CITATION: Adam v. GlaxoSmithKline Inc., 2019 ONSC 7066
COURT FILE NO.: CV-11-440375
DATE: 20191210

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
	)	
ABUDU IBN ADAM, MAY HYACENTH ABUDU, IBRAHIM A.C. ABUDU (a minor by his litigation guardian, Abudu Ibn Adam); and THE ESTATE OF AMINATAWALLA NAPOGA CHIDINMA ABUDU (by the litigation administrator, Abudu Ibn Adam)	)	*Jasmine M. Ghosn*, for the Plaintiffs
Plaintiffs	)	
– and –	)	
CHRISTINE J. LEDESMA-CADHIT, GLAXOSMITHKLINE INC., HER MAJESTY THE QUEEN IN RIGHT OF CANADA, HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO	)	*Randy C. Sutton*, *Kate Findlay*, and *Justine Smith* for the defendant GlaxoSmithKline Inc.
Defendants	)	
	)	**HEARD:** October 15-18, 21-25, 28-31, November 5-6, 2019

KOEHNEN J.

Overview

[1] A parent can suffer no greater loss than that of a young child. May Hyacenth and Abdu Adam suffered that loss. On November 28, 2009, their daughter, Amina Adam, died suddenly. She was five years old. An autopsy concluded that there was no definitive cause of death.

[2] Amina died five days after receiving a vaccine designed to protect her against H1N1 influenza, also known as "swine flu." At the time the World Health Organization ("WHO") had

declared H1N1 to be a pandemic which prompted the Government of Canada to promote a broad vaccination program.

[3] Amina's parents say the vaccine caused her death. They underscore that this is not an "anti-vaccination" case. Amina's mother was trained as a nurse and is not opposed to vaccines. Both Amina and her older brother Ibrahim received the usual childhood vaccinations and had received flu vaccines before 2009.

[4] Amina's parents argue that this is a case in which the manufacturer of the vaccine, GlaxoSmithKline ("GSK"), breached the standard of care they owed to Amina and her parents by failing to disclose the circumstances in which the H1N1 vaccine was rushed to market, failing to disclose unexplained health incidents among those who received the vaccine and failing to warn about the risks of the vaccine.

[5] Amina's parents are also understandably upset about the circumstances they experienced after the death of their daughter. It appears there was confusion in the coroner's office about the sort of tests her parents and brother were required to undergo in light of Amina's death and confusion about the location of certain body and blood tissue samples taken from Amina during her autopsy. Being forced to confront such confusion while struggling with the most intense emotional pain a parent can suffer could only worsen their anguish. The Queen in Right of Canada and Ontario were previously defendants in this proceeding. The claims against them were dismissed by Chiappetta J. at 2014 ONSC 5726.

[6] Although I realize that it may only increase their suffering, I am unfortunately unable to find in favour of Mr. Adam or Ms. Hyacenth.

[7] For the plaintiffs to succeed, they must establish that GSK breached the standard of care that it owed to Amina. In addition, they must prove that the vaccine caused Amina's death. I can make those findings only on the basis of first-hand evidence that was presented at trial. By first-hand evidence I mean a witness who comes to court and explains things directly to me. I cannot rely on the many news articles, blog postings or journal articles that the plaintiffs showed me throughout the trial unless there was an expert who could testify about the accuracy of the publications in question and whom I found credible.

[8] The plaintiffs introduced no expert evidence about the standard of care or about the way in which GSK breached the standard of care. While I do not necessarily need expert evidence to find a breach of the standard of care in all cases, the breaches alleged here relate to complex matters of science in which an expert was necessary. or at the very least, would have been very helpful. Without an expert, I am left to my own limited experience about the issues the plaintiffs raise.

[9] In addition, the plaintiffs have introduced no reliable evidence about causation. Causation in a case like this can be general or specific. General causation refers to evidence that would demonstrate that the H1N1 vaccine was generally capable of causing death and created a higher risk of death than other vaccines. Specific causation refers to evidence that proves that the H1N1 vaccine actually caused Amina's death.

[10] The only proven relationship between the vaccine and Amina's death was time. Amina died five days after receiving the vaccine. While that inflicts horrible loss and suffering upon Amina's parents, the fact that someone dies five days after receiving a medication does not mean that the medication caused the death.

[11] I also understand that the absence of a cause of death may only increase the pain of Mr. Adam and Ms. Hyacenth. Without a cause of death, closure is harder to find. Regrettably, the evidence demonstrated that the unexplained death of a child, although unusual, nevertheless happens with sufficient frequency across a large population that it is a recognized phenomenon among medical practitioners.

[12] I am deeply sorry that I cannot provide Mr. Adam and Ms. Hyacenth with the closure they no doubt need. I must however base my decision on the evidence before me. I hope Amina's parents can take some comfort in the fact that they have honoured their daughter's memory by trying hard to find a cause for her death. Unfortunately, the current state of science can give us no answer.

A. Background Facts

[13] The influenza virus mutates constantly. This is why a different influenza vaccine is developed each year. Some mutations are small. Others are large. Some mutations are so large that humans have developed no immunity to them. This latter situation is referred to as a pandemic.

[14] The seasonal flu vaccine is developed every year by the WHO. Its experts meet twice a year to examine what viruses have circulated in each of the northern or southern hemispheres and to examine how viruses have evolved over the past season. These investigations result in a decision about which antigens should be included in each year's vaccine. Antigens are substances that induce an immune response in the body.

[15] In early 2009, the WHO became aware of the development of a new strain of influenza virus: H1N1, commonly known as swine flu. It had not been seen in human populations before, as a result of which humans had no built up immunity. The WHO declared H1N1 to be a pandemic.

[16] On June 11, 2009, the WHO declared a phase 6 pandemic. This is the final and most serious stage of a pandemic. It marks sustained human-to-human transmission of the virus in more than one region of the world. By early July there had been 94,512 reported cases and approximately 429 recorded deaths attributable to H1N1.

[17] In the summer of 2009, the WHO called for manufacturers to begin clinical trials for a vaccine to combat H1N1.

[18] GSK developed two vaccines to combat H1N1: Arepanrix and Pandemrix. Both are substantially similar. Pandemrix was manufactured and distributed in Europe. Arepanrix was

manufactured and distributed in Canada. Clinical trials for Arepanrix began in 2008 but had not been completed when the pandemic was declared.

[19] The federal Minister of Health authorized the sale of the Arepanrix vaccine pursuant to an interim order dated October 13, 2009. Human trials of the vaccine were still underway. The Minister of Health is empowered to make interim orders if immediate action is required because of a danger to health, safety or the environment. In issuing the interim order, Health Canada deemed the risk profile of Arepanrix to be favourable for an interim order. The authorization was based on the risk caused by the current pandemic threat and its danger to human health. As part of the interim order process, Health Canada agreed to indemnify GSK for any claims brought against it in relation to the administration of the Arepanrix vaccine.

[20] Although human trials of Arepanrix were not finished by the time Health Canada authorized its use, the vaccine was not without clinical history.

[21] GSK had developed other pandemic vaccines on which the H1N1 vaccine was based. Its principal precursor was the H5N1 vaccine which was developed in the early 2000's against bird flu that had developed in Hong Kong. The H5N1 virus killed approximately 50% of the people it infected. That was an alarming fatality rate. To provide some context, the Spanish flu pandemic of 1918 which killed approximately 20 million people, killed only 1% - 2% of the people it infected. In the early 2000's, H5N1 had been transmitted only from birds to humans, not from human-to-human. A vaccine was nevertheless developed in case human to human transmission occurred.

[22] The H5N1 vaccine was developed for use with an adjuvant. An adjuvant is a substance that enhances the body's immune response to an antigen. When used with vaccines, an adjuvant is administered as a second injection separate from the vaccine. Use of an adjuvant is beneficial when dealing with an unexpected strain of influenza because manufacturing a sufficient number of vaccine doses for an unexpected virus can be problematic. An adjuvant, in effect, boosts the power of a vaccine, thereby allowing a lower dosage of the vaccine to be used. This in turn allows a given number of vaccines to be distributed over a larger population than would be possible without an adjuvant.

[23] The goal of approving the H5N1 vaccine was to evaluate and monitor the manufacturing and testing process so that the vaccine could be used in the event of another pandemic simply by replacing the specific antigen in the vaccine. This would provide a more efficient process to get a pandemic vaccine to approval quickly.

[24] The H5N1 vaccine went through several clinical trials. Although the adjuvant caused more adverse events, this was counterbalanced by the boost it provided to the vaccine's effectiveness and the resulting ability to make the vaccine available to more people.

[25] Arepanrix was based on the H5N1 vaccine. While clinical trials of both Arepanrix and Pandemrix showed a higher incidence of adverse events, particularly when used with an adjuvant, the intensity and frequency of the events were not sufficiently severe to cause concern.

[26] The adjuvant that was used together with the Arepanrix vaccine had already been approved by Health Canada in another context.

[27] In the fall of 2009, the Government of Canada promoted a large-scale vaccination campaign to combat H1N1. In the last week of November 2009 alone, H1N1 resulted in over 800 hospitalizations and 56 deaths in Canada.

[28] Amina received the Arepanrix vaccine on November 23, 2009 from her family physician, Dr. Ledesma-Cadhit. Amina's mother and older brother received vaccinations at the same time from the same vials as Amina. Ms. Hyacenth was told to give the children Tylenol in the event of discomfort or fever.

[29] Amina complained that she was not feeling well but continued to go to school for the balance of the week.

[30] On Saturday, November 28, Amina complained again about feeling unwell. She had pain in her feet and an upset stomach. She continued to eat, although not as much as usual. Ms. Hyacenth took the children to a pharmacy across the street from their apartment to buy more Tylenol. After returning home, Ms. Hyacenth had decided to bring Amina to the emergency ward of a nearby hospital but would give Amina a bath and something to eat before doing so.

[31] Ms. Hyacenth ran a bath for Amina. Amina needed to use the toilet. Ms. Hyacenth left her alone to do so but told her to call out when she was done. Ms. Hyacenth returned to the kitchen to check on the soup she was cooking. When Ms. Hyacenth had not heard anything for a few minutes, she sent her son Ibrahim to check on Amina. Upon entering the washroom he screamed for help. Amina appeared to have collapsed off of the toilet halfway into the tub. Ms. Hyacenth rushed to get Amina, laid her out on the living room floor and began administering cardiopulmonary resuscitation. An ambulance was called. Amina was taken to Scarborough General Hospital where she was pronounced dead shortly after arrival.

B. The Standard of Care

[32] To succeed in their case the plaintiffs must demonstrate on a balance of probabilities that GSK fell below the standard of care that it owed to Amina.

[33] The fundamental challenge with the plaintiffs' case in this regard is that they produced no expert to testify to this effect. While I agree with the plaintiffs' submission that expert evidence is not necessarily required to demonstrate a breach of the standard of care, the absence of such evidence when faced with complex issues beyond the day-to-day experience of the trier creates additional challenges for the plaintiffs' case.

[34] The plaintiffs' principal allegation with respect to the standard of care is that GSK failed to make adequate disclosure of the risks involved with Arepanrix.

[35] The plaintiffs began their challenge about disclosure with the evidence of Ms. Hyacenth who testified that she was not told that: (i) the vaccine had not been tested through the usual

route, (ii) the vaccine had been subject to a hastened approval process by Health Canada, (iii) adjuvants had never been used in children, (iv) the Government of Canada was indemnifying the vaccine manufacturer; and (v) some countries refused to make the vaccine available because of safety concerns. Ms. Hyacenth says that had she been told about these things she would not have risked having her children vaccinated.

[36] Part of the challenge of the plaintiffs' inadequate disclosure case is that Ms. Hyacenth was not the direct purchaser of the vaccine. Vaccines are administered through a "learned intermediary," in this case, her family physician. The issue is significant because any disclosures GSK makes are made in product monographs or inserts that accompany each vial of vaccine. The patient getting the vaccine does not receive the box containing the vaccine and whatever disclosure document it contains. It is the physician who receives this.

[37] GSK did disclose in its Product Information Leaflet for the Arepanrix vaccine and in its product monograph that Health Canada had authorized the sale of the vaccine based on only limited clinical testing and no clinical experience at all with children. Dr. Ledesma-Cadhit believes she knew this from the Health Canada website. She was also aware that Arepanrix was authorized through a special process because of the pandemic.

[38] The product monograph for Arepanrix disclosed that there was limited clinical experience with an investigational formulation of another adjuvanted vaccine but no clinical experience with children. In addition, the product information leaflet and product monograph disclosed a number of risks.

[39] Ms. Hyacenth says that Dr. Ledesma-Cadhit did not advise her of these risks. Although Dr. Ledesma-Cadhit was originally a defendant in the action, the plaintiffs released her from the action after being unable to find an expert who would opine that Dr. Ledesma-Cadhit breached her standard of care in administering the vaccine.

[40] With respect to some countries refusing to make the vaccine available because of safety concerns, there was evidence at trial that some countries did not make Arepanrix available. There was, however, no reliable evidence about: the reasons for that, other options those countries pursued or, if those countries took no other steps, the reasons for the failure to take other steps. I underscore that because different countries may have different risk profiles for influenza, may substitute another product for Arepanrix or may take alternative measures more appropriate for their own jurisdiction in lieu of distributing Arepanrix. The simple fact that certain jurisdictions did not approve Arepanrix is not enough to prove that GSK fell short of its standard of care by distributing Arepanrix in Canada.

[41] The plaintiffs also suggest that GSK fell short of the standard of care because Amina had asthma and GSK did not disclose that Arepanrix was not appropriate for people with asthma. I cannot accept that submission. The medical evidence at trial was consistent in that patients with asthma were preferred candidates for the vaccine because asthmatics can suffer more serious complications from flu than non-asthmatics. Moreover, although Amina, like many children, had a number of respiratory infections, she was never diagnosed with asthma.

[42] The next thrust of the plaintiffs' nondisclosure argument is that GSK failed to disclose problems with Arepanrix at an early stage. In advancing this argument, the plaintiffs rely on *Dow Corning Corporation v. Hollis* [1995] 4 S.C.R. 634 at paragraph 40 for the proposition that a manufacturer has a duty to convey findings concerning both "unexplained" phenomenon and harm caused by its product at an early stage. The onus is on the manufacturer to be forthcoming with information. While I agree with that proposition, there is no evidence that GSK did not meet that standard. In *Dow Corning*, the manufacturer was aware of problems for over six years without advising the medical community. In the case before me, there is no evidence that GSK knew or ought to have known of a risk of which it should have advised the medical community. On the contrary, the evidence was consistent that the clinical trials and actual experience with the vaccine were closely monitored for safety signals. Safety signals are adverse events arising in increased numbers or increased levels of seriousness which might be caused by the vaccine and that require further investigation.

[43] Before approving Arepanrix, GSK provided Health Canada with animal studies on the H5N1, Arepanrix and Pandemrix vaccines as well as with human studies on the H5N1 and Pandemrix vaccines. Health Canada reviewed the information. Details of the nature of what it took into account are found in the Health Canada Summary Basis for Decision for Arepanrix.

[44] There is no evidence that the information given to Health Canada was misleading.

[45] GSK team members were in contact with Health Canada and the Biologics Genetics Directorate on a weekly basis in June 2009 and on a daily or twice daily basis after that. GSK provided information on adverse events from clinical trials within 7 to 14 days of the information becoming available. Those trials, among other things, evaluated whether a half dose or full dose of the vaccine and/or adjuvant was better for children.

[46] After Arepanrix was authorized for use in Canada, Health Canada tested every lot of vaccine manufactured to ensure it met specifications before sale.

[47] Canada, like other countries, has a surveillance system that requires physicians to report to a surveillance network any unusual adverse events following a vaccination. Physicians do not assess causation at this stage. They are simply required to report adverse events that follow vaccination within a specified period of time.

[48] Health Canada sent notices to over 50,000 doctors, hospitals and pharmacists throughout Canada to encourage them to be on the lookout for adverse events following vaccination and to report them to the appropriate health authority.

[49] Healthcare workers who were vaccinated were asked to report directly to public health authorities if they experienced any symptoms after receiving the vaccine. The notices to physicians and the request that healthcare workers report any symptoms were more active forms of surveillance than usual.

[50] During the course of the pandemic, GSK provided Periodic Safety Update Reports once per month for the first 10 months of the pandemic. This compares to a single Periodic Safety

Update Report during a regular flu season. There is no evidence that the information in the Periodic Safety Update Reports was misleading or failed to disclose information that GSK had.

[51] Health Canada's monitoring did observe one abnormal cluster of adverse events: a larger than normal number of cases of anaphylaxis arose in one region using vaccine from a particular manufactured lot. That lot was removed from circulation. It was not the lot from which Amina received her vaccine.

[52] The plaintiffs submit that Amina's adverse event should have been included in the tracking data and was not. It appears that Amina's death was not noted in GSK's tracking data until the statement of claim was issued. That appears to have been the first time GSK became aware of Amina's death. Amina's death was nevertheless tracked through other data. Dr. Ledesma-Cadhit filed an adverse event report that was passed on to Toronto Public Health Authorities.

[53] There is some ambiguity about the extent to which Amina's death was included in provincial and federal tracking data because of the coroner's conclusion that there was no evidence to relate the death to the vaccine. Nevertheless, communications between federal health authorities and Mr. Adam did occur in response to inquiries by him.

[54] Even if Amina's death did not make it into the tracked data, there was no evidence to suggest that the tracking system that GSK or any of the public health authorities established somehow fell short of the standard of care applicable to tracking systems of this sort.

[55] The plaintiffs submit that, even though the doctrine of *res ipsa loquitur* has been abolished, there remain cases in which circumstantial evidence can raise an inference of negligence that calls for an explanation from the defendant: *Dickie v. Minett*, 2014 ONCA 265, at para. 3. In a similar vein, the plaintiffs submit that it is open to me to find negligence even without expert evidence on the standard of care.

[56] While I accept both propositions, there is no direct or circumstantial evidence in this case from which I can infer that GSK breached its standard of care.

[57] Arepanrix was developed based on the fully tested H5N1 vaccine. Even though Arepanrix was distributed and administered before the full course of clinical testing had run its course, that was done for valid public health concerns and with government approval, not by virtue of carelessness.

[58] There was no evidence at trial to suggest that GSK had failed to disclose relevant information to Health Canada or to physicians. Similarly, there is no evidence to suggest that GSK disclosed false or misleading information to Health Canada or to physicians. Manufacture of Arepanrix was subject to government testing. Proactive measures were taken to become aware of safety signals once administration of Arepanrix began.

[59] In the absence of contrary expert evidence about industry or regulatory standards, these circumstances indicate that GSK was acting responsibly and meeting its standard of care. While

I agree it is possible that GSK breached its standard of care in one or more of these steps or may have otherwise breached its standard of care, I am not able to make such a finding based on the evidence before me. I note that GSK had a standard of care expert whom they did not call at trial after I questioned whether it was necessary to take trial time for that expert given the absence of any evidence on the issue from the plaintiffs.

[60] The issues surrounding the standard of care here involve an understanding of the appropriate standards applicable to manufacturing, testing and approving drugs, as well as standards of disclosure to governments, physicians and the public when drugs are distributed. In the absence of expert evidence that GSK failed to meet a particular standard and in the face of evidence that demonstrates GSK acted responsibly to disclose information, test products and manufacture products all in circumstances of urgency, I cannot find any breach of a standard of care.

[61] The cases the plaintiffs cited where notice to physicians or end consumers was deficient involved situations where a manufacturer was clearly made aware of risks with their product which went undisclosed. There is simply no evidence here that GSK was aware of such risks.

[62] While the plaintiffs' expert, Dr. Al-Bayati, did at one point purport to testify about the lack of adequate testing of the vaccine, he was not qualified as an expert on the manufacture or approval of pharmaceuticals.

C. Causation

[63] In addition to establishing a breach of the standard of care, the plaintiffs must demonstrate that the particular standard of care that was breached also caused Amina's death. The approach the plaintiffs took at trial was considerably broader. Their submission was that Arepanrix caused Amina's death rather than a specific breach of a standard of care.

[64] The plaintiffs point to a number of witnesses, including defence experts, who agreed that the vaccine could not be excluded as a cause of death. That, however, is not the test that the plaintiffs must meet. The plaintiffs must prove on a balance of probabilities that the vaccine *caused* Amina's death. The fact that it could not be excluded as a possible cause does not meet the burden the plaintiffs must meet.

(i) Evidence of the Plaintiffs' Expert, Dr. Al Bayati

[65] The plaintiffs relied on the expert evidence of Dr. Al-Bayati for their arguments on causation.

[66] Dr. Al-Bayati received a PhD in comparative pathology from the University of California Davis in 1989. Comparative pathology compares the evolution of diseases in humans and animals. Dr. Al-Bayati has been qualified as an expert in human pathology by a variety of courts in the United States. He was tendered as an expert in "toxicology, pharmacology, pharmacokinetics of medications, drugs and other chemicals, analytical methodologies of drugs,

medications and toxicants in the blood and other biological samples and the evaluation of the effects of medications, drugs and toxic agents on the human body."

[67] There were, however, a number of significant limitations on the evidence of Dr. Al-Bayati. He is not a physician. He has never conducted an autopsy and has never examined the human body. Although he has done research on clinical trials with animals that led to human clinical trials, he has not worked on human clinical trials.

[68] Dr. Al-Bayati was hired by Mr. Adam directly, not by counsel. He prepared his expert report without being aware of the acknowledgement of expert duty, which he received only the day before testifying in court. Before preparing his report, he did not have any discussion with anyone about the requirements of an expert under Ontario law.

[69] Dr. Al-Bayati expressed the view that both the vaccine and Tylenol as a remedy for fever were not medically justified for Amina because she was suffering from chronic respiratory problems. As noted, Dr. Al-Bayati is not a physician. At least three physicians[1] testified that people with chronic respiratory problems should be vaccinated in priority to others because the consequences of influenza on such patients are more serious than on patients who do not suffer from such problems.

[70] Dr. Al-Bayati's theory is that the vaccine may have led indirectly to Amina's death by the following process. The vaccine caused Amina to have fever. In response to the fever, Ms. Hyacenth gave Amina Tylenol. The Tylenol caused metabolic acidosis, which is the lowering of the body's pH level. Metabolic acidosis leads to an increase in potassium levels in the body, which causes a condition known as hyperkalemia. Hyperkalemia can cause heart malfunction. According to Dr. Al-Bayati, the normal potassium level in the blood is between 3.5 and 5.4. An increase in potassium levels means that potassium is being extracted from the heart muscle. A potassium level of seven or higher interferes with heart function. Cardiac arrest occurs at a level of 7.5.

[71] A potassium test performed on Amina's vitreous fluid (fluid extracted from the eye) during the autopsy showed a potassium level of 16. Dr. Al-Bayati used a study published in the Kathmandu University Medical Journal which looked at 140 deaths and concluded that the average level of potassium in autopsies conducted 42 hours after death was 9.4. Dr. Al-Bayati used this information to extrapolate that Amina's potassium level at the time of her death must have been above 7.5 and that it was the high level of potassium that caused her heart to stop and caused her death.

[72] On cross-examination Dr. Al-Bayati appears to have stated that he could not say that the vaccine caused Amina's death but simply that there are circumstances that need to be investigated. I say "appears to have stated" because the context of the question and answer

[1] Dr. Ledesma-Chadit, Dr. De Serres and Dr. Langley.

does not make it entirely clear whether he was speaking about Amina's death in particular or a list of adverse events following vaccination. For purposes of this analysis I will give the plaintiffs the benefit of the doubt and assume he was speaking about a more general series of adverse events. This then leads me to compare Dr. Al-Bayati's evidence with that of a number of physicians who testified at trial.

(ii) Evidence of Dr. Pollanen

[73] Dr Pollanen has been working as a forensic pathologist since 2003. He became the chief forensic pathologist for Ontario in 2006. He is the founder of the forensic pathology residents' program at the University of Toronto and a professor of pathological biology at the University of Toronto. He has provided testimony in a wide variety of courts, including the International Criminal Court. He has performed thousands of autopsies.

[74] Dr. Pollanen was called by the plaintiffs. He conducted the autopsy on Amina.

As a forensic pathologist his role was to provide an opinion on cause of death.

[75] I found Dr. Pollanen to be a careful, reliable and unbiased witness. He was careful throughout his evidence to delineate his own expertise and indicate when questions went beyond his expertise or when a question required further investigation that he had not been given the opportunity to conduct. He also resisted suggestions by counsel on both sides that were favourable to each of their theories of the case. He did so in an unargumentative matter-of-fact way grounding his views on the application of his scientific knowledge to the facts as he observed them.

[76] Dr. Pollanen began his investigation by visiting the apartment in which Amina collapsed to determine if anything in the surroundings at the time of death would cast any light on the cause of death.

[77] Dr. Pollanen was aware that Amina had recently received the H1N1 vaccine and noted this in his postmortem report. He performed a comprehensive autopsy to see if he could find anything that would relate to complications arising out of the vaccine. He found no link between the vaccine and cause of death. While he noted the chronic inflammation of the lining of the windpipe, voice box and bronchial tubes, this was evidence of a cold or chronic inflammation or both. In his view inflammation of this is common in young children. He found no evidence of asthma.

[78] Dr. Pollanen concluded that the cause of death was unascertained with sudden arrhythmic death syndrome not excluded. Sudden arrhythmic death syndrome refers to a condition where the heart suddenly and inexplicably stops beating. He described it as ultimately an electrical problem within the body in which the heart appears normal. His description of sudden arrhythmic death syndrome not being excluded means that Dr. Pollanen does not know the cause of death but believes that it could be sudden arrhythmic death syndrome.

[79] Dr. Pollanen's report was reviewed by Dr. Carlisle, the investigating corner for Amina. Dr. Carlisle's report concluded that the most likely cause of death was sudden arrhythmic death syndrome. Dr. Carlisle's report was, in turn, reviewed by the Pediatric Death Review Committee, which classified the cause of death as "undetermined".

[80] Dr. Pollanen fairly agreed that he did not and could not say that the vaccine was not a cause of Amina's death. Instead, he stated that there was no evidence of the vaccine being the cause of Amina's death. He confirmed this in an email to the Chief Regional Coroner on February 23, 2010 stating:

> "This email will confirm that, as you have indicated, there was nothing in the autopsy to link the death to the vaccination."

[81] Although Dr. Pollanen surmised that Amina's death was attributable to sudden heart failure and such sudden heart failure is consistent with Dr. Al-Bayati's theory of hyperkalemia, Dr. Pollanen rejected the theory.

[82] Dr. Pollanen noted that potassium levels become very high after death. Although the level of potassium is time-dependent, it is too variable to form a reliable basis for extrapolation. Dr. Pollanen described the potassium levels in Amina's body as a typical finding.

[83] With respect to the theory that the use of Tylenol contributed to metabolic acidosis, the toxicology tests performed on Amina after death indicated the amount of acetaminophen in Amina's body was less than 50 mg/L, which he described as low and unlikely to be toxicologically significant. Dr. Pollanen testified that if acetaminophen had led to metabolic acidosis, one would expect to see necrosis of the liver. Amina's liver was normal, which excludes metabolic acidosis. According to Dr. Pollanen, there was no evidence in the autopsy that would allow one to conclude that Amina had suffered from either metabolic acidosis or hyperkalemia.

[84] I prefer the evidence of Dr. Pollanen to that of Dr. Al-Bayati. When Dr. Pollanen was testifying about cause of death and potassium, he was testifying from personal experience. When Dr. Al-Bayati was testifying about potassium levels, he extrapolated potassium levels from a single study in the Kathmandu University Medical Journal. He has no personal experience with potassium levels and could not demonstrate that his method of extrapolating potassium levels back to the time of Amina's death was generally scientifically accepted.

[85] On numerous occasions in his testimony, Dr. Al-Bayati testified well beyond his expertise. By way of example, he testified that the vaccine was not medically justified for Amina, even though he is not a physician. He testified about the proper conduct of clinical trials, even though he has never conducted clinical trials on humans. He purported to give evidence about the extent to which GSK's conduct violated drug regulations but has never reviewed Canada's drug laws or regulations, basing himself instead on the proposition that drug laws and regulations are universal.

[86] Although Dr. Al-Bayati advanced the theory of hyperkalemia caused by Tylenol, he could not point to any personal experience or expertise with respect to the effects of Tylenol or with respect to origin and progression of hyperkalemia. Nor could Dr. Al-Bayati point to any research by others which supported his theory.

[87] I had the distinct impression that Dr. Al-Bayati was simply advancing a theory he had pieced together from isolated pieces of information. Given that Dr. Pollanen and others rejected Dr. Al-Bayati's theory, and did so based on specific scientific knowledge that came from extensive personal experience, I have no choice but to reject Dr. Al-Bayati's evidence.

[88] During her examination of Dr. Pollanen, plaintiffs' counsel suggested that Amina's condition may have been caused by Guillain-Barré syndrome ("GBS"). GBS first manifests itself in the peripheral nerves. Dr. Pollanen did not examine the peripheral nerves but nevertheless disagreed that GBS could be present here. An examination for GBS would need to be conducted if one saw the appropriate clinical progression of GBS which includes weakness, neurological signs and sensory deficits. None of those were reported with Amina. GBS also takes weeks to progress, not minutes.

(iii) Evidence of Dr. Gaston De Serres

[89] Dr. Gaston De Serres was a medical expert called by GSK. He obtained his medical degree from Laval University in 1980 and has practiced as a physician since then.

[90] In 1996 he obtained a PhD in epidemiology. Since 1997 he has taught infectious diseases, epidemiology and advanced epidemiology. Epidemiologists play an important role in the analysis of adverse events following vaccinations. Adverse events following vaccinations must be recorded, quantified and analyzed. Epidemiologists, among other things, look at this information to determine whether there is an increased risk of adverse events among vaccine recipients. To determine whether there is such a risk, one must compare the incidence of the risk amongst vaccine recipients with the population at large.

[91] Since 1989, Dr. Serres has worked with the Quebec Public Health Institute, the scientific institution in Quebec that advises the Minister of Health about medical issues. Dr. De Serres has been active in its Immunization Unit since 1989. The Immunization Unit researches vaccine effectiveness, vaccine safety and methods of improving the immunization program. Today he is the medical chief of the Immunization Unit. The flu vaccine is the Institute's largest program by far and targets approximately 1,500,000 people per year in Quebec.

[92] Dr. Serres has been in charge of monitoring the flu vaccine for 20 years. He currently sits on the committee that makes recommendations to the Minister. In 2009 he was a member of the Pandemic Vaccine Working Group which looked at what vaccine should be used, what groups should be prioritized for the vaccine and whether particular sub-groups, such as pregnant women, should get a special vaccine.

[93] Dr. Serres has written approximately 200 peer-reviewed journal articles, the vast majority of which deal with vaccine issues. At least 15 of the articles deal with the H1N1 vaccine. Dr.

Serres was tendered as an expert in family medicine, epidemiology, adverse event reporting, collection and analysis of adverse events, clinical trials, vaccines and vaccine safety.

[94] Dr. De Serres provided three distinct opinions: First, that he is not aware of any epidemiological evidence that Arepanrix caused death. Second, that the vaccine was not contraindicated for Amina. Third, that Amina's death was not caused by the Arepanrix vaccine.

[95] Dr. De Serres sat on the Canadian national committee that reviewed all adverse events arising out of the Arepanrix vaccine. He also reviewed the adverse event reports arising out of Sweden, the United Kingdom, France, Switzerland and the Netherlands.

[96] His review of all of the adverse event reports from Canada and other countries gave him no concern that sudden death was a risk of the H1N1 vaccine. There was no evidence of increased risk of death among recipients of the H1N1 vaccine in any country that recorded adverse events.

[97] According to Dr. De Serres, the adverse event reports disclosed the typical symptoms one would expect following vaccination such as tenderness around the area inoculated, fever and a general feeling of unwellness for a few days following vaccination. The occurrence of more serious adverse events such as death was too diverse for there to be any discernible pattern that would relate it to the vaccine.

[98] Dr. De Serres was also of the view that the vaccine was indicated for Amina because children were a designated priority group to receive the vaccine. Although Dr. De Serres saw no diagnosis of asthma in Amina's medical records, he testified that, had there been such a diagnosis, the vaccine would have been even more strongly indicated. Patients with respiratory conditions were prioritized to receive the vaccine because the consequences of influenza in such patients are far more serious than in patients without respiratory disorders.

[99] Dr. De Serres is not aware of any evidence that the use of Tylenol after receiving the H1N1 vaccine caused death.

[100] While Dr. De Serres stated that he could not rule out the vaccine as the cause of Amina's death, he notes that the probability of the vaccine causing Amina's death was "minuscule".

[101] While cross-examining Dr. De Serres, plaintiffs' counsel followed a pattern that she would repeat with other defence experts. Counsel would take the expert to an article and put a proposition from the article to the defence expert. The approach was of limited help. Counsel would generally not have the defence expert acknowledge the authority of the authors; the defence expert almost always disagreed with the proposition and usually explained why they disagreed. In the absence of any reliable expert who adopted the proposition, the suggestions are of no evidentiary value. They simply consist of an effort to replace expert evidence at trial with published articles that the court is being asked to rely on without having anyone attest to the accuracy of the conclusion, the accuracy of the process followed in arriving at that conclusion and without providing defence counsel with any opportunity to cross-examine the author of the article.

[102] By way of example, plaintiffs' counsel tried to have Dr. De Serres draw adverse inferences from the suggestions that: (i) the adjuvant had never been tested with children in combination with the H1N1 vaccine; (ii) children with immune deficiencies should not be given the vaccine; (iii) Amina had an immune deficiency because she received an inhaler to dilate her bronchial tubes; (iv) children were not offered an unadjuvanted vaccine even though pregnant women were; (v) the administration of the H1N1 vaccine was akin to a large clinical trial in which recipients of the vaccine were not given the same information as participants in ordinary clinical trials. Dr. De Serres disagreed with most of the propositions and all of the inferences that plaintiffs' counsel sought to draw from them.

[103] Finally, plaintiffs' counsel sought to put Dr. De Serres' independence into question because he had, in the past, received research grants from GSK. I am comfortable in relying on Dr. De Serres evidence in spite of the fact that he has received research grants from GSK in the past. It had been a number of years since his last research grant. There was no evidence about the size and frequency of such grants or the degree of dependence that he may have had on such grants. I did not get the sense that Dr. De Serres was an apologist for any corporation or cause, unlike Dr. Al-Bayati. He was not argumentative and admitted points against him readily. When he disagreed with propositions put to him, his disagreement was based on scientific data, not on argument.

(iv) Evidence of Dr. Carole Legarre

[104] Dr. Legarre was a fact witness called by a GSK. She is a physician who practiced family medicine between 1988 and 1996. She then moved into the field of public health, initially with the Public Health Authority for the l'Outaouais region and then with Health Canada where she has worked since 2002. In 2008 she was assigned to the Biologics and Genetics Therapy Directorate of Health Canada.

[105] During the pandemic Dr. Legarre was involved in assessing the safety of the vaccines and revising the risk management plan for them. She met at least weekly with officials of the Public Health Authority of Canada ("PHAC") to review the reports they received. In addition, she held regular teleconference calls with public health officials from other provinces to review the types of adverse events that were presenting themselves in Canada as well as with officials from the WHO to review what types of adverse events were presenting themselves in other countries.

[106] Dr. Legarre was asked to participate in this role because vaccine safety fell within the scope of the Biologics and Genetics Therapy Directorate and because she had previous experience with drug safety and clinical trials.

[107] In her review of data from across Canada and around the world, Dr. Legarre did not observe any evidence of sudden death resulting from the vaccine or because of Tylenol use after vaccination. Dr. Legarre noted that Tylenol had been used to control fever after vaccination for decades.

[108] As with other witnesses, plaintiffs' counsel tried to put a number of propositions to Dr. Legarre with which she disagreed. By way of example, she put to Dr. Legarre an article entitled

"Incidents of Adverse Events Among Healthcare Workers Following in H1N1 Immunization in Ghana", pointed out that the article noted an incidence of adverse events more than 50 times greater than normal, which, according to plaintiffs' counsel, should have triggered questions about the safety of the vaccine. Dr. Legarre disagreed. The article in question focused on the immunization of healthcare workers at a single teaching hospital in Ghana where 5870 people were vaccinated of which 140 reported adverse events. Each vaccinee was given a card on which they were asked to record adverse events and to return those cards. This more active way of accumulating data about adverse events would likely result in a higher incidence of reported adverse events than a more passive system. The adverse events reported were those commonly associated with vaccines. The article itself noted that the background incidence of those adverse events was not calculated and that the method of adverse event reporting may be used for signal generation but not to prove causation. Signal generation refers to the incidence of an event that is sufficiently unusual so as to warrant investigation. It does not, however, indicate that the event was caused by the vaccine.

(v) Evidence of Dr. Joanne Langley

[109] By agreement of the parties, Dr. Joanne Langley was admitted as an expert on pediatric medicine, epidemiology, vaccines, community health and infectious diseases. On consent of both parties, her report of May 18, 2019 was admitted as an exhibit in lieu of examination in chief.

[110] Dr. Langley received her medical degree in 1984 from Dalhousie Medical School. In 1988 she became a fellow of pediatrics at the Toronto Hospital for Sick Children. She is currently head of pediatrics and infectious diseases at the Izaak Walton Killam Children's Hospital in Halifax. She is also currently a professor of community health and epidemiology at Dalhousie University.

[111] Dr. Langley was chair of the National Advisory Committee on Immunization at the time of the pandemic. This is a committee of expert representatives from public health authorities as well as physicians specializing in adult and pediatric infectious diseases. The Committee reviewed vaccine options and made recommendations to PHAC in respect of them. At the time of the pandemic, it, among other things, advised PHAC on measures to prevent an epidemic from erupting. Dr. Langley has also been involved in clinical research concerning the evaluation of vaccines for respiratory and influenza viruses. She has been involved in approximately 15 clinical trials concerning Arepanrix.

[112] Dr. Langley's report takes issue with the conclusions of Dr. Al-Bayati. Dr. Langley opines that young children such as Amina were prioritized to receive the vaccine because younger children have high influenza rates and are more likely to have more serious influenza than older children and adults. Although Amina was never diagnosed with asthma, if she did in fact have asthma, she would be in an even higher priority category to receive the vaccine.

[113] According to Dr. Langley, there is no evidence that the use of acetaminophen (such as Tylenol) to control Amina's fever in the days following her vaccination caused metabolic acidosis or hyperkalemia or that it contributed in any other way to her death. Acetaminophen is

routinely used in children to control fever and in the words of Dr. Langley, "has a stellar record of safety." Amina received a maximum of 400 mg per day. The maximum recommended dosage is 2600 mg in 24 hours. Dr. Langley is not aware of any scientific evidence that either of such doses could lead to metabolic acidosis or hyperkalemia although an overdose or chronic use of acetaminophen could do so. Dr. Langley noted that the doses Amina received were much lower than the recommended therapeutic dosage and that it is "not plausible" that Amina developed metabolic acidosis due to acetaminophen.

[114] The plaintiffs noted that Amina had been treated with corticosteroids, suggested that corticosteroids are immunosuppressive medications and that the vaccine should not have been given to children on immunosuppressive medications. Dr. Langley disagreed with these suggestions. She noted that Amina had been prescribed inhaled corticosteroids and had four short courses of oral steroids. The doses Amina received would not have resulted in any clinically significant immunosuppression. Moreover, immunosuppression does not mean that a vaccine should not be administered. It simply means that the protection afforded by the vaccine could be reduced in persons with compromised immune systems.

[115] In her testimony, Dr. Langley also repeated the evidence of other witnesses to the effect that there was no evidence of death as a safety signal following immunization with Arepanrix or Pandemrix. Dr. Langley was not shaken in any of these views on cross-examination.

Law on Causation

[116] Courts have long recognized that it is a logical fallacy to conclude that a vaccine has caused a particular medical issue simply because the medical issue arose after administration of the vaccine. Although the onset of a medical condition after receiving a vaccine may give rise to a hypothesis that the vaccine caused the problem, that hypothesis must be tested and proven: *Rothwell v. Raes,* [1988] O.J. No. 1847 (H.C.J.) aff'd [1990] O.J. No. 2298 (C.A.). Not every hypothesis or suspicion amounts to causation. Causation cannot be based on uninformed speculation: *Morgan v. Metropolitan Toronto (Municipality),* [2006] 44 C.C.L.T. (3d) 198 (Ont. S.C.) at para. 319.

[117] The H1N1 vaccine was administered on a large scale. In Canada over 11 million people received it. Worldwide the number was considerably higher. In any group of 11 million people there are bound to be adverse events, including death, within a week of receiving a vaccine. That does not, without more, mean that the vaccine caused any of the deaths among the 11 million people.

[118] The plaintiffs criticized the defendants' reliance on epidemiological evidence. They note that courts have cautioned against the use of such evidence because it cannot determine which factor caused a particular person's disease or death but only what factors are statistically associated with the occurrence of disease or death: *Andersen v. St. Jude Medical Inc.* 2012 ONSC 3660, at para. 394.

[119] Epidemiology does, however, remain a relevant to causation. As Perell J. noted in *Wise v. Abbott Laboratories Limited*, 2016 ONSC 7275, epidemiology focuses on the general causation of diseases and whether or not an agent has the capacity to cause a particular disease or medical condition, as opposed to specific causation, which asks whether an agent caused a specific death or injury. There was no evidence here that the vaccine was capable of causing death. I agree that this is not to say that the vaccine could not cause death. The absence of any safety signal to demonstrate that the vaccine could cause death does, however, make the plaintiffs' case on causation more difficult, especially in the absence of any medical evidence to suggest that Amina's death was caused by the vaccine.

[120] The plaintiffs submit that is not necessary to demonstrate that the vaccine caused the death but merely that it contributed to the death. While I accept that is correct, there is also no evidence here that the vaccine contributed to Amina's death. At best, Dr. Al-Bayati advanced a theory that the vaccine led to fever, which led to the use of Tylenol, which led to metabolic acidosis, which led to hyperkalemia, which led to cardiac arrest. That evidence rests not on Dr. Al-Bayati's personal expertise or experience but on a single study of potassium levels in 140 corpses in the University of Kathmandu Medical Journal. As noted earlier, Dr. Al-Bayati is not a physician. That theory was dispelled by both Drs. Pollanen and Dr. Langley. Both provided scientifically reasons grounded in their personal expertise and experience for disagreeing with Dr. Al-Bayati's theory. On that record alone I must prefer the evidence of Drs. Pollanen and Langley.

D. Damages

[121] In the event I am wrong in my analysis of standard of care and causation I will briefly address the issue of damages.

[122] Mr. Adams has produced a statement of damages that comes to $1,048,589.90. The vast majority of the expenses relate to the litigation. The largest component is for a claim of $1,000,000 which reflects 4,000 hours of his time at $250 per hour. Mr. Adam submits that this is the lost opportunity for which he claims damages.

[123] The concept of damages for lost opportunity has been recognized by the courts. It is an effort to reward the plaintiff for what it has lost by virtue of the negligence: *Folland v. Reardon*, [2005] O.J. No. 216 (C.A.) at para. 78. Mr. Adams has, however, failed to relate his claim of $1 million to any opportunity that he has forgone. He failed to produce tax returns or T4 slips that indicate his previous annual income which he described as roughly $50,000. Even if I find that Mr. Adams was wholly unable to work as a result of the death of his daughter, that would not in any conceivable way relate to lost opportunity costs in excess of $1 million. In closing argument counsel suggested a figure of $20,000 per year for loss of opportunity. If a breach of the standard of care and causation had been established, I would have been inclined to award a loss of opportunity claim of $20,000 for one year.

[124] In *Augustus v. Gosset*, [1996] 3 S.C.R. 268, the Supreme Court of Canada set out at para. 50 the following factors that should be considered when assessing damages for the death of a child: the circumstances of the death, the ages of the deceased and the parent, the nature and quality of the relationship between the deceased and the parent, the parent's personality and ability to manage the emotional consequences of the death, and the effect of the death on the parent's life in light, among other things, of the presence of other children or the possibility of having others.

[125] The circumstances of this case are particularly difficult. The parents have not had any further children. There was some evidence that the grief from the death led to a loss of consortium. Amina was five. The nature and quality of the relationship between a young child and a parent is one of the deepest emotional bonds within human relationships. Both Mr. Adam and Ms. Hyacenth are visibly affected by the loss. It has left them damaged and frail. It was particularly evident from Mr. Adam's testimony that he suffers from significant psychological challenges.

[126] Counsel took me to cases which established compensation of wrongful death for a child of $100,000 for each parent in 2001: *To v. Toronto Board of Education*, [2001] O.J. No. 3490 (C.A.) and $125,000 in 2010: *Fiddler v. Chiavetti*, 2010 ONCA 210. The plaintiffs agree that an award of $125,000 in 2010 translates into an award of $143,750 in current value. Had I found a breach of the standard of care and causation I would have awarded $143,750 to each of Ms. Hyacenth and Mr. Adam.

[127] In addition to compensatory losses, the plaintiffs submit they are entitled to aggravated and exemplary damages for Amina's estate. They rely on the Supreme Court of Canada's decision in *Whiten v. Pilot Insurance Co.*, 2002 SCC 18. The plaintiffs submit that punitive damages are appropriate here because GSK did not include Amina's death as part of its recorded data. That, say the plaintiffs, amounts to turning a blind eye. In addition, they cite the impropriety of having a five-year-old child receive an untested vaccine together with an adjuvant. Had a breach of a standard of care and causation been established, I would not have awarded aggravated or exemplary damages.

[128] Even if I were to accept that GSK failed to include Amina's death in its data, there is no evidence that that was done with any deliberate intent. Similarly, administering a newer vaccine with an adjuvant to children was not done with any adverse intent but was done with the approval of regulatory authorities in circumstances of public urgency. Had there been evidence that GSK had somehow misled regulatory authorities, the facts would be quite different. There is, however, no such evidence.

[129] Finally, the plaintiffs claim damages for Amina's brother, Ibrahim. In *To v. Toronto Board of Education* the court awarded $25,000 to the 11-year-old sibling of the 14-year-old deceased. If I apply the same proportional increase to the damage claim for Ibrahim as the defence applied to the damage claim for Amina's parents (43%), the award for Ibrahim would come to $35,750.

Conclusion

[130] No matter how much I may sympathize with the grief Ms. Hyacenth and Mr. Adam have been forced to live with because of the loss of their daughter, the evidence does not support any finding of a breach of the standard of care by GSK or any finding that the death was caused or contributed to by the Arepanrix vaccine.

[131] The pain of the loss of a child may dissipate but does not disappear. I sincerely hope that the effort and energy Ms. Hyacenth and Mr. Adam have put into finding a cause for Amina's death will help dissipate their pain. I hope that the knowledge that Amina's passing has not gone unnoticed by GSK, public health authorities or the courts gives them some comfort. Understandably they have fought long and hard for answer to a question that would overwhelm any parent in these circumstances: Why did my child die? I deeply regret having to answer the question by saying that, after 10 years of investigation, we do not know. The state of scientific and medical knowledge remains limited and imperfect. A court must, however, base its decisions on the evidence before it. That evidence does not establish on a balance of probabilities that Arepanrix caused or contributed to Amina's very unfortunate death. As a result, I must dismiss the plaintiffs' action.

[132] Any party seeking costs may provide me with written submissions sent to the judges' reception at 361 University Ave., Toronto, ON M5G 1T3 within 15 days of the release of these reasons. A responding party will have 10 days to respond. A further five days will be provided for reply.

Koehnen J.

Released: December 10, 2019.

CITATION: Adam v. GlaxoSmithKline Inc., 2019 ONSC 7066
COURT FILE NO.: CV-11-440375
DATE: 20191210

ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:

ABUDU IBN ADAM, MAY HYACENTH ABUDU, IBRAHIM A.C. ABUDU (a minor by his litigation guardian, Abudu Ibn Adam); and THE ESTATE OF AMINATAWALLA NAPOGA CHIDINMA ABUDU (by the litigation administrator, Abudu Ibn Adam)

Plaintiffs

– and –

CHRISTINE J. LEDESMA-CADHIT,
GLAXOSMITHKLINE INC.,
HER MAJESTY THE QUEEN IN RIGHT OF CANADA,
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO

Defendants

REASONS FOR JUDGMENT

Koehnen J.

Released: December 10, 2019