France: Permanent Injury Attributed to Gardasil

By Norma Erickson

Bordeaux: On September 18, 2013, Judge Patrick Mairé handed down a decision stating Gardasil was 50% responsible for the permanent injury of a French teenager who had received two injections of the HPV vaccine. The other 50% was attributed to a genetic pre-disposition for autoimmune disorders. Judge Mairé presides over lawsuits filed with a regional branch of the CRCI in France, which is the equivalent of the Vaccine Injury Compensation Program (VICP) court in the United States.

Marie –Océane's parents, Jean-Jacques and Yveline Bourguignon, have granted permission for their daughter's story to be published hoping they can help make people aware of the potential risks involved with HPV vaccinations. They do not want anyone else to go through what they have experienced without knowing of the possibility in advance.

In 2010, Marie-Océane Bourguignon, age 15, received two injections of Gardasil® the first on October 11th and the second on December 13th. Two weeks after the first injection, she experienced sensory and motor problems in the upper limbs, lasting approximately two weeks before spontaneously and gradually regressing.

Three months after the second injection, on the 13th of March 2011, Mlle. Bourguignon was hospitalized at *Centre Hospitalier de Dax* for deterioration in her general health, cerebral-vestibular disturbances and sensory-motor impairment (ataxia, vertigo). On March 15, 2011, an MRI of her brain revealed lesions in the white matter.

The initial diagnosis was that she was suffering from either multiple sclerosis or acute disseminated encephalomyelitis (ADEM). After multiple subsequent hospitalizations, it was determined that Marie had developed multiple sclerosis, a chronic, typically progressive disease involving damage to the sheaths of nerve cells in the brain and spinal cord, whose symptoms may include numbness, impairment of speech and of muscular coordination, blurred vision, and severe fatigue. Marie-Océane will live with this condition for the rest of her life.

Consequently, her parents filed for compensation on her behalf with CRCI, Regional Medical Injury Arbitration and Compensation Tribunal in Bordeaux on January 28, 2012. The decision was handed down on September 18, 2013.

The decision handed down by Judge Mairé was kindly translated into English by Helen Kimball-Brooke and is printed below in its entirety. The Bourguignon family had been successful. They could have accepted the compensation award from the French vaccine compensation program and gone on to live their lives.

But this family knew they were not the only ones to have had their lives turned upside down after using the HPV vaccine, Gardasil. They knew that the decision by CRCI would not be widely publicized in order to warn other families about the potential risks involved with the use of HPV vaccines.

Consequently, they decided to turn down the award and take their case to a traditional criminal court where the outcome of the adjudication could be made public. They decided that a just decision for their family was simply not good enough. They wanted justice for all victims of adverse events after Gardasil. They wanted to have the opportunity to warn others about the potential risks involved with consenting to the use of HPV vaccines. They wanted the opportunity to let the public be aware of the fact that HPV vaccines can be quite dangerous for some individuals.

The Decision Handed Down by the French Vaccine Injury Court:

CRCI

REGIONAL MEDICAL INJURY
ARBITRATION AND COMPENSATION
TRIBUNAL

NOTICE

(*Article L.1142-8 of the French Public Health Code)*

Case: Marie-Océane Bourguignon

File Number: 12.033.C.000071

THE AQUITAINE REGION MEDICAL INJURY, IATROGENIC AILMENT AND NOSOCOMIAL INFECTION ARBITRATION AND COMPENSATION TRIBUNAL, HELD IN BORDEAUX ON THE 18TH SEPTEMBER 2013 AND FORMED TO REACH AN AMICABLE SETTLEMENT

- Considering the French public health code, articles L. 1142-1 to L. 1142-24, D. 1142-1 to D. 1142-3 and R. 1142-13 to R. 1142-18 in particular; modified French Law no. 2002-303 of the 4th March 2002, regarding patients' rights and the quality of the health system; also considering the French Order of the 4th March 2003 regarding the documentary evidence to be included in a compensation request lodged with a regional medical injury, iatrogenic ailment and nosocomial infection arbitration and compensation tribunal,

- Considering the compensation request lodged with the secretariat of the Tribunal on the 28th of January 2012 and deemed to be complete the same day, by Mr. Jean-Jacques Bourguignon and Mrs. Yveline Bourguignon, née Cazaux, acting as the legal representatives for their daughter Marie-Océane Bourguignon, born on the 10th of June 1995, a claim then renewed on the 26th of July 2013 in the names of Mme. Marie-Océane Bourguignon and as indirect victims, Mr. and Mrs. Bourguignon, who are hereby suing:

    - Dr. Fabienne Chatelet
    - SNC Sanofi-Pasteur MSD, 8 rue Jonas Salk, 69007, Lyon 07, insured by Marsh S.A.

- Considering the various items of evidence included in the file,

- Considering that Dr. François Rouanet, neurologist, and Dr. Larbi Benali, medical examiner, specialist in compensation for injury, had been appointed by the presiding judge as co-examiners on the 31st of May 2012,

- Considering the medical examination report submitted on the 26th of June 2013,

- Considering the statement submitted by Attorney Coubris on behalf of Mr. and Mrs. Bourguignon,

- Considering the statement submitted by Attorney Annie Berland on behalf of Dr. Chatelet,

- Considering the statement submitted by Attorney Cécile Derycke on behalf of Sanofi-Pasteur,

Considering the following which was presented during the hearing

The case presentation report by Judge Patrick Mairé, presiding judge, the reports by Drs. Rouanet and Benali, along with the observations made by Attorney Coubris representing Mlle. Océane Bourguignon and her parents, Attorney Annie Berland representing Dr. Chatelet and Attorney Cécile Derycke representing Sanofi-Pasteur.

The tribunal pronounced on:

1. *The circumstances*:

In 2010, Marie-Océane Bourguignon, age 15 at the time, received two injections of Gardasil ®, a vaccine used to prevent cervical cancer, the first on the 11th of October and the second on the 13th of December that year. The vaccines were administered by her regular doctor, Dr. Fabienne Chatelet.

Two weeks after the first injection, she experienced sensory and motor problems in the upper limbs, lasting approximately two weeks before spontaneously and gradually regressing.

Three months after the second injection, on the 13th of March 2011, Mlle. Bourguignon was hospitalized at *Centre Hospitalier de Dax*, the main hospital in Dax, France, for deterioration in her general health, cerebral-vestibular disturbances and sensory-motor impairment (ataxia, vertigo).

She was successfully treated with steroids.

An MRI of the brain was performed on the 15th of March 2011 and revealed lesions in the white matter.

The initial diagnosis was that she was suffering from either multiple sclerosis or acute disseminated encephalomyelitis (ADEM).

Mlle. Bourguignon was later hospitalized on several occasions for the same cerebral-vestibular episodes and progressive flare-ups of inflammation until multiple sclerosis was finally diagnosed after she responded well to treatment with Tysabri ®.

On the day of the medical examination, Mlle. Bourguignon had not recovered her health due to the progressive nature of her pathology.

Mlle. Bourguignon does not display any neurological deficiency or functional disability but she is unable to walk more than 1 km. She takes mild analgesics for headaches and abdominal pains. She complains that she has difficulty concentrating and suffers from vertigo.

She feels that Sanofi Pasteur MSD should compensate her for the injury sustained which she attributes to the two injections of Gardasil ® she received.

2. *On the Jurisdiction:*

Considering that Mlle. Bourguignon's illness restricts her to life-long clinical and radiological supervision as well as a constant feeling of anxiety regarding the expected course of her disease, it is clear that Mlle. Bourguignon experiences particularly serious deterioration in her quality of life, including financial problems, and this justifies the jurisdiction of the tribunal.

3. *On the Substance:*

3.1. Responsibility of Dr. Chatelet

It is clear from the two medical examination reports and the information which the examiners provided to the tribunal that before administering the second injection, Dr. Chatelet performed a full clinical examination of Mlle. Bourguignon and did not observe any residual neurological disorder from the reaction which occurred immediately after the first injection. She could legitimately have attributed these sensory and motor disorders to an epicondylitis, particularly since the vaccine package insert did not include any mention of the type of reaction her patient had displayed.

There are therefore no grounds for claiming that she is responsible for any fault especially as the plaintiff does not reproach her for anything.

3.2. Responsibility of Sanofi-Pasteur

The two medical examiners were unable to agree on the diagnosis of the first inflammatory episode so they submitted their reports separately. Dr. Rouanet felt that it was not possible to specify with certainty whether the first episode could be attributed to a flare-up of multiple sclerosis or to acute disseminated encephalomyelitis (ADEM). Dr. Benali on the other hand felt that the first episode was a kind of pediatric ADEM. Aside from the failure to agree on this point, which had no medical or legal

impact on the case, the two medical examiners did agree on the fact that this first episode represented the beginning of a vaccine-induced neurological demyelinating inflammatory cascade.

They both concluded categorically that the neurological disorders presented by Mlle Bourguignon had been triggered by the immune decompensation of an unknown prior condition, a decompensation secondary to the vaccination process which led to the initial vaccine-induced acute demyelination, the prodromal physio-pathological substrate for a secondary multiple sclerosis, which is the currently accepted diagnosis.

The medical examiners were unable to establish a direct causal link with GARDASIL ®, stating "*that there are no scientific grounds to incriminate GARDASIL ® as the only causal factor for the demyelinating inflammatory pathologies of the central nervous system.*"

They did however feel that "*the vaccine-induced demyelinating inflammatory cascade from which the plaintiff suffers presents all the objective characteristics of medical and legal imputability.*

They concluded, after completing a conscientious examination of all the items in the file and substantiating their observations with information from scientific literature, that there is a definite causal link between the first injection of the vaccine and the onset of an acute inflammatory reaction in the central nervous system which then later, after the second injection, led to decompensation of a latent immune process.

They felt that total imputability of the observed damage to the vaccination could be assessed at 50%.

It was not up to the Tribunal to make a general pronouncement on whether the vaccine was defective since a discussion of the public health benefits and risks of the vaccine in question was not on the agenda but it was however expected to determine whether, given the defective nature of the doses administered, the facts before it represented serious, specific and corroborating evidence regarding both Mlle Bourguignon's personal situation and the specific circumstances (French Court of Appeal, 1st civil, 10 July 2013. Appeal # 12-21314).

In the case in point, the medical examiners had observed that Mlle Bourguignon presented with a family history of genetic vulnerability making her susceptible to the potential onset of a dysfunctional immune demyelination of the central nervous system.

Her sensory and motor disorders were triggered two weeks after the first injection and then regressed. Later, two months after the second injection, a cerebral-vestibular syndrome and a sensory-motor condition appeared.

According to the medical examiners, given the substrate of the central nervous system, the vaccination as an immunity stimulator played a role in the onset of the dysfunctional immune and inflammatory cascade. Stimulation of the immune system by the antigens in vaccines can indeed trigger an autoimmune pathology when there is a genetic predisposition against a particular hormonal and environmental background.

What stands out from the two reports therefore is that there is specific and corroborating serious evidence based not only on chronological sequence but also on factors specific to Mlle Bourguignon. This is sufficient to establish the link between the two injections of Gardasil which Mlle. Bourguignon received and the onset of her multiple sclerosis.

The patient was not informed of the possibility of such a risk and was therefore not granted the safety she could lawfully have expected. The vaccine package insert does not mention the risk of central

nervous system inflammation while this risk has been scientifically established by medical experts and was known at the time of vaccine authorization. This is an unusual risk inherent in the vaccination act itself, which does not always result in multiple sclerosis but in the case in point, the risk was real, and due to a predisposition, multiple sclerosis was triggered.

The manufacturer is therefore deemed responsible as per articles 1386-1 and 1386-4 of the French Civil Code.

Sanofi Pasteur MSD's insurance company must therefore make an offer of compensation for the injury caused.

4. *The Injury:*

Mlle. Bourguignon has not recovered her health.

The injury, with the exception of her two-year absence from school, was totally and properly assessed as is by the medical examiners. The examiners formally excluded any temporary aesthetic injury.

According to the examiners, 50% of the injury sustained was due to a pre-existing condition.

Judgment:

Article 1: Sanofi-Pasteur MSD's insurance company, Marsh S.A. must make Mlle. Bourguignon an offer of compensation amounting to 50% of her claims as specified below:

- Temporary Total Functional Disability: 73 days from 13th March to 2nd September 2011, dates as specified by the medical examiners.

- Temporary Partial Functional Disability:
  - Category IV: 41 days from the 22nd March to the 1st April 2011, then later from the 9th April 2011 to the 8th May 2011.
  - Category III: 10 days from the 27th May to the 5th June 2011
  - Category II: 62 days from the 1st March to the 18th August 2011, then later from the 3rd September 2011 to the 30th October 2012 which was the day of the medical examination.

- Assistance of an Unskilled Third Party Assistant (her mother):
  - 3 hours per day during the periods of category IV temporary functional disability,
  - 2 hours per day during the periods of category III temporary functional disability,
  - 1 hour per day during the periods of category II temporary functional disability.

- Permanent Functional Disability at the minimum rate of 5%
- Absence from School: loss of two academic years
- Suffering experienced: assessed at the minimum rate of 4/7

Article 2: If Mlle. Marie-Océane Bourguignon does not receive an offer within four months from receipt of this notice, it will be her responsibility to request ONIAM (*Office National d'Indemnisation des Accidents Médicaux*, the French National Medical Injury Compensation Authority) to come up with an alternative offer.

Article 3: This notice will be sent to all interested parties, to ONIAM and to the lawyers and insurance companies concerned, by registered letter with acknowledgement of receipt.

A copy will be sent to Mlle. Marie-Océane Bourguignon's medical team within her local Social Security unit.

Presiding Judge

Patrick Mairé

(A special thanks from the SaneVax Team to Helen Kimball-Brooke for providing the translation of this document.)