United States Court of Appeals for the Federal Circuit

NIKKO CERRONE,

Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee

2024 - 1281

Appeal from the United States Court of Federal Claims in No. 1:17-vv-01158-EGB, Senior Judge Eric G. Bruggink.

Decided: July 29, 2025

GARY A. KROCHMAL, Gary A. Krochmal, PLLC, Farmington Hills, MI, argued for petitioner-appellant. Also represented by AMBER WILSON, Wilson Science Law, Washington, DC.

ELEANOR HANSON, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by C. SALVATORE D'ALESSIO, LARA A. ENGLUND, MALLORI BROWNE OPENCHOWSKI, HEATHER LYNN PEARLMAN, YAAKOV ROTH.

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Before Moore, Chief Judge, Lourie and Bryson, Circuit Judges.

BRYSON, Circuit Judge.

Nikko Cerrone filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10–300aa-34 ("Vaccine Act"), claiming that the administration of certain vaccines caused him to develop ulcerative colitis ("UC"), a type of inflammatory bowel disease ("IBD"). The special master assigned to his petition denied his claim for compensation, and the Court of Federal Claims upheld that decision. We affirm.

I A

On October 7, 2015, Mr. Cerrone, who was sixteen years old at the time, visited his primary care physician complaining of jaw and ear pain. At that visit, he received the Gardasil human papillomavirus ("HPV") vaccine, the Flumist influenza vaccine, and the Hepatitis A vaccine. App. 2. No reaction to the vaccines was recorded on that day or for the remainder of 2015. *Id.* However, Mr. Cerrone later stated in an affidavit that in November 2015 his stamina and stability decreased, and in December 2015 he first experienced blood in his stools. *Id.*

On February 10, 2016, Mr. Cerrone returned to his physician complaining of a sore throat and congestion. App. 3. At that visit, he received a second dose of the HPV vaccine. *Id.* Although his medical records from that visit do not mention any gastrointestinal issues, he visited the emergency room three days later, complaining that he had been experiencing blood in his stools for three weeks and that his symptoms had worsened in the past several days. *Id.* Mr. Cerrone then underwent various diagnostic tests, and on March 24, 2016, he was diagnosed with UC. *Id.*

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On May 19, 2016, Mr. Cerrone returned to the emergency room to be treated for UC symptoms, and he reported that he had been experiencing symptoms for five months. App. 4. He began treatment for UC at around that time. *Id.* On June 24, 2016, he returned to his physician for more testing and received his third dose of the HPV vaccine. *Id.* No reaction to that vaccination was documented, and Mr. Cerrone has not alleged that the third dose of the HPV vaccine exacerbated his symptoms. *Id.*

On October 3, 2016, Mr. Cerrone was further evaluated for UC. *Id.* At that time, he reported that his symptoms had begun in December 2015. *Id.* Since October 2016, Mr. Cerrone has received treatment for UC and has periodically experienced acute exacerbation of his symptoms. App. 5.

В

On August 28, 2017, Mr. Cerrone filed a petition seeking compensation under the Vaccine Act for his alleged vaccine-related injury. App. 1. The case was assigned to the Chief Special Master of the National Vaccine Injury Compensation Program, who heard expert testimony from David Rosenstreich and John Santoro on behalf of Mr. Cerrone and from Chris Liacouras and Neil Romberg on behalf of the respondent. *Id.*; see App. 5–28.

Dr. Rosenstreich is a licensed clinician and immunologist, with a focus on allergies. App. 5–6. He testified that Mr. Cerrone's UC was caused by the three vaccines that Mr. Cerrone received on October 7, 2015. App. 5. Dr. Rosenstreich based that opinion on the theory of molecular mimicry, which is the theory that molecular similarities between different kinds of cells can cause the immune system to react similarly to both despite one (a foreign agent) being threatening and the other (the host's own cells) being non-threatening. App. 47. Dr. Rosenstreich explained that there are similarities between the viral proteins in the vaccines and the proteins in Mr. Cerrone's body relevant to

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UC, and that Mr. Cerrone's immune system may have mistakenly attacked those proteins. App. 8. Although Dr. Rosenstreich testified that any of the three vaccines could have triggered the molecular mimicry in Mr. Cerrone's case, he focused on the HPV vaccine. *Id*.

As an alternative to his molecular mimicry theory, Dr. Rosenstreich testified that the vaccines could have triggered Mr. Cerrone's UC through other less immunologically specific mechanisms, and he offered some examples of such mechanisms. App. 9. Dr. Rosenstreich supported his opinions by reference to various journal articles, the HPV vaccine package insert, case reports, and reports from the Vaccine Adverse Event Reporting System. App. 9–11.

Dr. Rosenstreich testified that his causation theory was consistent with Mr. Cerrone's medical history. He posited that Mr. Cerrone was likely susceptible to UC, either genetically or as a result of environmental factors. App. 13. According to Dr. Rosenstreich, Mr. Cerrone's report of decreased stamina and stability was an early manifestation of systemic inflammation. Id. Dr. Rosenstreich further testified that the fact that Mr. Cerrone's condition worsened after his second HPV vaccine supported the theory that an immune reaction caused Mr. Cerrone's disease, because immune responses to a second vaccine exposure typically manifest more quickly and robustly than responses to the first exposure. App. 14. Finally, Dr. Rosenstreich explained that his causation theory was consistent with the 81-day delay between Mr. Cerrone's vaccination and the onset of blood in his stools because it takes time for the immune response to cause such severe damage. App. 15. In

¹ The Vaccine Adverse Event Reporting System is a database maintained by the Centers for Disease Control and Prevention that compiles information from the public about reactions to immunizations. App. 11 n.28.

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Dr. Rosenstreich's opinion, a delay of that length was consistent with the pertinent medical literature. *Id*.

Dr. Santoro, Mr. Cerrone's other expert, is a gastrointestinal physician. App. 16. He did not testify live but submitted a report and affidavit. *Id.* The special master found his opinions to be largely duplicative of Dr. Rosenstreich's opinions. *Id.*

Dr. Liacouras, who testified for the respondent, is a pediatric gastroenterologist. App. 17. He explained that UC is considered an autoimmune disease that has a largely unknown etiology, although genetic, environmental, autoimmune, and bacterial factors are all possible explanations. App. 17. He did not dispute Mr. Cerrone's UC diagnosis. Based largely on the timing of Mr. Cerrone's disease progression, however, he disagreed that Mr. Cerrone's vaccinations were the likely cause of his disease. App. 18.

Dr. Liacouras focused on Mr. Cerrone's disease progression as documented in his medical records, noting that no gastrointestinal bleeding was recorded until February 13, 2016. App. 18. Dr. Liacouras discounted Mr. Cerrone's self-reported decreased stamina and stability, because those symptoms have many possible causes unrelated to UC. App. 19. Given the delay between the vaccinations and the onset of Mr. Cerrone's UC symptoms, Dr. Liacouras concluded that it was unlikely that vaccines caused Mr. Cerrone's UC. *Id.* Dr. Liacouras also based his opinion on a review of the relevant medical literature, which he described as suggesting that vaccines are not commonly associated with the development of UC. *Id.*

Dr. Romberg, the respondent's other expert, is an immunologist. App. 20. In his testimony, he addressed Dr. Rosenstreich's theory of causation. App. 21. Regarding molecular mimicry, Dr. Romberg explained that while the general theory of molecular mimicry has a reasonable scientific basis, it is unlikely to be the mechanism underlying any given autoimmune disease unless there is specific

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evidence to suggest its involvement. App. 23. He identified types of evidence that could suggest its involvement, none of which he found to be present in Mr. Cerrone's case. App. 23–24.

Following the evidentiary hearing, the special master denied Mr. Cerrone's claim for compensation. The special master explained that Mr. Cerrone had failed to prove by a preponderance of the evidence that his injuries were caused by one of the vaccines he had received.

Mr. Cerrone appealed the special master's decision to the Court of Federal Claims, which affirmed that decision in a detailed opinion. App. 44–59.

II

A

In Vaccine Act cases, the Court of Federal Claims reviews the factual findings of the special master under the arbitrary and capricious standard and reviews the legal rulings of the special master to determine whether they are in accordance with law. Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010) (citing Munn v. Sec'y of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)). On appeal from decisions of the Court of Federal Claims in such cases, we conduct de novo review. As such, "this court performs the same task as the Court of Federal Claims and determines anew whether the special master's findings were arbitrary or capricious." Lampe v. Sec'v of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). Therefore, "although we are reviewing as a matter of law the decision of the [Court of Federal Claims] under a non-deferential standard, we are in effect reviewing the decision of the special master under the deferential [arbitrary] and capricious standard on factual issues," and independently, that is, without

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deference on legal issues. Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011).²

The Vaccine Act distinguishes between "Table injuries" and "off-Table injuries." When a designated condition follows the administration of a designated vaccine within a designated period of time, the injury is referred to as a Table injury, and causation is presumed. 42 U.S.C. §§ 300aa-11(c), 300aa-14; see, e.g., Munn, 970 F.2d at 856–66; Lampe, 219 F.3d at 1360; Moberly, 593 F.3d at 1321; Porter, 663 F.3d at 1249. All other injuries alleged to be caused by a vaccine are considered off-Table injuries. For those injuries, causation must be proved in each case.

The Vaccine Act expressly states that in off-Table cases, such as this one, the petitioner must prove causation by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1); *Moberly*, 592 F.3d at 1321; H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986) (in off-Table cases, the petitioner "must affirmatively demonstrate that the injury or aggravation was caused by the vaccine").

B

In Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005), we explained that a petitioner seeking compensation for an off-Table injury

is to show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing: (1) a medical theory causally connecting

² Although we do not defer to the decisions of the Court of Federal Claims in Vaccine Act cases, we do not ignore them. To the contrary, we pay close attention to the views of the Court of Federal Claims in these cases and benefit from that court's careful analysis of the parties' legal and factual presentations when conducting our own independent review.

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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.

Id. at 1278.

The three requirements set forth in *Althen* are drawn from the earlier decisions of this court in *Grant v. Secretary of Department of Health & Human Services*, 956 F.2d 1144, 1148 (Fed. Cir. 1992), and *Hines ex rel. Sevier v. Secretary of Health & Human Services*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). In *Grant*, we explained that

temporal association alone does not suffice to show a causal link between the vaccination and the injury. To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury. . . . Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support the logical sequence of cause and effect.

956 F.2d at 1148; see also Hines, 940 F.2d at 1525. The Althen formulation, read in conjunction with Grant, thus requires not only temporal association between the vaccine and the injury, but also a reputable medical explanation for the relationship and a logical sequence of cause and effect. Moreover, as this court has made clear, the petitioner must prove "all three Althen prongs by a preponderance of the evidence." Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1355 (Fed. Cir. 2019); Oliver v. Sec'y of Health & Hum. Servs., 900 F.3d 1357, 1361 (Fed. Cir. 2018).

Mr. Cerrone's argument on appeal focuses on the first factor in the *Althen* formulation; as to that factor, he argues that he only needed to show that it was biologically

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plausible that the vaccine caused his injury. Br. 14. He explains that his experts identified a specific biological mechanism connecting his vaccination to his injury—molecular mimicry—and that they identified circumstantial evidence to support that causal theory. Br. 20. Based on that evidence, Mr. Cerrone concludes that he has satisfied his burden under the first *Althen* factor of showing a reputable medical theory demonstrating a causal connection between the vaccines he received and his injury.

Mr. Cerrone's argument understates the burden he bears under the first factor in the *Althen* formulation. He is correct that a Vaccine Act petitioner's showing need not rise to the level of scientific certainty, nor is the petitioner required to provide "detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of Dept. of Health & Hum. Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). But the petitioner must provide the basis for a finding of causation by a preponderance of the evidence. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010); *Moberly*, 592 F.3d at 1325. As such, we have repeatedly stated that "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); see also Boatmon, 941 F.3d at 1360 (same); W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (holding that a theory that is at best "plausible" does not satisfy petitioner's burden of proof); Moberly, 592 F.3d at 1325 (proof of actual causation "must be supported by a sound and reliable medical or scientific explanation." (quoting *Knudsen*, 35 F.3d at 548)).³

³ On a few occasions this court has used the term "plausible" in referring to *Althen*'s requirement to show a

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The second *Althen* factor underscores the need for a reputable—as opposed to merely plausible—medical theory explaining how the vaccine caused the petitioner's injury. Specifically, the second factor requires the petitioner to point to a logical sequence of cause and effect showing that the vaccination was the reason for the injury. See, e.g., Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1327 (Fed. Cir. 2006) ("The proper inquiry is whether a petitioner in an off-Table injury case establishes a logical sequence of cause and effect, the second prong of *Althen* [], by a preponderance of the evidence."). As such, it requires the petitioner to prove, by a preponderance of the evidence. that the medical theory was in fact the mechanism that resulted in the injury at issue. See Broekelschen, 618 F.3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case ").

The third *Althen* factor—a proximate temporal relationship between the vaccination and the injury—serves as a check on the first two factors. While this court's cases make clear that temporal association is not enough by itself to prove causation, *see Boatmon*, 941 F.3d at 1354; *LaLonde*, 746 F.3d at 1341; *Grant*, 956 F.2d at 1148, the

medical theory causally connecting the vaccination and the injury. But in those cases, the court was merely noting that the government had not disputed the medical plausibility of the petitioner's theory of causation. *Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1375, 1380 (Fed. Cir. 2015); *Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009). As noted, the court's precedents have consistently held that the first *Althen* factor requires the petitioner to show a reliable medical theory of causation specific to the vaccine and injury in question, not merely one that is plausible.

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absence of temporal association can be enough to defeat a claim of causation, see Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1356, 1358 (Fed. Cir. 2006).

When applying *Althen*, the special master must consider the degree to which each factor is satisfied. And then, after weighing the degree to which the petitioner has proved each factor and considering any remaining evidence bearing on causation, the special master must determine whether the petitioner has proved that it is more likely than not that the vaccine caused his injury. See, e.g., Andreu, 569 F.3d at 1382 (holding that "the totality of the evidence—including the striking temporal connection between the vaccine and [petitioner's] initial seizure, the testimony of treating physicians, and the biologic and scientific plausibility of [petitioner's expert's] theory of causation—[was] sufficient to meet the Vaccine preponderant evidence standard").

C

The special master found Mr. Cerrone's proof wanting as to all three *Althen* factors and concluded that Mr. Cerrone failed to prove causation by a preponderance of the evidence.

1

As for the first *Althen* factor, on which Mr. Cerrone principally focuses, the special master found that Mr. Cerrone failed to establish by a preponderance of the evidence that "UC can be vaccine-caused—and if so, that the immunologic processes would work as proposed to cause it (even if UC is immune-mediated, as the experts generally agreed)." App. 35–36.

Mr. Cerrone argues that the special master imposed an impermissibly heightened burden when concluding that Mr. Cerrone's medical theory failed to provide a causal connection between his injury and his vaccinations. We

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disagree. The special master correctly explained that "the evidence a claimant offers must, in totality, always accomplish one thing in the end: preponderantly establish that the vaccine(s) at issue more likely than not can cause the relevant disease." App. 35 (emphasis in original). The special master added that the plausibility of a theory "does not mean this burden has been carried, unless the overall weight of evidence . . . balances out in a claimant's favor." Id. (emphasis in original).

The special master then proceeded to weigh the relevant evidence offered by Mr. Cerrone, including the testimony from his experts, the testimony from the respondent's experts, and the medical literature offered by each party. App. 35–39. Ultimately, the special master concluded that the testimony offered by Dr. Rosenstreich was less persuasive than the testimony offered by the respondent's experts. Based on that conclusion, the special master determined that Mr. Cerrone's evidence "does not amount to a preponderant showing, even if individual items of evidence offered in this case had their own specific reliability or reputability—or even if the core idea that vaccines could cause UC has some degree of plausibility." App. 39.

Mr. Cerrone challenges the special master's reliance on medical literature, arguing that there is no requirement that Mr. Cerrone must "provide preponderant proof of vaccine causation in the medical literature." Reply Br. 8. We agree with Mr. Cerrone that he is not required to present medical literature to support his causation theory. See Andreu, 569 F.3d at 1378–79. But we disagree that the special master implicitly imposed such a requirement on Mr. Cerrone. Rather, the special master noted that "Dr. Rosenstreich had sufficient qualifications to offer an opinion on the purported immunologic processes due to vaccination that theoretically could cause UC," but he found that Dr. Rosenstreich "relied on no specific research or experience of his own" to support his theory. App. 39. In

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reviewing the evidence, the special master found that the respondent's experts were "more credentialed, better able to connect their testimony to their personal experience, and proved significantly more persuasive in explaining" their opinions. *Id*.

Moreover, with respect to the medical literature, the special master noted that the respondent pointed to several studies that found no relationship between vaccines and UC, including one study that found no relationship between IBD and two of the three vaccines at issue in this case. App. 36. While Mr. Cerrone takes issue with the factual findings underlying the special master's decision with respect to factor one of *Althen*, we do not find those findings to be arbitrary or capricious.

2

With regard to the second *Althen* factor—whether the evidence supported a logical sequence of cause and effect showing that the vaccines were the reason for his injury—Mr. Cerrone again contends that the special master imposed an impermissible legal burden on him by concluding that "the record is 'lacking' in the type of direct evidentiary proof that is necessary to prove causation." Br. 49.

Nothing in the special master's analysis of the facts suggests that he was imposing an improper legal burden on Mr. Cerrone to prove a causal connection between the vaccines he received and his injury. Rather, the special master appropriately considered the facts in evidence, including Mr. Cerrone's circumstantial evidence. Ultimately, the special master determined that the evidence failed to meet Mr. Cerrone's burden given that (1) none of Mr. Cerrone's treating physicians proposed an association between Mr. Cerrone's vaccinations and his subsequent diagnosis, (2) there was no evidence of an initial vaccine reaction that would reflect the start of an inflammatory process, and (3) there was an absence of any corroboration of the symptoms Mr. Cerrone reported experiencing in

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November 2015, which in any event were non-specific for UC. App. 39–40.

The special master also found that Mr. Cerrone's "rechallenge" argument was unsupported by the record. While the special master acknowledged that Mr. Cerrone's symptoms worsened shortly after his receipt of a second HPV vaccine dose in February 2016, the special master noted that the temporal gap between the first HPV vaccine dose and any likely UC-related symptoms was inconsistent with an "initial 'challenge' that could reasonably be measured against his medical history after the second dose." App. 40. Based on the evidence, the special master concluded that it is "as likely that Petitioner was already progressing symptomatically, independent of the second dose" prior to February 2016. *Id.* The special master added that the third HPV dose did not result in any reaction that could be viewed as a further rechallenge event. Id. Based on those findings, which are supported by the record, we uphold the special master's conclusion that Mr. Cerrone failed to show a logical sequence of cause and effect connecting the vaccines with his injury.

3

With respect to the third *Althen* factor—a showing of a proximate temporal relationship between vaccination and injury—Mr. Cerrone argues that the evidence shows that the 81-day delay between the administration of the vaccine and the development of his UC symptoms was not contrary to his theory of causation. After reviewing Mr. Cerrone's evidence on the temporal relationship factor, the special master concluded otherwise. App. 41.

As to the aspect of Mr. Cerrone's theory focusing on an innate response to the vaccines, the special master concluded, based on Dr. Romberg's testimony and the record evidence, that there was "simply no medical record support that would establish an aberrant, subacute immune response that was occurring in November or most of

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December 2015, that would (a) later manifest 81 days after vaccination, but (b) remain tolerable another four to six weeks, before becoming severe enough to encourage Petitioner to seek emergency treatment." *Id.* As to Mr. Cerrone's argument that he suffered symptoms of fatigue or stamina loss in November 2015, the special master found that those symptoms were uncorroborated and in any event were not shown to be typical precursors to a UC diagnosis. App. 42.

In response to Mr. Cerrone's reliance on other evidence bearing on the third Althen factor, the special master found Mr. Cerrone's showing to be "unsupported by sufficient reliable independent proof." Id. The special master concluded that the individual case reports cited by Mr. Cerrone were "facially inconsistent with the timeframe at issue, with one in particular involving an extremely short onset period not at all compatible to what occurred herein." *Id.* Similarly, the special master found that animal models specific to IBD and UC "suggested a very rapid response time after insult—less than one week." Id. Although the special master did not make a finding as to what period of time would support a finding that UC was vaccine-caused, the special master concluded that the evidence "at least shows that a lengthy timeframe has reliability issues that Petitioner's evidence did not fully address or refute." App. 42 - 43.

With respect to the third *Althen* factor, we do not find the special master's conclusion that Mr. Cerrone failed to show a proximate relationship between his vaccinations and his injury by a preponderance of the evidence to be arbitrary or capricious.

4

Finally, Mr. Cerrone challenges the special master's credibility determinations with regard to the testifying experts. Reply Br. 18. In addition to finding Dr. Rosenstreich's testimony less credible than Dr. Romberg's

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on particular points, the special master found that although Dr. Rosenstreich offered his theory in good faith, "his opinion ultimately seemed more designed to serve the needs of Petitioner in this case than to reflect an independent trustworthy view." App. 39. By contrast, the special master found the respondent's testifying experts to be "more credentialed, better able to connect their testimony to their personal experience, and . . . significantly more persuasive in explaining why the three vaccines Petitioner received could not likely cause UC." *Id.* The special master further found their rejection of Mr. Cerrone's theory "to be derived less from a claim-oriented desire to assist their side to prevail, but more to reflect their own independent and honest assessment of the theories and facts at issue." *Id.*

As we have held in this context and others, credibility determinations are virtually unreviewable on appeal. See Porter, 663 F.3d at 1249; Lampe, 219 F.3d at 1362; Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993); Munn, 970 F.2d at 871 ("[O]f course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."). The special master's credibility determinations thus buttress his findings on the Althen factors, which cannot reasonably be found to be arbitrary or capricious.

III

For the foregoing reasons, we uphold the special master's analysis and conclusions regarding the *Althen* factors and thus the ultimate issue of causation. We therefore affirm the decision of the Court of Federal Claims.

AFFIRMED

Costs

No costs.