United States Court of Appeals for the Federal Circuit

MONA PORTER,
Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2010-5162

Appeal from the United States Court of Federal Claims in case no. 99-VV-639, Judge Nancy B. Firestone.

AMANDA KNIGHT, PERSONAL REPRESENTATIVE OF THE ESTATE OF CLAUDIA J. ROTOLI-BARR, DECEASED,
Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2010-5163

Appeal from the United States Court of Federal Claims in case no. 99-VV-644, Judge Nancy B. Firestone.

Decided: November 22, 2011

SYLVIA CHIN-CAPLAN, Conway, Homer & Chin-Caplin, P.C., of Boston, Massachusetts, argued for both petitioners-appellees. On the brief was RONALD C. HOMER

SARANG V. DAMLE, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellant. With him on the brief were TONY WEST, Assistant Attorney General, and THOMAS M. BONDY, Attorney.

Before RADER, *Chief Judge*, PROST and O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST.
Opinion concurring-in-part, dissenting-in-part filed by *Circuit Judge* O'MALLEY.

PROST, *Circuit Judge*.

The government appeals the combined decision of the United States Court of Federal Claims ("Claims Court") reversing a special master's decision denying Mona Porter's and Claudia Rotoli's petitions for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"), 42 U.S.C. §§ 300aa–1 to –34. The special master concluded that Ms. Porter and Ms. Rotoli did not prove by a preponderance of the evidence that the hepatitis B vaccine—which they both received in three

doses in the 1990s—caused them to suffer autoimmune hepatitis ("AIH"). The Claims Court, incorrectly applying *Andreu v. Secretary of Health & Human Services*, 569 F.3d 1367 (Fed. Cir. 2009), set aside the special master's findings in their entirety on the ground that the special master allegedly erred by considering the credibility of the petitioners' expert witness. Having rejected the special master's findings, the Claims Court entered its own findings and determined that both Ms. Porter and Ms. Rotoli were entitled to recover for their AIH under the Vaccine Act. We conclude that the Claims Court's interpretation of *Andreu* was legally erroneous and inconsistent with this court's precedent. We further conclude that the special master's determination that the petitioners were not entitled to compensation under the Vaccine Act was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. As such, we reverse and remand with instructions to affirm the special master's determination that neither petitioner is entitled to recover under the Vaccine Act.

BACKGROUND

I

The two appeals before us present overlapping legal and factual issues. The first, case number 2010-5162, concerns petitioner Mona Porter. Ms. Porter was born on September 28, 1962. The first date in her medical history that has relevance to this case is May 15, 1991. On that day, Ms. Porter's dermatologist prescribed minocycline for Ms. Porter's acne. Minocycline is well-known in the literature to cause AIH. On May 11, 1992, her dermatologist indicated that she should "finish off" her minocycline dosage and then discontinue treatment with the drug.

On July 8, 1992, Ms. Porter received the first of three doses of the hepatitis B vaccine. She also had a liver function blood test that day. Her liver function tests were within the normal range. Ms. Porter's second dose was administered on August 7, 1992. The record does not indicate whether she had any blood work performed on that day. Ms. Porter received her final vaccine dose on February 5, 1993. A liver function test performed on March 1 revealed that her liver enzymes were elevated well beyond the normal range. The liver function test was repeated four days later and yielded comparable results. Blood tests from this date indicated that Ms. Porter was immune to hepatitis B and was not infected with hepatitis A, B, or C.

On March 11, 1993, Ms. Porter started feeling nauseated, itching, and turning yellow. She visited a doctor who was her employer's colleague, but the office did not create a record of this visit. Ms. Porter next saw a gastroenterologist, Dr. Richard Gilmore. At the initial visit, Dr. Gilmore's impression was that Ms. Porter suffered from "acute hepatitis of undetermined etiology. The possibility that this is related to her vaccine cannot be excluded." He prescribed a steroid to minimize the body's immune response, and requested additional blood work. The blood work, which was performed on April 1, 1993, was consistent with a diagnosis of AIH. A liver function test showed that Ms. Porter's liver enzymes had decreased but were still above normal. In light of these test results, a liver biopsy was performed on May 14, 1993. The pathologist and Dr. Gilmore interpreted the results as being consistent with AIH.

AIH continued to affect Ms. Porter for several additional years. On August 4, 1999, she filed a petition

seeking compensation under the Vaccine Act. *See* 42 U.S.C. §§ 300aa-I *et seq*.

The second appeal, case number 2010-5163, concerns petitioner Claudia Rotoli.[1] Ms. Rotoli was born on January 25, 1969. As pertinent to this case, Ms. Rotoli's medical history began in 1984, a decade before she received the hepatitis B vaccine. From March 1984 to February 1990, Ms. Rotoli was treated for skin rashes, shoulder pain, and severe anxiety. In addition, Ms. Rotoli received treatment for anxiety and depression in 1994. Her symptoms included slow and difficult speech, episodes of blurred vision, chest pains and difficulty thinking. Ultimately, she was treated at a Florida hospital emergency room for confusion, stuttering, and speech difficulty. Her examination at that time included a CT head scan, thyroid profile, and blood count, which were all normal.

On October 10, 1994, Ms. Rotoli received the first dose of the hepatitis B vaccine as well as a flu vaccine. Two days later, she began to experience coughing, congestion, and fever. On October 21, 1994, her doctor recommended that she take cough medicine for these symptoms. She was given the next dose of the hepatitis B vaccine on November 9, 1994. She visited her doctor approximately two months later to be treated for a prolonged upper respiratory infection, bronchitis, and conjunctivitis. She further reported that she began to have pain in her "right upper quadrant" in May 1995. On May 5, 1995, Ms. Rotoli received her final dose of the hepatitis B vaccine. Four days later, she donated blood. On May 19, 1995, the

[1] Ms. Rotoli passed away after the Claims Court's decision in this case. For simplicity, we continue to refer to her as the petitioner.

blood service informed her that her donated blood contained an elevated amount of a certain enzyme diagnostic for some forms of liver disease.

Ms. Rotoli sought information about her abnormal liver test results. Blood tests from May 25, 1995 confirmed that she had elevated liver enzyme levels. Ms. Rotoli was diagnosed as having hepatitis of unknown origin. She saw a general practitioner on May 31, 1995 for a follow up. That doctor noted that Ms. Rotoli had a slight tremor in her hand, and ordered additional blood tests, which again confirmed that Ms. Rotoli's liver function was not normal. She subsequently saw Dr. Katz, a gastroenterologist, on June 20, 1995. Dr. Katz thought that Ms. Rotoli might have either a viral illness or AIH and ordered additional blood tests. The test results were consistent with a diagnosis of AIH. On June 29, 1995, Ms. Rotoli had a liver biopsy. This biopsy showed that Ms. Rotoli had chronic, active hepatitis with fibrosis and moderate necrosis. Based on her blood test results and liver biopsy, Dr. Katz diagnosed Ms. Rotoli as having AIH and prescribed a steroid to moderate the reaction of her immune system.

AIH and other health problems continued to plague Ms. Rotoli. In October of 1996, she was further diagnosed with Sjogren's disease. The following year, she was diagnosed with systemic lupus erythematosus, another autoimmune disorder. In 1998, she was diagnosed with central nervous system lupus. She filed a Vaccine Program petition on August 4, 1999, seeking compensation for her AIH and associated injuries.

II

Ms. Porter's and Ms. Rotoli's cases, along with several

other cases in which the petitioners alleged that the hepatitis B vaccine caused them to suffer from AIH, were assigned to the same special master in 2006. The parties agreed to conduct a joint hearing for all of these cases. The special master heard five days of live testimony over two separate sessions. The proceedings focused principally on the competing opinions of the government's two experts, Dr. Burton Zweiman, an immunologist, and Dr. Raymond Koff, a specialist in hepatology, and petitioners' expert, Dr. Joseph Bellanti, an immunologist. The first hearing session was held over three days in September 2007. The second two-day session was held many months later in March 2008. Notably, petitioners did not offer testimony from an expert in gastroenterology or hepatology despite being given an opportunity to do so.

During the hearing, petitioners' expert (Dr. Bellanti) presented a series of theories directed at showing that the hepatitis B vaccine could cause autoimmune hepatitis. The government's experts (Dr. Zweiman and Dr. Koff) disagreed, explaining that "the evidence does not show that the hepatitis B vaccine can cause autoimmune hepatitis." Dr. Koff, who offered the only testimony from a specialist in hepatology, provided further testimony regarding petitioners' individual cases. Regarding Ms. Rotoli, he testified that her June 29, 1995 liver biopsy (eight-and-a-half months after her first vaccination) showed such extensive fibrosis that, in his experience, Ms. Rotoli's hepatitis had to have predated her vaccination. Pertaining to Ms. Porter, he opined that her liver problems were more likely caused by her use of minocycline—a known cause of AIH—than by the hepatitis B vaccine.

The special master denied Ms. Porter's and Ms. Rotoli's petitions, providing alternative rationales for denying each petitioner's claim. *Porter v. Sec'y of Health &*

Human Servs., No. 99-639V, 2008 WL 4483740 (Fed. Cl. Oct. 2, 2008) ("*Special Master Porter Op.*"); *Rotoli v. Sec'y of Health & Human Servs.*, No. 99-644V, 2008 WL 4483739 (Fed. Cl. Oct. 2, 2008) ("*Special Master Rotoli Op.*").[2] After examining Dr. Bellanti's theories at length, as well as considering Dr. Zweiman's and Dr. Koff's testimony, the special master concluded that "none of [Dr. Bellanti's] theories presents a reliable explanation of how the hepatitis B vaccine can cause autoimmune hepatitis." *Special Master Porter Op.* at *5. Accordingly, he found by a preponderance of the evidence that both petitioners had failed to establish a medical theory causally connecting the hepatitis B vaccine to AIH. *Id.* at *15-16. In addition, the special master specifically found that Ms. Rotoli failed to establish an appropriate temporal relationship between her vaccinations and AIH in light of Dr. Koff's opinion that her extensive fibrosis could not have developed in eight months. *Special Master Rotoli Op.* at *17-18. Because petitioners' burden included establishing (1) a medical theory causally connecting the vaccination and the injury; and (2) a proximate temporal relationship between vaccination and injury, *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), the special master concluded that both petitioners had failed to demonstrate that the hepatitis B vaccine was the cause in fact of their injuries. *Id.* at 18; *Special Master Porter Op.* at *21.

Although he had already concluded that Ms. Porter was not entitled to compensation because she had not established causation in fact, the special master also addressed an independent and wholly distinct reason for

[2] The special master's opinions in *Porter* and *Rotoli* substantially overlap. For simplicity, we cite only to the *Porter* opinion in these instances.

denying her claim. *Id.* at *21-22. The government argued that an alternative cause, i.e., the drug minocycline, induced Ms. Porter's AIH. The special master found that a preponderance of the evidence established that it was more likely than not that the minocycline caused Ms. Porter's AIH.

III

Petitioners sought review of the special master's decisions in their respective cases in the Claims Court. The Claims Court set aside the special master's factual findings, reasoning that this court's decision in *Andreu* required that result. *Rotoli v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 71, 80-82 (2009). The Claims Court read *Andreu* to mean that a special master may not use credibility determinations to reject a petitioner's theory of causation. *Id.* at 82. The Claims Court, based on that understanding of our case law, set aside the special master's factual findings on the ground that the special master had "erroneously used his assessment of Dr. Bellanti's credibility . . . as a basis for rejecting Dr. Bellanti's expert testimony regarding causation." *Id.* at 81-82. Indicating that the special master's credibility determinations "permeated his analysis of the petitioners' claims," the Claims Court set aside the entirety of the special master's factual findings, rather than specific adverse credibility findings. *Id.* at 82.

Having discarded all of the special master's fact finding because he made credibility assessments about Dr. Bellanti's testimony, the Claims Court entered its own findings based on the record. The court credited Dr. Bellanti's medical theories causally connecting the hepatitis B vaccine to AIH and ruled that petitioners had satisfied their burden with respect to this element of causation

in fact. *Id.* at 83-88. As for the timing of Ms. Rotoli's injuries, the Claims Court found an appropriate temporal relationship between the vaccine and the disease, discounting Dr. Koff's opinion that Ms. Rotoli's liver biopsy demonstrated that her AIH predated her receipt of the vaccine by several years. Instead, the Claims Court credited Ms. Rotoli's alternative theory that substantial "fibrosis might be able to form in as little as sixteen weeks." *Id.* at 89. The Claims Court also rejected the government's showing that Ms. Porter's AIH was caused by minocycline, instead crediting Dr. Bellanti's testimony that minocycline was not the cause because her symptoms did not improve after discontinuing the drug. *Id.* at 97-98. The court ultimately concluded that both petitioners were entitled to compensation.

After further proceedings concerning damages, final judgment was entered for petitioners and damages awarded. These appeals followed. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

I

We review de novo decisions of the Claims Court arising under the Vaccine Act, applying the same standard of review as the Claims Court applied to its review of the special master's decision. *Andreu*, 569 F.3d at 1373. We owe no deference to the Claims Court or the special master on questions of law. *Id.* We uphold the special master's findings of fact unless they are arbitrary or capricious. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). "'Thus, although we are reviewing as a matter of law the decision of the Claims Court under a non-deferential standard, we

are in effect reviewing the decision of the special master under the deferential and capricious standard on factual issues.'" *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1350 (Fed. Cir. 2011) (quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1369 (Fed. Cir. 2000)). We do 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—these are all matters within the purview of the fact finder. *Broekelschen*, 618 F.3d at 1349 (citing *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992)). Rather, as long as a special master's finding of fact is "'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.'" *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe*, 219 F.3d at 1360). It is not our role to "'second guess the Special Master[']s fact-intensive conclusions' particularly in cases 'in which the medical evidence of causation is in dispute.'" *Id.* (quoting *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)).

A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury at issue was caused by a vaccine. 42 U.S.C. §§ 300aa–11(c)(1); –13(a)(1). Causation under the Vaccine Act can be shown in one of two ways. The first method of proving causation involves demonstrating that the petitioner sustained an injury in association with a vaccine listed in the Vaccine Injury Table. *Id.* § 300aa–11(c)(1)(C)(i). In such cases, causation is presumed. *See Andreu*, 569 F.3d at 1374. Alternatively, if the complained-of injury is not listed in the Vaccine Injury Table, the petitioner may seek compensation by proving causation in fact. *Moberly v. Sec'y of Health & Human Servs.*,

592 F.3d 1315, 1321 (Fed. Cir. 2010); *see also* 42 U.S.C. § 300aa–11(c)(1)(C)(ii). Ms. Porter's and Ms. Rotoli's petitions are based on such "off-Table" injuries. Once causation is established, the petitioner 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, i.e., an alternative cause. *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); *see also* 42 U.S.C. § 300aa–13(a)(1)(B).

When a petitioner has suffered an off-Table injury, we apply the test for establishing causation in fact outlined in *Althen*:

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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.

418 F.3d at 1278. "[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury.'" *Lombardi*, 656 F.3d at 1351 (quoting *Andreu*, 569 F.3d at 1382).

On appeal, the government contends that the Claims Court's threshold decision to set aside the special master's fact-finding in its entirety was legally erroneous because this court has consistently recognized the special master's

authority to consider and assess the credibility of expert witnesses in evaluating Vaccine Act claims. The government notes that the Claims Court can issue its own fact-finding based on the record only if the special master's underlying decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. The government argues that the special master's factual findings were based on a full and amply reasoned consideration of the record evidence and that no proper basis exists for setting those findings aside under the deferential standard of review.

Petitioners counter that the Claims Court correctly determined that the special master had impermissibly framed his rejection of the petitioners' theory of causation under the rubric of a credibility determination to immunize himself from appellate review. Petitioners contend that this constitutes legal error under *Andreu*, and provides a basis for the Claims Court to set aside the special master's findings under 42 U.S.C. § 300aa-12(e)(2)(B). Petitioners further contend that they met their burden by establishing the three factors required to show causation in fact under *Althen*. Finally, Ms. Porter asserts that once she established her prima facie case, the burden shifted to the government to show that the hepatitis B vaccine did not cause her injury. She argues that the special master's conclusion that minocycline caused her injury was arbitrary and capricious.

II

We first consider whether the Claims Court's wholesale rejection of the special master's fact-finding based on his use of credibility assessments was legally erroneous. The Claims Court cited to this court's decision in *Andreu* in support of its ruling. In that case, we explained that a

special master cannot "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu*, 569 F.3d at 1379. The Claims Court here made no determination that the special master applied an erroneous legal standard. Rather, the Claims Court read *Andreu* to mean that it is inappropriate for a special master to consider a petitioner's expert's credibility in evaluating a petitioner's showing of causation in fact.

The Claims Court's reading of *Andreu* is incorrect. Indeed, this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act. Recent decisions of this court subsequent to the Claims Court's opinion here are instructive. In *Moberly,* we reiterated that a special master may not cloak the application of an erroneous legal standard in the guise of a credibility determination to shield it from appellate review. 592 F.3d at 1325 (discussing *Andreu*, 569 F.3d at 1379). We went on to clarify that this does not mean that "a special master, as the finder of fact in a Vaccine Act case, is prohibited from making credibility determinations regarding expert testimony." *Id.* We indicated that "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations" and "[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Id.* at 1326. Our discussion of the issue in *Broekelschen* is equally clear. In that case, we recognized that "[e]xpert medical testimony is often very important in Vaccine Act cases based on off-Table injuries requiring proof of actual causation." *Broekelschen*, 618 F.3d at 1347. We again explained that "the special master's decision often times

is based on the credibility of the experts and the relative persuasiveness of their competing theories" and such credibility findings "'are virtually unchallengeable on appeal.'" *Id.* (quoting *Lampe*, 219 F.3d at 1361). Finally, in *Doe*, we upheld a special master's factual findings as not arbitrary and capricious "particularly in light of the credibility findings made as to the parties' respective experts." 601 F.3d at 1351. We found no basis for disturbing the special master's credibility findings as to those experts, and again emphasized that "the special master's unique position to see the witnesses and hear their testimony" makes "such credibility assessments . . . 'virtually unreviewable on appeal.'" *Id.* at 1355-56 (quoting *Lampe*, 219 F.3d at 1362).

In the present cases, the special master recognized that all three experts were well-qualified, but found Dr. Zweiman's and Dr. Koff's testimony to be more persuasive than Dr. Bellanti's in several instances when the experts' opinions were in conflict. Rather than rejecting the special master's findings in their entirety, the Claims Court should have applied the deferential arbitrary and capricious standard of review to these findings. The Claims Court's blanket approach of setting aside the factual findings without ever determining whether the findings were arbitrary and capricious failed to accord the deference to those findings required by the Vaccine Act and constitutes legal error.

III

Because the Claims Court did not have a proper basis for setting aside the special master's findings of fact and substituting its own findings, we now turn to the special master's findings in order to assess whether they were arbitrary and capricious. The special master made find-

ings on each of the three elements of the *Althen* test for causation in fact, finding that petitioners had failed to carry their burden on each *Althen* factor. He also made findings regarding the government's evidence of alternative cause with respect to Ms. Porter's AIH. To establish a prima facie case, the petitioners bear the burden of proving all three factors required under *Althen*.

A

The special master found that petitioners had failed to carry their burden of demonstrating "a medical theory causally connecting" the hepatitis B vaccine to AIH, as required by the *Althen* test, 418 F.3d at 1278. *Special Master Porter Op.* at *15-16. At bottom, petitioners do not dispute that the special master applied the proper legal standard in evaluating their claims. Rather, their arguments relate entirely to the special master's evaluation of the competing evidence and his ultimate findings based on the evidence.

At the hearing, both Dr. Zweiman and Dr. Koff testified that they were unaware of any scientific or epidemiological evidence of a causal link between the hepatitis B vaccine and AIH. Petitioners' expert, Dr. Bellanti, proffered a number of theories he claimed demonstrated that the hepatitis B vaccine might cause AIH. The special master examined each of these theories in great detail, weighing all of the scientific evidence presented by both sides.

Dr. Bellanti's first theory was based on a biological mechanism known as "molecular mimicry." *Id.* at *6. Dr. Bellanti initially described molecular mimicry as a theory he believed was "most likely to be valid." Dr. Zweiman presented an article that undermined the reliability of

molecular mimicry as a theory causally connecting the hepatitis B vaccine with AIH. *Id.* Dr. Bellanti abandoned this theory at the hearing after being confronted with the contrary research. He agreed that the article "doesn't support molecular mimicry . . . so we have to seek another explanation." *Id.*

Dr. Bellanti's next two theories involved "bystander activation" and "polyclonal activation," respectively. *Id.* at *6-9. Dr. Zweiman testified that there is no evidence that the hepatitis B vaccine induces polyclonal activation. *Id.* at *9. A 2002 report of the National Academy of Sciences' Institute of Medicine ("IOM") likewise concluded that "[t]here is no evidence that the hepatitis surface antigen (in the [hepatitis B vaccine]) is capable of bystander activation . . . or otherwise induces non-specific polyclonal activation." The special master noted that IOM reports are favored, although not dispositive, in the Vaccine Program. *Id.* at *7. Dr. Bellanti presented no response to the IOM report, which had been filed before he testified, nor did he present any rebuttal articles. *Id.* When he was questioned about the report, he dismissed it as "opinion," without further articulating any reason for his disagreement with that report. *Id.* Crediting Dr. Zweiman and the IOM report, the special master found that neither of these biological mechanisms constituted a reliable theory for explaining how the hepatitis B vaccine can cause AIH. *Id.* at *8-9.

Dr. Bellanti's fourth theory implicated "dysfunction in regulatory T-cells." *Id.* at *9-11. Regulatory T-cells are responsible for suppressing immune reactions against the body's own tissues. Dr. Bellanti's expert report posited that "[s]tudies suggest that a decrease in the number of regulatory T-cells and their ability to expand may lead to autoimmune liver disease." *Id.* at *9. In support of the T-

cell dysfunction theory, Dr. Bellanti pointed to an article by Maria Serena Longhi, et al., entitled "Impairment of CD4+ CD25+ regulatory T-cells in autoimmune liver disease," 41 Journal of Hepatology 31-37 (2004) ("Longhi article"). *Id.* at *10. Dr. Zweiman agreed that a problem with regulatory T-cells may be associated with AIH, but testified that it is unclear whether the AIH causes the dysfunction or the dysfunction causes the AIH. He further testified that "nobody has ever reported whether or not hepatitis immunization induces alteration of immunoregulatory T-cells." *Id.* at *11. Dr. Bellanti did not dispute this assertion. *Id.* The special master observed that none of the testimony linked the observation in the Longhi article that people with AIH have a T-cell imbalance with the hepatitis B vaccine. *Id.* In fact, he noted that Dr. Bellanti's own report stopped short of identifying the vaccine as a cause of regulatory T-cell dysfunction. When the special master specifically asked Dr. Bellanti whether his theory was "that something in the hepatitis B vaccine causes the T-cell regulatory deficiency," Dr. Bellanti responded: "That isn't known . . . the article simply referred to a deficiency in patients with autoimmune hepatitis. Whether it was the cause or the result, it isn't clear. . . . I would favor it being a preexisting deficiency, but . . . that would be speculative." *Id.* at *10. In view of the testimony and the article, the special master found that Dr. Bellanti "could not connect the hepatitis B vaccine to his belief that an imbalance in T-regulatory cells causes autoimmune hepatitis." *Id.* at *11. Accordingly, the special master concluded that T-cell dysfunction does not qualify as a medical theory causally connecting the vaccination and the injury.

Dr. Bellanti presented two additional observations in support of a causal link between the hepatitis B vaccine and AIH. First, he contended that, because the hepatitis

B virus itself may cause autoimmune disease, one can assume that the hepatitis B vaccine can also cause autoimmune disease. *Id.* at *12. Relying on a review article in the New England Journal of Medicine by Dr. Edward Krawitt, a leading researcher in AIH, the special master rejected the underlying premise of Dr. Bellanti's claim, i.e., that hepatitis B virus causes AIH. *Id.* at *13. The Krawitt review article concluded that autoimmune hepatitis had been associated with hepatitis A and hepatitis C infections, but significantly, the article did not mention a similar association with respect to hepatitis B infection. *Id.* Dr. Bellanti offered four articles that minimally support the proposition that the hepatitis B virus can cause AIH. *Id.* Dr. Koff testified that the subject in one of the articles actually had chronic hepatitis B, not AIH. *Id.* at *12. He also testified that the subject in another article likely had hepatitis C, not AIH. *Id.* The special master found that the remaining two articles, both describing single case studies, did not contain any meaningful analysis about causation. *Id.* at *13. The special master found that "[a] preponderance of the direct evidence regarding the hepatitis B virus contradicts an assertion that it can cause autoimmune hepatitis." *Id.* at *14.

Dr. Bellanti also asserted that there were "reports in the literature" that the hepatitis B vaccine had caused a "rechallenge event" in people with autoimmune diseases, supporting a causal connection between the vaccine and AIH. *Id.* at *15. "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006). The special master recognized that such an event can be persuasive evidence that a vaccine is causing an adverse reaction. *Special*

Master Porter Op. at *15. Problematically, at the hearing, Dr. Bellanti did not cite any specific literature about rechallenge with the hepatitis B vaccine nor could he explain the basis for his assertion. *Id.* The special master acknowledged that experts are not required to produce literature under *Althen*; however, Dr. Bellanti's expert report stated that there were such reports in the literature. The special master noted that "Dr. Bellanti's inability to prove what he wrote implicated his persuasiveness and his veracity." *Id.* at *15 n.7. The special master also considered a 2005 study by J. Beran, et al., in the Central European Journal of Public Health submitted by Dr. Zweiman. *Id.* at *15. The study reported that the condition of people with preexisting AIH did not worsen after receiving the hepatitis B vaccine. The special master found that the Beran study was further evidence contrary to Dr. Bellanti's assertion regarding the applicability of the rechallenge. *Id.*

After carefully considering Dr. Bellanti's numerous theories, the special master found each to be flawed and concluded that "none . . . presents a reliable explanation of how the hepatitis B vaccine can cause autoimmune hepatitis." *Id.* at *5. As we have previously indicated, "reversible error will be extremely difficult to demonstrate" where the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

The special master's decision reveals a thorough and careful evaluation of all of the evidence including records, tests, reports, and medical literature, as well as the experts' opinions and their credibility. The special master weighed the conflicting evidence and concluded that

petitioners had not carried their burden of demonstrating "a medical theory causally connecting" the hepatitis B vaccine to AIH. This court does not reweigh the factual evidence or assess whether the special master correctly evaluated the evidence, nor does it examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder. *Broekelschen*, 618 F.3d at 1349; *Lombardi*, 656 F.3d at 1354. Accordingly, the special master's determination that petitioners had failed to prove causation in fact by a preponderance of the evidence and that neither petitioner was entitled to compensation under the Vaccine Act was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 42 U.S.C. § 300aa12(e)(2)(B).

B

Putting aside the special master's findings implicating Dr. Bellanti's credibility, the special master also made findings that did not rest on the adverse credibility of Dr. Bellanti and were separate and independent reasons for denying petitioners' claims. In Ms. Rotoli's case, the special master found that she failed to satisfy the timing prong of *Althen* because her AIH predated her vaccinations. *Special Master Rotoli Op.* at *17-18. These findings did not involve Dr. Bellanti's credibility. Rather, the special master based these findings on Dr. Koff's analysis of Ms. Rotoli's liver biopsy.

Dr. Koff explained that Ms. Rotoli's liver biopsy, which was taken less than nine months after she received her first dose of the hepatitis vaccine, showed such extensive damage that she must have had a liver disease for many years prior to the biopsy. *Id.* at *17. The special master acknowledged Dr. Koff's training and thirty years

of experience treating people with liver disease. *Id.* at *18. He found Dr. Koff to be "quite certain and quite persuasive" in his testimony that such extensive fibrosis "cannot develop in nine months." *Id.* at *17. Ms. Rotoli did not offer any expert testimony from a hepatologist to rebut Dr. Koff's analysis of her biopsy or his assertion that the damage could not have occurred in the relevant timeframe. To offset this deficiency, Ms. Rotoli offered an article by Hans-Iko Huppertz documenting a single case study of a subject who was diagnosed with AIH following hepatitis A infection. *Id.* The subject's liver biopsy showed fibrosis, and Ms. Rotoli argued that this supports that fibrosis such as hers could have developed over a short time frame. *Id.* Dr. Koff provided an alternative interpretation of the Huppertz case study. He testified that the subject in that case study likely had AIH before his infection with hepatitis A. According to Dr. Koff, the AIH caused the fibrosis but was not discovered until the hepatitis A infection. *Id.* In view of the evidence, the special master's finding that Ms. Rotoli's AIH began before she received the hepatitis B vaccine was not arbitrary and capricious.

The special master's finding that the government had proven by a preponderance of the evidence that Ms. Porter's longtime use of minocycline was the cause of her AIH likewise did not rest on Dr. Bellanti's lack of credibility. Rather, the special master relied on the undisputed fact that minocycline is known to cause AIH, Ms. Porter's medical records, and Dr. Koff's testimony. *Special Master Porter Op.* at *21-22. Ms. Porter's medical records indicated that "[a] dermatologist prescribed minocycline for Ms. Porter as early as May 15, 1991," prior to her receipt of doses of the hepatitis B vaccine. *Id.* at *21. Dr. Koff testified that Ms. Porter's records also indicated that Ms. Porter took minocycline "on again and off again through

at least 2002." Based on his review of Ms. Porter's records, Dr. Koff concluded that "the natural history of minocycline-induced autoimmune hepatitis is very much like we are seeing in Ms. Porter," and that minocycline was the more likely cause of her condition. The special master also noted that one of Ms. Porter's treating doctors had "discontinued her prescription of minocycline after Ms. Porter reported that she had hepatitis." *Id.* at *22. The special master found that action to be "consistent with a belief that the minocycline could be causing Ms. Porter's liver troubles." *Id.*

To rebut the government's showing on alternative cause, Dr. Bellanti testified that "minocycline was not likely to be the cause of Ms. Porter's hepatitis because her condition did not improve when she stopped taking the minocycline." *Id.* at *21. The special master noted, however, that the medical literature "contains more than one example of cases in which the hepatitis continued after the minocycline was stopped." *Id.* Dr. Koff also testified that "minocycline-induced disease does not invariably get better when you discontinue the drug." He further opined that "if you keep taking [minocycline] intermittently over years, as in the case of Ms. Porter, it's not going to get better." We cannot say that the special master's treatment of the conflicting evidence and his finding that Ms. Porter's AIH was caused by minocycline was "so clearly wrong as to be arbitrary or capricious." *Lampe*, 219 F.3d at 1367.

In sum, we conclude that the Claims Court committed legal error when it set aside the special master's findings of fact in their entirety based on its erroneous interpretation of *Andreu*. We further conclude that the special master's determination that the petitioners were not entitled to compensation under the Vaccine Act was not

arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

CONCLUSION

We reverse the judgment of the Claims Court and remand with instructions to affirm the special master's determination that neither petitioner is entitled to recover under the Vaccine Act.

REVERSED AND REMANDED

United States Court of Appeals for the Federal Circuit

MONA PORTER,
Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2010-5162

Appeal from the United States Court of Federal Claims in case no. 99-VV-639, Judge Nancy B. Firestone.

AMANDA KNIGHT, PERSONAL REPRESENTATIVE OF THE ESTATE OF CLAUDIA J. ROTOLI-BARR, DECEASED,
Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2010-5163

Appeal from the United States Court of Federal Claims in case no. 99-VV-644, Judge Nancy B. Firestone.

O'MALLEY, *Circuit Judge*, concurring-in-part, dissenting-in-part.

Although I believe the trial court erred in setting aside the entirety of the special master's findings based solely on his misuse of "credibility" determinations, I cannot agree with the majority's decision to ignore completely the special master's improper use of those determinations. In several instances, the special master's reliance on "demeanor" and "credibility" to reject the petitioner's theories undoubtedly was contrary to this court's case law. In addition, the special master's unusual and relentless attacks on the expert's truthfulness color the remainder of the special master's flawed analysis.

I also cannot endorse, as the majority does, the special master's arbitrary findings and erroneous legal conclusions with respect to Mona Porter's claim. While our review of special masters' decisions in Vaccine Act cases is deferential, it is not a rubber stamp. And our standard of review is not a license for special masters to discount medical literature on a whim or misapply legal standards. As explained below, because the special master made arbitrary and capricious findings and applied erroneous legal standards in rejecting Ms. Porter's claim, I would affirm the decision of the United States Court of Federal Claims ("Claims Court") on that claim. Accordingly, I must dissent from that portion of the majority's opinion. For the reasons stated by the majority, however, because there are independent bases that bar Claudia Rotoli's claim, I agree that the decision of the Claims Court must be reversed as to that claim.

I.

I start by supplementing the majority's recitation of the procedural history and discussion of the special master's unusual opinions in these five consolidated petitions. Originally, eight petitioners, including Mona Porter and Claudia Rotoli,[1] filed petitions alleging that the hepatitis B vaccine caused them to suffer from autoimmune hepatitis ("AIH").[2] All eight claims were assigned to the same special master. Ms. Porter and Ms. Rotoli, along with several other petitioners, relied on the opinion of the same expert, Dr. Joseph A. Bellanti, to support their claims.

Dr. Bellanti is an immunologist whose qualifications and credentials have not been challenged, and whose expert opinion has been accepted by special masters in other Vaccine Act cases. *See Keenan v. Sec'y of Health & Human Servs.*, No. 99-561V, 2007 WL 1231592 (Fed. Cl. Apr. 5, 2007); *Bowes v. Sec'y of Health & Human Servs.*, 01-481V, 2006 WL 2849816, at *4 (Fed. Cl. Sept. 8, 2006) (finding Dr. Bellanti persuasive in part because "Dr. Bellanti is a physician with excellent academic credentials and experience in the medical specialities [sic] of pediatrics and immunology."). Indeed, one special master familiar with Dr. Bellanti from several prior cases de-

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[1] Ms. Rotoli passed away on November 11, 2009, at the age of 40, following the Claims Court's decision in this case. Her daughter, Amanda Knight, was appointed as the personal representative of Ms. Rotoli's estate, but we refer to Ms. Rotoli as the petitioner for continuity and clarity.

[2] AIH is a chronic liver disease in which an individual's immune system attacks the individual's liver as if it is a foreign tissue. *See Rotoli v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 71, 76 n.2 (2009) (citing Michael P. Manns & Arndt Vogel, *Autoimmune Hepatitis, From Mechanisms to Therapy*, 43 Hepatology No. 2, Suppl. 1 S 132 (2006)).

scribed him, and his counterpart, as being "as well-versed in their fields as any two experts one could hope to obtain." *Keenan*, 2007 WL 1231592, at *3. That special master found it "worth noting that the Court received Dr. Bellanti's testimony with credibility." *Id.* at *10.

Of the eight original cases below, three settled before the special master's joint hearings, two for $100,000 and one for $120,000. *See Zaskoda v. Sec'y of Health & Human Servs.*, No. 05-241V (Fed. Cl. May 29, 2007); *Wadie v. Sec'y of Health & Human Servs.*, No. 99-493V (Fed. Cl. Jan. 18, 2008); *Kay v. Sec'y of Health & Human Servs.*, 01-476V (Fed. Cl. Jan. 18, 2008). One of the petitioners whose case settled, Jeffrey Zaskoda, relied on Dr. Bellanti's opinion to support his claim.

The remaining five cases were consolidated for purposes of trial before the special master. Following joint hearings, the special master denied all of the petitions—including Ms. Porter's and Ms. Rotoli's—finding that the petitioners failed to establish by a preponderance of the evidence that their AIH was caused by the hepatitis B vaccine. *See Porter v. Sec'y of Health & Human Servs.*, No. 99-639V, 2008 WL 4483740 (Fed. Cl. Oct. 2, 2008) ("*Special Master Porter Op.*"); *Rotoli v. Sec'y of Health & Human Servs.*, No. 99-644V, 2008 WL 4483739 (Fed. Cl. Oct. 2, 2008) ("*Special Master Rotoli Op.*"). With respect to Ms. Porter, the special master also found that the government met its burden of showing that Ms. Porter's AIH was caused by an alternate cause, namely the acne drug minocycline. *Special Master Porter Op.* at *21.

Although the majority makes no mention of this point, the special master's opinions in these cases are remarkable for the sheer number of references to credibility, demeanor, and veracity. For example, in referring to Dr. Bellanti in his *Porter* decision, the special master used

terms relating to credibility a total of 31 times throughout his 36-page opinion, including the words "credibility" or "credible" a combined 17 times, the word "demeanor" eight times, and the words "veracity" and "truthfulness" a combined six times. The following passages are illustrative: "[t]his evasive answer decreased Dr. Bellanti's credibility," *id.* at *15; "[t]his evasive answer decreased Dr. Bellanti's credibility and calls into question the truthfulness of Dr. Bellanti's report," *id.* at *24; "this lack of forthrightness lessens Dr. Bellanti's credibility." *id.* at *28; "Dr. Bellanti's demeanor during his testimony strongly reinforces the doubts about Dr. Bellanti's veracity," *id.* at *29; "[a] consideration of Dr. Bellanti's report, his testimony, and his demeanor while testifying raises significant concerns not just about Dr. Bellanti's persuasiveness but also his truthfulness," *id.* at *30.[3] In his *Rotoli* decision, the special master found that "Dr. Bellanti lacked credibility about when the autoimmune hepatitis began," and that "his demeanor when he testified suggested, at a minimum, that he lacked confidence in his statement" or "[a]t worst, his demeanor suggested that he was not truthful." *Special Master Rotoli Op.*, at *17.

Many of the special master's comments appear in a special nine page section of the opinion entitled "Additional Comments Regarding Dr. Bellanti," which he devoted exclusively to attacking Dr. Bellanti's preparedness and veracity. In addition to calling Dr. Bellanti's expert report "misleading and not accurate," the special

[3] Like the majority, unless otherwise noted, I cite only to the *Porter* opinion when referring to issues that overlap between the special master's two decisions in these cases. Any cite to the Joint Appendix likewise refers to the appendix submitted in connection with that appeal.

master included a subsection about "Dr. Bellanti's Demeanor," in which he identified ten instances during the hearings in which Dr. Bellanti "appear[ed] uncomfortable," "appear[ed] unsettled," "appear[ed] unfamiliar," "lack[ed] confidence," or was "being evasive." *Id.* at *28-30. Based on this, the special master drew what he believed was a "reasonable" inference that Dr. Bellanti "was aware that his opinion was flawed, yet he chose to provide it anyway." *Id.* at *30.

This section of the special master's opinion concludes with the following:

> Here, so many questions about the basis for Dr. Bellanti's statements, contained in either his report or his testimony, have led to a question about Dr. Bellanti's veracity. As a professor and published author, Dr. Bellanti should appreciate the need for some evidence to substantiate his theories. Dr. Bellanti failed to present any evidence that was credible and persuasive to support his statements and opinions. *Consequently, Dr. Bellanti's opinion, as a whole, lacks any persuasiveness*.

Id. (emphasis added). Notably, although there is no reason for a special master to enunciate the standard under which his own decision will be reviewed, the special master in this case announced that "[a] decision about the persuasiveness of an expert is virtually not reviewable on appeal." *Id.* at *3 (citing *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993); *Sword v. Sec'y of Health & Human Servs.*, 44 Fed. Cl. 183, 188 (1999)).

The special master's pronouncement, however, did not hold true upon motion for review of his decisions in the Claims Court. In a combined opinion addressing all five

cases, the Claims Court reversed the special master as to three of the decisions after finding that his credibility determinations ran afoul of this court's decision in *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009). *See Rotoli v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 71, 80-82 (2009). Specifically, the Claims Court found that, "[j]ust as the special master did in *Andreu*, the special master in these cases erroneously 'cloaked' much of his rejection of petitioners' theory of causation under the rubric of a 'credibility' determination regarding [Dr. Bellanti]." *Id.* at 80 (citation and some internal quotation marks omitted). In so finding, the court relied on our decision in *Andreu* in which we stated that credibility determinations are used "to assess the candor of a fact witness, not to evaluate whether an expert witnesses' medical theory is supported by the weight of epidemiological evidence." *Id.* (quoting *Andreu*, 569 F.3d at 1379).

The Claims Court went on to set aside all of the special master's findings and enter its own findings of fact and conclusions of law pursuant to 42 U.S.C. § 300aa-12(e)(2)(B). *Id.* at 82.[4] In a thorough analysis, the Claims

[4] This is not the only time the Claims Court has set aside the findings of or rebuked this particular special master. *See e.g.*, *Campbell v. Sec'y of Health & Human Servs.*, 90 Fed. Cl. 369, 383-84 (2009) ("Despite the special master's attempt to insulate his decision from review by the incantation of magic words, the court finds that he erroneously relied on an assessment of Dr. Brawer's credibility as a basis for rejecting Dr. Brawer's testimony and concluding that Ms. Campbell had not met her burden to establish causation in fact."); *Dobrydnev v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 190, 208 (2011) (reversing the special master and noting, among other criticisms, that "[e]ither the Special Master did not carefully review the record or purposefully neglected to dis-

Court found in favor of three of the petitioners, including Ms. Porter and Ms. Rotoli, and for the government with respect to the other two petitioners. *Id.* at 102.

The government appealed the Claims Court's decision awarding compensation to the three petitioners. With respect to Ms. Porter's and Ms. Rotoli's cases, the government argues that the Claims Court erred because it incorrectly believed that the special master was prohibited from assessing the credibility of an expert witness. The government goes on to argue that, even if the special master made improper credibility determinations, any such error was harmless because the special master's decisions rested on independent grounds unrelated to credibility. The majority agrees on both points and, therefore, reverses the judgment of the Claims Court and remands this matter with instructions to affirm the special master's determinations.

With due respect to the majority, I cannot endorse the decision of the special master in Ms. Porter's case. For the reasons explained below, I believe the majority gives our recent case law regarding credibility determinations an unduly broad reading, and then errs in overlooking the many places in which the special master improperly considered demeanor or credibility, made arbitrary and capricious findings, or applied an improper legal standard. With respect to Ms. Porter's claim, these errors warrant overturning the special master's decision even under our generous standard of review. Accordingly, I would affirm the Claims Court's decision as to Ms. Porter's claim.

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cuss highly relevant evidence from [the petitioner's] primary treating physician.").

II.

The majority first determines that the Claims Court incorrectly read *Andreu* to mean that a special master is prohibited from making any credibility determinations in its causation analysis. It is debatable whether the Claims Court interpreted *Andreu* as creating such an absolute principle, or whether it merely believed that the credibility determinations in this case were improper because they were used in an attempt to mask the special master's personal preferences. Even accepting the majority's characterization, the Claims Court's reading of *Andreu* is understandable, given that we unambiguously stated in that decision that "[a] trial court makes a credibility determination in order to assess the candor of a fact witness, *not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence*." *Andreu*, 569 F.3d at 1379 (emphasis added) (citing *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1373-74 (Fed. Cir. 2010) (Plager, J., dissenting)).

The Claims Court in this case, of course, did not have the benefit our subsequent decision in *Moberly v. Secretary of Health and Human Services*, 592 F.3d 1315, at 1325-26 (Fed. Cir. 2010). In *Moberly*, we clarified *Andreu* and explained that special masters must make determinations about the reliability of evidence, including expert testimony, which "often turn on credibility determinations, particularly where . . . there is little supporting evidence for the expert's opinion." *Id.* at 1326. We also explained that "[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, *if appropriate*, as to the credibility of the persons presenting that evidence." *Id.* (emphasis added).

Based on its reading of *Moberly*, as well as statements in two other cases in which we have endorsed the concept of a special master making credibility determinations, the majority finds that the Claims Court erred in setting aside the special master's findings. Majority Slip. Op. 14-15 (citing *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010); *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010)). The majority draws from these cases that "this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act." Majority Slip Op. 14.

I disagree with the majority's characterization of our case law for two reasons. First, the explicit statement in *Andreu* that credibility determinations are more appropriate for fact witnesses than for experts must retain some vitality. The decision in *Moberly* was by a three-judge panel, not by the court sitting en banc, and, as a procedural matter, could not have discarded that principle.[5] Second, the majority in this case overstates the holding of *Moberly* by saying that "special masters are *expected to consider the credibility* of expert witnesses" in Vaccine Act cases. Majority Slip Op. 14 (emphasis added). That is not what *Moberly* says. Rather, the panel in *Moberly* explained that special masters are expected to consider *reliability*, which often turns on credibility,

[5] To the extent that *Moberly* conflicts with *Andreu*, the holding of the earlier panel decision would control. *See e.g.*, *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1579 (Fed. Cir. 1989) ("Where conflicting statements . . . appear in our precedent, the panel is obligated to review the cases and reconcile or explain the statements, if possible. If not reconcilable and if not merely conflicting dicta, the panel is obligated to follow the earlier case law which is the binding precedent").

particularly where there is a dearth of evidence supporting the expert's opinion. *Moberly*, 592 F.3d at 1326. Thus, as we stated in *Moberly*, credibility can be considered "if appropriate." *Id.* In other words, the majority takes our statements that credibility assessments of experts are permissible in Vaccine Act cases and interprets them to mean that credibility assessments are expected. That is not the law, and it invites, or at least tolerates, the very mischief that occurred in these cases.

Indeed, our post-*Moberly* decisions demonstrate that the majority's interpretation is erroneous. In *Broekelschein*, we expressly stated that, "[i]n general, when two expert witnesses, both highly qualified, dispute an issue of medical fact with supporting and contradictory evidence, *it is immaterial whether one witness makes a better appearance on the stand*." 618 F.3d at 1349 (emphasis added). In that case, the majority excused the error of the special master (who was the same special master as in the present cases), finding that it was harmless even "[t]hough the special master may have improperly considered Dr. Greenberg's demeanor." *Id.* Here, there is no dispute that Dr. Bellanti was well-qualified, yet the special master nonetheless made extensive findings about his demeanor and body language. *Special Master Porter Op.* at *29-30. He even went so far as to draw what he called a "reasonable inference" based on Dr. Bellanti's demeanor that Dr. Bellanti "was aware that his opinion was flawed, yet he chose to provide it anyway." *Id.* at *30. That constitutes legal error, even under our post-*Moberly* case law.

Given that the special master made such a universal demeanor-based "inference" that Dr. Bellanti offered a knowingly flawed opinion, it is difficult to review his decision without the taint of this pervasive legal error, particularly in light of his numerous other "credibility"

assessments. It is not surprising, therefore, that the Claims Court would simply discard the special master's findings in their entirety and render its own findings in the first instance. While I understand the temptation to reach that result, I agree with the majority that our case law does not justify that blanket approach. Nonetheless, we cannot overlook, as the majority does, the many places in which the special master's "demeanor" or "credibility" assessments were improper. Considering those legal errors, and the special master's other arbitrary and capricious findings identified below, application of the proper standard of review leads to the same conclusion the Claims Court reached. With that background, I now turn to the merits of Ms. Porter's claim.

III.

Because Ms. Porter seeks compensation for an off-table injury, she must prove by preponderant evidence that the hepatitis B vaccine brought about her AIH by providing: "(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 & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). A petitioner that satisfies this burden is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

In establishing causation, a petitioner's medical or scientific explanation need only be "legally probable, not medically or scientifically certain." *Moberly*, 592 F.3d at 1322 (quoting *Knudsen*, 35 F.3d at 548-49). A petitioner

is not required to provide medical literature or epidemiologic studies linking the vaccine to the injury, as that would raise impermissibly the petitioner's burden and preclude the use of circumstantial evidence permitted under the Vaccine Act compensation program. *Andreu*, 569 F.3d at 1378; *Althen*, 418 F.3d at 1280. Nor is a petitioner required to demonstrate a "general acceptance in the scientific or medical communities." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). "[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," even if the possible link between the vaccine and the injury is "hitherto unproven." *Althen*, 418 F.3d at 1280. Under the vaccine compensation system created by Congress, "close calls regarding causation are resolved in favor of injured claimants." *Id.* (citing *Knudsen*, 35 F.3d at 549).

In this case, the special master based his decision as to each of the three *Althen* prongs on improper credibility determinations, arbitrary findings, or erroneous applications of law. As explained below, the petitioners demonstrated a medical theory causally connecting the hepatitis B vaccine to AIH, namely that, because the hepatitis B virus itself can cause AIH, it is more likely than not that the hepatitis B vaccine can cause AIH. Ms. Porter also satisfied the second and third *Althen* prongs because tests revealed that her liver enzyme levels spiked shortly after receiving her third hepatitis B vaccine dose, an indication of AIH, which the unrebutted evidence showed was a medically appropriate timeframe for the occurrence of such injuries. Finally, the government failed to meet its burden of proving that Ms. Porter's use of minocycline more likely than not caused her AIH because Ms. Porter's AIH did not improve after discontinuing use of mino-

cycline, a known characteristic of drug-induced hepatitis. As explained in more detail below, the special master's findings as to each of these issues fail to survive even our generous standard of review.

A.

With respect to the first prong of *Althen*, we have stated that it would be inconsistent with the Vaccine Act's compensation program "to require identification and proof of specific biological mechanisms." *Knudsen*, 35 F.3d at 549. Even a possible link between a vaccine and an injury that has not been proven, and in which there is an absence of direct proof, is sufficient. *Althen*, 418 F.3d at 1280. In this case, petitioners advanced several theories causally connecting the hepatitis B vaccine to AIH, only one of which is necessary to satisfy this prong. At a minimum, the evidence showed that, because the hepatitis B virus itself can cause AIH, it is more likely than not that the hepatitis B vaccine can cause AIH.

The special master rejected Dr. Bellanti's theory because he found there was no support for the underlying premise – i.e., that the hepatitis B virus itself can cause AIH. In doing so, however, the special master held Dr. Bellanti to a heightened burden on this point. In his expert report, Dr. Bellanti stated that "infection with hepatitis B virus is known to cause automminue hepatitis." Joint Appendix ("J.A.") 123. The special master latched onto Dr. Bellanti's statement that the causation "is known" and focused more on disproving Dr. Bellanti's precise statement than on applying the correct legal standard, which does not require the theory to be "known." Indeed, in his special "Additional Comments Regarding Dr. Bellanti," the special master found that, "[a]lthough Dr. Bellanti states this fact 'is known,' a preponderance of the evidence indicates that *Dr. Bel-*

lanti's statement was in error." *Special Master Porter Op.*, at *23 (emphasis added); *see also id.* at *12 (noting that lack of citations in the report "seems inconsistent with a fact that Dr. Bellanti asserts 'is known.'"). But it is irrelevant whether Dr. Bellanti is correct that the link is "known"; the relevant inquiry is whether a preponderance of the evidence supports this theory, whether or not it is medically certain or generally accepted in the scientific community. *See Moberly*, 592 F.3d at 1322 (quoting *Knudsen*, 35 F.3d at 548-49); *Capizzano*, 440 F.3d at 1325. Accordingly, to the extent the special master focused on whether the causal connection between the hepatitis B virus and AIH "is known" rather than on the correct legal standard, the special master applied an impermissibly strict burden on petitioners.[6] That error alone warrants setting aside his findings.

In addition to the special master's error in holding petitioners to a heightened burden, the special master's factual findings also are arbitrary and capricious. In support of his assertion that the hepatitis B virus could cause AIH, Dr. Bellanti relied on a medical textbook entitled *The Autoimmune Diseases* (Noel R. Rose and Ian R. Mackay, eds., 3d ed. 1998). The special master found that this textbook "appears to supports [sic] Dr. Bellanti's assertion." *Special Master Porter Op.*, at *12. He also noted that "[n]ormally, a textbook would be a reliable basis for a statement." *Id.* at *24.

The special master, however, took the extraordinary step of discounting unequivocal statements in a textbook

[6] Although the special master also concluded that a preponderance of the evidence does not support that the hepatitis B virus can cause AIH, presumably applying the correct standard, it is difficult to separate this statement from the special master's otherwise improper legal burden.

based on the fact that the articles which the textbook cites are dated in 1989 and 1984.[7] Even more remarkable, the special master discounted one of the articles, which was written in German, because he found that it involved chronic hepatitis B, not AIH, a finding that was based on testimony from a witness who admittedly could not even read the article. Specifically, the special master cited the testimony of the government's expert, Dr. Raymond Koff, for his finding that "[t]he patient in the German study actually had chronic hepatitis B, not autoimmune hepatitis." *Id.* at *12. But Dr. Koff testified about only one of the four cases discussed in the article, and he admitted that he reached his conclusion "without going through the text in German." J.A. 1005. He then stated that, "[t]he other three I need more information about. *I need a translation*." *Id.* (emphasis added).[8] I can conceive of

[7] The government's expert, Dr. Burton Zweiman, criticized Dr. Bellanti for relying on the third edition of this textbook instead of the fourth edition, but he failed to introduce the fourth edition to support his point. *See Special Master Porter Op.*, at *12 n.6 ("[T]o the extent that Dr. Zweiman is implying that the third edition of the Rose and Mackay textbook is out-of-date and that the fourth edition eliminates any mention of the hepatitis B virus, respondent should have submitted the corresponding chapter, chapter 26, from the fourth edition."). There is no indication that the fourth edition also did not cite these same articles from 1989 and 1984.

[8] Portions of Dr. Koff's testimony also reflect a general bias against finding problems with the hepatitis B vaccine, as he is concerned about inviting a flood of claimants. *See Rotoli* J.A. 977 ("But what worries me the most is if we accept this notion that hepatitis B vaccine, which has this extraordinary safety record, can induce, cause, aggravate, whatever, we are going to be inundated with people who will make claims, and I think it would not be good precedent to set."). The special master did not question Dr. Koff's admitted bias when evaluating his

nothing more arbitrary than rejecting medical literature, cited in a medical textbook, based on the testimony of a witness who did not, and could not, read the text of the literature. Even our deferential review does not permit such a conclusion, and I cannot agree with the majority that this represents "a thorough and careful evaluation of all of the evidence." Majority Slip Op. 20.

In addition to this textbook, which on its face supported Dr. Bellanti's medical theory, Dr. Bellanti also relied on two other articles that, according to the special master, "seem to offer some modest support for his assertion." *Special Master Porter Op.*, at *12. One article described the case study of a 26-year old man who received a Twinrix vaccine, which is a vaccine for both hepatitis A and hepatitis B, that resulted in an acute exacerbation of his pre-existing AIH. *See* Antal Csepregi, et al., *Acute Exacerbation of Autoimmune Hepatitis Induced by Twinix*, 11 World J. Gastroenterol, 4114-4116 (2005) (the "Csepregi article"). The second article reported a case study about a child with both AIH and hepatitis B, which the authors said "strengthens the possibility that hepatitis B virus may also act as a trigger for this rare autoimmune disease [AIH]." Valerio Nobili, et al., *Co-occurrence of Chronic Hepatitis B Virus Infection and Autoimmune Hepatitis in a Young Senegalese Girl*, 18 Eur. J. Gastroenterol Hepatol., 927-29 (2006) (the "Nobili article").

Although the special master found that these articles supported Dr. Bellanti's theory, the special master discounted them because he felt they lacked a meaningful causation analysis. He also found that, because they involved single case studies, "ruling out a possible coinci-

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testimony, apparently reserving all credibility assessments for Dr. Bellanti alone.

dence is impossible." *Special Master Porter Op.*, at *13. In rejecting the persuasiveness of these studies, the special master relied on the testimony of the government's expert, Dr. Zweiman, despite the fact that Dr. Zweiman testified that he would require "suitable epidemiologic evidence" before accepting the theory that the hepatitis B vaccine can cause AIH. J.A. 586. Dr. Zweiman's strict standard of proof, however, is in direct conflict with our case law. *See Capizzano*, 440 F.3d at 1325 ("[R]equiring . . . epidemiologic studies . . . is contrary to what we said in *Althen*.").

The special master then credited an article written by a Dr. Krawitt to find against petitioners. In describing potential causes for AIH, the article explained that the most convincing evidence of viral infections leading to AIH "is related to the *hepatitis viruses*." *See* Krawitt, *Autoimmune Hepatitis*, 354 N Eng. J. Med. 54-66 (2006) (the "Krawitt article") (emphasis added). Although the text of the article on its face actually supports Dr. Bellanti's theory, the special master looked beyond the text to find significance in the types of studies cited in footnotes to support that statement, which consisted of three studies involving patients with hepatitis A or hepatitis C viruses.

The special master's decision to credit the Krawitt article over the Rose and Mackay textbook, the Csepregi article, and the Nobili article is arbitrary and capricious. First, the Krawitt article does not even directly address the hepatitis B virus and, if anything, supports that hepatitis B may be a cause because it refers generally to "the hepatitis viruses" causing AIH. The special master concluded that omitting hepatitis B was "intentional," but that conclusion is devoid of any support. Put simply, nothing was "omitted"; rather the Krawitt article makes a blanket statement that "the hepatitis viruses" may cause

AIH, then cites three studies in a footnote at the end of the article to support that proposition. Although these studies involve hepatitis A and hepatitis C viruses, suggesting that there was an "omission" that was "intentional" reads a conclusion into the article that is simply absent.

The special master's only support for his conclusion is the testimony of the government's expert, Dr. Koff, who said that he spoke to Dr. Krawitt *between hearing sessions* and learned in these out-of-court discussions that Dr. Krawitt is not aware of the hepatitis B virus causing autoimmune hepatitis. *Special Master Porter Op.*, at *14. Like the Claims Court, I am "deeply suspicious" of these discussions. *Rotoli*, 89 Fed. Cl. at 86 n.18. If the government had testimony from Dr. Krawitt, it should have presented it directly rather than relying on belated out-of-court discussions between hearing sessions. Even accepting Dr. Krawitt's statements, the fact that Dr. Krawitt, or anyone in the field for that matter, is not aware of a possible link between a vaccine and an injury does not preclude a finding of causation as a matter of law. *See Althen*, 418 F.3d at 1280 (allowing a finding of causation even if the possible link between the vaccine and the injury is "hitherto unproven"); *cf. Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 436 (6th Cir. 2009) (Boggs, C.J., dissenting) ("Of course, the absence of evidence is not the same as evidence of absence.").

In short, the special master discredited a medical textbook (in part based on testimony from a witness who could not read one of the underlying articles) and two case studies supporting Dr. Bellanti's theory. Instead, he found against the petitioner based on an article that on its face also supports Dr. Bellanti's theory by placing great weight on an imagined omission. Even putting aside that the special master imposed an improper burden on peti-

tioners to show what "is known" about causation, these findings warrant reversal.

It is important to remember that a petitioner is not required to produce medical literature definitively linking the vaccine to the injury. *Althen*, 418 F.3d at 1280. Circumstantial evidence is both appropriate and sufficient to demonstrate causation, including where the link between a vaccine and an injury is previously unknown and without direct evidence supporting causation. Here, there can be no dispute that the petitioners' evidence meets that standard, and the special master's reliance on an alternative article that is, at most, silent on the issue exceeds the scope of his authority. This is particularly true given that the special master dismissed Dr. Bellanti's opinion in its entirety through an improper assessment of his "demeanor."

While I am sensitive to our standard of review – i.e., that this court is not to reweigh evidence or assess the special master's evaluation of evidence, we also are not required to affirm a special master's findings that are wholly implausible. Because the special master's findings in this case rise to that level, I would find that the petitioners have satisfied the first prong of *Althen*.

B.

The government does not focus on the second and third *Althen* prongs – which relate to the logical sequence of cause and effect and the temporal proximity between the vaccine and injury – in arguing that independent grounds unrelated to credibility support the special master's rejection of Ms. Porter's claim. *See* Appellant's Br. 10 ("In Porter's case, the special master primarily based his decision on two separate and independent rationales," identifying *Althen* prong one and the alternative cause of minocycline). Likewise, the majority's findings in sup-

port of the special master do not address these two prongs. There is perhaps good reason for that, as the special master's findings on these points are perhaps the most egregious of his decisions. Here, the special master held Ms. Porter to an unreasonably strict burden by requiring her to identify the specific date of the onset of her disease, rather than a medically appropriate time-frame, to demonstrate a relationship between her vaccine and her injury. At the same time, the special master himself recognized that the particulars of Ms. Porter's AIH made such a specific finding virtually impossible. Based on this unreasonable standard, the special master rejected Dr. Bellanti's unrebutted testimony as being too "vague." The special master's findings on this point must be overturned because they are not in accordance with our well-established law.

The majority recites the undisputed facts showing the strikingly close connection between the dates of Ms. Porter's hepatitis B vaccine doses and the date of her blood tests showing abnormal liver function. Majority Slip Op. 3-4. A few points are worth emphasizing. A blood test taken the same day Ms. Porter received her first dose of the hepatitis B vaccine, which was also two months after she was ordered to finish off and discontinue use of the drug minocycline, revealed that her liver functions were normal. Over the next seven months, Ms. Porter received her second and third doses of the hepatitis B vaccine. Less than one month after receiving her third dose of the vaccine, Ms. Porter's blood tests showed that her liver enzymes were elevated well beyond the normal range. Three tests within the next 17 days all revealed the same elevated liver enzyme levels. During that time, Ms. Porter began feeling nauseated, itching, and turning yellow. Later blood work and a liver biopsy both revealed results consistent with AIH.

Dr. Bellanti testified that a reasonable time to expect AIH to develop following a hepatitis B vaccination is between 14 and 40 days. In his expert report, he concluded that "[t]he temporal relationship between her immunizations and the onset of symptoms is medically appropriate . . . ." J.A. 126. The undisputed facts of this case fully support Dr. Bellanti's opinion. The blood test run on the date of Ms. Porter's first hepatitis B vaccine showed normal liver enzyme levels, and a blood test taken 24 days after Ms. Porter's third hepatitis B vaccine dose revealed elevated liver enzymes. This 24-day period fits squarely within Dr. Bellanti's 14 to 40 day timeframe.

There is no indication in the record that the government challenged this testimony or offered any evidence to contradict it, and the special master did not rely on any contrary evidence to reject Dr. Bellanti's theory on this issue. Rather, the special master found that Dr. Bellanti's testimony was "vague" and faulted Dr. Bellanti because he "simply does not know the date of onset." *Special Master Porter Op.*, at *16-17. At the same time, however, the special master acknowledged that "Dr. Bellanti's lack of knowledge is justified because the available information prevents anyone from establishing when the disease began." *Id.* at *17 n.8. He also found that "determining the onset of Ms. Porter's autoimmune hepatitis is difficult, *if not impossible*, due to the disease's insidious onset." *Id.* at *17 (emphasis added). Nonetheless, the special master required Ms. Porter to establish the specific "date" her AIH began, finding that, "[i]f she does not establish the *date* her disease began, she cannot establish the interval between a vaccination and the onset of her disease." *Id.* (emphasis added) (citing *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006)).

The special master's decision is plainly erroneous. It

is well-established in our case law that the proximate temporal relationship between the vaccine and injury must only be within a "medically acceptable" timeframe. *See de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (stating that the standard 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"); *Althen*, 418 F.3d at 1281 (referring to a "medically-acceptable temporal relationship"). Indeed, even the case to which the special master cites to support his conclusion refers to a "medically acceptable time frame for the onset of the disease following the vaccination," not a specific date. *Pafford*, 451 F.3d at 1358. By requiring Ms. Porter to identify a specific date of onset for her disease, which the special master acknowledged was nearly impossible, the special master held Ms. Porter to an unreasonably high standard. Using this improper standard to reject Dr. Bellanti's unrebutted testimony was erroneous, and the special master's findings on this issue should be set aside.

C.

Because Ms. Porter has met all three *Althen* prongs, she has established causation. *Althen*, 418 F.3d at 1278. Therefore, she is entitled to compensation unless the government can show by preponderant evidence that her AIH is due to factors unrelated to the vaccine. *Althen*, 418 F.3d at 1278; *see also* 42 U.S.C. § 300aa-13(a)(1)(B). The special master found that the government met its burden of proving that Ms. Porter's use of minocyline was more likely than not the cause of her AIH, a finding that the majority affirms. The special master's finding on this point again is erroneous, for the three independent reasons discussed below, and must be reversed.

First, contrary to the majority's statement that the special master did not make credibility determinations to reach his conclusions on this issue, the special master expressly and improperly assessed Dr. Bellanti's demeanor in evaluating the evidence about Ms. Porter's use of minocycline. Specifically, in determining that Dr. Bellanti's demeanor reinforced doubts about his credibility, the special master noted that Dr. Bellanti "appear[ed] uncomfortable when asserting that the history of Ms. Porter's autoimmune hepatitis shows that the hepatitis B vaccine, not the minocycline, caused her disease." *Special Master Porter Op.*, at *30. This was one of ten findings the special master used to draw the "reasonable inference" that Dr. Bellanti deliberately offered a flawed opinion. Given our statement that it is generally inappropriate to rely on demeanor to discount the testimony of an otherwise qualified expert, *Broekelschen*, 618 F.3d at 1349, the special master's evaluation of Dr. Bellanti's demeanor on this question again ran afoul of our case law.

Second, the special master erroneously placed the burden on Ms. Porter to *disprove* that minocycline was an alternative cause, rather than placing the burden on the government to prove its case affirmatively. Although both sides agreed that minocycline can cause hepatitis, Dr. Bellanti opined that minocycline did not cause Ms. Porter's AIH because her condition did not improve when she stopped taking minocycline, a characteristic of drug-induced hepatitis that is supported by medical literature. The facts supporting Dr. Bellanti's theory are undisputed. *See Special Master Porter Op.*, at *21 ("The factual predicate for Dr. Bellanti's opinion is accurate. Ms. Porter discontinued using minocycline. After this time, Ms. Porter's hepatitis did not improve."). Dr. Bellanti also stated that only in rare cases does hepatitis persist and become chronic after discontinuance of the drug.

In light of this evidence, it should have been the government's burden to show that Ms. Porter was the rare exception to the general rule that an individual's condition will improve after stopping use of the drug. But the special master flipped the burden by placing it on Ms. Porter, faulting Dr. Bellanti for not explaining why Ms. Porter was *not* one of the rare cases. *See id.* ("Although Dr. Bellanti was asked to explain why Ms. Porter was not one of these rare cases, he failed to answer the question and provided no basis for distinguishing Ms. Porter's case from other cases reported in the literature."). By misplacing the burden on this issue, the special master's decision is contrary to the statutory scheme and to our case law, an error that the majority overlooks.

Finally, the special master's findings must be set aside because he used a clear double-standard when evaluating whether the government met its burden of demonstrating that minocycline was the alternative cause of Ms. Porter's AIH. We have explained that "the standards that apply to a petitioner's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549. Despite this rule, the special master held Ms. Porter to a higher standard than the government on identical issues in two specific findings.

First, although the special master found that Dr. Bellanti's inability to identify a specific date of onset for Ms. Porter's injury was fatal to her claim, he excused the government from this exacting standard. When he considered whether the government made the same impossible showing that Dr. Bellanti could not make, the special master found summarily that, "[t]he temporal window, despite the inherent uncertainty in stating when the hepatitis began, is appropriate." *Special Master Porter*

Op., at *22. This finding is in stark contrast to his finding on the same issue that, "[i]f [Ms. Porter] does not establish the date her disease began, she cannot establish the interval between a vaccination and the onset of her disease." *Id.* at *17. There is no evidence the government established the date Ms. Porter's disease began, yet that failing was not fatal to the government's ability to show an alternative cause, as it was to Ms. Porter.

In addition, the special master also considered the significance of single case studies supporting the government's position while summarily discounting single case studies that supported Dr. Bellanti's theory of causation. Here, the government relied on examples in the medical literature where an individual's hepatitis continued after stopping use of minocycline to show that Ms. Porter's AIH was more likely than not cause by minocycline. The special master found these significant, noting that "special masters are not to discount the possibility that a statistically rare event actually occurred in a particular case." *Id.* at *21. When Dr. Bellanti submitted articles to support his theory that the hepatitis B virus itself can cause AIH, however, the special master rejected these case studies because they were single studies, such that "ruling out a possible coincidence is impossible." *Id.* at *13. The special master, therefore, treated the government's examples as "statistically rare event[s] [that] actually occurred" but found that Ms. Porter's examples were mere "coincidence." *Id.* at *13, 21. Applying different standards to the identical types of evidence offered by Ms. Porter and the government without explanation is, by definition, arbitrary and capricious. If that standard is to mean anything short of unfettered discretion, the special master's decision on this point cannot stand.

IV.

Despite the special master's inappropriate credibility assessments, arbitrary findings, and application of erroneous legal standards in his decisions in these cases, I agree with the majority that the special master's rejection of Ms. Rotoli's claim rests on independent grounds that are within the proper scope of his discretion. Specifically, the special master's finding that Ms. Rotoli failed to meet the third *Althen* prong based on Ms. Rotoli's liver biopsy is not arbitrary and capricious. Dr. Koff testified that Ms. Rotoli's liver biopsy showed such an advanced stage of fibrosis that she must have had the disease for many years, but the biopsy was taken only eight months after her first dose of the hepatitis B vaccine. On the other hand, Dr. Bellanti did not opine that the fibrosis seen on Ms. Rotoli's liver could have developed in as little as eight months. Based on this evidence, the special master was within his discretion to find that "[a] preponderance of the evidence establishes that Ms. Rotoli's autoimmune hepatitis began long before she received the hepatitis B vaccine." *Special Master Rotoli Op.*, at *17. I, therefore, agree with the majority that the Claims Court's decision should be reversed as to Ms. Rotoli's claim.[9]

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[9] I reach this conclusion despite the special master's inappropriate credibility assessments of Dr. Bellanti as to this prong. *See id.* ("Dr. Bellanti lacked credibility about when the autoimmune hepatitis began . . . . Dr. Bellanti's demeanor when he testified suggested, at a minimum, that he lacked confidence in his statement. At worst, his demeanor suggested that he was not truthful."). Even though the special master's demeanor assessments were in error – indeed, glaringly so – the evidence of Ms. Rotoli's liver biopsy, and Dr. Koff's testimony interpreting that biopsy, were independently sufficient to support the special master's conclusion.

V.

For the foregoing reasons, although I agree with the majority as to Ms. Rotoli's claim, I would affirm the Claims Court with respect to Ms. Porter's claim, finding that she is entitled to compensation. I cannot join the majority in endorsing the special master's pervasive errors in his "credibility" and "demeanor" assessments, the erroneous legal standards he applied at several steps in his analysis, and his double standard in evaluating the parties' respective evidence. Accordingly, I respectfully dissent as to that portion of the majority opinion.