v. Sec'y of Health & Hum. Servs.*, 133 Fed. Cl. 535, 549 (2017) ("[T]o prove causation-in-fact, a petitioner must satisfy all three prongs of the *Althen* test; a failure to satisfy one prong is fatal to the case. Because petitioners failed to establish that the special master erred in rejecting their theory of causation, the special master's conclusion regarding the *Althen* test's second prong is of no moment." (internal citations omitted)), *aff'd per curiam*, 730 F. App'x 938 (Fed. Cir. 2018); *Druery v. Sec'y of Health & Hum. Servs.*, 169 Fed. Cl. 557, 585 (2024) ("[B]ecause a petitioner must meet all three *Althen* prongs, [the special master] was not obligated to evaluate the *Althen* prong 2 or *Althen* prong 3 after determining [the] petitioner did not meet her burden of proof on *Althen* prong 1."). The Special Master nevertheless reviewed the evidence on *Althen* prong two, and Ms. Goff challenges the Special Master's finding that she failed to satisfy this prong. Thus, the court likewise addresses *Althen* prong two.

Althen prong two requires the petitioner to establish by a preponderance of the evidence "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." 418 F.3d at 1279; *see Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1327 (Fed. Cir. 2006) ("There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine."). Like with prong one, Ms. Goff argued on prong two that "the inflammation caused by vaccination coupled with the carotid web [led] to the creation of a clot and ultimately an ischemic stroke." ECF No. 67 at 40.

The Special Master offered two primary reasons why Ms. Goff did not meet her burden of proof on prong two: (1) Ms. Goff did not suffer inflammatory symptoms following the influenza vaccine and leading to her stroke, and (2) the preponderance of the evidence indicating her carotid web was more likely the cause of her stroke. *Goff*, 2025 WL 431582, at *24–25. Ms. Goff challenges both reasons as arbitrary or capricious. ECF No. 88 at 16–17.

1. Ms. Goff's medical records do not indicate that she suffered inflammation from her March 2016 influenza vaccine to support her prong two theory.

The Special Master considered Ms. Goff's medical records in detail and found that none contained objective indications of an inflammatory response to the influenza vaccine:

> During the eight days between the vaccination and Petitioner's stroke, she made no complaints to any medical providers of symptoms that might be indicative of inflammation, such as fever, rash, edema, bruising, or purpura, which are common post-vaccination reactions. Likewise, when she went to the hospital on March 30, 2016, the records show she did not report recently feeling unwell. To the contrary, she reported being in "good chronic health" and that "[p]rior to her ER visit she was in her usual state of health." She underwent multiple examinations at the hospital, with no observations of clinical signs of inflammation. Lab work done in the hospital showed normal levels of inflammatory markers such as CRP and ESR, as well as a negative hypercoagulable workup, signifying that she did not have a blood condition predisposing her to thrombosis.

Goff, 2025 WL 431582, at *24 (internal citations and footnotes omitted). And Dr. Boylan "did not dispute that the hospital records did not show clinical or laboratory indications of inflammation before or at the time of the initial stroke." *Id.* at *25. But as Dr. Messé explained, an inflammatory response sufficient to cause a stroke "would be expected" to be recognized, but no such inflammation appears in Ms. Goff's medical records. *Id.* at *24. The Special Master also recognized that no treating physician attributed her stroke to the influenza vaccine and that Ms. Goff's VAERS report did not describe inflammatory symptoms. *Id.* The Special Master found Ms. Goff did not prove she suffered from inflammation after her March 2016 influenza vaccine, so Ms. Goff failed to meet her burden on prong two. *Id.*

Ms. Goff does not challenge the accuracy of her medical records. "Medical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). As a result, the court does not see any error in the Special Master's treatment of Ms. Goff's medical records as accurately reflecting her lack of inflammatory symptoms. Ms. Goff's lack of inflammation undercuts her theory of causation on prong two.

Even if the court accepted Dr. Boylan's theory of causation, Ms. Goff could not prove causation. Recall that Dr. Boylan's theory is premised on the influenza vaccine causing inflammation that in turn caused a stroke. The record does not reflect that Ms. Goff suffered

inflammation after she received her influenza vaccine on March 22, 2016, and before her stroke on March 30, 2016. As Dr. Messé testified, he "would expect to see something" if Ms. Goff had suffered a "systemic inflammatory state . . . bad enough to cause a stroke." Hr'g Tr. 220:9–13. Thus, the record adequately supports the Special Master's conclusion that Ms. Goff did not suffer inflammation from her influenza vaccine, which would be necessary under Dr. Boylan's theory.

Ms. Goff first challenges this conclusion because the Special Master relied in part on the fact that none of Ms. Goff's treating physicians attributed her first stroke to the influenza vaccine. ECF No. 88 at 16. It is true, as Ms. Goff contends, that "the opinion of a treating physician is not required for [her] to prevail under *Althen*." *Id.*; *Moberly*, 592 F.3d at 1325. Still, such an opinion "can provide supporting evidence of causation." *Moberly*, 592 F.3d at 1325. Given Dr. Messé's testimony he would expect to see something in the record if Ms. Goff had sufficient inflammation to cause the stroke, the Special Master's recognition that no such record exists is appropriate. It reflects a conclusion that the Special Master considered that portion of Dr. Messé's testimony persuasive. This court does not second guess that conclusion. Thus, the Special Master did not act arbitrarily or capriciously by noting the absence of a treating physician opinion tying Ms. Goff's strokes to her influenza vaccine. *Cf. Greene v. Sec'y of Health & Hum. Servs.*, 841 F. App'x 195, 202 (Fed. Cir. 2020) (upholding the special master's finding that the petitioner did not meet his burden on prong two, and mentioning that the special master considered that none of the patient's treating physicians attributed his injury to his vaccine).

Next, Ms. Goff argues the Special Master's consideration of her VAERS report is arbitrary or capricious because "Ms. Goff is not a doctor" and she "did not draft this document with the intent of meeting her burden of proof under *Althen*." ECF No. 88 at 16. But the Special Master considered the lack of any symptoms of inflammation on the VAERS report as *another* indication that there was not sufficient evidence of inflammation in the record. ECF No. 92 at 14–15. In fact, the Special Master only mentioned the VAERS report after recounting all the contemporaneous objective medical records that showed no inflammatory symptoms. *Goff*, 2025 WL 431582, at *24. Thus, the Special Master's consideration of the VAERS report was not improper.

2. The Special Master did not arbitrarily or capriciously find that Ms. Goff's carotid web is an alternative cause of her stroke.

The Special Master could consider alternative causes of Ms. Goff's stroke as part of the prong two analysis. *See Capizzano*, 440 F.3d at 1327 (explaining a petitioner may fail to meet the prong two burden "where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence"). Here, the Special Master explained "both experts agreed" that Ms. Goff had carotid webs and that carotid webs are a risk factor for stroke. *Goff*, 2025 WL 431582, at *25. The experts agreed the medical literature supported that people at Ms. Goff's age may suffer strokes from carotid webs without suggesting the need for a "catalyzing agent" to cause a stroke. *Id.*

Ms. Goff, however, contends that Dr. Boylan's testimony is sufficient to counter that the carotid web was more likely the cause of her stroke than the vaccine. ECF No. 88 at 16–17. Dr.

Boylan testified that Ms. Goff's stroke was "much more likely to have been the reaction to the flu shot than . . . [the] carotid web [because] the underlying carotid web alone has not been sufficient [to cause] . . . any prior or subsequent events." Hr'g Tr. 91:4–9. The Special Master explained why she did not credit that testimony from Dr. Boylan—her testimony was not supported in her submitted medical literature. *Goff*, 2025 WL 431582, at *25. Again, the Special Master reviewed the relevant medical literature on the relationship between carotid webs and strokes and rationally found that the literature does not support that an inflammatory trigger is needed to cause a stroke in a person with carotid webs. *See supra* Section III.A.1. The Special Master thus gave less weight to Dr. Boylan's opinion than Ms. Goff would have liked. But this court does not reweigh the evidence, it ensures the Special Master considered the evidence and came to a rational conclusion. *Hines*, 940 F.2d at 1527 (explaining that "arguments as to the weighing of evidence . . . do not demonstrate reversible error[r]egardless of whether the Claims Court . . . would have found different facts on a retrial of the case" because "the issue the Claims Court resolve[s] . . . is only whether the findings and conclusions of the special master were 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))).

In the end, the Special Master's conclusion that Ms. Goff failed to satisfy *Althen* prong two was not arbitrary or capricious.

C. The Special Master did not arbitrarily or capriciously find that Ms. Goff did not meet her burden of proof on *Althen* prong three.

Like prong two, the Special Master did not need to reach *Althen* prong three. Because she did, the court reviews her conclusions and Ms. Goff's arguments that those conclusions were arbitrary or capricious.

To satisfy *Althen* prong three, a petitioner must show "a proximate temporal relationship between vaccination and injury." 418 F.3d at 1279. This showing requires proof of both a "medically acceptable time frame" and that the petitioner's injury occurred in that time frame. *Pafford*, 451 F.3d at 1358; *de Bazan*, 539 F.3d at 1352 ("[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact."). Here, the Special Master found that Ms. Goff "did not supply reliable expert testimony or other evidence supporting an eight-day onset of stroke following flu vaccination." *Goff*, 2025 WL 431582, at *26.

Ms. Goff contends this holding is arbitrary and capricious because Dr. Boylan testified that eight days is an appropriate timeframe for onset of a stroke following vaccination. This, according to Ms. Goff, was sufficient to "establish[] that the onset of her condition occurred within a medically acceptable timeframe." ECF No. 88 at 18. But the Special Master explained that she did not find this testimony persuasive or credible because it contradicted Dr. Boylan's first export report. *Goff*, 2025 WL 431582, at *26. That report cited medical literature providing

neurological illness[22] typically occurs two to six weeks after infection. Pet'r's Ex. 16 at 3 (citing Pet'r's Ex. 32). Yet, at the entitlement hearing, Dr. Boylan testified that Ms. Goff's stroke, which occurred eight days after her vaccination, was "within the time frame [of] . . . other inflammatory responses." Hr'g Tr. 48:13–49:3. Thus, Dr. Boylan's opinion changed from two to six weeks being the appropriate timeframe to eight days being within the appropriate timeframe, and it was unclear how she got there. In fact, Dr. Boylan admitted that she did not know how long the immune system's response to the influenza vaccine lasts, but she said that the response "lasts at least as long as the time period from the [March 2016] vaccine to the first stroke." Hr'g Tr. 119:18–120:6. The Special Master, however, found Dr. Boylan's testimony equivocal and inconsistent with her first report, which "undermined the persuasiveness" of her opinion. *Goff*, 2025 WL 431582, at *26. Again, it is not the role of this court to second-guess the weight the Special Master gave to Dr. Boylan's testimony. The Special Master gave a reasoned explanation why she did not credit Dr. Boylan's testimony on the eight-day timeframe, so her finding was not arbitrary or capricious.

Ms. Goff next takes issue with the Special Master's decision based on its reference to Dr. Messé's opinion that although eight days would be within the expected time of onset of a stroke following infection, he concluded that it was also within the time that the medical literature found a reduced risk of stroke from vaccination. ECF No. 88 at 17 (quoting *Goff*, 2025 WL 431582, at *26). Dr. Messé testified that eight days after an influenza vaccine is "in the time frame where we saw a reduced risk of stroke in people who are vaccinated; certainly no evidence that it increases the risk of stroke in that time frame." Hr'g Tr. 212:19–213:2. Ms. Goff argued that the Special Master's reasoning does not align with the reasoning in *Irwin v. Secretary of Health and Human Services*, No. 16-1454V, 2024 WL 863690 (Fed. Cl. Spec. Mstr. Jan. 23, 2024). ECF No. 88 at 17–18.

But a "[s]pecial [m]aster is not bound to follow the opinions of other [s]pecial [m]asters," and "special masters are not required to distinguish non-binding decisions of other special masters." *Boatmon*, 941 F.3d at 1358 (quoting *Boatmon v. Sec'y of Health & Hum. Servs.*, 138 Fed. Cl. 566, 571 (2018)). Although not required, the Special Master did compare this case to similar cases, including *Irwin*. *Goff*, 2025 WL 431582, at *27.[23] That said, she recognized the

[22] The Special Master recognized that the literature did not concern strokes, it addressed "encephalitis, myelitis, and encephalomyelitis." *Goff*, 2025 WL 431582, at *26 (discussing Pet'r's Ex. 32); *see also* Pet'r's Ex. 32.

[23] Although Ms. Goff does not address them, the Special Master considered two other cases asserting that the influenza vaccine caused strokes. In *Sokol v. Secretary of Health and Human Services*, another Special Master found that a subarachnoid hemorrhagic stroke ten days after vaccination was outside the medically acceptable time frame of four days. No. 16-1631V, 2020 WL 553842, at *7–8, *10 (Fed. Cl. Spec. Mstr. Jan. 9, 2020); *see also Goff*, 2025 WL 431582, at *27 (analyzing *Sokol*, 2020 WL 553842, at *2, *5–6, *8). And in *Schultz v. Secretary of Health and Human Services*, the Chief Special Master found that the petitioner's medical record did not support that her hemorrhagic stroke thirty days after an influenza vaccination was "likely caused by the flu vaccine." No. 16-539V, 2020 WL 1039161, at *24 (Fed. Cl. Spec. Mstr. Jan. 24, 2020); *see Goff*, 2025 WL 431582, at *27 (analyzing *Schultz*, 2020 WL 1039161, at *13, *22–24). Here, the Special Master recognized that Dr. Boylan has previously distinguished between

proper legal standard when considering these other cases, explaining that although the prior decisions did not control the analysis, they could inform that analysis. *Id*. at *26.

As for *Irwin*, the Special Master meaningfully distinguished it because Ms. Goff did not fall ill immediately after her vaccine like the *Irwin* petitioner did. *Id.* at *27. In *Irwin*, Special Master Gowen concluded that a 24-hour timeframe for onset of symptoms followed by a stroke within two days was a "medically acceptable timeframe to infer causation." 2024 WL 863690, at *22. As Special Master Shah stated: "the petitioner in *Irwin* fell ill immediately after receiving a seasonal flu vaccination and suffered a stroke two days later." *Goff*, 2025 WL 431582, at *27. But in this case, Special Master Shah found that conclusion inapplicable because Ms. Goff's stroke was eight days post-vaccination and there was no history of significant inflammation between Ms. Goff's vaccination and her stroke. *Id*. The record adequately supports this conclusion. Recall that Ms. Goff did not fall ill immediately after she received her influenza vaccine. She reported she was in good health during the days before her stroke. Pet'r's Ex. 6 at 220. Some of Ms. Goff's self-reports following her stroke and her testimony indicate her left arm was red or swollen following her influenza vaccine. Pet'r's Ex. 1 ¶ 5; Pet'r's Ex. 3; Hr'g Tr. 7:20–22. But Ms. Goff's medical records from her admission at the Abrazo ER do not reflect such symptoms when she was receiving treatment for her stroke. Pet'r's Ex. 6 at 220, 222, 280–81. The Special Master credited Ms. Goff's medical records more than her self-reporting documents and testimony. *Goff*, 2025 WL 431582, at *25. And the court will not second-guess the Special Master's well-reasoned weighing of the evidence.

Thus, the court upholds the Special Master's conclusion that Ms. Goff failed to meet her burden under *Althen* prong three.

IV. Conclusion

For these reasons, the court DENIES Petitioner's motion for review, ECF No. 86. The Clerk's Office is DIRECTED to enter judgment accordingly.

It is so ORDERED.

s/ Edward H. Meyers
Edward H. Meyers
Judge

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the hemorrhagic strokes in these cases and ischemic strokes like Ms. Goff suffered, and found Dr. Boylan less persuasive because she conflated the two. *Goff*, 2025 WL 431582, at *27.