IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: July 18, 2008)

DO NOT PUBLISH

SHARON SANCHEZ, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 04-1361V Entitlement; Hepatitis B Vaccine; Juvenile Rheumatoid Arthritis (JRA); Medical Witness Credibility; Proffer on Damages

DECISION ON ENTITLEMENT AND DAMAGES[1]

Petitioner, Sharon Sanchez (Ms. Sanchez),[2] seeks compensation under the National Vaccine Injury Compensation Program (Program).[3] Ms. Sanchez suffers systemic Juvenile Rheumatoid

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] Ms. Sanchez's mother, Geovanna Tarabocchia (Ms. Tarabocchia), commenced this action on Ms. Sanchez's behalf. Ms. Sanchez attained the age of majority on December 27, 2007. *See, e.g.*, Petitioner's Motion to Amend the Caption (Motion), filed April 7, 2008. She pursues now the action in her own right.

[3] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

Arthritis (JRA).[4] *See generally* Petitioner's exhibit (Pet. ex.) 22; Respondent's exhibit (R. ex.) A. Ms. Sanchez relates her systemic JRA to an initial Hepatitis B vaccination that she received on September 14, 2001. *See* Petition (Pet.) at 1; Pet. ¶ 3. Ms. Sanchez understands that she pursues necessarily her claim upon an actual causation theory. *See generally* Petitioner's Prehearing Memorandum (P. Memo).

THE LEGAL FRAMEWORK

The United States Court of Appeals for the Federal Circuit (Federal Circuit) endorses the Restatement (Second) of Torts as a "uniform approach" to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to prevail, a petitioner must demonstrate by the preponderance of the evidence that (1) "but for" the administration of a vaccine listed on the Vaccine Injury Table (Table), petitioner would not have been injured, and (2) a vaccine listed on the Table was "a 'substantial factor' in bringing about" petitioner's injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431. The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148-50 (Fed. Cir. 1992). Rather, long-standing, well-established Federal Circuit precedent instructs that a petitioner establishes a *prima facie* actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317 (Fed. Cir. 2006); *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d 1144. The "*prima facie* case" is "a party's production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party's favor." BLACK'S LAW DICTIONARY 1228 (8th ed. 2004).

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[4] JRA is "rheumatoid arthritis of children, with swelling, tenderness, and pain in one or more joints, which may lead to impaired growth and development, limitation of movement, ankylosis, and flexion contractures." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 149 (30th ed. 2003). The condition "is often accompanied by systemic manifestations such as spiking fever, transient rash on the trunk and extremities, hepatosplenomegaly, generalized lymphadenopathy, and anemia." *Id.* JRA "with systemic features is also called *Still's disease*." *Id.* (italics in original).

The centerpiece of a *prima facie* actual causation case is the "medical theory." In a petitioner's *prima facie* actual causation case, the "medical theory" is the "reliable medical or scientific explanation" buttressing the proposition that a vaccine listed on the Table can cause a particular injury. *Grant*, 956 F.2d at 1148. Thus, the medical theory must consist of "more than subjective belief." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (An "expert's bald assurance of validity is not enough."). Instead, the medical theory must be grounded "in the methods and procedures of" medicine or science. *Daubert*, 509 U.S. at 590; *see also Daubert*, 43 F.3d at 1317 ("[T]he analysis undergirding" the medical theory must fall "within the range of accepted standards governing" medical or scientific research.). Nevertheless, the medical theory need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. The medical theory need only be "logical" and "probable," given "the circumstances of the particular case." *Id.* at 548-49.

If a petitioner mounts a *prima facie* actual causation case, respondent may present rebuttal evidence. In respondent's rebuttal case, respondent may contest perhaps a petitioner's medical theory through medical expert testimony. Or, respondent may challenge perhaps the factual assumptions that a petitioner's expert adopts in rendering an opinion. Then, the special master weighs all of the evidence to determine if a petitioner has met the evidentiary burden on the merits of the actual causation case.

However, a petitioner does not gain Program compensation upon proving successfully the merits of the petitioner's actual causation case. *See Grant*, 956 F.2d at 1149. The Vaccine Act requires specifically the special master to "also determine that 'there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine,'" or "alternative etiologies." *Grant*, 956 F.2d at 1149, citing § 300aa-13(a)(1). The Vaccine Act provides that "factors unrelated to the administration of the vaccine," or alternative etiologies

> may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

§ 300aa-13(a)(2)(B). The Vaccine Act provides also that "factors unrelated to the administration of the vaccine," or alternative etiologies, do not encompass "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." § 300aa-13(a)(2)(A).

The Federal Circuit has decreed that the burden of proving alternative actual causation rests squarely with respondent. *See, e.g.*, *Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007); *Althen*, 418 F.3d at 1281-82; *Knudsen*, 35 F.3d at 547, citing *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376 (Fed. Cir. 1994). In addition, the Federal Circuit has decreed that "the standards that apply to a petitioner's proof of actual causation in fact" are "the same as those that apply to the

government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549. Thus, respondent establishes a *prima facie* alternative actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the [factor unrelated to the administration of the vaccine] and the injury; (2) a logical sequence of cause and effect showing that the [factor unrelated to the administration of the vaccine] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the factor unrelated to the administration of the vaccine] and injury." *Althen*, 418 F.3d at 1278; *see also Capizzano*, 440 F.3d 1317; *Knudsen*, 35 F.3d 543; *Grant*, 956 F.2d 1144.

If respondent mounts a *prima facie* alternative actual causation case, a petitioner may present rebuttal evidence. Then, the special master weighs all of the evidence to determine if respondent has met the evidentiary burden on the merits of the alternative actual causation case. However, American tort jurisprudence recognizes that many cases involve "a number of events" which have "an appreciable effect" on a party's "harm." Restatement 2d Torts § 433 cmt. d; *see also Shyface*, 165 F.3d at 1352. Thus, in addressing respondent's alternative actual causation case, a petitioner need not eliminate *per se* other causes for the petitioner's injury. *See, e.g.*, *Shyface*, 165 F.3d 1344; *but see Althen*, 418 F.3d at 1281 (A prong of a proposed actual causation formula "requiring that the claimant provide proof of . . . the elimination of other causes is merely a recitation of this court's well-established precedent" regarding actual causation.). Rather, in addressing respondent's alternative actual causation case, a petitioner need only establish that the administration of a vaccine constitutes a substantial factor in the development of an injury, even in the presence of other potential causes. *See Shyface*, 165 F.3d at 1352, citing Restatement 2d Torts, § 430 cmt. d ("It is not necessary that [the administration of a vaccine] be *the* cause, using the word 'the' as meaning the sole and even the predominant cause.") (emphasis in original). In contrast, by mandating the showing that an alternative "agent" is "*principally* responsible for causing the petitioner's illness, disability, injury, condition, or death," § 300aa-13(2)(B) (emphasis added), Congress expected apparently any factor unrelated to the administration of a vaccine to be the "predominant" cause of a petitioner's injury, thus preventing the administration of a vaccine "from being a substantial factor" in the petitioner's injury. Restatement 2d Torts § 433, cmt. d; *see also Knudsen*, 35 F.3d at 549-50.

BACKGROUND

The parties do not dispute the relevant facts. Ms. Sanchez was born on December 27, 1989. *See, e.g.*, Pet. ex. 18 at 1, ¶ 1. In infancy and in early childhood, Ms. Sanchez received a full complement of routine vaccinations through the Elizabeth, New Jersey Department of Health and Human Services, including a diphtheria-tetanus-pertussis (DTP) vaccination and oral polio vaccine (OPV) on March 28, 1990; a DTP vaccination and OPV on May 16, 1990; a DTP vaccination on August 1, 1990; a measles-mumps-rubella (MMR) immunization and a Hemophilus influenzae type b (Hib) vaccination on April 3, 1991;[5] OPV on May 29, 1991; a DTP vaccination on August 28,

[5] Ms. Sanchez may have received a Hib vaccination on January 30, 1991. *See* Pet. ex. 4 at (continued...)

1991; and a DTP vaccination, OPV and an MMR immunization on May 17, 1994. *See* Pet. ex. 4 at 1. Ms. Sanchez's medical history during Ms. Sanchez's infancy and early childhood is not otherwise remarkable. *See generally* Pet. ex. 1.

On February 19, 2001, Ms. Sanchez presented to her pediatrician, Alfredo Tutiven, M.D. (Dr. Tutiven). *See* Pet. ex. 1 at 10. She measured 58 inches in height. *See* Pet. ex. 1 at 10. She weighed 134 pounds. *See* Pet. ex. 1 at 10. She complained about a "rash on all her body." Pet. ex. 1 at 10.

On July 12, 2001, Ms. Sanchez presented to Dr. Tutiven. *See* Pet. ex. 1 at 11. She measured 58 inches in height. *See* Pet. ex. 1 at 11. She weighed 136 pounds. *See* Pet. ex. 1 at 11. She complained again about a "rash" that covered "all" of her "body." Pet. ex. 1 at 11. She indicated that the rash itched. *See id.* In addition, she complained about a "fever" of "102" degrees Fahrenheit. Pet. ex. 1 at 11.

On July 16, 2001, Steven J. Weiss, M.D. (Dr. Weiss), a board-certified allergist and immunologist, evaluated Ms. Sanchez for "allergies." Pet. ex. 5 at 1. According to Dr. Weiss, Ms. Sanchez reported that during the previous "6 months," she had exhibited intermittently "dots on [her] legs, stomach, arms [and] face" that were "itchy" at times and "hot to touch." *Id.* Ms. Sanchez related that the "dots" were "better inside" and "worse outside." *Id.* Ms. Sanchez believed that the "dots" improved with the use of "Zyrtec." *Id.* Dr. Weiss determined apparently that Ms. Sanchez was "allergic to dust and grass." Pet. ex. 2 at 5.

On September 14, 2001, Ms. Sanchez received a Hepatitis B vaccination through the Elizabeth, New Jersey Department of Health and Human Services. *See* Pet. ex. 11 at 1.

On October 12, 2001–approximately one month after her September 14, 2001 Hepatitis B vaccination–Ms. Sanchez presented to Dr. Tutiven. *See* Pet. ex. 1 at 11. She measured 59 inches in height. *See* Pet. ex. 1 at 11. She weighed 140 pounds. *See* Pet. ex. 1 at 11. She complained about "bone pain, loose hair" and "rash." Pet. ex. 1 at 11. Dr. Tutiven referred Ms. Sanchez for laboratory testing. *See* Pet. ex. 4 at 8-9. Two results were abnormal. *See* Pet. ex. 4 at 8-9. Ms. Sanchez's "C reactive protein" was "positive." Pet. ex. 4 at 8. Ms. Sanchez's "sedimentation rate" was "H[igh]" at "82." Pet. ex. 4 at 9. Based upon the results, Dr. Tutiven suspected rheumatoid arthritis. *See* Pet. ex. 1 at 11. Dr. Tutiven recommended a rheumatology evaluation. *See* Pet. ex. 1 at 11.

Ms. Sanchez suffered greater "joint pain" in her "wrist, elbow, ankles [and] knees" preceding a scheduled examination by a rheumatologist. Pet. ex. 8 at 4. So, on October 20, 2001, Ms. Sanchez sought medical attention in the Emergency Department of Saint Barnabas Medical Center in Livingston, New Jersey. *See generally* Pet. ex. 8. A triage nurse observed that Ms. Sanchez displayed "difficulty ambulating." Pet. ex. 8 at 4. And, the triage nurse recorded that Ms. Sanchez

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[5](...continued)
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was "now experiencing hair loss" following a "Hep[atitis] B vaccine [one] month ago." *Id.* Finally, the triage nurse noted Ms. Sanchez's "seasonal allergies" treated with "Zyrtec." *Id.*

The Emergency Department physician directed the administration of a medication "for pain." Pet. ex. 8 at 5; *see also* Pet. ex. 8 at 3, 6. Then, the Emergency Department physician obtained x-rays of Ms. Sanchez's "left foot and ankle." Pet. ex. 8 at 8-9; *see also* Pet. ex. 8 at 3, 6. The x-rays were "normal." Pet. ex. 8 at 8-9; *see also* Pet. ex. 8 at 3.

The Emergency Department physician considered a number of "disorders" as the source for Ms. Sanchez's pain. Pet. ex. 8 at 3. But, the Emergency Department physician diagnosed simply "Musc[ulo]/Skel[etal] Pain." Pet. ex. 8 at 6. The Emergency Department physician prescribed "Motrin." *Id.*; *see also* Pet. ex. 8 at 3. In addition, the Emergency Department physician advised "f[ollow]/u[p]" with a "rheumatologist." Pet. ex. 8 at 6; *see also* Pet. ex. 8 at 3.

On October 22, 2001, Yukiko Kimura, M.D. (Dr. Kimura), Chief of Pediatric Rheumatology at Hackensack University Medical Center, and April Bingham, M.D. (Dr. Bingham), Pediatric Rheumatology Fellow at Hackensack University Medical Center, evaluated Ms. Sanchez for "joint pain" and "hair loss" following a "Hepatitis vaccine." Pet. ex. 2 at 8; *see also* Pet. ex. 2 at 5. Ms. Sanchez reported "pain" and "swelling" that occurred "in her knees, left ankle, and left wrist," as well as in "her finger joints" and in her "upper back," beginning "[o]ne week after" the "vaccination." Pet. ex. 2 at 5-6; *see also* Pet. ex. 2 at 8. Although Ms. Sanchez experienced "morning stiffness," she related that "[h]er symptoms were worse" following activity and "in the evening." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 8. According to Ms. Sanchez, her pain interfered with common tasks, such as "writing and walking up the stairs," and with "sleeping." Pet. ex. 2 at 5-6; *see also* Pet. ex. 2 at 8. Ms. Sanchez believed that "Advil [and] Motrin" eased the pain. Pet. ex. 2 at 8; *see also* Pet. ex. 2 at 5.

Dr. Kimura and Dr. Bingham noted Ms. Sanchez's "history of a rash," depicted as "pruritic red bumps over [Ms. Sanchez's] entire body," during Summer 2001. Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 8. They understood that based upon "allergy testing" that was positive for "dust and grass," Ms. Sanchez's treating physicians "attributed" the rashes "to allergies." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 8. They understood also that "Zyrtec" appeared to "alleviate [Ms. Sanchez's] symptoms." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 8. In addition, Dr. Kimura and Dr. Bingham noted that Ms. Sanchez exhibited apparently "no fevers except for one episode of a temperature of 103° in August" 2001. Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 8. Finally, Dr. Kimura and Dr. Bingham noted Ms. Tarabocchia's concern that while Ms. Sanchez had "been gaining weight," she had "not been growing well with regards to height." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 9. Nevertheless, Dr. Kimura and Dr. Bingham considered Ms. Sanchez's medical history to be "unremarkable." Pet. ex. 2 at 5.

Upon examining Ms. Sanchez, Dr. Kimura and Dr. Bingham commented that Ms. Sanchez was "in a wheelchair" because she was "unable to walk due to left ankle pain." Pet. ex. 2 at 5-6; *see also* Pet. ex. 2 at 8-9. Ms. Sanchez measured 59 inches in height. *See* Pet. ex. 2 at 6. She weighed

137 pounds. *See* Pet. ex. 2 at 6. Dr. Kimura and Dr. Bingham determined that Ms. Sanchez displayed "swelling" and "tenderness," accompanied by decreased "motion," at various points throughout her "musculoskeletal" system. Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 9. Dr. Kimura and Dr. Bingham observed an "erythematous papule" on Ms. Sanchez's "right cheek." Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 9. And, Dr. Kimura and Dr. Bingham observed "a few short hairs anteriorly on [Ms. Sanchez's] scalp," but "no obvious alopecia." Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 9.

Based upon their clinical impressions of Ms. Sanchez's condition, Dr. Kimura and Dr. Bingham offered a "differential" diagnosis that included "reactive arthritis, pauciarticular juvenile rheumatoid arthritis, spondyloarthritis, Lyme arthritis, and a post[-]vaccine arthritis/serum sickness." Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 10. Dr. Kimura and Dr. Bingham considered "spondyloarthritis" to be "the most likely" explanation for Ms. Sanchez's symptoms. Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 10. They planned "further blood work." Pet. ex. 2 at 6; *see also* Pet. ex. 2 at 10. They advised Ms. Sanchez to pursue "an ophthalmology slit lamp exam." Pet. ex. 2 at 7; *see also* Pet. ex. 2 at 10. They "referred" Ms. Sanchez "for physical therapy." Pet. ex. 2 at 7; *see also* Pet. ex. 2 at 10. They prescribed "Naprosyn." Pet. ex. 2 at 7; *see also* Pet. ex. 2 at 10. They instructed Ms. Sanchez to return for additional evaluation "in 4-6 weeks." Pet. ex. 2 at 7; *see also* Pet. ex. 2 at 10.

On October 27, 2001, a physical therapist assessed Ms. Sanchez during a "Physical Therapy Initial Orthopedic Evaluation." Pet. ex. 10 at 1. The physical therapist remarked that Ms. Sanchez's "pain" prevented accurate results on various tests. *Id.* The physical therapist recommended one therapy session per week, augmented by a "H[ome]Exercise]P[rogram]," to "maximize R[ange]O[f]M[ovement]," to improve "strength," and to decrease "pain." Pet. ex. 10 at 2.

On November 1, 2001, Warren Klein, M.D. (Dr. Klein), performed an ophthalmologic examination on Ms. Sanchez. *See* Pet. ex. 7 at 1.

By November 6, 2001, Ms. Sanchez developed "stomach pain." Pet. ex. 2 at 10. Dr. Tutiven attributed apparently Ms. Sanchez's "abd[ominal] complaints" to Naprosyn. Pet. ex. 2 at 12. Ms. Sanchez "stopped" the medication on Dr. Tutiven's "advice." *Id.*

Ms. Sanchez presented to Hackensack University Medical Center Division of Pediatric Rheumatology on November 19, 2001, for further evaluation. *See* Pet. ex. 2 at 12-14. Ms. Sanchez's "arthritis" was "more active." Pet. ex. 2 at 14. Ms. Sanchez reported "a lot of pain in" her mid-to-upper "back," as well as "generalized body aches" and stiffness in the morning. Pet. ex. 2 at 12. In addition, Ms. Sanchez reported that she had "no energy." *Id.* According to Ms. Sanchez, she had experienced "fever" and "rash." *Id.* Indeed, Ms. Sanchez exhibited "scattered patches of erythema" on her "cheeks." *Id.* And, according to Ms. Sanchez, she had experienced additional hair loss. *See id.*

Dr. Kimura reviewed laboratory results from October 25, 2001. *See* Pet. ex. 2 at 14. Believing that Ms. Sanchez's "fever" reflected a "probable viral illness," Dr. Kimura directed more

"labs," including a "throat" culture and a test for "E[pstein]B[arr]V[irus]." Pet. ex. 2 at 14. Dr. Kimura substituted "Vioxx" for "Naprosyn." *Id.*

Ms. Sanchez returned to Hackensack University Medical Center Division of Pediatric Rheumatology on November 26, 2001. *See* Pet. ex. 2 at 16. Since November 19, 2001, Ms. Sanchez had experienced "daily temp[erature] spikes" with "intermittent rash." Pet. ex. 2 at 16. In addition, she had received emergent medical treatment for "fever, chills, shaking" and "abdominal pain." *Id.* She was using "Celebrex" rather than Vioxx. *Id.* Examining medical personnel suspected "systemic JRA." Pet. ex. 2 at 18.

Dr. Kimura and Dr. Bingham continued to monitor Ms. Sanchez for fever, rash and joint pain. *See, e.g.* Pet. ex. 2 at 19. On December 3, 2001, they changed their clinical impression of Ms. Sanchez's condition from "[questionable] systemic JRA," Pet. ex. 2 at 19, to "probable systemic JRA." Pet. ex. 2 at 21. They referred Ms. Sanchez to "onc[ology] for" a "bone marrow" analysis. *Id.*

On December 6, 2001, Ms. Sanchez presented to Tomorrows Children's Institute for Cancer and Blood Disorders at The Children's Hospital, Hackensack University Medical Center, "for a bone marrow aspirate." Pet. ex. 3 at 2. In reviewing Ms. Sanchez's medical history, Paul Harlow, M.D. (Dr. Harlow), noted that Ms. Sanchez was well apparently until September 2001, when "she noticed left wrist pain and swelling and left ankle pain and swelling." *Id.* Dr. Harlow understood that after Ms. Sanchez "developed pain in her left knee and pain and swelling in her left fingers," she consulted "her local medical doctor" who "referred" her "to rheumatology." *Id.* According to Dr. Harlow, Ms. Sanchez was experiencing also "intermittent rashes of two varieties." *Id.* Dr. Harlow described one rash–detected perhaps in "June" 2001, Pet. ex. 3 at 14–as "an urticaria rash which is all over [Ms. Sanchez's] body." Pet. ex. 3 at 2; *see also* Pet. ex. 3 at 14. Dr. Harlow reflected that an allergist had "diagnosed [Ms. Sanchez] with dust mite and grass allergies." Pet. ex. 3 at 2; *see also* Pet. ex. 3 at 14. Dr. Harlow described the other rash as "a macular rash which is non-pruritic," occurring "on various parts of [Ms. Sanchez's] body." Pet. ex. 3 at 2. Indeed, upon examining Ms. Sanchez, Dr. Harlow observed "a macular erythematous rash" on Ms. Sanchez's "chest." Pet. ex. 3 at 3.

Dr. Harlow obtained several bone marrow "specimens" for diagnostic testing, including "smear" and various cultures. Pet. ex. 3 at 3. Dr. Harlow determined that Ms. Sanchez's marrow was "normal," demonstrating "a good myeloid to erythroid ratio with no signs of leukemic infiltration." *Id.* As a consequence, Dr. Harlow did not contemplate additional hematology/oncology evaluation. *See, e.g.*, Pet. ex. 3 at 3.

On December 10, 2001, Ms. Sanchez "started on prednisone" following an episode of "[increased] rash" and "itching." Pet. ex. 2 at 21; *see also* Pet. ex. 2 at 23. Although Ms. Sanchez's arthritis appeared "better," Pet. ex. 2 at 25, Ms. Sanchez "stopped abruptly" the prednisone on December 16, 2001, when she experienced a likely "drug eruption." Pet. ex. 2 at 23. On December

19, 2001, Dr. Kimura considered either another attempt with prednisone or a trial of methotrexate. *See* Pet. ex. 2 at 25.

By December 24, 2001, Ms. Sanchez's "c[omplaints]/o[f] joint pain" had "[decreased]." Pet. ex. 2 at 26. In addition, Ms. Sanchez's "systemic" symptoms had "improved." Pet. ex. 2 at 28. Nevertheless, Dr. Kimura instituted methotrexate and "folic acid" on December 24, 2001. *Id.* In addition, Dr. Kimura, or a member of Dr. Kimura's staff, administered an "Influenza vaccine" to Ms. Sanchez on December 24, 2001. *Id.* Ms. Sanchez did not experience apparently any adverse reaction to the vaccination.

Ms. Sanchez's arthritis remained "very active." Pet. ex. 2 at 31. Indeed, on March 6, 2002, Ms. Sanchez suffered a "severe arthritis flare" accompanied by "mild M[acrophage]A[ctivation]S[yndrome]." Pet. ex. 2 at 78. Ms. Sanchez entered the hospital for "pulse steroid" treatment. *Id.*

After Ms. Sanchez's hospitalization, Dr. Kimura encountered difficulty controlling Ms. Sanchez's arthritis. *See, e.g.*, Pet. ex. 2 at 34-36, 38-46.[6] In the ensuing years, Dr. Kimura has prescribed a variety of additional medications, like Humira and Remicade. *See, e.g.*, Pet. ex. 17 at 155-56, 159-61.[7] Yet, Ms. Sanchez has suffered frequent flares of her arthritis. *See, e.g.*, Pet. ex. 28 at 24-25. Nevertheless, Ms. Sanchez has been able to achieve several typical milestones of adolescence, including obtaining employment as a life guard at an indoor pool, *see* Pet. ex. 30 at 3, and obtaining a driver's license. *See* Pet. ex. 28 at 79.

[6] On August 26, 2002, Dr. Kimura's staff decided to "defer" the administration of additional Hepatitis B vaccines to Ms. Sanchez. Pet. ex. 17 at 79.

[7] Also, in the ensuing years, Dr. Kimura, or a member of Dr. Kimura's staff, administered additional influenza vaccines to Ms. Sanchez, without apparent adverse effects. *See, e.g.*, Pet. ex. 17 at 56, 81.

THE MEDICAL TESTIMONY

Robert P. Sundel, M.D. (Dr. Sundel)[8]

Dr. Sundel opined that Ms. Sanchez's September 14, 2001 Hepatitis B vaccination was "the trigger" for Ms. Sanchez's systemic JRA. Tr. at 23; *see also* Tr. at 11-12. Dr. Sundel based his opinion upon "biologic plausibility;" the "severity" of Ms. Sanchez's initial symptoms of systemic JRA and the "close temporal relationship" between Ms. Sanchez's September 14, 2001 Hepatitis B vaccination and the onset of Ms. Sanchez's systemic JRA. Tr. at 108; *see also* Tr. at 11-12. In addition, Dr. Sundel based his opinion upon "the absence of" an alternative "explanation" for Ms. Sanchez's systemic JRA. Tr. at 23; *see also* Tr. at 12.

Acknowledging "all sorts of difficulties with nomenclature," Dr. Sundel defined generally JRA as "arthritis that occurs without explanation in a child" and that persists "for at least six weeks." Tr. at 14; *see also* Tr. at 15, 30, 114. Dr. Sundel classified "systemic JRA as a subset of" JRA. Tr. at 104; *see also* Tr. at 22 ("[T]here are different forms of JRA."). Dr. Sundel stated that systemic JRA presents with "evidence of systemic inflammation, such as fever and rash and abnormal laboratory studies." Tr. at 14-15. Dr. Sundel characterized the fever associated "[c]lassically" with systemic JRA as "a double quotidian fever." Tr. at 15. Dr. Sundel explained that a double quotidian fever occurs "in the morning" and again "in the evening." *Id.* Dr. Sundel said that the double quotidian fever tends to be "persistent and prolonged," rather than "transient or intermittent." *Id.* Dr. Sundel characterized the rash associated classically with systemic JRA as "a salmon pink rash." Tr. at 16. Dr. Sundel depicted "the lesions" of the rash as "typically raised," measuring approximately one-half-of-one "centimeter in diameter." *Id.* According to Dr. Sundel, the rash

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[8] Dr. Sundel received his medical degree in an accelerated program from Boston University in 1982. Pet. ex. 21 at 1; *see also* Tr. at 6. He is Director of the Rheumatology Program, and Medical Director of the Center for Ambulatory Treatment and Clinical Research, at Children's Hospital Boston. Pet. ex. 21 at 2; *see also* Tr. at 7. As Director of the Rheumatology Program, he supervises "six attending pediatric rheumatologists and five trainees," coordinating services "for the patients with rheumatologic diseases." Tr. at 7. In addition, he maintains a clinical practice, treating "a significant percentage of" the pediatric rheumatology patients at Children's Hospital Boston. *Id.*; *see also* Tr. at 10. Further, he manages "the training" of future "pediatric rheumatologists." Tr. at 8. As Medical Director of the Center for Ambulatory Treatment and Clinical Research, he supervises "the major outpatient research arm of" the hospital. *Id.* He holds an academic appointment as an Associate Professor of Pediatrics at Harvard Medical School. Pet. ex. 21 at 1; *see also* Tr. at 7. As one of approximately 200 pediatric rheumatologists "in the country," he has published articles in "virtually all" topics regarding "pediatric rheumatologic diseases." Tr. at 9. However, he identified his "major" research interests as "vasculitis and Kawasaki Disease." *Id.* He is certified in pediatrics by the American Board of Pediatrics; in allergy and immunology by the American Board of Allergy and Immunology; and in pediatric rheumatology by the American Board of Pediatrics. Pet. ex. 21 at 1; *see also* Tr. at 9-10. He has served on at least one American Academy of Pediatrics committee with respondent's expert. Tr. at 43.

appears particularly with "fever" or with exposure "to warmth." *Id.*; *see also* Tr. at 47. Dr. Sundel said that the rash is not usually "itchy," Tr. at 16; *see also* Tr. at 18, or "hot." Tr. at 47. Dr. Sundel described the onset of joint pain in systemic JRA as "variable." Tr. at 16. However, Dr. Sundel asserted that joint pain in systemic JRA mostly "occurs within six months of the onset of the fever." *Id.*

Dr. Sundel distinguished systemic JRA from "adult[-]onset Still's disease." Tr. at 26-27. Dr. Sundel recognized that systemic JRA and adult-onset Still's disease "are manifested by fever, rash, and arthritis." Tr. at 27. However, Dr. Sundel emphasized that systemic JRA and adult-onset Still's disease occur in populations of "widely[-]disparate ages." *Id.* Moreover, Dr. Sundel indicated that, at times, "a potentially[-]fatal" condition, "Macrophage Activation Syndrome," complicates systemic JRA, but not "essentially" adult-onset Still's disease. *Id.*

Dr. Sundel labeled systemic JRA as "a rare disease." Tr. at 15; *see also* Tr. at 106. According to Dr. Sundel, systemic JRA represents "only 10 percent of all" JRA. Tr. at 106. And, Dr. Sundel estimated that 5,000 to 10,000 "children in this country" suffer currently systemic JRA. Tr. at 36. Indeed, Dr. Sundel stated that in his practice, he has treated just 40 children with systemic JRA. *See id.*

Dr. Sundel conceded that the "cause" of systemic JRA is "unclear." Tr. at 27; *see also* Tr. at 22. Nevertheless, Dr. Sundel maintained that the medical community considers presently systemic JRA, like "all forms of inflammatory arthritis," Tr. at 22; *see also* Tr. at 106, to be an "autoimmune disease." Tr. at 104; *see also* Tr. at 22, 28. Dr. Sundel said that in autoimmune disease, "the body is responding to something intrinsic to the body." Tr. at 21-22; *see also* Tr. at 107. Yet, Dr. Sundel commented that "autoimmune" as a "term implies that" the medical community understands "more" about the phenomenon than the medical community understands about the phenomenon "[i]n reality." Tr. at 22. Dr. Sundel elaborated that the medical community suspects simply that "one of a variety of triggers in a genetically[-]susceptible host leads through some complicated and poorly[-]understood mechanism to a disease." Tr. at 23; *see also* Tr. at 48, 106. Although Dr. Sundel cited "infections" and "presumably some things in the environment," Tr. at 22; *see also* Tr. at 48, 104-05, among the "many triggers" for autoimmune disease, he offered that "the chances of finding any particular trigger is [sic] low." Tr. at 36; *see also* Tr. at 106. In fact, Dr. Sundel admitted that in "[m]ost cases" of autoimmune disease, "the trigger is not known." Tr. at 22; *see also* Tr. at 48. Thus, Dr. Sundel declared that until the medical community develops "an exclusive list of" triggers of autoimmune disease, "anything" constitutes a potential trigger of autoimmune disease. Tr. at 48. Moreover, Dr. Sundel posited that in "chronic" autoimmune diseases such as systemic JRA, Tr. at 26, there exists "often a difference between the triggering mechanism and the perpetuating mechanism." Tr. at 35.

According to Dr. Sundel, the latency between exposure to a trigger of autoimmune disease and onset of autoimmune disease is "basically" seven days "at one end of the spectrum." Tr. at 107; *see also* Tr. at 13. Dr. Sundel explained that in order to prompt manifestations of autoimmune disease, "the body" requires time "to find an antigen, . . ., to absorb [the antigen] into the immune

cells, to process [the antigen], and then to present [the antigen] to the rest of the immune system." Tr. at 107; *see also* Tr. at 13. Dr. Sundel said that the medical community does not "know" the latency between exposure to a trigger of autoimmune disease and onset of autoimmune disease at the other end of the spectrum. Tr. at 107. Dr. Sundel commented that the latency between Lyme Disease and an "inflammatory arthritis indistinguishable from JRA," Tr. at 105, is as much as "a year." Tr. at 107. So, Dr. Sundel suggested that "the outside" of the spectrum "is probably a very long time." *Id.*; *see also* Tr. at 13 (immunologic process "typically takes from a week on up").

Dr. Sundel recognized that "one major paper published in the last couple of years" advances that certain "abnormalities" in systemic JRA are more consistent with "autoinflammatory disease," Tr. at 104; *see also* Tr. at 28, or "the periodic fever syndromes," than with autoimmune disease. Tr. at 28; *see also* Tr. at 104. Even so, Dr. Sundel insisted, "every" autoinflammatory disease involves necessarily the "activation of the immune system." Tr. at 28; *see also* Tr. at 29. Proclaiming "fever" to be "the archetype of manifestation of inflammation," Dr. Sundel asserted that fever arises from the "release of cytokines" and "macrophagias," which "by definition are part of the immune system." Tr. at 29.

Dr. Sundel testified that in its "native state," Hepatitis B "is a particularly immuno-reactive virus that is very want to cause [a] variety of autoimmune and inflammatory diseases." Tr. at 109; *see also* Tr. at 31. Likewise, Dr. Sundel testified that "case reports" reflect "a variety of inflammatory and immunologic abnormalities following" the administration of Hepatitis B "vaccine." Tr. at 31; *see also* Tr. at 109. Dr. Sundel acknowledged "some differences" between Hepatitis B virus and Hepatitis B vaccine. Tr. at 116; *see also* Tr. at 115. For instance, Dr. Sundel said that because Hepatitis B vaccine is "attenuated," the vaccine will not cause "active infection." Tr. at 114; *see also* Tr. at 110. Nevertheless, Dr. Sundel asserted that one can compare validly "reactions" to Hepatitis B virus and Hepatitis B vaccine. Tr. at 114-15. Dr. Sundel stated that "the goal" of vaccination "is for the body to mount an immune response to a piece of the virus," rendering the vaccinee "immune to the native virus." Tr. at 115; *see also* Tr. at 112 (vaccine activates the immune system). Dr. Sundel maintained that the "protein" in Hepatitis B virus "is exactly the same as the protein" in Hepatitis B vaccine. Tr. at 114; *see also* Tr. at 110 ("wild-type" Hepatitis B "virus" and Hepatitis B vaccine are "essentially the same organism with the same biologic characteristics"), 115. In addition, Dr. Sundel maintained that the "antibodies" generated after exposure "to the protein" in either Hepatitis B virus or Hepatitis B vaccine "are the same." Tr. at 115. Thus, Dr. Sundel insisted that "certain stereotypical reactions to" the "protein," including autoimmune "disease" which "is caused by the body's" response to a protein, will occur following either infection with "the live" Hepatitis B virus" or Hepatitis B "immunization." *Id.*

In particular, Dr. Sundel contended that "precedent" demonstrates that like Hepatitis B virus, Hepatitis B vaccine "[c]auses arthritis." Tr. at 108-09; *see also* Tr. at 101. Dr. Sundel urged that the "different patterns" described in "each of the patients in the reports of post[-]hepatitis or post[-]hepatitis vaccine arthritis" appear to be "due" only to each patient's distinct "genetic make-up." Tr. at 101. Therefore, Dr. Sundel argued that he can "ascribe the same causality to" systemic JRA in the susceptible individual. *Id.*

Although Dr. Sundel has never identified a "trigger" for systemic JRA in any of his patients, Tr. at 36, Dr. Sundel attributed Ms. Sanchez's systemic JRA to Ms. Sanchez's September 14, 2001 Hepatitis B vaccination. *See* Tr. at 11-12, 23-24. Dr. Sundel depicted Ms. Sanchez as "a healthy girl" without "apparent reason to develop systemic JRA" before her September 14, 2001 Hepatitis B vaccination. Tr. at 12-13; *see also* Tr. at 23. Dr. Sundel agreed that Ms. Sanchez exhibited "a transient rash" on several occasions preceding the September 14, 2001 Hepatitis B vaccination. Tr. at 12; *see also* Tr. at 16-17, 23-25, 46. However, Dr. Sundel doubted that the rashes were "an initial manifestation of systemic JRA." Tr. at 14; *see also* Tr. at 17-18, 20, 24-26. Dr. Sundel commented that Ms. Sanchez did not experience "systemic features," like "fever or malaise," with the rashes. Tr. at 18; *see also* Tr. at 16 (no evidence suggesting a "double quotidian fever" before September 14, 2001). In addition, Dr. Sundel commented that Ms. Sanchez's treating physicians related the rashes to "allergies." Tr. at 12; *see also* Tr. at 20, 25. Further, Dr. Sundel commented that Ms. Sanchez's rashes responded to "antihistamine medications." Tr. at 12; *see also* Tr. at 18, 20, 24. Finally, Dr. Sundel commented that Ms. Sanchez's growth remained normal. *See* Tr. at 18, 21, 112. Thus, in Dr. Sundel's view, Ms. Sanchez "developed a severe systemic disabling arthritis" approximately "one week after" her September 14, 2001 Hepatitis B vaccination. Tr. at 23; *see also* Tr. at 13, 19, 50, 111-12. Dr. Sundel said that the initial manifestations of Ms. Sanchez's systemic JRA were "joint complaints" and "fever," Tr. at 13; *see also* Tr. at 19, 112, followed within a "month" by "gradually thinning" hair as Ms. Sanchez's hair "replacement" ceased as a consequence of the "insult" from "the onset of" Ms. Sanchez's systemic JRA. Tr. at 111-12; *see also* Tr. at 49-51. Moreover, Dr. Sundel noted that laboratory studies during Ms. Sanchez's first pediatric rheumatology evaluation in late October 2001 revealed "very significant inflammation." Tr. at 111; *see also* Tr. at 13, 19. Dr. Sundel proffered that the theoretical "immunologic mechanisms" of systemic JRA, Tr. at 11-13; *see also* Tr. at 108-09; the "close temporal relationship" between vaccination and disease onset, Tr. at 108-09; *see also* Tr. at 11-13; and "the absence of any other plausible explanation" for Ms. Sanchez's systemic JRA, Tr. at 23; *see also* Tr. at 12, allow him to conclude that Ms. Sanchez's September 14, 2001 Hepatitis B vaccination induced Ms. Sanchez's systemic JRA. *See* Tr. at 11-12, 23-24.

Carlos D. Rosé, M.D. (Dr. Rosé)[9]

Dr. Rosé opined that Ms. Sanchez's September 14, 2001 Hepatitis B vaccination did not cause Ms. Sanchez's systemic JRA. *See* Tr. at 57, 60. Dr. Rosé disputed the "biological" basis for ascribing systemic JRA to vaccination. Tr. at 60-64; *see also* Tr. at 97. In addition, Dr. Rosé advocated that before her September 14, 2001 Hepatitis B vaccination, Ms. Sanchez exhibited "symptoms" that are "compatible" with systemic JRA. Tr. at 57-60.

Dr. Rosé agreed that infection with wild Hepatitis B virus is associated with arthritis. *See* Tr. at 62. However, Dr. Rosé distinguished the arthritis following infection with wild Hepatitis B virus from systemic JRA. *See* Tr. at 62-63. According to Dr. Rosé, the arthritis following infection with wild Hepatitis B virus is "usually" an "episodic" arthritis that is "symmetrical" in "the small joints of the hands." Tr. at 62-63. And, according to Dr. Rosé, the arthritis following infection with wild Hepatitis B virus does not present "with [a] high white count and high fevers." Tr. at 63.

Regardless, Dr. Rosé maintained that one should not project consequences of Hepatitis B vaccination based upon experience with infection with wild Hepatitis B virus. *See* Tr. at 64. Dr. Rosé cited particularly the laboratory model for "persistent arthritis." Tr. at 64. Dr. Rosé said that the model demands "recurrent stimulation of the immune system to perpetuate the arthritis." *Id.* Thus, Dr. Rosé asserted that he "would not expect" on biological grounds "a single vaccination with an inert product," like Hepatitis B vaccine, to produce "a chronic disease," such as systemic JRA. *Id.*; *see also* Tr. at 68 ("[B]y definition," JRA and its "five subsets" are "chronic."). Yet, Dr. Rosé conceded that he is "not an expert on post-vaccine arthritis." Tr. at 85. Moreover, Dr. Rosé stated that he "wouldn't oppose" a "theory" that vaccines are potential environmental factors in the development of a rheumatological disorder. Tr. at 88. Indeed, Dr. Rosé acknowledged "reports" of "two different" arthritis "patterns" following Hepatitis B vaccination. Tr. at 63; *see also* Tr. at 89-90. Dr. Rosé described one pattern of arthritis as "very similar" to the arthritis associated with infection with wild Hepatitis B virus. Tr. at 63. Dr. Rosé described the other pattern of arthritis as a "disease" of just a "few" joints. *Id.* Still, Dr. Rosé insisted that neither pattern "meets the definition of" systemic JRA. *Id.*

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[9] Dr. Rosé received his medical degree from the University of Buenos Aires in Buenos Aires, Argentina, in 1977. R. ex. B at 1; *see also* Tr. at 53. He obtained his license to practice medicine in the United States after completing a "pediatric residency" at Thomas Jefferson University, Jefferson Medical College, in Philadelphia, Pennsylvania, in the late 1980s. Tr. at 54. He is Chief of the Division of Rheumatology at the Alfred I. duPont Hospital for Children associated with Thomas Jefferson University. R. ex. B at 6; *see also* Tr. at 54. He maintains a clinical practice. *See* Tr. at 54-55. In addition, he trains residents in pediatrics and fellows in pediatric rheumatology. *See* Tr. at 54-55. He holds an academic appointment as a Professor of Pediatrics at Thomas Jefferson University, Jefferson Medical College. R. ex. B at 6. He is certified in pediatrics by the American Board of Pediatrics and in pediatric rheumatology by the American Board of Pediatrics. R. ex. B at 4; *see also* Tr. at 53. He has served on at least one American Academy of Pediatrics committee with Dr. Sundel. *See* Tr. at 55-56.

In any event, Dr. Rosé proclaimed that he does not "assume" to know "the cause of" systemic JRA. Tr. at 64; *see also* Tr. at 61, 86, 89, 97. Thus, Dr. Rosé declared that he cannot identify "triggers," if any, for systemic JRA. Tr. at 86; *see also* Tr. at 64, 87, 89-90, 97. Likewise, Dr. Rosé declared that he cannot identify "the latency between" a "trigger," if any, for systemic JRA and the development of "the disease." Tr. at 86; *see also* Tr. at 97-98. Further, Dr. Rosé declared that "of all the forms of juvenile rheumatoid arthritis," systemic JRA encompasses few "of the classic autoimmune features." Tr. at 61. Dr. Rosé explained specifically that systemic JRA lacks "markers of autoimmunity," like "antibodies to self[-]antigens." *Id.* Rather, Dr. Rosé proposed that systemic JRA represents an "up[-]regulation of the inflammatory system." *Id.*; *see also* Tr. at 87 (comparing a known, genetic, "autoinflammatory disease" to systemic JRA). Approaching admittedly "speculative territory," Dr. Rosé urged that "many" aspects of systemic JRA "resemble more" the body's "response" to "toxins" or to "a bacterial product" than to "viruses." Tr. at 62. However, Dr. Rosé agreed that if he accepted "the immune paradigm" for systemic JRA, a seven-day latency period is appropriate to allow the body "to build up that immune response." Tr. at 86.

Dr. Rosé recognized that Ms. Sanchez's medical records do not reflect any evidence of frank arthritis preceding Ms. Sanchez's September 14, 2001 Hepatitis B vaccination. *See* Tr. at 70. In addition, Dr. Rosé recognized that Ms. Sanchez's medical records from 2001 place the onset of Ms. Sanchez's joint pain approximately one week after Ms. Sanchez's September 14, 2001 Hepatitis B vaccination. *See* Tr. at 83-85. Nevertheless, Dr. Rosé asserted that Ms. Sanchez's medical records reveal "isolated situations in the pre-vaccination phase" that "could" indicate "an ongoing unchecked inflammatory process." Tr. at 66; *see also* Tr. at 57, 71, 96. Thus, Dr. Rosé questioned the "temporal association" between Ms. Sanchez's September 14, 2001 Hepatitis B vaccination and Ms. Sanchez's systemic JRA. Tr. at 57.

At the outset, Dr. Rosé commented that Ms. Sanchez exhibited "unexplained urticarial rash" prior to her September 14, 2001 Hepatitis B vaccination. Tr. at 66; *see also* Tr. at 57, 60, 71. Although Dr. Rosé characterized urticarial rash as "an unusual manifestation" of systemic JRA, he claimed that he has encountered two patients in his practice who presented with urticarial rash as the initial symptom of systemic JRA. Tr. at 58. Thus, in Dr. Rosé's view, Ms. Sanchez's urticarial rashes were "suggestive" of an early manifestation of Ms. Sanchez's systemic JRA. Tr. at 71-72; *see also* Tr. at 60, 66.

Then, Dr. Rosé commented that Ms. Sanchez exhibited "unexplained fevers" prior to her September 14, 2001 Hepatitis B vaccination. Tr. at 66; *see also* Tr. at 57, 72-73, 80-81. In Dr. Rosé's view, the fevers were also "suggestive" of an early manifestation of Ms. Sanchez's systemic JRA. Tr. at 71-72; *see also* Tr. at 57, 66. Dr. Rosé conceded that Ms. Sanchez's medical records document only one episode of fever in Summer 2001. *See* Tr. at 70-73, 81. However, Dr. Rosé offered that parents or others fail commonly to appreciate "fevers" in a child when the "episodes of fever" occur transiently. Tr. at 73. Thus, Dr. Rosé speculated about the presence "of under[-]reported fever." Tr. at 72; *see also* Tr. at 57 (referring to "episodes of fever"), 66, 80-81 ("I am speculating.").

Further, Dr. Rosé considered notations regarding Ms. Sanchez's "hair loss" in Fall 2001 to be suspicious for "telogen effluvium." Tr. at 65-66; *see also* Tr. at 80-83, 94-97. Dr. Rosé testified that telogen effluvium appears "about 30-35 days," Tr. at 65, or "four to six weeks," Tr. at 81, or "six to eight" weeks, Tr. at 82; *see also* Tr. at 96, following "a quite intense inflammatory phenomenon," Tr. at 65; *see also* Tr. at 81, 97, or injury. *See* Tr. at 81. Dr. Rosé said that in telogen effluvium, "an insult" will "stall all [hair] growth for a period." Tr. at 97. Dr. Rosé elaborated that "alopecia" occurs as "hairs" that "die" naturally are not "replaced because of" the disrupted growth cycle. *Id.* Based upon the assumption that Ms. Sanchez exhibited hair loss in late September 2001, Dr. Rosé calculated that the "incident" leading to telogen effluvium preceded Ms. Sanchez's September 14, 2001 Hepatitis B vaccination by a number of weeks. Tr. at 96; *see also* Tr. at 65, 80-83. But, Dr. Rosé granted that he did not evaluate Ms. Sanchez in Fall 2001. *See* Tr. at 81. So, Dr. Rosé indicated that he is not able to determine "for sure" whether Ms. Sanchez experienced telogen effluvium in Fall 2001. Tr. at 81.

Finally, Dr. Rosé stated that "documented" evidence, Tr. at 66, of "growth failure," Tr. at 99, in a child who develops systemic JRA is medically significant. *See, e.g.*, Tr. at 66, 99. Indeed, Dr. Rosé recalled that Ms. Tarabocchia reported at some point that Ms. Sanchez's growth appeared to have slowed. *See* Tr. at 66. However, Dr. Rosé remarked that in his review of the case, he "did not focus that much on [Ms. Sanchez's] growth pattern." Tr. at 98. As a consequence, Dr. Rosé expressed that he had "no opinion" regarding any potential "delay in growth." Tr. at 99.

DISCUSSION

A Program action involves potentially the analysis of two *prima facie* cases: a petitioner's *prima facie* actual causation case and respondent's *prima facie* alternative actual causation case. When respondent does not adduce any evidence of alternative actual causation, as in the instant case, a special master evaluates only the petitioner's *prima facie* actual causation case. However, a special master does not consider a petitioner's evidence of actual causation in isolation. Rather, a special master must assess a petitioner's evidence of actual causation in the context of the "record as a whole." § 300aa-13(a)(1). The "record as a whole" includes clearly respondent's evidence impeaching petitioner's evidence of actual causation, which may be wholly distinct from respondent's evidence of alternative actual causation.

Through Dr. Sundel, Ms. Sanchez presents a simple, if not simplistic, claim. Dr. Sundel identified systemic JRA as an "autoimmune disease." Tr. at 104; *see also* Tr. at 22, 28. Dr. Sundel explained that in autoimmune disease, an immune stimulus prompts an aberrant immune response resulting in the development of autoimmune disease. *See* Tr. at 21-23, 48, 106-07. According to Dr. Sundel, the latency between exposure to the immune stimulus and the aberrant immune response in autoimmune disease ranges from "a week," Tr. at 13; *see also* Tr. at 107, to "a very long time." Tr. at 107; *see also* Tr. at 13. Dr. Sundel asserted that Hepatitis B vaccine is an accepted immune stimulus. *See* Tr. at 112, 115. In Dr. Sundel's view, Ms. Sanchez did not exhibit any manifestations of systemic JRA before the administration of her September 14, 2001 Hepatitis B vaccination. *See*

Tr. at 12-13, 23. Dr. Sundel noted that Ms. Sanchez's medical records indicate that Ms. Sanchez suffered "joint complaints" and "fever" approximately one week after her September 14, 2001 Hepatitis B vaccination. Tr. at 13; *see also* Tr. at 19, 23, 50, 111-12. Dr. Sundel characterized Ms. Sanchez's symptoms approximately one week after Ms. Sanchez's September 14, 2001 Hepatitis B vaccination as the initial expression of Ms. Sanchez's systemic JRA. *See* Tr. at 12, 19, 112. Dr. Sundel observed that the one-week period between Ms. Sanchez's September 14, 2001 Hepatitis B vaccination and the onset of Ms. Sanchez's systemic JRA is consonant with the latency between exposure to an immune stimulus and the aberrant immune response in autoimmune disease. *See* Tr. at 11-13, 108-09. Therefore, Dr. Sundel deemed Ms. Sanchez's September 14, 2001 Hepatitis B vaccination to be the "trigger" for Ms. Sanchez's systemic JRA. Tr. at 23-24; *see also* Tr. at 11-12.

Through Dr. Rosé, respondent presents two defenses to Ms. Sanchez's claim. First, Dr. Rosé posited that Ms. Sanchez experienced symptoms of an "unchecked inflammatory process," likely systemic JRA, before the administration of her September 14, 2001 Hepatitis B vaccination. Tr. at 66; *see also* Tr. at 57, 71, 96. Dr. Rosé cited especially Ms. Sanchez's reported recurrent rash from February 2001 through July 2001. *See, e.g.*, Tr. at 57-58, 60, 66, 71-72. Second, Dr. Rosé advanced that because the medical community knows so little about the cause of systemic JRA, it is difficult to ascribe systemic JRA to Hepatitis B vaccination. *See, e.g.*, Tr. at 61, 64, 68, 86, 89-90, 97.

I.

When a petitioner contends that a vaccination is responsible for the initial onset of a particular condition, the petitioner has to "show that no evidence of the injury appeared before the vaccination." *Shalala v. Whitecotton*, 514 U.S. 268, 274 (1995). As colleagues and peers in the rarefied medical subspecialty of pediatric rheumatology, *see, e.g.*, Tr. at 9 ("only about 200 pediatric rheumatologists in the country"), Dr. Sundel and Dr. Rosé possess certainly commensurate qualifications to render opinions regarding systemic JRA in this case. Based upon his education, his training, his experience and other factors, each espouses a different interpretation of Ms. Sanchez's reported recurrent rash preceding Ms. Sanchez's September 14, 2001 Hepatitis B vaccination. Relying predominantly upon Ms. Sanchez's medical records reflecting several treating physicians' clinical impressions of Ms. Sanchez's reported recurrent rash; reflecting that Ms. Sanchez's reported recurrent rash appeared to respond to medication and reflecting the absence of other manifestations of systemic illness coinciding with Ms. Sanchez's reported recurrent rash, Dr. Sundel concluded that Ms. Sanchez's reported recurrent rash preceding Ms. Sanchez's September 14, 2001 Hepatitis B vaccination was probably related to allergies. *See, e.g.*, Tr. at 12, 16-18, 20, 23-25, 46-48. Relying predominantly upon the anecdotal, personal observation of two patients who displayed urticarial rash as the presenting symptom of systemic JRA, Dr. Rosé concluded that Ms. Sanchez's reported recurrent rash preceding Ms. Sanchez's September 14, 2001 Hepatitis B vaccination was related perhaps to Ms. Sanchez's systemic JRA. *See, e.g.*, Tr. at 57-60, 66, 71-72. Dr. Rosé added that Ms. Sanchez suffered "unexplained fevers," another hallmark of systemic JRA, preceding her September 14, 2001 Hepatitis B vaccination. Tr. at 66; *see also* Tr. at 57, 72-73, 80-81. Likewise, Dr. Rosé added that, assuming that Ms. Sanchez exhibited hair loss in late September 2001, she experienced

probably a significant inflammatory process compatible with systemic JRA several weeks before her September 14, 2001 Hepatitis B vaccination. *See, e.g.*, Tr. at 65-66, 80-83, 94-97.

The statute enacting the Program commands a special master to "consider. . . any diagnosis, conclusion, [or] medical judgment. . . which is contained in the record regarding the nature . . . of the petitioner's illness, disability, injury, [or] condition" and "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions," even though "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master." § 300aa-13(b)(1). As a consequence, the Federal Circuit has recognized certainly the inherent value of a petitioner's medical records in Program proceedings. In *Cucuras v. Secretary of HHS*, 993 F.2d 1525 (1993), the Federal Circuit counseled that "[m]edical records, in general, warrant consideration as trustworthy evidence," remarking that "generally contemporaneous" medical records "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Id.* at 1528. Then, in *Capizzano*, the Federal Circuit described medical records as "favored" evidence, noting the unique relationship between a treating physician and a patient in the clinical setting. *Capizzano*, 440 F.3d at 1326, citing *Althen*, 418 F.3d at 1280.

After evaluating Ms. Sanchez for her recurrent rash, Dr. Tutiven and Dr. Weiss believed that the rash was a manifestation of allergy. *See, e.g.*, Pet. ex. 2 at 5. Indeed, Ms. Sanchez experienced relief from the rash following the use of a common allergy medicine. *See, e.g.*, Pet. ex. 2 at 5. When they evaluated Ms. Sanchez in October 2001 for "joint pain," Pet. ex. 2 at 8, Dr. Kimura and Dr. Bingham knew certainly about Ms. Sanchez's "history of a rash" during Summer 2001. Pet. ex. 2 at 5. Dr. Kimura and Dr. Bingham are trained ostensibly to appreciate the constellation of a patient's symptoms when formulating a diagnosis for a patient's condition. Yet, Ms. Sanchez's medical records do not suggest that Dr. Kimura and Dr. Bingham accorded any significance to Ms. Sanchez's reported recurrent rash. *See generally* Pet. ex. 2. Drawing reasonable inferences from information within the confines of the record, Dr. Sundel–who is board-certified in allergy and immunology, Pet. ex. 21 at 1–endorsed the treating physicians' impressions that Ms. Sanchez's reported recurrent rash was associated with allergy. *See, e.g.*, Tr. at 12, 16-18, 20, 23-25, 46-48.

In discussing the import of Ms. Sanchez's reported recurrent rash, Dr. Rosé invoked appropriately his clinical experience with two patients who displayed urticarial rash as the presenting symptom of systemic JRA. *See, e.g.*, Fed. R. Evid. 702 ("If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise."). However, Dr. Rosé exceeded the scope of his role as an expert in this case by asserting that Ms. Sanchez suffered "unexplained fevers" before her September 14, 2001 Hepatitis B vaccination, Tr. at 66; *see also* Tr. at 57, 72-73, 80-81, based upon his view that parents often do not recognize "fevers" in a child when the "episodes of fever" occur transiently. Tr. at 73. Acknowledging that Ms. Sanchez's medical records reflect just one instance of fever in Summer 2001, Dr. Rosé conceded that he was "speculating," Tr. at 80-81, regarding the presence of "of under[-]reported fever." Tr. at 72; *see also* Tr. at 57 (referring to "episodes of

fever"), 66. Thus, Dr. Rosé grounded at least a portion of his opinion that Ms. Sanchez experienced symptoms of her systemic JRA preceding her September 14, 2001 Hepatitis B vaccination upon improper speculation. Dr. Rosé's unprompted willingness to engage in speculation is not helpful to the special master. Rather, Dr. Rosé's unprompted willingness to engage in speculation leads the special master to question seriously Dr. Rosé's credibility as a witness, detracting significantly from the weight that the special master would otherwise accord to Dr. Rosé's testimony.

The special master comprehends clearly Dr. Rosé's proposition that if Ms. Sanchez exhibited "loose hair," Pet. ex. 1 at 11, or "telogen effluvium," Tr. at 65-66; *see also* Tr. at 80-83, 94-97, as early as one week following her September 14, 2001 Hepatitis B vaccination, she suffered likely an inflammatory event representing maybe systemic JRA before her September 14, 2001 Hepatitis B vaccination. *See* Tr. at 65, 80-83, 96. Yet, the special master notes that Dr. Rosé's testimony about the latency between an "inflammatory phenomenon" and telogen effluvium was highly inconsistent. Tr. at 65. Dr. Rosé cited several different latency periods, ranging from "30-35 days," *id.*, to "four to six weeks," Tr. at 81, to "six to eight" weeks. Tr. at 82; *see also* Tr. at 96. Regardless, Ms. Sanchez's medical records do not identify a precise date for the onset of Ms. Sanchez's hair loss. Ms. Sanchez's medical records allow only the factual conclusion that Ms. Sanchez exhibited "loose hair" sometime between the administration of her September 14, 2001 Hepatitis B vaccination and October 12, 2001. *See, e.g.*, Pet. ex. 1 at 11; *see also* Pet. ex. 8 at 4; Pet. ex. 2 at 5, 8. As a consequence, the special master determines that Dr. Rosé's factual predicate for Dr. Rosé's opinion regarding telogen effluvium–Ms. Sanchez's hair loss occurred one week after Ms. Sanchez's September 14, 2001 Hepatitis B vaccination–cannot be sustained. *See, e.g.*, *Mobley v. Secretary of HHS*, 22 Cl.Ct. 423, 428-29 (1991)

After considering comprehensively Ms. Sanchez's medical records, Dr. Sundel's testimony and Dr. Rosé's testimony, the special master holds that Ms. Sanchez did not exhibit symptoms of her systemic JRA preceding her September 14, 2001 Hepatitis B vaccination.

II.

In *Daubert*, the United States Supreme Court recognized that many "innovative theories" may not receive widespread medical or scientific "scrutiny" because they "are too particular, too new, or of too limited interest." *Daubert*, 509 U.S. at 593. Nevertheless, the Supreme Court stated that a claimant may establish the medical or scientific reliability of a novel hypothesis through medical opinion that is "supported by appropriate validation, *i.e.*, 'good grounds,' *based on what is known*." *Id.* (emphasis added). Moreover, the Federal Circuit has iterated that the Program's generous evidentiary standard permits "the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280.

Dr. Sundel and Dr. Rosé agreed that systemic JRA is very uncommon. *See, e.g.*, Tr. at 15, 106. In addition, Dr. Sundel and Dr. Rosé agreed that the medical community has not identified yet a specific cause for systemic JRA. *See, e.g.*, Tr. at 22, 27, 61, 64, 86, 89, 97. However, the Program

does not require a medical expert's opinion to be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. Instead, a medical expert's opinion need only adhere to "methods and procedures of" medicine or science. *Daubert*, 509 U.S. at 590.

Dr. Sundel constructed his theory regarding the association between Ms. Sanchez's systemic JRA and Ms. Sanchez's September 14, 2001 Hepatitis B vaccination upon the medical community's current understanding that systemic JRA is an autoimmune disease; upon general principles of autoimmunity and upon the accepted premise that Hepatitis B vaccine is designed to elicit an immune response. Thus, Dr. Sundel used "*what is known*" to formulate his medical conclusion in the case. *Id.* at 593 (emphasis added). Dr. Sundel's methodology appears perfectly legitimate under *Daubert* and *Althen*.

Dr. Rosé did not challenge directly Dr. Sundel's opinion as wrong, or even as a significant misinterpretation of current medical knowledge, however limited that knowledge may be. At most, Dr. Rosé advanced that "of all the forms of juvenile rheumatoid arthritis," systemic JRA shares little in common with autoimmune diseases because systemic JRA is not classical for autoimmune disease. Tr. at 61. Dr. Rosé offered specifically that systemic JRA does not appear to involve "antibodies to self[-]antigens." *Id.* Rather, Dr. Rosé rested his opinion mostly upon his view that since he does not "assume" to know "the cause of" systemic JRA, Tr. at 64, *see also* Tr. at 61, 86, 89, 97, he cannot under any circumstances attribute Ms. Sanchez's systemic JRA to Ms. Sanchez's September 14, 2001 Hepatitis B vaccination. *See* Tr. at 64, 86-87, 89-90, 97. However, when Dr. Rosé considered the autoimmune "paradigm" for systemic JRA, as proposed by Dr. Sundel, Dr. Rosé stated that the seven-day latency period that Dr. Sundel described is correct. Tr. at 86.

Two aspects of Dr. Sundel's presentation are troubling, at least superficially. First, according to Dr. Sundel, he has not been able to determine in his patients any of the potential immune stimuli for their systemic JRA. *See* Tr. at 36. Yet, as a paid expert in litigation, Dr. Sundel offered an opinion to a reasonable degree of medical certainty that Ms. Sanchez's September 14, 2001 Hepatitis B vaccination was "the trigger" for Ms. Sanchez's systemic JRA. Tr. at 23; *see also* Tr. at 11-12. One could conclude rationally that Dr. Sundel's opinion is disingenuous or fundamentally suspect. However, the special master has reviewed thoroughly Dr. Sundel's credentials. And, while interrogating intently Dr. Sundel, the special master assessed critically Dr. Sundel's demeanor. Dr. Sundel works for a fine, respected medical institution. He has achieved prominent status in his field. In addition, Dr. Sundel was exceptionally studied in the expression of his opinion throughout his testimony. The special master is impressed that, unlike some medical experts whom the special master has evaluated during his long tenure, Dr. Sundel would not risk his professional reputation and the derision of his colleagues by offering intellectually dishonest or absurd medical opinion in a lawsuit just for the prospect of additional income. Second, Dr. Sundel acknowledged that in systemic JRA, "the triggering mechanism" of the disease is probably different from "the perpetuating mechanism" of the disease. Tr. at 35; *see also* Tr. at 64 (Dr. Rosé explaining that "recurrent stimulation of the immune system" is necessary "to produce a persistent arthritis"). Therefore, Ms. Sanchez's September 14, 2001 Hepatitis B vaccination would not be necessarily the "medical cause" of Ms. Sanchez's systemic JRA. But, the Act does not require Ms. Sanchez to prove "medical

cause." Rather, the Act requires Ms. Sanchez to prove "legal cause" under the preponderance of the evidence standard. *See Shyface*, 165 F.3d at 1352; *Althen*, 418 F.3d at 1278. Ms. Sanchez may show that her September 14, 2001 Hepatitis B vaccination is the "legal cause" of her systemic JRA by establishing that her September 14, 2001 Hepatitis B vaccination sparked an aberrant immune process that contributed substantially to her chronic condition.

Based upon the record as a whole, the special master holds that Ms. Sanchez has proven by the preponderance of the evidence the elements of her actual causation claim. The special master's decision is not fanciful. Indeed, the special master notes that at least one of his colleagues has found that medical evidence supports an association between vaccination and systemic JRA. *See Pafford* v. *Secretary of HHS*, No. 01-0165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed.Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006).

DAMAGES

On July 11, 2008, respondent filed a proffer reflecting respondent's recommendation on damages in this case. *See* Respondent's Proffer on Award of Compensation (Proffer), filed July 11, 2008. Ms. Sanchez agrees with all aspects of the Proffer. *See generally* Proffer. Based upon the record as a whole, the special master finds that the Proffer is reasonable and appropriate.[10]

1. As provided in the Proffer, respondent shall purchase, and take ownership of, as soon as practicable after entry of judgment an annuity contract that will provide during Ms. Sanchez's lifetime the amount reflected in the Proffer, Tab A, for each year after the one-year anniversary of entry of judgment. *See* Proffer at 2, ¶ II(A); Proffer at 4, ¶ III(C); Proffer at 5, ¶ IV(C); *see also* § 300aa-15(a)(1)(A). The annuity payments shall be payable directly to Ms. Sanchez, only so long as Ms. Sanchez is alive at the time a particular payment is due. *See* Proffer at 4, ¶ III(C). *As provided in the Proffer, the annuity contract shall provide for a 4% growth rate for all non-medical life care items listed in Proffer, Tab A. See* Proffer at 4, ¶ III(C)(1). *As provided in the Proffer, the annuity contract shall provide for a 5% growth rate for all medical life care items listed in Proffer, Tab A. See* Proffer at 4, ¶ III(C)(1). *As provided in the Proffer, the growth rate shall be applied and compounded beginning on the date of judgment. See* Proffer at 4-5, ¶ III(C)(1). The insurer from whom respondent shall purchase the annuity contract must meet two criteria:

[10] By reference, the special master incorporates respondent's Proffer into this decision on entitlement and damages.

a. The company must have a minimum of $250,000,000.00 of capital and surplus, exclusive of any mandatory security valuation reserve; and

b. The company must have one of the following ratings from two of the following rating organizations:

(i) A.M. Best Company: A++, A+, A+g, A+p, A+r, or A+s;

(ii) Moody's Investor Service Claims Paying Rating: Aa3, Aa2, Aa1 or Aaa;

(iii) Standard and Poor's Corporation Insurer Claims-Paying Ability Rating: AA-, AA, AA+ or AAA;

(iv) Fitch Credit Rating Company Insurance Company Claims Paying Ability Rating: AA-, AA, AA+ or AAA.

See Proffer at 4, n.3.

2. As provided in the Proffer, respondent shall pay as soon as practicable after entry of judgment $571,004.31 in a lump sum to Ms. Sanchez. *See* Proffer at 3, ¶ III(A); Proffer at 5, ¶ IV(A). The amount represents compensation for Ms. Sanchez's life care expenses for the year following judgment, *see* Proffer at 3, ¶ III(A); Ms. Sanchez's lost future earnings, *see* Proffer at 2, ¶ II(B); Proffer at 3, ¶ III(A); Ms. Sanchez's actual and projected pain and suffering and emotional distress, *see* Proffer at 2, ¶ II(C); Proffer at 3, ¶ III(A); and Ms. Sanchez's unreimbursable expenses before the date of judgment. *See* Proffer at 3, ¶ II(D); Proffer at 3, ¶ III(A); *see also* § 300aa-15(a)(4).

3. As provided in the Proffer, respondent shall pay as soon as practicable after entry of judgment $525,276.48 in a lump sum *jointly* to Ms. Sanchez and to Treasurer, State of New Jersey, Medicaid, Bureau of Budget and Accounting, 5 Quaker Bridge Road, Quaker Bridge Plaza, Building 5, Mail Code #6, 2nd Floor, Room 200, Trenton, New Jersey, 08619, Attention: Ms. Maureen Brey. The amount represents compensation for satisfaction of the state's Medicaid lien. Proffer at 3, ¶ II(E); Proffer at 3, ¶ III(B); Proffer at 5, ¶ IV(B).

CONCLUSION

Based upon the record as a whole, the special master rules that Ms. Sanchez is entitled to Program compensation. Therefore, in the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment in Ms. Sanchez's favor in complete conformity with this decision. Under Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing the right to seek review. Then, under Vaccine Rule 12(a), Ms. Sanchez may expedite payment by filing an election to accept the judgment.

s/John F. Edwards
John F. Edwards
Special Master