In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 09-0039V
Filed: April 7, 2014
(TO BE PUBLISHED)[1]

AMY CRUTCHFIELD, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Vaccine Act Entitlement; Causation-in-fact; MMR vaccine; Diabetes Type I

John F. McHugh, New York, NY, for Petitioner.

Michael P. Milmoe, U.S. Department of Justice, Washington, D.C., for Respondent

DECISION

HASTINGS, ***Special Master***

This is an action in which the Petitioner, Amy Crutchfield, seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[2]), because Petitioner believes that the measles-mumps-rubella ("MMR") vaccination that she received on January 26, 2006, caused her to develop Type 1 diabetes. For the reasons set forth below, I conclude that the Petitioner has failed to demonstrate that the vaccination contributed in any way to the causation of her Type 1 diabetes.

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[1] Because I have designated this document to be published, this document will be made available to the public unless petitioner files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." *See* 42 U.S.C. §300aa-12(d)(4)(B); Vaccine Rule 18(b).

[2] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2006). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table" corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table.[3] If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1278; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the *sole* cause or even the *predominant* cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

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[3] As will be detailed below, no Table Injury is alleged in this case.

> Concisely stated, Althen'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. If Althen satisfies this burden, she 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."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting the petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program factfinder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program factfinders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), discussed the circumstances under which determination concerning an expert's "credibility" may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11 v. HHS*, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the *reliability* of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in

evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert's* factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases. One of the factors listed in *Daubert* is whether the scientific theory "has been subjected to peer review and publication." 509 U.S. at 593. The Court noted that while publication does not "necessarily" correlate with reliability, since in some instances new theories will not yet have been published, nevertheless "submission to the scrutiny of the scientific community is a component of 'good science,'" so that the "fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity" of a theory. *Id*. at 593-94.

II

FACTS AND PROCEDURAL HISTORY

A. Facts[4]

Amy Crutchfield was born on October 17, 1970. (Petition at ¶3.) During her childhood, she received the vaccinations typically recommended; including the live measles vaccine on October 18, 1971, with a booster measles vaccine on May 24, 1978; the mumps vaccine on May 21, 1972; and the rubella live virus vaccine on January 31, 1972. (Ex. 7, p. 119.)

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[4] Petitioner filed Exhibits 1 through 7 with the petition, and filed Exhibits 8 through 84, and 100 through 102, on several occasions thereafter. Respondent filed Exhibits A through Z, AA through OO, and AAA through NNN, at various times. "Ex." references will be to those exhibits. "Tr." references will be to the pages of the transcript of the evidentiary hearing held on March 30, 2011.

It should be noted that both parties sometimes assigned the same exhibit number or letter to more than one document in the record. Specifically, there is more than one version of Exhibits 1 through 8, and more than one version of Exhibits A through T. In this Decision, all references to Exhibits 1 through 7 will pertain to Petitioner's Exhibits 1 through 7 filed in paper format on January 16, 2009. All references to Exhibits A through G, will pertain to the *expert reports* and *curriculum vitae* filed on several occasions.

On March 31, 2009, and July 17, 2009, Petitioner filed a total of 69 *medical articles*, as addenda to Dr. Shoenfeld's expert report. These items were sometimes identified as "Exhibits" 1-69 by the parties, which may result in confusion due to the repetition of certain exhibit numbers (*i.e.* – numbers 1-8.). In this Decision, I will refer to any *medical articles* labeled as duplicate Exs. 1 through 8 as "Article 1," "Article 2", etc. Petitioner later filed additional medical articles as Exs. 70-80 on May 12, 2011.

On August 21, 2009, Respondent filed Exhibits A to Z and AA to OO, which are medical articles relevant to Dr. Bercu's expert report. Some of the letters of identification (*i.e.* – letters A through G) had previously been used to identify other exhibits. Moreover, Respondent later filed, on August 4, 2011, additional medical articles, labeled as Exs. H through T, creating further duplication of exhibit identification. Accordingly, when referring to *medical articles* filed by Respondent, I will refer to the exhibit letter followed by the date of filing (either 8-21-09 or 8-4-11).

Likewise, both parties sometimes passed over the next consecutive number or letter, leaving gaps in their exhibit lists. For example, there are no Petitioner's Exhibits 85 through 99, and no Respondent's Exhibits PP through ZZ.

While this case was pending, the U.S. Court of Federal Claims implemented a transition in document format from paper to electronic format. Therefore, the docket of this case lists some exhibits that were filed via paper, some that were filed as electronic documents, and some filed on compact discs.

In the course of routine health care as an adult, occasionally Ms. Crutchfield's blood glucose was tested. Prior to 2006, Ms. Crutchfield did not experience any significant problems with her health. (Ex. 6, pp. 93-113.)

During a medical visit on October 5, 2005, Ms. Crutchfield reported that she was trying to conceive a child. (Ex. 6, p. 93.) Her gynecologist, Dr. Julie Beyers, examined Ms. Crutchfield on December 15, 2005, and recorded "normal exam." (Ex. 2, p. 4.) That evaluation included laboratory blood tests, which revealed her lack of immunity to measles (Ex. 2, p. 9), an "equivocal" immune response to mumps, and a response to rubella indicating immunity. (Ex. 2, p. 6.) A repeat blood test on January 6, 2006, produced an "equivocal" result for measles, a "non-immune" result for mumps, and a result for rubella again indicating immunity. (Ex. 2, p. 11.) As part of her pre-conception planning, therefore, Ms. Crutchfield received a measles-mumps-rubella ("MMR") vaccination on January 26, 2006,[5] when she was 35 years old. (Ex. 4, p. 19.)

On April 4, 2006, Dr. Beyers noted that Ms. Crutchfield had used Monistat to self-treat an episode of vaginal pruritis, about two weeks previously. Since that problem persisted, Dr. Beyers prescribed treatment with Diflucan. (Ex. 2, p. 10.) On April 20, and May 4, 2006, Dr. Beyers noted recurrent episodes of pruritis and subsequent treatments for a vaginal yeast infection. (Ex. 2, pp. 13, 16.) According to laboratory analysis, by May 5, 2006, there were no indications of any urogenital infections present. (Ex. 2, p. 18). Dr. Beyers commenced treatment of Ms. Crutchfield with Clomid, on May 30, 2006, to promote fertility.

Ms. Crutchfield visited her internist, Dr. Orli Etingin, on June 19, 2006, to report a problem with increased thirst, unintentional weight loss, and hair loss, over the past three to four months. (Ex. 6, p. 90.) Based on her own internet research of these symptoms, Ms. Crutchfield states, she insisted on blood tests to determine whether she had diabetes. (Pet. at ¶17, 18.) Tests performed at that time indicated that Petitioner was, in fact, suffering from diabetes.

Dr. Carol Levy, an endocrinologist, evaluated Ms. Crutchfield on June 23, 2006, and described her as a thirty-five-year-old female with a family history of autoimmune issues, who complained of three months of recurrent yeast infections and weight loss. (Ex. 6, p. 79.) That family history included rheumatoid arthritis in her mother and aunt, myasthenia gravis afflicting her maternal grandmother, and celiac disease afflicting a maternal cousin. No one else in Ms. Crutchfield's family suffered from diabetes mellitus. (Ex. 5, p. 33.)[6] Dr. Levy's impression, on June 22, 2006, was Type 1 diabetes. (Ex. 5, p. 34.) She commenced treatment with insulin. (Ex. 5, p. 35.)

By July 5, 2006, Dr. Levy noted that Ms. Crutchfield's condition had improved; that is, her "sugars" were "better." (Ex. 5, p. 31.) Dr. Levy continued to provide regular care for

[5] Respondent acknowledges the administration of a MMR vaccination around January 26, 2006, but suggests that the actual date may have been two days earlier, on January 24, 2006. (Resp. Report at 3; Resp. Pre-Hearing Memo at 2.) The exact date, however, is not relevant--it is relevant only that she definitely received a MMR vaccination on or about January 26, 2006.

[6] The notes in the medical record at this cite are not easily legible. However, both Dr. Shoenfeld, for petitioner (Ex. 1, p. 2), and Dr. Bercu, for respondent (Ex. A, p. 2), agree on at least those aspects of the family history presented here.

Ms. Crutchfield's diabetic condition, and she prescribed continuous treatment via insulin pump, beginning in February 2007. (Ex. 6, p. 77; Ex. 5, p. 24.)

On January 24, 2011, Dr. Noel Maclaren, respondent's expert, recommended that certain laboratory tests of Ms. Crutchfield's blood be performed, to determine for certain whether she suffered from Type 1 or Type 2 diabetes. (Ex. F, p. 2.) These tests were performed on January 31, 2011, and the results, submitted as Exs. 101 and 102, confirmed that Petitioner suffered from Type 1 diabetes.

B. Procedural history

Petitioner filed her Program petition on January 16, 2009, along with the expert report of Dr. Yehuda Shoenfeld (Ex. 1) and various medical records (Exs. 2-7). The case was assigned to Special Master Richard Abell. The petition alleged that the measles-mumps-rubella ("MMR") vaccination that Petitioner received on January 6, 2006, caused her to develop diabetes. Respondent filed a "Rule 4 report" and an expert report of Dr. Barry Bercu on May 8, 2009 (Ex. A), contending that compensation is not appropriate.

Dr. Bercu's report described Respondent's concern that the medical records were ambiguous as to whether Ms. Crutchfield's final diagnosis was Type 1 or Type 2 diabetes. He opined that if the correct diagnosis was actually Type 1 diabetes, then the expected latency period for the development of that disease was far too long to causally connect Petitioner's diabetes onset to the MMR vaccination of January 26, 2006. (Ex. A, pp. 3, 7.) Petitioner filed a second report by Dr. Shoenfeld, on July 6, 2009,[7] asserting that the correct diagnosis was, in fact, Type 1 diabetes, and arguing that in petitioner's situation the rapid onset of that disease would be consistent with vaccine injury because it was a "secondary" immunological response to the vaccine. Specifically, Dr. Shoenfeld characterized the onset of Type 1 diabetes in this case as an "anamnestic" response to Ms. Crutchfield's second exposure to the MMR vaccine components. On August 21, 2009, Respondent filed a large volume of medical articles, Tabbed from A to Z and AA to OO. On September 9, 2009, Respondent filed another report by Dr. Bercu (Ex. C), which reiterated his opinion that the typical period for the development of of Type 1 diabetes, before symptoms occur, is far longer than the time period between Petitioner's MMR vaccination on January 26, 2006, and the onset of Petitioner's diabetes symptoms one to two months later.

Given the complexities of this case, the parties were allowed additional time to file supplemental expert reports. (Order, Oct. 1, 2009.) Respondent indicated the desire to file the report of an additional endocrinologist. (Order, Dec. 10, 2009.)

On March 29, 2010, this case was reassigned to my docket, on account of the pending retirement of Special Master Abell.

Respondent filed the expert report of Dr. Noel Maclaren (Ex. D) on April 1, 2010, who opined that the appropriate diagnosis of Petitioner's condition was most likely Type 1 diabetes. Dr. Maclaren

[7] The "Reply Report" of Dr. Shoenfeld (ECF Doc. #11) is a paper document, without an exhibit number. I will refer to this report as "ECF #11." I have reviewed this very brief report of Dr. Shoenfeld, but it does not add anything of persuasive value to Petitioner's case.

repeated Dr. Bercu's opinion that Type 1 diabetes requires an extended period of time to develop into a symptomatic disease. Petitioner then submitted a letter (Ex. 100) from her treating endocrinologist, Dr. Carol Levy, who opined that Ms. Crutchfield suffered from Type 1 diabetes. On January 12, 2011, respondent filed another report of Dr. Maclaren (Ex. F), which proposed that certain laboratory tests could be performed that would distinguish for certain between Type 1 and Type 2 diabetes in Petitioner's case. Blood samples were drawn from Petitioner on January 31, 2011, and the results, filed as Exhibits 101 and 102, confirmed that she has Type 1 diabetes.

Pre-hearing memoranda were filed by both Respondent and Petitioner, on March 4 and March 7, 2011, respectively. An evidentiary hearing convened on March 30, 2011. Dr. Shoenfeld testified on behalf of Petitioner, while Drs. Maclaren and Bercu testified on behalf of Respondent. Various items of medical literature were introduced by Petitioner during the hearing. Petitioner filed copies of those medical articles, along with several others, on May 12, 2011. (*See* Articles 70 – 80.) Respondent was allowed to submit a response. (Order, June 28, 2011.) On July 18, 2011, Respondent filed the supplemental expert report of Dr. Maclaren (Ex. G), which discussed the medical literature recently filed by Petitioner. On August 4, 2011, Respondent also filed additional medical articles, intended to support Dr. Maclaren's supplemental report.[8]

On August 31, 2011, Petitioner filed a Post-Hearing Memorandum that summarized Petitioner's allegations concerning vaccine-causation of her diabetes. Respondent filed a Post-Hearing Memorandum on October 31, 2011. Within that document, respondent noted the publication of a new report by the Institute of Medicine ("IOM"), which had not been available at the time of the evidentiary hearing. (*See* Resp. Post-Hearing Memo, p. 11.) Respondent argued that the IOM report was highly relevant to the Crutchfield case because it specifically examined the issue of a possible causal relationship between the *MMR vaccine* and Type 1 diabetes. On January 31, 2012, respondent filed a motion to introduce that IOM report, with a copy of the relevant portion attached, labeled as Ex. NNN.[9]

On February 13, 2012, petitioner filed an "Objection" to the inclusion of Exhibit NNN in the record of this case. On May 14, 2012, I filed an abbreviated Ruling, that Exhibit NNN would be considered as part of the evidentiary record in this case.

In response to the filing of Ex. NNN, the IOM report, Petitioner was permitted to file another report by Dr. Shoenfeld, on October 27, 2012, which critiqued the validity and relevance of the 2011 IOM Report. (Ex. 84.) Petitioner was also allowed additional time to file a reply to the Respondent's post-hearing brief. Finally, on April 18, 2013, Petitioner filed a Reply to Respondent's Post-Hearing Memorandum.

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[8] The filing of medical articles and other exhibits in this case is summarized above in fn. 4.

[9] Respondent filed numerous medical articles on January 17, 2012, in support of the contentions set forth in Respondent's Post-Hearing Memorandum. These filings were identified as Exs. AAA – MMM. Those exhibits, however, played no significant role in my analysis of this case.

III

ISSUE TO BE DECIDED

In this case, Petitioner seeks a Program award, contending that she developed Type 1 Diabetes as a result of an MMR vaccination received on January 26, 2006. For the reasons set forth below, I conclude that Petitioner has *failed* to show that it is "more probable than not[10] that her MMR vaccination contributed to causing her diabetes.

IV

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS

In this case, each side relies upon the expert reports and hearing testimony of medical experts. At this point, I will briefly summarize the qualifications of those expert witnesses.

A. Petitioner's expert – Yehuda Shoenfeld, M.D.

Dr. Yehuda Shoenfeld graduated from the Hadassa Medical School, in Israel in 1972. He was appointed lecturer in internal medicine at the Tel-Aviv University Medical School in 1975, then advanced to senior lecturer in 1980. He received a diploma, *cum laude*, for his studies in internal medicine at the Postgraduate Medical School of Tel Aviv University in 1978. Beginning in 1976, he served as senior resident in the Department of Internal Medicine and the Out-Patient Clinic of Hematology and Immunology of Beilinson Medical Center in Israel. He conducted research in hematology and internal medicine there, and became head of those departments in 1985. Between 1976 and 1982, Dr. Shoenfeld also participated in clinical fellowships in hematology/oncology at City of Hope, in Duarte, California; at the Tufts New England Medical Center of Boston, Massachusetts; and at the Cornell Medical Center of New York. (Ex. 1, pp. 22-24)

In 1984, Dr. Shoenfeld became head of the Department of Medicine at the Sheba Medical Center of Tel-Aviv University, where he continued to serve at the time of his testimony in this case. He received an academic appointment as Associate Professor in 1985, then Professor of Medicine in 1990, at the Tel-Aviv University Medical School, Sackler Faculty of Medicine. Concurrently, he was the head of the Hybridoma Unit and Research Laboratory for Autoimmune Diseases of the Soroku Medical Center of Ben-Gurion University of the Negev. In that capacity, he founded the Center for Autoimmune Diseases, and continues to serve as its Director. (Ex. 1, pp. 1-2 and 22-24.)

Dr. Shoenfeld's *curriculum vitae*, as of 2006, listed over 1,200 professional articles, 43 books, and 130 chapters in medical texts, which he authored or co-authored, many of them focusing on autoimmune diseases. (Ex. 1, pp. 41-120.) He has served on the editorial boards of numerous medical journals, primarily concerning autoimmunology and rheumatic diseases. (Ex. 1, pp. 30-31.) He has also been an organizer of many medical conferences, and a member of numerous professional organizations, both in Israel and internationally. (Ex. 1, pp. 25-29.)

[10] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

In his testimony before this court, Dr. Shoenfeld described his ongoing clinical work as head of the Department of Medicine at the largest hospital in Israel, the Sheba Medical Center. In that capacity, over the previous 27 years, he collaborated with other specialists daily in treating all types of patients, including 15 to 20 percent who were diagnosed with diabetes mellitus. (Tr., pp. 5-7.)

B. Respondent's experts

1. Barry B. Bercu, M.D.

Dr. Barry Bercu received his medical degree at the University of Maryland in 1969. He performed his medical internship at Boston City Hospital in 1969-70, and his residency in pediatrics at the Massachusetts General Hospital in Boston, from 1970 to 1972. He served in the U.S. Air Force as a pediatrician in 1972-74. Dr. Bercu participated in two post-graduate research fellowships concurrently, between 1974 and 1977; one in pediatric endocrinology and metabolism at Massachusetts General Hospital, and the other in endocrinology at Tufts University Medical School in Boston. (Ex. A, p.1; Ex. B, pp. 2-4.) He is board-certified in the fields of pediatrics and pediatric endocrinology. (Tr., p. 161.)

Dr. Bercu joined the U.S. Public Health Service in 1974, as a senior surgeon, and continued in that role until 1984. In addition, beginning in 1977, he was appointed to a series of positions involving children's health at the National Institutes of Health ("NIH"). From 1982 to 1984, he served as head of the Pediatric Endocrine Unit of the NIH, while concurrently teaching as an Associate Research Professor of Child Health and Development at the George Washington University School of Medicine and Health Sciences. (Ex. B, p. 4.)

In 1984, Dr. Bercu began his affiliation with the University of South Florida College of Medicine, in Tampa, Florida, where he was still employed as a Professor at the time of his testimony in this case. During that time period, his area of specialization expanded from pediatrics, to include pharmacology and therapeutics. Along with this academic employment, Dr. Bercu maintained a clinical practice at the Tampa General Hospital and the Shriner's Hospital of Tampa. (Ex. B, pp. 2, 7.) He was also a participant in more than sixty medical and pharmaceutical research grants. (Ex. B, pp. 7-10.) Dr. Bercu has published the results of his scientific research in over 170 articles in medical journals, many of them focused on endocrine disorders. (Ex. B, pp. 14-23.) He holds several patents concerning growth hormones. (Ex. B, p. 10.)

2. Noel Maclaren, M.D.

Dr. Noel Maclaren received his medical degree at the University of Otago, in New Zealand, in 1963. His early medical training specialized in Medicine and Pediatrics, primarily at the Wellington Hospital in New Zealand, between 1963 and 1968. He also served as senior resident Medical Officer of the Queen Elizabeth Hospital for Sick Children, in London, in 1969. Dr. Maclaren participated in a Fellowship in Pediatric Endocrinology and Metabolism at the University of Maryland School of Medicine and Johns Hopkins School of Medicine, from 1972 to 1973. Between 1973 and 1978, he continued his practice in the fields of pediatrics, endocrinology, and metabolism as an Associate Professor at the University of Maryland School of Medicine. (Ex. E, pp. 1-2.) Dr. Maclaren became

board-certified in pediatrics in 1976, then received a certification in pediatric endocrinology in 1978. (Ex. E, p. 5.)

In 1978, Dr. Maclaren began his affiliation with the College of Medicine of the University of Florida, in Gainesville, as a Professor of Pathology and Pediatrics, then served as Chairman of the Department of Pathology from 1987 to 1997. In 1997, he was appointed Professor of Pediatrics at Louisiana State University College of Medicine, then became a Professor of Biometry and Genetics in 1998. Concurrently, Dr. Maclaren served as Director of the Research Institute for Children at the Children's Hospital of New Orleans, Louisiana, from 1997 to 1999. In 1999, he commenced five years of service as a Professor of Pediatrics at the Weill College of Medicine of Cornell University, in New York. During that same time period, Dr. Maclaren was Director of the Cornell Juvenile Diabetes Program, and a member of the medical staff at both the Rockefeller University Hospital and the Hospital of Special Surgery. From 2004 until the time of his testimony in this case, Dr. Maclaren was a Professor of Pediatrics at the Weill-Cornell College of Medicine and New York Hospital. (Ex. E, p. 2.)

In his testimony in this case, Dr. Maclaren stated that the emphasis of all of his training was endocrinology, with a primary focus on Diabetes, Type 1. (Tr., pp. 108-09.) His *curriculum vitae* lists him as author or co-author of over 200 articles in medical journals, and more than 80 books or book chapters, concerning mostly endocrinology and Diabetes, Type 1. (Ex. E, pp. 8-28.)

Dr. Maclaren has participated in the development of several reports published by the Institute of Medicine. (Tr. 109-10, 115.) He is listed as one of the reviewers of an IOM report that was filed in this case as Exhibit U, titled *Immunization Safety Review: Multiple Vaccinations and Immune Dysfunction* (National Academy Press 2002).

V

DESCRIPTION OF PETITIONER'S CONDITION AND THE OPINIONS OF THE PARTIES' EXPERTS

A. Petitioner's Type 1 Diabetes Mellitus

The parties ultimately agreed, as noted above, that Petitioner suffers from "Type 1 diabetes mellitus"; I will use the term "Type 1 diabetes" for short. Type 1 diabetes is a condition in which certain cells in the patient's pancreas, known alternatively as "islet cells" or "beta cells," have been destroyed to an extent that causes serious damage to the pancreas' function, so that the patient needs insulin to survive. (Ex. 1, p. 4; Ex. A, p. 3; Ex. B filed 8-21-09, p. 333; Tr. 197-98.) Type 1 diabetes is an "autoimmune" disease, meaning that the patient's *own immune system* is mistakenly attacking and destroying the islet cells. (Ex. 1, p. 4; Tr. 148, 197-98.)

For many years, the onset of Type 1 diabetes symptoms was usually seen in patients during their childhood years, not during adulthood, so that the disease was formerly known as "juvenile diabetes." (Tr. 117.) However, in recent years the onset of Type 1diabetes *symptoms* has often been seen in adults as well as children. (Tr. 117-18.) When the first symptoms of Type 1 diabetes are seen in an adult, the condition is sometimes described as "latent autoimmune diabetes in adulthood," or "LADA." (Ex. A, p. 3; Tr. 21.)

The causation of Type 1 diabetes is not well understood, as the experts in this case agreed. (Ex. 1, p. 4; Ex. A, p. 6; *see also* Ex. A, filed 8-21-09, p. 1.) The experts in this case also agreed that certain persons are genetically susceptible to autoimmune disease, and thus more likely than average to experience Type 1 diabetes. (Ex. A, p. 6; Tr. 8, 21-22, 59, 96; *see also* Ex. A filed 8-21-09, pp. 1, 2.) The experts also agree that *environmental* factors can play a role in causation. (Ex. 1, p. 4; Ex. A, p. 7; Tr. 8, 148; *see also* Ex. A filed 8-21-09, pp. 1-2.)

B. Summary of opinion of Dr. Shoenfeld

Dr. Shoenfeld stated the opinion that Petitioner's Type 1 diabetes was caused by her MMR vaccination of January 26, 2006. He relied upon several factors. First, he noted that Petitioner's Type 1 diabetes is an autoimmune condition, so that Petitioner's family history of autoimmune disease made her more likely to develop an autoimmune disease. (Tr. 22, 59, 96.) He also asserted that it is "widely accepted" that environmental factors, such as infections, can cause Type 1 diabetes, and that the mumps virus in its "*wild*" form has been reported as preceding the onset of Type 1 diabetes; he concludes therefrom that the *wild mumps virus* can cause Type 1 diabetes, and that therefore the mumps *vaccine* can also likely cause Type 1 diabetes. (Ex. 1, pp. 4-7; Tr. 28-33.)

Dr. Shoenfeld opined that one of the components of the MMR vaccine caused Petitioner's Type 1 diabetes by a process known as "molecular mimicry," in which a body part (here, the islet cells) has a similar molecular structure to an invasive agent that the immune system has been programmed to attack. The immune system, mistaking that body part for the invasive agent, mistakenly attacks the body part. (Ex. 1, pp. 7-8; Ex. 84, p. 3; Tr. 48-49.)

Dr. Shoenfeld also relied heavily on the fact that the first symptoms of Petitioner's Type 1 diabetes were noticed one to two months after the vaccination in question, which circumstance he believes to be supportive of a conclusion that the vaccination caused the disease. (Tr. 24-26, 44-47.) He stressed that Petitioner had displayed no symptoms of diabetes *prior* to the vaccination. (Tr. 24, 26.)

C. Summary of the opinions of Respondent's experts

Drs. Maclaren and Bercu both opined that there is no good reason to believe that Petitioner's MMR vaccination played a role in causing her diabetes. The chief reason for their position is their assertion that the process of destruction of islet cells in Type 1 diabetes by necessity takes a lengthy period, at least a year or more likely years; therefore, since Petitioner's diabetes symptoms began only one to two months after her MMR vaccination, that vaccination could not possibly have been a cause of her diabetes. (Ex. A, pp. 3, 7; Ex. D, p. 3; Tr. 118, 129, 131, 139-40, 152, 163-64, 169.)

Secondly, Respondent's experts rely heavily on the fact that many studies have been done on the issue of whether vaccines can cause autoimmune disease in general, or Type 1 diabetes in particular, and such studies have *failed* to find any association between *any* vaccines and *any* autoimmune disease, much less Type 1 diabetes. (Ex. A, pp. 3-4; Ex. D, p. 3; Ex. G, p. 2; Tr. 112-13, 132, 191.)

VI

SUMMARY OF MY ANALYSIS

After fully considering the record, I conclude that Petitioner has *failed* to demonstrate that it is "more probable than not" that Petitioner's MMR inoculation of January 26, 2006, played any role in causing her Type 1 Diabetes. The shortest summary of my reasoning is that I find the testimony of Respondent's experts to be substantially more persuasive than that of Petitioner's expert, as well as better supported by the filed medical articles.

More specifically, there are many different factors leading to my conclusion. First, I find that the most persuasive point in the record is the Respondent's argument that in Type 1 diabetes it takes a lengthy period, usually *years*, for the destruction of enough islet cells in the pancreas to produce noticeable symptoms. Thus, since Petitioner's diabetes symptoms began only one to two months post-vaccine, it is not credible that the Petitioner's diabetes was caused by her MMR vaccination. (*See* Section VII of this Decision below.)

Second, there were many flaws in Dr. Shoenfeld's testimony, which made his opinion unpersuasive in general. (*See* Section VIII of this Decision, below.)

Third, the record of this case demonstrates that many studies have been done seeking evidence of an association between vaccinations and autoimmune diseases, yet all of the credible studies have *failed* to find any association. (*See* Section IX of this Decision below.)

Fourth, committees of the prestigious Institute of Medicine have on several occasions studied the issue of whether vaccines can cause Type 1 diabetes, and concluded ultimately that the medical evidence preponderates *against* the proposition that there is a causal connection between the MMR vaccine and Type 1 diabetes. (*See* Section X of this Decision below.)

Fifth, there are a number of other reasons to reject Petitioner's causation claim in this case. (*See* Section XI of this Decision below.)

Sixth, the Petitioner's case clearly fails the *Althen* test. (*See* Section XII of this Decision below.)

VII

TYPE 1 DIABETES REQUIRES YEARS OF ISLET CELL DESTRUCTION TO PRODUCE SYMPTOMS

Respondent's experts, Drs. Maclaren and Bercu, both stressed that the process of destruction of islet cells in Type 1 diabetes by necessity takes a considerable period of time, usually years, before diabetes symptoms occur; therefore, since Petitioner's diabetes *symptoms* began only one to two months after her MMR vaccination, that vaccination could not possibly have been a cause of her diabetes. (Ex. A, pp. 3, 7; Ex. C, p. 1; Ex. D, p. 3; Tr. 118, 129, 131, 139-40, 152, 163-64, 169, 191.)

I found this argument to be the most persuasive item of evidence in this case. This is particularly true since Dr. Maclaren has exceptional qualifications in the *specific* area of Type 1 diabetes. As Dr. Maclaren testified, in his 50-year medical career he has spent most of his time in academic pursuits, especially in the field of Type 1 diabetes. (Tr. 108.) He has studied that particular disease for three decades. (*Id*.) In his clinical practice, Dr. Maclaren has seen about 20,000 patients who suffer from diabetes, about 25% of which had Type 1 diabetes. (Tr. 116.) Further, Dr. Maclaren has participated in a number of studies concerning Type 1 diabetes, and published numerous articles concerning that condition. (Ex. D, p. 1; Ex. E, pp. 8-28.) Therefore, Dr. Maclaren's testimony, that Type 1 diabetes *necessarily* requires a *year-long or longer period* of islet cell destruction prior to the onset of symptoms, is very persuasive.

To be sure, Dr. Shoenfeld for the Petitioner also has a *very* impressive overall medical background, as set forth in detail above. Moreover, Dr. Shoenfeld has tremendous experience with autoimmune disease in general, which is certainly quite relevant to this case. However, Dr. Shoenfeld clearly does not have the type of specialized knowledge of *Type 1 diabetes* itself that makes Dr. Maclaren's testimony so credible.

Moreover, the testimony of Drs. Maclaren and Bercu in this regard was well supported by their citation of studies and medical articles filed in this case. For example, Dr. Maclaren explained that careful studies have been made of people with Type 1 diabetes in their families. Such studies have shown that in individuals who ultimately exhibit Type 1 diabetes, there was actually a *years-long* process of islet cell destruction before diabetes *symptoms* began. (Ex. D, pp. 2-3; Tr. 121-22, 129.) Further, a medical text excerpt filed into the record in this case confirms that when adults exhibit Type 1 diabetes, the process of islet cell destruction has typically taken *years* before clinical symptoms manifest. (Ex. B, filed 8-21-09; p. 333.)

To be sure, Dr. Shoenfeld did testify emphatically that an MMR vaccination *could* cause the onset of Type 1 diabetes symptoms only one to two months post-vaccine. In this regard, he stressed the fact that since this was not Petitioner's first MMR vaccination, her prior vaccination would have primed her immune system to a *faster* reaction to the vaccination than would be the case with a first vaccination (which faster response he termed a "memory" response or an "anamnestic" response). (*E.g.*, Tr. 45-47, 72-74; see also the unnumbered report filed by Dr. Shoenfeld on July 6, 2009 as ECF 11.) But Dr. Shoenfeld did not coherently explain *why* or *how* an "anamnestic" response could result in symptoms of Type 1 diabetes appearing without a year or more of preceding islet cell destruction. Does a *second* MMR vaccination actually cause the body's immune system to react *more than a year* sooner than would be the case after a *first* MMR vaccination? Dr. Shoenfeld did not explain**.** And Drs. Maclaren and Bercu were persuasive in their testimony that there is no reason to believe that the mere fact of a second vaccination could cause symptoms of Type 1 diabetes without a year-long (or longer) process of islet cell destruction. (*E.g.*, Tr. 129, 131-32, 139-40, 168.)

Further, Dr. Shoenfeld noted that certain blood tests done on Petitioner prior to her vaccination appeared normal, and argued that these results meant that at that time of those tests Petitioner could not have been undergoing an ongoing process of pancreas islet cell destruction, as Drs. Maclaren and Bercu theorize. (*E.g.*, Tr. 24.) However, Dr. Maclaren answered that the type of pre-vaccination blood test results to which Dr. Shoenfeld points do *not* mean that Petitioner was not already experiencing islet cell destruction at the time of the tests. Dr. Maclaren explained that those particular tests can yield

inaccurate results. (Tr. 124-25, 142-43.) Further, he stressed that the type of test which would have been the *best* at identifying whether a cell destruction process was underway--*i.e.*, a hemoglobin A1c test (also described as "HbA1c" test--Ex. D, p. 2)--was *not* performed on Petitioner prior to her vaccination. (Ex. D, p. 2; Tr. 125-29.) Further, when such test *was* actually performed after Petitioner's clinical diabetes symptoms appeared, the results of that hemoglobin A1c test were so high that it indicated that the islet cell destruction must have been going for a long time, *prior* to the vaccination in question. (Tr. 125-26, 129 lines 5-12.[11]) Dr. Shoenfeld did not effectively refute this testimony of Dr. Maclaren, the expert in Type 1 diabetes.

In sum, the most important reason that I must reject Dr. Shoenfeld's theory is his failure to get around the problem that it is not credible that islet cell destruction in Petitioner's pancreas could be initiated by her MMR vaccination, then cause symptoms within a period of only one to two months.

VIII

DR. SHOENFELD'S OPINION WAS POORLY EXPLAINED, FLAWED, AND UNPERSUASIVE ON ITS FACE

A second important reason for my conclusion is that Dr. Shoenfeld failed to explain his causation theory well, and his attempted explanations simply left me unpersuaded. Unlike respondent's experts, he was often unable to cogently respond to questions about his causation theory. He failed to cite any support in medical literature for many parts of his testimony. At times he seemed to acknowledge that his theory in this case amounted to mere speculation. At other times, he seemed to contradict himself, or to, in effect, offer more than one possible theory of causation, without explaining which approach seemed persuasive to himself. Further, at times he seemed to suggest that *any* type of vaccination can cause *any* type of autoimmune disease, with the time of onset at *any* interval after vaccination being acceptable.

I will start with Dr. Shoenfeld's statements described in my previous sentence. For example, at one time, he stated that *any* vaccination that contains an "adjuvant,"[12] which would seem to describe a great many types of vaccinations, "can cause any autoimmune disease." (Tr. 75, lines 16-17.) At another time, he stated that "it's very reasonable that * * * *every* vaccine can induce *any* autoimmune disease." (Tr. 85, lines 15-17, emphasis added.) These statements may well set up Dr. Shoenfeld to act as a paid expert in any Vaccine Act case involving an autoimmune disease, but they do not inspire confidence in me that he can *reasonably* say in any *particular* case that causation was "more probable than not."

As another example of the general lack of persuasiveness of Dr. Shoenfeld's testimony, at times he acknowledged that his causation theory in this case amounts to mere *speculation*. When asked to summarize his opinion, he acknowledged that his theory was "in the way of speculation." (Tr. 54, lines 9-10.) He later said that he would "like to speculate" that Petitioner would not have developed diabetes but for the vaccination. (Tr. 55, lines 1-6.) And after reading his reports and listening to his

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[11] At p. 126, line 12 of the transcript, it appears that Dr. Maclaren's mention of the "A1c" test was mistranscribed as "A13."

[12] See discussion of "adjuvants" at p. 22 below.

entire hearing testimony, it strikes me, as well, that Dr. Shoenfeld's opinion amounts to no more than mere "speculation."

Another example of the dubious overall nature of Dr. Shoenfeld's presentation is his assertion that "molecular mimicry" was the most likely mechanism[13] by which the vaccination instigated Petitioner's Type 1 diabetes. (*E.g.*, Tr. 32, 48-49.) As noted above, in molecular mimicry, a body part has a similar molecular structure to an invasive agent that the immune system has been programmed to attack, so that the immune system, mistaking the body part for the invasive agent, mistakenly attacks that body part. In Petitioner's case, it is the Petitioner's pancreas islet cells that have been attacked by her immune system, and Dr. Shoenfeld speculates that there are molecular "similarities" between the "viral particles" of the MMR vaccine and the "pancreatic structure," thus prompting Petitioner's autoimmune system to mistakenly attack the islet cells. (Tr. 32, lines 21-24.)

To be sure, the *general concept* of molecular mimicry, as an explanation for autoimmune attacks, is a well-established concept. As Dr. Shoenfeld pointed out, there have been many articles noting molecular mimicry as a potential cause of various autoimmune diseases. (Tr. 48-49.) Respondent's experts did not take issue with the *general* concept of molecular mimicry as a possible explanation for autoimmune disease. (*E.g.*, Tr. 168.)

However, Dr. Shoenfeld never explained why there is good reason to point to molecular mimicry *in this case*. That is, he never explained why he believes that there are molecular "similarities" between Petitioner's islet cells and any "particles" in the MMR vaccine. (See Tr. 32, lines 21-24.) Dr. Shoenfeld indicated in a *different* autoimmune disease that he studied, he suspected a process of molecular mimicry precisely because he had found in patients "the same sequence of amino acids" in both the suspected invasive agent and in the attacked body parts. (Tr. 49, lines 11-14.) But as to his allegation of potential similarities between MMR vaccine "particles" and Petitioner's islet cells, Dr. Shoenfeld did *not* point to any identical or similar sequences of amino acids.

Dr. Maclaren, the Type 1 diabetes expert, on the other hand, testified that he was unaware of any molecular similarities between the MMR vaccine parts and the islet cells that are actually attacked by the immune system in Type 1 diabetes. (Tr. 139.) Dr. Bercu also noted that there is "absolutely no evidence" that molecular mimicry plays a role in the *particular* autoimmune disease from which Petitioner suffers, Type 1 diabetes. (Tr. 168-69.) Dr. Bercu opined that Dr. Shoenfeld's assertion that molecular mimicry can be the cause of Type 1 diabetes amounts to mere "speculation." (Tr. 168, line 21.)

In short, I found *many* flaws in Dr. Shoenfeld's general presentation, too numerous to discuss here. Some of those deficiencies have been described above, and some will be described below. In

[13] In his first written report, Dr. Shoenfeld admitted that he did not know the exact method by which the MMR vaccine caused Petitioner's diabetes, but indicated that it could be any one of four mechanisms. (Ex. 1, pp. 7-9.) Those four mechanisms included "molecular mimicry," plus "polyclonal activation," "tissue damage," and "bystander activation." (*Id*.) During his hearing testimony, however, Dr. Shoenfeld appeared to focus exclusively on "molecular mimicry," discussed above at p. 15 of this Decision, and did not present any detailed discussion concerning the other potential mechanisms mentioned at page 8 of Ex. 1. I find that Dr. Shoenfeld did not make a persuasive presentation concerning *any* of his proposed mechanisms. (Dr. Shoenfeld also suggested in passing that "the rubella can cause diabetes mellitus" (Tr. 32, lines 12-13), but the next two lines of his testimony demonstrate that he was referring to "congenital rubella syndrome," *i.e.*, infection of a fetus by rubella *in utero*, a syndrome that of course did not happen in this case.)

general, I simply did not find Dr. Shoenfeld's presentation in this case to be persuasive, while I found that the contrary arguments of Drs. Maclaren and Bercu were convincing.

IX

THE EPIDEMIOLOGICAL STUDIES OFFER SUPPORT TO RESPONDENT'S EXPERTS RATHER THAN PETITIONER'S EXPERT

The Vaccine Act case law makes it clear that in order to show causation under the Act's "more probable than not" standard, a petitioner need *not* supply epidemiologic or other medical literature supporting causation. (See, *e.g., Capizzano v. HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006); *Andreu v. HHS*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).) However, when epidemiologic literature concerning the vaccine in question is placed into the record of the case, the special master may give such literature weight, as appropriate, if such literature either offers support for, or tends to contradict, the petitioner's causation theory. (See, *e.g., Taylor v. HHS*, 108 Fed. Cl. 807, 819-21 (Fed. Cl. 2013) (the special master did not err in considering epidemiological evidence); *Andreu v. HHS*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (a special master may assess epidemiological evidence in "reaching an informed judgment as to whether a particular vaccination likely caused a particular injury").)

In this case, a number of epidemiological studies have specifically looked at the issue of whether vaccines, including the MMR vaccine, are associated[14] with Type 1 diabetes. The experts in this case have discussed those studies, and medical articles describing such studies have been filed into the record of this case. After carefully reviewing those medical articles and the expert testimony relevant to them, I conclude that all of the large reliable studies have found *no association* between any vaccine and Type 1 diabetes. I conclude that as a whole those studies offer support to the opinions of respondent's experts, not to the opinion of petitioner's expert.

First, Dr. Maclaren explained that a succession of very large studies conducted internationally have all *failed* to find any association between vaccines and Type 1 diabetes. (Ex. D, p. 3; Tr. 113, lines 23-25.) He stated that there have been at least 20 such studies that looked for, but failed to find, an association between vaccines and Type 1 diabetes. (Tr. 132-33.) Dr. Maclaren in his expert report cited several such studies, pointing to articles describing those studies by DeStefano (2001), Hviid (2004 and 2006), and Hyoty (1993).[15] (Ex. G, pp. 4-5.)

Dr. Bercu also reviewed the relevant medical literature and, like Dr. Maclaren, explained that many large epidemiological studies have failed to find any association between any vaccine and Type 1 diabetes. (Ex. A, pp. 3-4; Tr. 163.) Dr. Bercu pointed to articles describing several different studies in

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[14] Technically, epidemiological studies do not address the question of whether Factor A "causes" Condition B, but instead whether the two are "associated." Two factors are said to be "associated" if they occur together more often than would be expected by chance. (*Dorland's Illustrated Medical* Dictionary (32nd ed. 2012), p. 167.) If an "association" is found, then medical experts will evaluate other factors to determine if that association is "causal." But if no association is found, then that result casts doubt on (though does not entirely disprove) the proposition that Factor A is a significant cause of Condition B.

[15] See Exs. P, Q, R, and S, filed August 4, 2011.

this regard, including Blom 1991, Graves 1999, Halsey 1999, the EURODIAB study 2000, Hummel 2000, DeStefano 2001, Hviid 2004, and Zingg 2005.[16] (Ex. A, p. 4.)

Further, Dr. Maclaren specifically discussed some of the studies in this regard. He pointed, for example, to a large study performed by the U.S. Centers for Disease Control ("CDC") that looked at whether a number of different vaccinations are associated with Type 1 diabetes, and found no association between any vaccine and Type 1 diabetes. (Tr. 112-13.) An article describing that study by DeStefano and colleagues is filed into the record of this case as Ex. I. (Filed 8-21-09.) That article indicates that one of the vaccines involved in that large CDC study was in fact the MMR vaccine, and no association between the MMR vaccine and Type 1 diabetes was found. (Ex. I, p. 3.)

Dr. Maclaren also described another huge study that followed more than 5.5 million doses of MMR vaccine administered in Germany between 1978 and 1989. (Ex. 73, p. 1; Ex. G, p. 2.) That study again found no association between MMR vaccination and Type 1 diabetes. (Ex. 73, pp. 7, 9; Ex. G, p. 2.) Instead, the study found *fewer* cases of the onset of diabetes within 30 days after vaccination than would be expected by chance alone. (Ex. G, p. 2.)

Dr. Bercu further noted that the Hviid 2004 article described a huge study that followed all children born in Denmark for the full decade of 1990-2000, a total of almost five million "person-years" of follow-up, but found no increased risk of diabetes associated with any vaccination. (Ex. A, p. 4; Ex. S, filed August 21, 2009.)

In this regard, there are three articles in the record authored by Dr. John B. Classen, who suggested, after re-analyzing data from the studies of others, that diabetes *can* be caused by vaccines, with symptoms usually appearing two to four years after vaccination. (Exs. E, F, and G, filed on August 21, 2009.) But Dr. Bercu indicated that the evidence *contradicting* Dr. Classen's causation conclusion was much stronger. (Ex. A, pp. 3-4.) Moreover, petitioner's own expert, Dr. Shoenfeld, did *not* rely on the Classen articles to support his causation theory in this case. This is not surprising, because Dr. Classen's conclusion that vaccines can cause diabetes assumes that typically symptoms of the patient's diabetes would arise only two-to-four *years* after vaccination (Ex. E, p. 1), which obviously contradicts Dr. Shoenfeld's conclusion in this case that the MMR caused diabetes with symptoms appearing only one to two *months* post-vaccination.[17]

To be sure, in response to the reliance of Drs. Maclaren and Bercu on the epidemiological studies described above, Dr. Shoenfeld supplied an interesting argument. Dr. Shoenfeld noted that there exists at least some evidence that the mumps virus in its "wild" ("natural"), non-vaccine form, might cause, or at least trigger the onset of, Type 1 diabetes.[18] He suggested that the wild *rubella* virus also might cause diabetes. And he acknowledged that the MMR vaccine, as is its purpose, *does* reduce

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[16] See Exs. C, O, V, L, R, I, S and MM, filed on August 21, 2009.

[17] Petitioner's *counsel* discusses Dr. Classsen's work briefly in his opening post-hearing brief (Brief filed 8-31-11, pp. 36-37.) But counsel, as is typical in his briefs, failed to cite to any page numbers in the Classen articles. Nor does counsel's discussion claim that his own expert, Dr. Shoenfeld, relied upon or endorsed the Classen conclusions. In short, counsel's brief discussion of the Classen articles was not persuasive, or helpful to Petitioner's case.

[18] The issue of whether environmental factors, including "wild" mumps infection, can cause Type 1 diabetes, will be discussed in greater detail below. (See pp. 23-24.)

the incidence of subsequent "wild" mumps or rubella *infections* in the vaccinated population. Therefore, he argues, the MMR vaccine's undoubted protective effect against "wild" mumps and rubella infection might, in the studies discussed above, be "masking," or covering up, the actual *causation* of Type 1 diabetes in a *very few* individuals by the MMR vaccine. In other words, Dr. Shoenfeld does not take issue with the studies' conclusion that *overall*, the MMR vaccination does not raise the risk of Type 1 diabetes in the vaccinated population. He argues rather, that the MMR vaccination might be causing Type 1 diabetes in a very small number of genetically susceptible individuals, and yet, because the MMR vaccination does reduce the incidence of Type 1 diabetes in *most* of the vaccinated population, by reducing subsequent mumps and rubella infections which might in turn cause diabetes, the MMR-causation of a small number of cases of diabetes *simply would not show up* in the studies. (Ex. 1, pp. 9-10; Tr. 83-84, 90, 100-01.)

Dr. Shoenfeld's argument in this one aspect is quite logical. He is likely correct that *if* the MMR vaccine causes Type 1 diabetes in only a relatively few genetically-susceptible persons, then such causation would likely *not* show up in the epidemiological studies on which the respondent's experts rely.

However, Dr. Shoenfeld's reasonable logic on that point offers no *practical* support toward carrying the *Petitioner's burden* in this case. It is, in fact, *always* true that epidemiological studies can *never* prove definitively that Factor A *never* causes Condition B. Even when large studies fail to identify an association between Factor A and Condition B, it is *always theoretically possible* that Factor A causes Condition B in a very small number of cases, an effect too rare for the study to detect. But it is not the Respondent's burden in this case to prove that it is *impossible* that the MMR vaccination can cause Type 1 diabetes. It is, rather, the *Petitioner's burden* to show not only that the MMR vaccine *can* cause Type 1 diabetes (*Althen* Prong 1, see p. 25 below), but also that her own MMR vaccination *did* cause Petitioner's Type 1 diabetes (*Althen* Prong 2, see p. 25 below). And, therefore, the epidemiological studies cited in this case, including Dr. Classen's articles, clearly do *not* help Petitioner carry her burden. As Dr. Shoenfeld argues, the studies, like *all* epidemiological studies, do not prove that the MMR vaccine can *never* cause Type 1 diabetes. But they offer *no support at all* to Petitioner in carrying *her burden* of showing that the MMR vaccine *can* cause Type 1 diabetes. To the contrary, because so many studies have looked for an association between vaccines (including MMR vaccines) and Type 1 diabetes, and *failed* to find any association, then on an overall basis, the existence of the many studies offers at least some support for the argument that it is *unlikely* that the MMR vaccine causes Type 1 diabetes.

X

THE IOM REPORTS ADD SUPPORT TO MY CONCLUSION IN THIS CASE

The record of this case *prior* to the evidentiary hearing contained a report of a committee of the Institute of Medicine ("IOM"), which addressed the issue of whether Type 1 diabetes can be caused by *vaccines in general*. That IOM committee, in 2002, concluded that "the epidemiological literature favors *rejection* of a causal relationship between multiple immunizations and [an increased risk of] type 1 diabetes." (Ex. U, filed 8-21-09, p. 110, emphasis added.) The conclusion of that committee of the prestigious IOM was in the record of this case as of the time of the evidentiary hearing in this case on March 30, 2011, and, of course, offers at least some support to the position of the Respondent in this case.

Respondent's Post-Hearing Memorandum, filed on October 31, 2011, noted the publication of a *new* report by the Institute of Medicine that was not available at the time of the hearing in this case. (*See* Resp. Post-Hearing Memo, p. 11.) Respondent argued that this new IOM report should be included in the record of this case because it examined the possibility of a causal relationship between the *MMR vaccine* in particular and Type 1 diabetes. On January 31, 2012, respondent filed a motion to introduce that IOM report, with a copy of the relevant portion attached, labeled as Ex. NNN.[19] On February 13, 2012, petitioner filed an "Objection" to the inclusion of Exhibit NNN in the record. On May 14, 2012, I filed an abbreviated Ruling, allowing Exhibit NNN to be considered as part of the evidentiary record, and indicating that a detailed opinion explaining the reasons would follow. The paragraphs below discuss the reasons why it is appropriate to consider the IOM report within the context of this case.

The Institute of Medicine is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (*see* An Act to Incorporate the National Academy of Sciences, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. When it enacted the Vaccine Act in 1986, Congress *specifically directed* that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. *See* § 300aa–1 note.

> [T]he Vaccine Act establishes a broad program to study and reduce the risk of childhood vaccines. *See, e.g.,* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99–660, §§ 312(a)-(d), 313(a), 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779–82 (directing the Secretary to request that the Institute of Medicine of the National Academy of Sciences conduct studies exploring the link between childhood vaccines with certain illnesses). Congress clearly intended the Secretary to be guided by the findings from such studies when she decides to promulgate regulations to revise the injury table. *See id*. § 312(c)-(d), 100 Stat. at 3780; 42 U.S.C. § 300aa–14(d) (1994).

Terran v. HHS, 195 F.3d 1302, 1315 (Fed. Cir. 1999). Such studies have been used frequently to guide the United States Department of Health and Human Services regarding the identification of vaccine-related injuries in Vaccine Act regulations. *See*, *e.g., Hanlon v. HHS*, 191 F.3d 1344, 1348 n. 1 (Fed. Cir. 1999) (discussing substantive revisions of the Vaccine Injury Table that were based on reports by the IOM); *Loving v. HHS*, 86 Fed. Cl. 135, 142 (Fed. Cl. 2009).

During the 25-year history of the Vaccine Act, special masters have consistently relied upon the reports of the Institute of Medicine, and reviewing judges have consistently indicated approval of such reliance. *E.g., Isaac v. HHS*, 108 Fed. Cl. 743, 755 (2013), *aff'd*, 2013 WL 5952008 (Fed. Cir. Nov 8, 2013) (affirming the special master's reliance on findings of the IOM); *Porter v. HHS*, 663 F.3d 1242, 1252 (Fed. Cir. 2011)(noting the special master's comment that "IOM reports are favored, although not dispositive, in the Vaccine Act Program," then affirming the special master's decision); *Cedillo v. HHS*, No. 98-916V, 2010 WL 331968, at *94 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl.

[19] Exhibit NNN: excerpts from Kathleen Stratton, *et al.,* Institute of Medicine*, Adverse Effects of Vaccines: Evidence and Causality* (National Academy Press, Prepublication ed. 2011). (The final edition of that report was published in 2012.)

158 (Fed. Cl. 2009) (affirming special master's reliance on conclusions of IOM), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Rodriguez v. HHS*, 67 Fed. Cl. 409, 410 (Fed. Cl. 2005) (relying on IOM report regarding vaccine causation of an injury); *Althen v. HHS*, No. 00-170V, 2003 WL 21439669, *11, n. 28 (Fed. Cl. Spec. Mstr. 2003) ("Due to the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee reviewing the adverse events associated with vaccines, the court considers their determinations authoritative and subject to great deference."), *rev'd on other grounds*, 58 Fed. Cl. 270, 272-74 (Fed. Cl. 2003)(citing IOM reports frequently in support of various scientific propositions), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005); *Terran v. HHS*, 41 Fed. Cl. 330, 337 (1998)(affirming special master's reliance on conclusions of IOM), *aff'd*, 195 F.3d 1302 (Fed. Cir.1999), *cert. denied*, 531 U.S. 812 (2000); *Cucuras v. HHS*, 993 F.2d 1525, 1529 (Fed. Cir. 1993) (noting that the special master had placed "a great deal of weight" on an IOM report in reaching a decision, then affirming the special master's decision); *Stroud v. HHS*, 113 F.3d 1258 (Fed.Cir. 1997)(unpublished)(special master may rely upon an IOM report that neither party filed as evidence); *Ultimo v. HHS*, 28 Fed. Cl. 148, 152 (1993) (proper for a special master to rely on IOM report); *Manville v. HHS*, 63 Fed. Cl. 482, 491 (2004) (same); *Ryman v. HHS*, 65 Fed. Cl. 35, 39 (2005) (same); *Capizzano v. HHS*, No. 00–759V, 2004 WL 1399178 at *2, n. 6 (Fed. Cl. Spec. Mstr. June 8, 2004) ("Considering the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee, the special masters have consistently accorded great weight to the IOM's findings."), *rev'd on other grounds*, 440 F.3d 1317 (Fed. Cir. 2006); *Larive v. HHS*, No. 99-429V, 2004 WL 1212142, *11 (Fed. Cl. Spec. Mstr. May 12, 2004); *Falksen v. HHS*, No. 01–317V, 2004 WL 785056 at *13 (Fed. Cl. Spec. Mstr. Mar. 30, 2004) ("[T]he Court gives great deference to the findings of the Institute of Medicine on the issue of cause and effect between vaccines and discrete injuries."); *King v. HHS*, No. 03-584V, 2010 WL 892296 at *76 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Kelley v. HHS*, 68 Fed. Cl. 84, 91, n. 11 (Fed. Cl. 2005); *Doe v. HHS*, 2004 WL 3321302 at *24 (Fed. Cl. Spec. Mstr. Oct. 5, 2004) (special masters frequently rely on IOM conclusions to answer questions about plausibility and causation); *Kuperas v. HHS*, No. 01-60V, 2003 WL 2292885 at *9, n. 25 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Malloy v. HHS*, No. 99–193V, 2003 WL 22424968 at *15 (Fed. Cl. Spec. Mstr. Aug. 6, 2003); *Watson v. HHS*, No. 96-639V, 2001 WL 1682537 at *5, n. 11 (Fed. Cl. Spec. Mstr. Dec. 18, 2001); *Hill v. HHS*, No. 96–783, 2001 WL 166639 at *3, n. 2 (Fed. Cl. Spec. Mstr. Jan. 29, 2001); *Salmond v. HHS*, No. 91-123V, 1999 WL 778528 at *5 (Fed. Cl. Spec. Mstr. Sept. 16, 1999); *Castillo v. HHS*, No. 95–652V, 1999 WL 605690 at *11 (Fed. Cl. Spec. Mstr. July 19, 1999); *Ashe Robinson v. HHS*, No. 94–1096V, 1998 WL 994191 at *7, n. 8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998); *Cohen v. HHS*, No. 94–353V, 1998 WL 408784 at *8 (Fed. Cl. Spec. Mstr. July 1, 1998); *Schell v. HHS*, No. 90–3243V, 1994 WL 71254 at *5 (Fed. Cl. Spec. Mstr. Feb. 22, 1994); *Aldridge v. HHS*, No. 90–2475V, 1992 WL 153770 at *2, n.12 (Cl. Ct. Spec. Mstr. June 11, 1992); *Woodcock v. HHS*, No. 90–1030V, 1992 WL 92169 at *11, n. 50 (Cl. Ct. Spec. Mstr. Apr. 10, 1992).

It is notable that the particular IOM report filed post-hearing in this case has been considered in a previous case in which a special master relied on that report in concluding that the testimony of a petitioner's medical expert was unreliable. Upon review, the presiding judge, after specifically noting such reliance, affirmed the special master's decision, and that ruling was also affirmed. *Isaac v. HHS*, 108 Fed. Cl. 743, 779 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013).

The admission of evidence during a Vaccine Act proceeding is governed by Vaccine Rule 8.[20] The critical factors to be considered are the relevance and reliability of the evidence in question. In

[20] Vaccine Rule 8 Taking Evidence; Hearing Argument

this case, Petitioner agrees that the contested IOM report is relevant, but argues that it is not dispositive of the causation issue. (*See* Petitioner's Objection, February 13, 2012, p. 2.) Since Exhibit NNN contains an excerpt of the IOM report that addresses the possibility of a causal relationship between the MMR vaccine in particular and Type 1 diabetes, that discussion is directly relevant to the issue in this case. Based on the Congressional direction that the IOM provide reports for use in Vaccine Act cases, as well as the history of Vaccine Act decisions in which special masters have relied on the findings of IOM reports, I conclude that evidence from IOM reports should be considered when relevant. Therefore, pursuant to Vaccine Rule 8, I have chosen to admit the contested IOM report into evidence and consider it carefully, since the report is both relevant and reliable. *Stroud v. HHS*, 113 F.3d 1258 (Fed. Cir. 1997)(unpublished) ("The special master determines what constitutes the record, and there is nothing to preclude the special master from including in the record evidence that is relevant and reliable. In the proceedings before the Court of Federal Claims, that court concluded that petitioner failed to discredit the IOM report or explain how it was misconstrued or misapplied. We find no error in that determination.")

In reaching this conclusion, I note that in most circumstances, I would *not* permit the Respondent to introduce new evidence after the evidentiary hearing in a case, although in a few cases I have permitted a *petitioner* to do so. However, the circumstances here are unusual. As noted above, Congress has *specifically directed* the IOM provide such reports, concerning whether vaccines can cause injury. And here, an IOM committee had just issued a new report, after the hearing in this case, concerning the *exact causation issue* pending before me in this case. I concluded that the best course was to heed the direction of Congress, and consider the new IOM report in deciding the case. I therefore gave the Petitioner's expert the chance to file a new expert report addressing the new IOM report, and gave Petitioner's counsel the opportunity to address the report in the final brief filed in this case, filed on April 18, 2013.

I have considered the arguments concerning the new IOM report raised by Dr. Shoenfeld in his post-hearing expert report (Ex. 84) and in Petitioner's final brief (filed 4-8-13). Dr. Shoenfeld argued that I should disregard the new IOM report because in his view IOM reports are typically "not based upon science but [are issued] * * * largely due to political considerations." (Ex. 84, p. 2.) Dr. Shoenfeld also made the same point that I discussed above at pp. 17-18, relating to reasons for caution in interpreting the epidemiological studies upon which the IOM committee relied. (*Id*., p. 3.) Petitioner's final brief then simply quoted Dr. Shoenfeld. (Brief filed 4-8-13, p. 2.)

However, neither Dr. Shoenfeld nor Petitioner's counsel has persuaded me to simply ignore the IOM report's conclusion. A committee of highly qualified experts has reviewed all of the available evidence, and explicitly stated a firm negative conclusion on the exact "general causation" issue that I face in this case, *i.e.*, whether the MMR vaccination causes Type 1 diabetes. I would be remiss in my duty if I chose to disregard this important item of evidence. I find that this new IOM report adds another significant item of evidence that *supports my decision* to reject Petitioner's causation claim in this case.

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a) In General. The special master will determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties.

b) Evidence.

1) Rules. In receiving evidence , the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fairness to both parties.

I do also stress, however, that the existence of this new IOM report was *not* a crucial item of evidence in this case. For all of the reasons set forth in Sections VI, VII, VIII, IX, XI, and XII of this Decision, my ruling would have been *exactly the same* even if no IOM report existed.

XI

ADDITIONAL ANALYSIS

There are a few additional points worthy of brief discussion.

A. Dr. Shoenfeld's testimony concerning "adjuvants" and "ASIA Syndrome"

Another factor that contributed to the unpersuasive nature of Dr. Shoenfeld's presentation is the fact that at various times in his presentation, he mentioned a number of points that he seemed to present as support for his causation opinion in this case, but which he (1) never developed, (2) never explained, (3) never offered evidence for, (4) never fit within his general causation theory, and/or (5) eventually retracted.

For example, at various times, Dr. Shoenfeld seemed to suggest that the MMR vaccine contains one or more "adjuvants,"[21] and that such factor supports his theory that the MMR vaccination instigated a very rapid autoimmune process of islet cell destruction in Petitioner. (Ex. 1, p. 9; Tr. 33-36, 54, 82.) But Dr. Shoenfeld did not explain with any clarity how the supposed existence of adjuvants in the MMR vaccine makes it likely that the vaccine instigated Petitioner's diabetes. Moreover, in his post-hearing expert report, which was supposed to address the post-hearing IOM report, Dr. Shoenfeld finally admitted that there are *no adjuvants* in the MMR vaccine. (Ex. 84, p. 3.)

And to add further confusion to this very confused portion of Dr. Shoenfeld's presentation, Petitioner's counsel in his main post-hearing brief (filed on 8-31-11) refers to the alleged adjuvants in the MMR vaccine as "adjuvinants" (pp. 16-17), and does not seem to have noticed that Dr. Shoenfeld in his post-hearing expert report apparently retracted the "adjuvant" part of his theory, since Dr. Shoenfeld there admitted that there are *no adjuvants* in the MMR vaccine. (Ex. 84, p. 3.)

In any event, this part of Dr. Shoenfeld's testimony, in which he pointed to alleged adjuvants in the MMR vaccine as support for his theory, underlines the disjointed and confused nature of his overall testimony, and adds yet more reason to *doubt* the validity of Dr. Shoenfeld's testimony.

Similarly, in his hearing testimony and in his post-hearing expert report, Dr. Shoenfeld referred to an apparent theory of his about an alleged entity that he called "ASIA Syndrome"--he described "ASIA" as an acronym for "autoimmune syndrome induced by adjuvants." (Tr. 37, 83-84; Ex. 84, p. 1.) He seemed to offer his "ASIA Syndrome" theory in support of his causation opinion. But the "ASIA syndrome" would seem to have no application to this case in light of his above-described post-hearing acknowledgement that there are *no adjuvants* in the MMR vaccine. And once again, Dr. Shoenfeld seemed to just haphazardly throw the references to "ASIA syndrome" into his

[21] An "adjuvant" is an extra ingredient added to some immunizations in order to prompt an enhanced reaction from the immune system. (Tr. 33.)

presentation as an afterthought, without any coherent explanation of how the alleged syndrome fit into his overall causation theory.

There were a number of other instances in which Dr. Shoenfeld seemed to randomly throw concepts, allegations, or ideas into his presentation, without explaining them clearly or fitting them into his causation theory. These instances are too numerous to enumerate here, so I will just say that I found no persuasive value in any of these references or suggestions.

B. Allegations that other environmental factors have instigated Type 1 diabetes

Dr. Shoenfeld at many places in his report asserted that a number of other environmental factors, such as infections, have caused cases of Type 1 diabetes. (*E.g.*, Ex. 1, pp. 6-7, 10-11; Ex. 84, pp. 1, 4; Tr. 45, 176-85.) For example, Dr. Shoenfeld asserted that the "wild," natural form of the mumps virus can cause Type 1 diabetes. (Ex. 84, p. 1; Tr. 45, 176-85.) (An intentionally weakened ("attenuated") form of the mumps virus is contained in the MMR vaccine.) (Ex. BB, filed 8-21-09, p. 1.)

Petitioner also submitted articles in which single cases of Type 1 diabetes appeared after infection by the wild mumps virus (Exs. 74 and 76), and infection by the cytomegalovirus (Ex. 71). Dr. Shoenfeld seemed to suggest that because the wild mumps infection and other environmental factors might cause Type 1 diabetes, then the weakened forms of the mumps, measles, and rubella viruses contained in the MMR vaccine can cause Type 1 diabetes.

However, this argument of Dr. Shoenfeld was not persuasive either. For one thing, Dr. Shoenfeld admitted that he himself in 2002 published an article in which he stated that there was no good evidence that vaccines cause environmental diseases. (Tr. 186-87.) Then, at the end of the evidentiary record in this case, Dr. Shoenfeld admitted that the suspicion that the mumps *wild* virus can cause Type 1 diabetes "has not been scientifically confirmed."[22] (Ex. 84, p. 4.)

Further, single case reports of Disease X occurring after Factor Y, such as Exs. 71, 74, and 76, do not offer strong evidence that the *temporal* relationship is a *causal* one--the temporal relationship could be pure random chance.[23] (See statement to that effect by Dr. Maclaren at Ex. G, bottom of page. 2.)

To be sure, there is *some* evidence that the *wild* mumps virus might be capable of instigating Type1 diabetes, as Dr. Shoenfeld pointed out. But Dr. Bercu noted contrary evidence indicating that while some viruses can destroy islet cells, the mumps virus has *not* been shown to do so. (Ex. A, p. 4.) Moreover, even if there were *strong* proof that the *wild* mumps virus could instigate Type 1 diabetes,

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[22] Dr. Maclaren also testified that it has not been scientifically established whether the wild mumps *infection* can cause diabetes. (Tr. 159-60.)

[23] Petitioner also submitted Ex. 75, a single case report in which, as with Petitioner, symptoms of Type 1 diabetes appeared soon after a mumps *vaccination*. But again, as Dr. Maclaren pointed out in response, the above-discussed epidemiological studies strongly suggest that the occurrence of Type 1 diabetes after a mumps vaccination was likely mere chance, coincidence. (Ex. G, bottom of p. 2.)

that would not automatically demonstrate that the MMR *vaccine*, which contains an intentionally *weakened* form of the mumps virus, could cause Type 1 diabetes.

Further, even when Dr. Shoenfeld pointed to evidence potentially linking the *wild* mumps virus to Type 1 diabetes, Dr. Shoenfeld did not dispute that after the mumps infections the diabetes seemed to occur two or more *years* later, a far cry from the one-to-two month time separation in this case. (Tr. 45.) In this regard, it is true that it is accepted that if an unborn child experiences infection by the rubella virus while *in utero--i.e.*, "congenital rubella," Type 1 diabetes can be caused. (Ex. A, p. 7.) However, Dr. Bercu pointed out that with congenital rubella, the Type 1 diabetes does not appear for *years*.[24] (*Id*.) Dr. Bercu later noted again that after congenital rubella, Type 1 diabetes does not appear for years, even *decades*. (Tr. 169.)

Similarly, Dr. Maclaren acknowledged that he could not say that viral infections can *never* cause Type 1 diabetes. He even acknowledged that a case of the *wild mumps infection* (not mumps *vaccine*) *might* be capable of causing Type 1 diabetes. (Tr. 194-95.) He simply argued that there is no good reason to believe that the *MMR vaccine* causes Type 1 diabetes at all, or that it did in Petitioner's case.

In sum, I found that the evidence in this case concerning the possible causation of Type 1 diabetes by a few environmental factors did *not* add any significant weight to the allegations that the *MMR vaccine* can cause Type 1 diabetes.

C. Allegation concerning "factor unrelated"

In his first post-hearing brief, Petitioner's counsel argued that "the respondent has not met its burden of establishing the existence of a factor unrelated." (Brief filed 8-31-11, p. 50.) Petitioner's counsel, however, misstates the applicable law.

If a petitioner has established a *prima facie* case that the vaccine contributed to causing the injury in question, *then* the burden shifts to the Respondent to show, by a preponderance of the evidence, that the injury was caused by factors unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); *Shalala v. Whitecotton*, 514 U.S. 268, 270-71, 115 S. Ct. 1477, 131 L.Ed.2d 374 (1995) ("The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused by factors unrelated to the administration of the vaccine* * *. If the Secretary fails to rebut, the claimant is entitled to compensation" (citation & internal quotation marks omitted)); *De Bazan*, 539 F.3d at 1352 ("Once the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact, the burden shifts to the government to prove '[by] a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition.'") However, if, as in the case here, a petitioner *fails* to establish a *prima facie* case, the burden does *not* shift. *Bradley v. HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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[24] Dr. Bercu acknowledged that there is some evidence that the Coxsackie virus and the rubella *wild* virus (perhaps a reference to *in utero* infection by the rubella wild virus) may also cause Type 1 diabetes. (Ex. A, p. 7.) But he added that there is no evidentiary support for causation of diabetes by any of the three weakened viruses contained in the MMR vaccine. (*Id*.)

In this case, Petitioner did not come close to establishing a *prima facie* case, for the reasons set forth above. Accordingly, the Respondent was *not* required to demonstrate that Petitioner's condition was caused by some specific non-vaccine factor.

XII

PETITIONER'S CASE FAILS THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen'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. If Althen satisfies this burden, she 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."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioner's "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits *specifically* within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioner's evidence in this case clearly does not satisfy *any* of the three parts of the *Althen* test.

A. Application of Althen Prongs 1 and 2 to this case

One interpretative issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that a petitioner must provide "(1) a medical theory causally connecting the vaccination and the injury," and "(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. *See*, *e.g.*, *Kuperus v. HHS*, No. 01-60V, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, No. 96-518V, 2002 WL 31441212, at *18 n.42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See*, *e.g.*, *Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30,

2008). And, most importantly, the *Federal Circuit itself* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question *can* cause the *type* of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the *particular* vaccination *did* cause the *particular* condition of the vaccinee in question.

A few decisions of judges and special masters have discussed issues with respect to the *precise* interpretation of Prongs 1 and 2 of *Althen*. *E.g.*, *Doe 11*, 83 Fed. Cl. at 173-74; *Scott v. HHS*, 2006 WL 2559776, at *18 (Fed. Cl. Spec. Mstr. Aug. 21, 2006); *Nussman v. HHS*, 2008 WL 449656, at *12-13 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd*, 83 Fed. Cl. 111 (2008); *Fields v. HHS*, 2008 WL 2222141, at *7 n.5 (Fed. Cl. Spec. Mstr. May 14, 2008). However, it is *not* necessary, in this case, to delve into any such potential interpretative issues, since under any reasonable interpretation of *Althen*, the Petitioner's causation evidence put forward in this case could *not* satisfy either of the first two prongs of the *Althen* test.

That is, as set forth in detail above, I have concluded that Petitioner has fallen far short of demonstrating either that the vaccine *can* contribute, in *general*, to the causation of Type 1 diabetes, or that Petitioner's own MMR vaccination *did* cause Petitioner's own case of Type 1 diabetes. Thus, Petitioner's causation arguments in this case would fail under *any* interpretation of *Althen's* Prongs 1 and 2.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an *overall matter*, a petitioner must demonstrate that it is "more probable than not" that the *particular* vaccine was a substantial contributing factor in causing the *particular* injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that the MMR vaccine contributed to the causation of Petitioner's Type 1 diabetes.

B. Application of Prong 3 of the Althen test to this case

Since I have concluded that Petitioner has failed to satisfy either of the *first two* prongs of *Althen*, I need not determine whether Petitioner's case satisfies the *third* prong. But in the interest of completeness, I will add a brief discussion of Prong 3.

To be sure, one striking aspect of this case is that Petitioner suffered the first symptoms of her Type 1 diabetes about one-to-two months after her MMR vaccination in question; that temporal relationship might naturally cause a lay person to consider whether a *causal* relationship exists. However, for all of the reasons detailed above, the evidence in this case failed, by a large margin, to provide any reason to believe that MMR vaccinations *can* cause a case of Type 1 diabetes *in general*, or that Petitioner's MMR vaccination *did* cause her own case of diabetes.

Moreover, as explained above in Section VII of this Decision, the occurrence of Petitioner's first diabetes symptoms only about one to two months post-vaccine in fact militates strongly *against*

Petition on the timeliness issue, since the evidence strongly indicates that *whatever* caused the Type 1 diabetes, it would take a *year or more* for the islet cell destruction to proliferate to the point where symptoms would develop.

C. This is not a close case

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a close case. As set forth in detail in the sections above, I find that the testimony of the Respondent's experts was *much* more persuasive than that of Petitioner's expert Dr. Shoenfeld, concerning all of the issues raised by Dr. Shoenfeld's causation theory. Overall, I found the evidence in this case to be quite one-sided.[25]

XIII

CONCLUSION

The record of this case demonstrates plainly that Amy Crutchfield has been through a painful medical ordeal. She is certainly deserving of great sympathy. Congress, however, designed the Program to compensate only the individuals whose injuries can be linked causally, either by a Table Injury presumption or causation-in-fact evidence, to a listed vaccine. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that Petitioner in this case is *not* entitled to a Program award.[26]

/s/ George L. Hastings, Jr.

George L. Hastings, Jr.
Special Master

[25] While it does *not* constitute "evidence" in this case, it is still noteworthy that in several other Vaccine Act cases special masters have rejected claims that vaccines caused Type 1 diabetes. *Hennessey v. HHS*, No. 01–190V, 2009 WL 1709053 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd* 91 Fed. Cl. 126 (Fed. Cl. 2010) (rejecting Dr. Shoenfeld's theory that the hepatitis B vaccine caused Type 1 diabetes or aggravated an underlying pre-diabetic condition); *Meyers v. HHS*, No. 04-1771V, 2006 WL 1593947 (Fed. Cl. Spec. Mstr. May 22, 2006) (petitioner failed to establish a causal link between DTaP vaccine and Type 1 diabetes); *Baker v. HHS*, No. 99-653V, 2003 WL 22416622 (Fed. Cl. Spec. Mstr. Sept. 26, 2003) (rejecting claim that multiple vaccinations caused Type 1 diabetes).

It is also noteworthy that in a number of other Vaccine Act cases, Dr. Shoenfeld's theories have been rejected, and sometimes strongly criticized. See, *e.g.*, *Lombardi v. HHS*, 656 F.3d 1343, 1355 (Fed. Cir. 2011); *Shapiro v. HHS*, 105 Fed. Cl. 353, 359-60 (2012) ("Dr. Shoenfeld's own published work contradicts his theory"); *Hennessey v. HHS*, 91 Fed. Cl. 126, 135-42 (2010); *Hennessey v. HHS*, No. 01-190V, 2009 WL 1709053, at *44, *52-*53, *56, * 59 (Fed. Cl. Spec. Mstr. May 29, 2009) (Dr. Shoenfeld was "tailoring his opinion" and violated the "intellectual rigor" test--*id*. at *44); *John Doe 54 v. HHS*, No. 99-454V, 2009 WL 5196160 (Fed. Cl. Spec. Mstr. Dec. 22, 2009) (Dr. Shoenfeld's report described as "misleading," "unreliable," and containing "errors"--*id*. at *22; his opinion was "unpersuasive"--*id*. at 21, 23); *Doe 60 v. HHS*, 2010 WL 1506010 at *25-30 (Fed. Cl. Spec. Mstr. Jan. 29, 2010) (Dr. Shoenfeld took "inconsistent positions" (*id*. at *28); was "not persuasive" (*id*. at 29); and did "stretch well beyond what the facts" indicate—*id*. at *30), *aff'd*, 94 Fed. Cl. 597, 618-19 (2010).

[26] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.