

**ONTARIO
SUPERIOR COURT OF JUSTICE**

B E T W E E N :

YVONNE MARCHAND

Plaintiff

- and -

**THE HOSPITAL FOR SICK CHILDREN, GIDEON KOREN and
JOEY GARERI**

Defendants

Proceeding under the *Class Proceedings Act, 1992*

**STATEMENT OF CLAIM
(Notice of action issued on December 22, 2015)**

1. The plaintiff, on behalf of the Class and the Family Class as described herein, claims:
 - (a) an order certifying this action as a class proceeding and appointing the plaintiff as representative plaintiff for the Class and the Family Law Class;
 - (b) a declaration that the defendants were negligent in its operation and supervision of MDTL;
 - (c) a declaration that the defendants are liable to the plaintiff, the Class and the Family Law Class for damages for its negligence in its operation and supervision of MDTL;

- (d) a declaration that the defendants are liable to the Family Class for damages resulting from the injuries to members of the Family Class;
- (e) damages for negligence in the amount of \$200,000,000, or such other sum as this Honourable Court may find appropriate;
- (f) damages pursuant to section 61 of the *Family Law Act*, R.S.O. 1990, c. F.3 and/or the equivalent legislation in other provinces;
- (g) punitive damages in the amount of \$250,000,000;
- (h) prejudgment and postjudgment interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C.43;
- (i) costs of the action on a substantial indemnity basis or in an amount that provides full indemnity to the plaintiff;
- (j) the costs of notice and of administering the plan of distribution of the recovery in this application, plus applicable taxes, pursuant to section 26 of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6; and,
- (k) such further and other relief as this Honourable Court may deem just.

A. OVERVIEW

2. The Motherisk Drug Testing Laboratory (“MDTL”) at Toronto’s Hospital for Sick Children (“SickKids”) held itself out as a leading authority in the field of hair testing for drugs and alcohol abuse. The main customers of MDTL were Ontario child protection agencies seeking to determine if a parent or caregiver had used drugs or alcohol.

3. Between January 2005 and April 2015, MDTL tested 24,000 hair samples for drugs of abuse and alcohol for child protection purposes. The samples represent hair from more than 16,000 different individuals, approximately 54 percent of which tested positive.

4. MDTL held out their testing as providing adequate and/or reliable results and expert opinions on the results. The child protection agencies, and those who were subjected to the tests, expected that the results of tests and expert opinions were adequate and reliable for use in decisions involving issues of child protection. However, neither the hair test results nor the opinions delivered by MDTL were adequate or reliable.

5. As will be explained below, the hair strand drug and alcohol tests used by MDTL were inadequate and unreliable for use in child protection and criminal proceedings. At no time did MDTL adhere to the internationally accepted forensics standards to which it was required to follow. SickKids did not provide adequate oversight over MDTL.

6. As a result of these failures, the use of hair testing evidence in child protection and criminal proceedings systemically impaired the fairness of those proceedings.

7. The defendants owed those people who tested positive common law duties, which were breached by, amongst other things, failing to properly and effectively supervise the hospital and the laboratory to ensure that the hair strand tests were reliable and appropriate for their intended purpose, namely to provide forensic evidence in child protection and criminal proceedings.

8. Society places great value on the parent-child relationship. The law protects that relationship and the right of parents to nurture and care for their child. The loss of a child, or the deprivation of liberty, on account of a false-positive test, in addition to the anxiety, depression, insult to character and mental anguish to which these people have been subjected, has grossly violated their rights and fundamentally altered the paths of their lives.

B. THE PARTIES

9. The plaintiff, Yvonne Marchand, resides in Scarborough, Ontario. The plaintiff lost custody of her daughter as a result of a false-positive test result for alcohol abuse conducted by the defendants.

10. The plaintiff brings this action pursuant to the *Class Proceedings Act, 1992* on her own behalf and on behalf of all the following classes:

all persons who tested positive from a hair-strand drug and/or alcohol test administered by the Motherisk Drug Testing Laboratory between January 2005 and April 2015 (the "Class" or "Class Members"); and

all parents, grandparents, children, grandchildren, siblings and spouses (within the meaning of section 61 of the Family Law Act, R.S.O. 1990, c. F-3, as amended) of a Class Member (the "Family Law Class" or the "Family Law Class Members").

11. The defendant, The Hospital for Sick Children ("SickKids"), is a hospital located in Toronto, Ontario and is governed by the *Public Hospitals Act*, R.S.O. 1990, c. P.40. The Motherisk Drug Testing Laboratory ("MDTL") was one facet of SickKids' Motherisk Program, which provides information and guidance to members of the public and to physicians about the potential risks to a developing fetus or infant from exposure to drugs, chemicals, diseases, radiation, and environmental agents. MDTL was a department of SickKids. At all relevant times, it was owned, staffed, operated, and overseen by SickKids. MDTL's main customers were Ontario child protection agencies seeking to determine if a parent or caregiver had used drugs or alcohol. The child protection agencies expected that MDTL was providing adequate and reliable expert opinions to them to use in making decisions involving issues of child protection.

12. The defendant, Gideon Koren, is a physician and clinical toxicologist. He joined SickKids in 1982. He was the founder and laboratory director of MDTL at all relevant times. Koren has never had any formal training in forensic toxicology or any experience in a forensic toxicology laboratory.

13. The defendant, Joey Gareri, was the laboratory manager at MDTL at all relevant times. Koren appointed Gareri as acting laboratory manager in September 2006. At the time, Gareri was a research trainee at MDTL and was a Master of Science student in clinical pharmacology and biomedical toxicology. At the time of his appointment, Gareri had no formal training or experience in forensic toxicology or hair analysis and no management training.

14. Collectively, SickKids, Koren, and Gareri will be referred to as the “defendants.”

C. MDTL’S ANALYTICAL METHODS WERE INADEQUATE AND UNRELIABLE

15. For the reasons explained below, MDTL’s analytical methods were required to meet internationally recognized forensic standards. At no time did MDTL’s analytical methods meet internationally recognized forensic standards.

Drugs of Abuse: January 2005 to August 2010 Timeframe

16. During the January 2005 to August 2010 time period, MDTL’s analytical practices for drugs of abuse suffered from numerous fatal flaws, thereby falling short of the internationally recognized forensic standards, including, without limitation, the following:

- (a) **Improper use of ELISA Results:** MDTL relied on the unconfirmed results of its enzyme-linked immunosorbent assay (“ELISA”) tests, which are only preliminary screening tests, both qualitatively (to distinguish positive from negative) and quantitatively (to calculate the drug concentration in the sample);
- (b) **Absence of Standard Operating Procedures and Contemporaneous Documentation:** MDTL had no written standard operating procedures for the hair tests it carried out;
- (c) **Absence of Oversight:** there was an absence of any oversight of the laboratory technician who was assigned to carry out the ELISA tests, with the result that there were significant reporting anomalies or errors in case files;
- (d) **Washing:** MDTL failed to wash hair samples routinely before analysis as required;

- (e) **Chain-of-Custody:** MDTL had inadequate chain-of-custody procedures; and,
- (f) **Record Keeping:** MDTL had inadequate record keeping practices.

Improper use of ELISA Results

17. From January 2005 to August 2010, MDTL tested all hair samples for drugs of abuse using ELISA. The particular ELISA test that MDTL used came in the form of a “kit” supplied by Immunalysis Corporation (Immunalysis), a well-known and well-respected company in California. MDTL used the following ELISA kits from Immunalysis: cocaine, benzoylecgonine (a metabolite of cocaine), opiates, oxycodone, methadone, meperidine, amphetamine, methamphetamine, cannabis / THC, benzodiazepines, barbiturates, PCP, and LSD. The drugs and metabolites that MDTL tested most frequently during this period were cocaine, benzoylecgonine, and cannabis / THC.

18. ELISA is widely used in both clinical and forensic toxicology as a screening test. It is intended to determine quickly if a sample is negative and merits no further testing or if it is a preliminary positive, in which case the sample must be tested using another method (a confirmation test) to determine if the sample is in fact positive.

19. The requirement to carry out a confirmation test on any preliminary positive results from immunoassay-based screens, such as ELISA, was highlighted in both the literature and in all internationally recognized hair-testing standards well before 2005.

20. Moreover, the Immunalysis kits that MDTL used throughout the period from January 2005 to August 2010 included an insert that warned the user about the preliminary nature of the ELISA results (the example below is taken from the ELISA kit for cocaine):

THE IMMUNALYSIS COCAINE DIRECT ELISA KIT IS INTENDED
FOR FORENSIC USE ONLY.

The Immunalysis COCAINE Direct ELISA Kit provides only a preliminary analytical test result. A more specific alternate chemical

method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GS-MS) is the preferred confirmatory method. Professional judgement should be applied to any drug of abuse test result, particularly when *preliminary positive results* are used. [Emphasis added.]

21. Despite the international consensus and the unambiguous instruction from the manufacturer about the manner in which the ELISA tests could be used, MDTL did not have the capability to test hair samples using a confirmation method, such as GC-MS or LC-MS/MS, in-house. From January 2005 to August 2010, it also did not send its preliminary positive ELISA samples to its reference laboratory, USDTL, for analysis.

22. By not sending its ELISA positive samples for GC-MS confirmation, MDTL was not in compliance with internationally recognized forensic standards (or, indeed, the instructions on the face of the ELISA kits it used). Nevertheless, from January 2005 to August 2010, MDTL reported its ELISA results – both qualitatively (as positive vs. negative) and quantitatively (in the form of a numerical drug concentration for positive samples) – to its customers. Such a practice was unacceptable in two important respects.

23. First, unlike confirmation techniques such as GC-MS or LC-MS/MS, ELISA does not and cannot identify the substances within a sample. Because ELISA relies on reactions with biological compounds (antibodies), and because other structurally related or nondrug-related compounds may bind to (or “cross-react” with) the antibodies in the test, there is a material risk of false-positive results. Accordingly, until a confirmation test has been performed and has identified the presence of a drug or metabolite in a sample, the ELISA result cannot be reported to the customer as a positive. At best, it can be reported as a preliminary, unconfirmed, or tentative positive that requires further testing. Because MDTL did not provide such a caveat, its unconfirmed ELISA results should not have been relied on at all.

24. Second, MDTL’s practice of using ELISA to quantify drug concentrations is simply unheard of in forensic toxicology laboratories. Forensic toxicology laboratories use ELISA as a screening tool, meaning that it is used only as a qualitative test – to

distinguish between preliminary positive and negative samples. ELISA is not designed to, and cannot, quantify drug concentrations for several reasons:

- (a) ELISA produces different responses for the different structurally related compounds with which it reacts or cross-reacts;
- (b) Non-drug-related compounds, including substances that are naturally occurring in the body, may cross-react or interfere with the ELISA test;
- (c) The ELISA test does not create a linear response, particularly at low and high concentrations. This lack of linearity means, for example, that at higher concentrations, doubling the concentration of a drug in a sample would not result in double the response from the ELISA test. In addition, some drugs do not respond to ELISA in a linear manner at all (and for those drugs, doubling the concentration may result in up to a 10-fold increase in the ELISA response).

25. In short, the response generated by the ELISA test does not reflect, and cannot be equated with, the actual drug or metabolite concentration in the sample. A confirmation test such as GC-MS or LC-MS/MS must be carried out both to identify and to quantify the amount of the drug or metabolite present. Indeed, the warning label on the ELISA kits that MDTL used said as much.

Absence of Standard Operating Procedures and Contemporaneous Documentation

26. From 2005 to 2010, MDTL had no written analytical procedures for its drug tests.

27. In addition, from 2005 to 2010, MDTL did not maintain contemporaneous documentation of the steps it performed for a specific sample, including records of who performed which steps in the process, what was performed, or when or how it was performed.

28. Standard operating procedures form an integral part of any quality management system. They provide laboratory staff with a clear description of the process to be followed for a particular test, from sample preparation through to the reporting of the result. A step-by-step guide of how to carry out the analytical test. Standard operating procedures help to ensure that laboratory staff have a fixed process to follow for the analytical tests carried out by the laboratory as well as the non-analytical aspects of laboratory practice. Standard operating procedures should be kept up to date, and staff should be instructed not to deviate from them.

29. From 2005 to 2010, it was standard practice for both clinical and forensic laboratories to have standard operating procedures in place for each of the analytical tests they performed. In addition, forensic laboratories were required to maintain records of the tests they performed, including documents identifying what steps were taken in respect of a sample, who took them, when and why, as well as any decisions that were made that might be relevant to the result. In the forensic context, standard operating procedures, together with contemporaneous documentation of the steps taken, have the added benefit of maintaining the chain of custody of the sample within the laboratory.

30. The absence of standard operating procedures from January 2005 to August 2010 created inconsistencies in MDTL's analytical methods and destroys the reliability of MDTL's results.

Absence of Oversight

31. There was no oversight of the laboratory technician who was assigned to carry out the ELISA tests, with the result that there were significant reporting anomalies or errors in the case files.

32. As laboratory director, Koren signed each results report before it was released without ever checking the quality, efficacy or reliability of the analysis. Koren was not trained as a laboratory technician. When he signed the reports, he was not verifying that the numbers or analysis was correct; rather, he was signing to confirm that he had confidence in the technician who performed the analysis.

33. Oversight was required to ensure that MDTL's analytical methods were in compliance with the recognized standards and practices and that its tests are performed properly each time. MDTL failure to implement any oversight mechanisms, preferring instead to rely on the experience and judgement of laboratory technicians demonstrates a failure to adhere to internationally recognized forensic standards and renders the analysis unreliable.

34. As a result of the inadequate oversight, the following reporting discrepancies resulted:

- (a) transcription errors;
- (b) transposed results; and,
- (c) other errors that occurred when results in the report did not appear in the spreadsheets in the case file and the discrepancies do not appear to result from a transcription error.

35. These discrepancies are significant and further demonstrate the unreliability of MDTL's reported results.

Inadequate Washing Procedures

36. Under internationally recognized forensic standards, washing a hair sample before analysis is an important step in the process because it helps to remove dirt and grime, as well as other substances on the surface of the hair, including drugs that are present from external contamination. Because external contamination may be significant, there can be substantial variation between the test results for washed and unwashed hair. In fact, washing can have a substantial impact on the results, in some instances decreasing the result by a factor of four.

37. MDTL did not routinely wash samples before conducting analysis of the samples.

38. Washing a hair sample before analysis is a step that can significantly affect the result. However, without any written procedures or documentation regarding a step as critical as the washing of hair samples, there can be no level of certainty about the process that MDTL followed during this time period.

39. MDTL failed to keep records of whether a sample was washed or even which laboratory technician prepared the sample for testing. As a result, there is no reliable way before September 2010 to identify whether a particular hair sample was washed.

40. Under internationally recognized forensic standards, where a laboratory is testing for exposure (rather than use), the laboratory must clearly explain that the hair was not washed before testing and the reasons for its decision not to do so. From January 2005 to August 2010, MDTL made no indication one way or the other about whether the sample was washed before testing for drugs of abuse. Accordingly, users of the test results would not have known or understood that the samples likely were not washed or, indeed, the significance of MDTL's failure to do so.

Inadequate Chain-of-Custody Procedures

41. Chain of custody is a critically important forensic principle. The purpose behind maintaining a chain of custody is to ensure that a sample can be traced from the time it was collected until the time the test is completed in order to minimize the risk of tampering or contamination along the way.

42. While MDTL used "Chain of Custody Requisition" forms, which recorded who collected the sample and which courier company delivered it to MDTL, for samples collected outside of SickKids, it failed to meet the accepted forensic standards in practice in several ways, including the following:

- (a) Incomplete and missing Chain of Custody Requisition forms. Accordingly, even though MDTL had correctly identified the need to maintain chain of custody of its samples by using these forms, it did not ensure that it routinely maintained chain of custody in practice.

- (b) MDTL did not require Chain of Custody Requisition forms for samples collected within SickKids. As a consequence, for those samples there was no record of whether the sample was sealed or when the sample was received within MDTL and by whom.
- (c) No chain-of-custody documentation was kept at all once MDTL received the sample, whether it originated from an outside source or from within SickKids. MDTL kept no records at all of who handled a particular sample, for what purpose, or when.

43. The problems associated with a lack of chain of custody within MDTL are compounded by the fact that MDTL did not limit access to its samples only to the laboratory technicians who were preparing and testing the hair samples. Ultimately, MDTL operated just like any other research laboratory in a hospital setting. Students and researchers had unfettered access to MDTL, including the locations in which the samples were stored. Although visitors to MDTL needed a pass to enter, they were not required to sign in or out.

44. MDTL's conclusion that there was no need to maintain the chain of custody of a sample once it was within SickKids or MDTL demonstrates a misunderstanding about the purpose for maintaining chain of custody and ensuring the traceability of samples. Missing or incomplete Chain of Custody Requisition forms raises questions about the integrity of the samples submitted for analysis. Moreover, because MDTL staff did not witness and document sample transfers, there was an increased risk of sample contamination or human error.

Inadequate Record Keeping

45. Under internationally recognized forensic standards, forensic laboratories are required to maintain their data and documentation for a specific case for the purpose of a subsequent independent review of the test.

46. MDTL failed to adhere to internationally recognized forensic standards by not maintaining adequate records of the tests it carried out. For the records it did maintain, its practices were deficient because:

- (a) MDTL did not maintain its documents relating to a particular case in a central location;
- (b) MDTL failed to maintain complete files as many of the case files are incomplete and missing documents; and,
- (c) MDTL failed to keep spreadsheets used to generate the ELISA results.

47. As a result, without the underlying data, a reviewing toxicologist would be unable to assess independently the test that MDTL performed, including to determine if controls were run and whether the result was calculated properly.

Drugs of Abuse: September 2010 to April 2015 Timeframe

48. Starting in September 2010, MDTL began routinely to confirm the majority of its test results for drugs of abuse, initially using gas chromatography–mass spectrometry (“GC-MS”) and, after May 2014, liquid chromatography–tandem mass spectrometry (“LC-MS/MS”).

49. MDTL improved some of its laboratory practices by adopting written standard operating procedures and a quality management system.

50. However, even in the September 2010 to April 2015 period, MDTL continued to fall short of internationally recognized forensic standards by:

- (a) relying on a flawed GC-MS procedure;
- (b) continuing to rely on unconfirmed ELISA results for certain drugs and for neonatal samples (though MDTL stopped reporting the quantitative results generated by those tests);

- (c) continuing to test unwashed hair samples from children and neonates; and,
- (d) not maintaining appropriate chain of custody of the samples it tested.

Deficiencies in GC-MS Procedure

51. There are several deficiencies in the manner in which MDTL carried out its GC-MS analysis from September 2010 to May 2014 based on MDTL's standard operating procedure. These deficiencies relate to MDTL's ability to identify the presence of a drug or metabolite reliably and its ability to quantify that drug or metabolite reliably.

52. MDTL's GC-MS procedure did not meet the accepted practice for GC-MS confirmation in several respects.

53. First, the accepted practice when relying on results obtained by the GC-MS instrument in full scan mode is to require a match of 95 percent or higher. MDTL's procedure, which required a similarity index of only 65 percent or higher, was therefore inadequate. MDTL's use of the lower similarity index created a risk that the appropriate identification criteria for the drug or metabolite (including the assessment of the ion ratios from the target and qualifier ions) were not met.

54. In fact, it is unclear why MDTL included a list of diagnostic ions in its GC-MS procedure if it was running the GC-MS instrument in full scan mode. When the instrument is run in full scan mode, the percentage match (or similarity index) reflects the match between the compounds separated in the sample and those contained in the instrument's library. The selection of diagnostic ions applies when the instrument is operated in selected ion monitoring mode (the diagnostic ions being those ions that the instrument are selected to monitor).

55. The accepted practice before a positive identification can be made is that at least three diagnostic ions (one target ion and two qualifier ions) must be identified, and their relative intensities must match those contained in the library or the internal standards. However, MDTL used only:

- (a) one diagnostic ion (the target ion) to identify six (6) of the drugs: amphetamine, methamphetamine, MDA, MDMA, methadone, and meperidine; and
- (b) two (2) diagnostic ions (one target ion and one qualifier ion) to identify three (3) of the drugs: hydromorphone, oxycodone, and norcocaine.

56. To the extent that MDTL used only one diagnostic ion (the target ion) in its confirmation tests, its practice fell below the accepted standards for GC-MS confirmation. It created a risk that samples reported as positive for those drugs were not sufficiently identified in those samples; in other words, a false-positive.

57. Second, it was inappropriate for MDTL to rely solely on the GC-MS instrument to identify the drug or metabolite. When identifying compounds using mass spectrometry, the analyst must not only identify the diagnostic ions and examine their relative intensities, but also ensure that there is an absence of other significant ions on the mass spectra that might suggest the presence of something else. The presence of another significant ion would alert the analyst to the fact that the substance may not be the target drug or metabolite. By relying solely on the similarity index for the diagnostic ions generated by the GC-MS instrument, MDTL did not take this important step to ensure the accuracy of its identification.

58. Third, while using background subtraction to remove any significant ions near the peak of interest is an accepted practice when the requisite match criteria have not been satisfied, this approach was not contained in MDTL's standard operating procedure, and there were no guidelines to establish when background subtraction should be used or how. Nor was the ultimate match obtained as a result of the background subtraction recorded. As a result, in the many cases obtained where the similarity index generated by the instrument was less than 65 percent, but a drug or metabolite was positively identified, it would not be possible to verify that the drug or metabolite reported was indeed confirmed by this background subtraction approach.

59. MDTL's failure to record the background subtraction that ultimately resulted in the match is further compounded by the fact that there was no checking of the mass spectra to ensure that MDTL's acceptance criteria had been met before the result was reported. As a result, the only person who could confirm that a sufficient match had been obtained after using background subtraction was the laboratory technologist who carried out the test.

Continued Reliance on Unconfirmed ELISA Results

60. While MDTL stopped reporting ELISA results quantitatively in September 2010, it continued to report its result qualitatively in violation of internationally recognized forensic standards.

61. What MDTL should have done was refer every preliminary positive result to its reference laboratory for confirmation before sending any results to the customers. Alternatively, MDTL should have made it clear in its results reports that the result obtained from its ELISA test was only preliminary in nature. Such a caveat would have alerted users of its results reports to the limitations in its ELISA-only results and given them an opportunity to request a confirmation test. However, MDTL took none of these steps and continued to fall short of internationally recognized forensic standards.

Routine Failure to Wash Neonatal and Child Samples

62. Even in the post-September 2010 period, MDTL did not wash child (under 16 years of age) and neonatal (under 6 months) samples before analysis. MDTL drew this distinction because, for child and neonatal samples, it considered that it was important to detect exposure (not necessarily use) of a drug or metabolite, and because (given the smaller sample size) the instrument might not have been sensitive enough to detect the small amounts of drug or metabolite that might be in the hair.

63. If MDTL was testing hair solely to detect exposure to (rather than use of) a drug, in theory its decision against washing the hair would not have been problematic as long as it made it clear to customers and other users of its test results that the sample was not washed, as well as its reasons for deciding not to wash the sample and the implication of

this decision. In practice, however, MDTL's methods were inappropriate given the interpretations that it provided: MDTL suggested that conclusions could be drawn about the frequency of a caregiver's use or the level of risk in the child's environment based on a child's or neonate's results.

64. Moreover, MDTL's results reports did not make it clear to the user of the test results that the samples were not washed. In contrast to the results reports that indicated that the adult samples were "washed" before testing, there was no similar notation on the reports to indicate that the child and neonatal samples were "unwashed." Without this indication, MDTL failed to alert the users of the test results that the samples were not washed, along with the implications of its decision not to do so.

Continued to Have Inadequate Chain-of-Custody Procedures

65. The same inadequate chain-of-custody procedures outline above continued in the September 2010 to April 2015 time period.

Alcohol Markers: January 2005 to April 2015 Timeframe

66. Internationally recognized forensic standards require forensic laboratories to have standard operating procedures and record retention policies. As detailed below, MDTL breached internationally recognized forensic standards by failing to maintain records and documents that outlined the analytical steps taken in its tests for alcohol markers.

67. With respect to tests for alcohol, MDTL's hair-testing methodology for fatty acid ethyl esters ("FAEEs") were inadequate and unreliable for forensic purposes for several reasons, including without limitation:

- (a) deficiencies in its GC-MS procedures;
- (b) failure to correct for interference from a compound in its chromatograms;
- (c) failure to consistently apply the same preparation and extraction procedures for each sample; and,

- (d) its misapplication of cut-offs to assess alcohol consumption.

68. First, the FAEEs method suffers from the same shortcomings to those outline above in the GC-MS method for drugs of abuse, and include, without limitation, the following:

- (a) MDTL ran the GC-MS instrument in full scan mode, requiring only a 60 percent similarity index. Again, for the reasons set out above, that match percentage was insufficient.
- (b) MDTL did not give sufficient guidance to the analyst on the acceptance criteria to be followed when subtracting background ions to search for a match. That absence led to the same issues with uncertainty of results that were identified above for drugs of abuse.

69. Second, MDTL failed to correct for interference from a compound in its chromatograms. As a result of the interference, the peak for ethyl stearate on the chromatograph was not completely separate from the peak caused by the interfering compound. Such interference resulted in MDTL's analysis being unreliable because of issues with both identification (the compound is identified by the retention time for the peak) and accurate quantification (the compound is quantified by calculating the area under the peak).

70. Third, MDTL failed to consistently apply the same preparation and extraction procedures for each sample, thereby calling into questions the accuracy of their results. When samples from MDTL cases were re-tested, results varied by a factor of 10. Such wild disparities demonstrated the lack of robust methods and the invalidity of MDTL's analysis.

71. Fourth, MDTL misapplied the cut-offs to assess alcohol consumption in two material respects:

- (a) MDTL used cut-offs that were not justified by internationally recognized standards or the academic literature, instead preferring to create its own

cut-offs to describe what it called “social drinkers” or “moderate / non-drinks.” It was not appropriate to create categories in this manner.

- (b) Although internationally recognized standards recommended a cut-off of 30 pg/mg for EtG to assess chronic excessive alcohol consumption, MDTL applied a 20 pg/mg cut-off. Again, the use of a cut-off in this manner was not supported by internationally recognized standards or academic literature. For results between 20 and 30 pg/mg, for example, MDTL would have interpreted the result as evidence of chronic excessive alcohol use, though the consensus in internationally recognized standards and academic literature would not have interpreted the result in this way.

72. Accordingly, MDTL’s method for FAEEs were deficient, rendering its analysis inadequate and unreliable.

D. INTERPRETATIONS AND OPINIONS GIVEN BY MDTL WERE INADEQUATE AND UNRELIABLE

73. Under internationally recognized forensic standards, it is critical that hair test results not be misinterpreted or over-interpreted and that the limitations on any interpretation be clearly conveyed to the recipient of the result. Between 2005 and 2015, the interpretation practices of MDTL and its communications with customers were inadequate, and they further undermined the reliability of its results that MDTL provided for use in child protection and criminal proceedings.

74. MDTL generated ranges that purported to be able to identify concentrations for drugs and metabolites as “very low” (or “trace”), “low,” “medium,” “high,” and “very high.” MDTL relied heavily on these concentration ranges to interpret its test results for drugs of abuse and to communicate the meaning of those test results to its customers. Its interpretations of test results that were based on its concentration ranges were inadequate and unreliable for forensic purposes for several reasons:

- (a) The concentration ranges used from 2005 to 2011 were created from unconfirmed ELISA results that were preliminary in nature and unreliable

both qualitatively and quantitatively. The concentration ranges were as unreliable as the underlying data;

- (b) Until August 2011, the concentration ranges were created from data that pooled washed and unwashed hair samples, which rendered them inherently unreliable;
- (c) The ranges failed to take into account inter-subject variation; and,
- (d) MDTL used the ranges improperly to reach opinions on whether a person had used drugs, in what amount, and how frequently (referred to as over-interpretation).

75. Effective communication is an important element of forensic toxicology. Forensic toxicologists are charged with ensuring not only that their tests yield accurate and reliable results but also that the results are communicated effectively to users of the results, including the justice system. MDTL inadequately communicated its test results because:

- (a) No one at MDTL had the expertise to provide a forensic toxicology interpretation;
- (b) MDTL did not interpret the test result in all cases;
- (c) When MDTL did interpret the test results, staff often provided the interpretation over the telephone and not in writing;
- (d) MDTL did not communicate the limitations of its ELISA testing or the effect of the change in test methodology that began in 2010; and,
- (e) MDTL made particular interpretation errors when reporting on its tests for cocaine (and its metabolites) and cannabis / THC, two of the most common drugs for which MDTL tested.

76. MDTL's leadership was aware of the pitfalls of using concentration ranges to interpret hair test results. Despite this knowledge, MDTL's practices made clear that it used concentration ranges to draw inappropriate and incorrect conclusions about level and frequency of use.

77. Despite these pitfalls, MDTL used concentration ranges inappropriately. MDTL did provide copies of its concentration ranges in a newsletter that it sent to child protection agencies, as well as in many presentations that it gave to child protection workers, hospitals, policing organizations, legal organizations, and the courts. In newsletters published in December 2005 and December 2006 (which included the concentration ranges), for example MDTL correctly informed customers that a hair test cannot determine the exact dose of the drug taken, and that a dose-response relationship has not been established across individuals. Nevertheless, MDTL also included the concentration ranges and suggested that meaningful information could still be obtained from these ranges.

78. Further undermining any of the caveats provided, MDTL did not convey adequately the limitations of its hair test results in the case-specific interpretations that it provided in its telephone calls and reports. To the contrary, in those case-specific interpretations, MDTL routinely relied on its concentration ranges to give opinions about the level and frequency of a person's drug use, using such terms as "repeated," "isolated," or "frequent" to describe how often a person used a drug; and "bingeing" or "intensive use" to describe the quantity.

79. Accordingly, MDTL used its concentration ranges to draw conclusions regarding the level and frequency of use by an adult not only in its internal documents but also in its communications to users of the test results. Such a practice was not acceptable for a laboratory providing forensic services for the following reasons, including without limitation:

- (a) MDTL advised that the results indicated use of drugs rather than exposure to drugs. Such a conclusion cannot be determined simply by placing a

result within a set of concentration ranges and is particularly inappropriate where samples have not been washed before testing.

- (b) Because of inter-subject variation, concentration ranges cannot be used with a hair result to determine the amount of drugs that a person has consumed or how often the individual has used the drug within the time frame being tested.

80. It was overly simplistic, and misleading, for MDTL to reach conclusions about the frequency and intensity of a person's drug use based solely on where a result placed in MDTL's concentration ranges. Similar problems were caused by MDTL's use of concentration ranges in child samples. MDTL used concentration ranges for cocaine and benzoylecgonine for its unwashed samples (for children) to draw inferences about how the drug or metabolite may have got into the child's hair.

81. After 2010, MDTL stopped using unconfirmed ELISA tests for many, but not all, of the drugs of abuse for which it tested. MDTL's continued use of concentration ranges for drugs of abuse in the post-September 2010 period remained flawed for a number of reasons.

82. First, from September 2010 until August 2011, MDTL interpreted its GC-MS results using its March 2006 concentration ranges (which were created using MDTL's unconfirmed ELISA results). The data underlying the March 2006 concentration ranges was flawed. Interpreting a GC-MS result using those ranges is equally flawed.

83. Second, as a result of the deficiencies in MDTL's GC-MS procedure, the data underlying the August 2011 concentration ranges did not accurately reflect the drug concentrations in the samples that MDTL tested.

84. Third, the use of concentration ranges continue to include results from unwashed samples. Accordingly, the data underlying the August 2011 concentration ranges for cocaine and benzoylecgonine in child samples continued to be based on results from samples that were not washed before testing.

85. For the reasons set out above, no meaningful conclusions can be drawn from concentration ranges created from such data.

No One at MDTL Had Expertise to Give Forensic Interpretations

86. Under internationally recognized forensic standards, the interpretation of a hair test result for forensic purposes requires a significant level of expertise. It should be performed only by a properly trained and qualified expert. The MDTL staff members who provided the interpretations did not have the necessary expertise to provide forensic interpretations.

87. Given the serious flaws in the analytical methods used at MDTL, it is clear that Koren did not understand the basic elements of forensic toxicology that are necessary to provide interpretations of test results. As the laboratory director, Koren was responsible for ensuring that the individuals who were providing routine interpretations were properly trained and qualified to do so, and that they provided reliable interpretations to customers and other users of the test results in individual cases. He did not do so.

88. When Gareri was appointed laboratory manager, he had no formal training or experience in forensic toxicology, hair analysis, or the interpretation of hair test results. In particular, Gareri lacked the necessary training and expertise:

- (a) on the interpretive aspects of hair analysis, including the limitations on interpretations and the many factors that should be considered when interpreting a specific result;
- (b) on the analytical aspects of MDTL's hair tests for drugs of abuse and their limitations (including knowledge that ELISA tests were preliminary screening tests only);
- (c) to explain the adequacy and reliability of the test results, even if he was not capable of performing the tests personally; and,
- (d) to understand the role of the expert witness in legal proceedings.

89. SickKids and Koren should have never given Gareri the responsibility to interpret hair tests results nor held him out as an expert to participants in the child protection and criminal justice system. Nevertheless, shortly after he was appointed, Gareri began frequently and routinely interpreting the test results for those involved in child protection and criminal proceedings. Gareri was not provided with the training required to offer adequate and reliable interpretations of MDTL's hair test results either on the stand as an expert witness or on the telephone or in writing to customers and other users of MDTL's hair tests.

90. As part of the Independent Review, discussed below, Gareri acknowledged that he should not have been hired as laboratory manager in 2005:

Ultimately, [I] had no training in management and only [my] Master's degree research experience in analytics when [I] took over management of the laboratory in 2005. The reality is that [I] learned "on the job" on a job that you should not be learning on. In retrospect, [I] would not have hired [my]self back in 2005 to act as the Laboratory Manager unless a formal training program was in place (i.e. taking over after being trained by an existing manager for an extended period of time).

91. SickKids should have provided Gareri with training regarding the need to be objective and to communicate the limitations on or controversies surrounding the expert's opinion in a clear and transparent manner. If SickKids did not have someone capable of providing this training, it should have obtained the necessary expertise.

92. Starting in 2008, Gareri assigned a graduate student (whom MDTL called a "laboratory counsellor") to assist in providing the over-the-phone consultations regarding MDTL's hair test results. By 2015, 16 individuals had worked at MDTL as laboratory counsellors. With two (2) exceptions, all 16 were at the time graduate students or fellows in pharmacology or clinical pharmacology and toxicology at the University of Toronto.

93. MDTL promoted its use of laboratory counsellors as an efficient way to provide over-the-phone interpretations to child protection agencies. In its December 2009 "Motherisk Drug Testing Newsletter for Children's Aid Societies," MDTL noted that its "free consultations had snowballed into one of the major components of our service."

94. The title “laboratory counsellor” masked the fact that these graduate students and fellows worked only short-term and part-time for MDTL and provided no counselling function whatsoever. They provided opinions interpreting MDTL’s hair test results, which should have been given by experts in hair analysis with the training and qualifications to do so.

95. The laboratory counsellors were not properly trained or qualified to provide reliable interpretations of the test results in individual cases. Nevertheless, the laboratory counsellors became responsible for answering what MDTL referred to as “routine” calls for interpretations of hair test results and were instructed to refer any “non-routine” calls to Gareri.

96. Beginning in 2011, the laboratory counsellors also drafted the majority of the interpretation reports that MDTL issued, basing them on previously issued reports and templates that Gareri had prepared.

97. Until 2012, the laboratory counsellors had no formal training whatsoever. Instead, the training consisted of having the graduate students or fellows sit in on consultation calls with Gareri, to listen to how he answered questions from MDTL’s customers. MDTL also gave the graduate students and fellows a binder of sample interpretation reports and other material relevant to the interpretation of hair test results. In November 2009, MDTL developed its interpretation guidelines and provided them to the laboratory counsellors to use as a “script” when speaking to customers.

98. In 2012, MDTL developed a more formalized training program for its laboratory counsellors, which included five (5) one- to two-hour presentations on the principles of hair analysis generally, as well as neonatal and pediatric hair analysis specifically. The laboratory counsellors also continued to receive reference materials and “shadowed” the more experienced laboratory counsellors by sitting in on calls before answering any themselves. This training was woefully inadequate. The laboratory counsellors lacked the necessary training and expertise:

- (a) on the interpretive aspects of hair analysis, including the limitations on interpretations and the many factors that should be considered when interpreting a specific result;
- (b) on the analytical aspects of the Laboratory's hair tests for drugs of abuse and their limitations, including that ELISA tests were preliminary screening tests only; and,
- (c) to explain the adequacy and reliability of the test results.

99. An opinion interpreting a hair test result is an expert opinion, which should be provided only by an individual with appropriate training and qualifications. The graduate students and fellows MDTL employed to interpret hair test results – who had no experience in the analytical aspects of the tests on which their opinions were being sought and no formal training in forensic toxicology or the science of hair testing – were not experts in hair analysis. They lacked the training and expertise to provide adequate and reliable opinions for use in child protection and criminal cases.

MDTL's Interpretations Were Not Appropriate

100. Hair test results, viewed in isolation, cannot provide any meaningful information about drug use or alcohol consumption and can be potentially misleading. To provide any meaningful insight into a person's use of or exposure to drugs or alcohol, the hair test result must be interpreted in the context of the particular case, with regard for the various factors that may affect the result.

101. MDTL did not routinely provide an interpretation of the hair test results to its customers. Instead, it provided the numerical test results to customers (who may have also had the concentration ranges) and invited the customer to call an MDTL staff person or laboratory counsellor for further information. Providing the numerical test results, and nothing more, suggested a degree of precision and ease of interpretation that was incorrect and would have misled customers.

102. MDTL failed to communicate to the customer adequately, or at all, the limitations in hair analysis – including the lack of a dose–response relationship across individuals and the potential impact of external contamination on the interpretation of hair test results for drugs of abuse. Without an adequate understanding of what the hair test result can and cannot say in the circumstances of a particular case, there was misinterpretation or over-interpretation of the results by the end-user.

MDTL Rarely Provided Written Interpretations

103. Given the complexities in hair testing and the various factors that must be considered in the interpretation of a hair test result, opinions interpreting hair test results must be provided in writing to avoid any misunderstanding by the user. However, throughout the period from 2005 to 2015, unless the customer requested a written interpretation report, MDTL’s practice was to provide interpretations of its test results over the telephone.

104. Without a written expert opinion, it is impossible to determine if an opinion interpreting a hair test result was provided in a particular case and, if it was, by whom and what was said.

105. Given the many complexities involved in the interpretation of hair test results for drugs of abuse and alcohol markers and the need to reduce the risk of misinterpretation or over-interpretation, a written opinion interpreting the hair test results should have been provided every time given the forensic nature of the test, interpretation and ultimate application.

MDTL Did Not Communicate the Limitations of ELISA

106. MDTL failed to inform users of what test or tests it carried out and of any limitations on the analysis or the result.

107. Between January 2005 and August 2010, MDTL failed to advise customers that they used only ELISA to test its hair samples. MDTL also failed to identify for customers or other users of its test results the significant limitations in the ELISA test,

including its inability to identify or quantify the drug or metabolite concentration in a sample.

108. MDTL routinely reported its unconfirmed quantitative ELISA results from January 2005 to August 2010 and interpreted those results in the context of its concentration ranges, without any suggestion that the ELISA test could not be used reliably either to identify or quantify the amount of drug in the sample.

109. Instead, MDTL reported and interpreted its unconfirmed ELISA results throughout this period as though it had positively identified and quantified the drug or metabolite in question, when in fact it had not.

110. MDTL routinely interpreted its unconfirmed ELISA results, both qualitatively and quantitatively, without regard for the fact that those results were only preliminary in nature.

E. OVERSIGHT FAILURES AT SICKKIDS

111. From 2005 to 2015, MDTL was testing an average of 2,000 hair samples each year for child protection agencies and, from time to time, its hair tests were also used in criminal proceedings. The hair tests were, necessarily, forensic in nature, and the service that MDTL was offering to customers should have been a forensic one.

112. Whether a hair test is clinical or forensic does not turn on whether the test result is ever tendered as evidence in court proceedings, criminal or otherwise. A hair test can be forensic even where no court proceeding is ever initiated. What distinguishes a clinical test from a forensic test is the purpose behind the test: if the test is carried out or is used for a legal purpose, then it is a forensic test.

113. MDTL acknowledges that its tests were for “forensic purposes” in its internal documents. In a booklet MDTL published in 2012 entitled *The Motherisk Guide to Substance Abuse Monitoring*, MDTL described itself as translating “established forensic toxicology methods” to children and neonates.

114. MDTL was originally a research laboratory housed in the SickKids Research Institute. By no later than 2005, SickKids became aware of the nature and quantity of the testing that MDTL was carrying out for non-research purposes. When the leadership at SickKids became aware that MDTL was carrying out hair tests for child protection cases, SickKids viewed MDTL's work as being a shift from research toward clinical practice. SickKids gave no consideration to the reality that MDTL was carrying out hair tests for forensic, not clinical, purposes. Nor did SickKids give consideration to the need to ensure that MDTL was complying with forensic standards.

115. Notwithstanding the knowledge of the nature and quantity of MDTL's hair tests, SickKids focused on bringing MDTL into its clinical licensing and accreditation process and did so only and in the absence of any oversight of MDTL's work. With SickKids knowledge, MDTL continue to perform hair tests that were inadequate and unreliable because they failed to follow internationally recognized forensic standards.

116. MDTL did not participate in SickKids' Ontario Laboratory Accreditation inspection until January 2011, over a decade after it had begun offering hair tests to child protection agencies and more than five (5) years after Sick Kids became aware of how frequently MDTL was conducting hair tests for child protection agencies. Had SickKids acted sooner to bring MDTL into the Ontario Laboratory Accreditation process, many improvements could have been put into place sooner.

117. SickKids took no steps to oversee MDTL's work. None of SickKids departments relevant to MDTL's oversight exercised any oversight over MDTL's operations from 2005 to 2015.

118. When SickKids learned that MDTL was doing tests for non-research purposes, it did not charge any of its programs, departments, or divisions with the responsibility of ensuring that MDTL was subject to appropriate oversight mechanisms.

119. While SickKids, took steps to bring MDTL into the Ontario Laboratory Accreditation process to ensure that it complied with the relevant clinical licensing and accreditation requirements (albeit far too slowly), it took no steps to ensure that MDTL's

hair tests were fit for their intended purpose or that MDTL had the appropriate equipment, infrastructure, personnel, and expertise to carry out hair tests for drugs of abuse and alcohol markers.

120. Ultimately, none of the programs, departments, or divisions within SickKids ever took ownership of MDTL as a laboratory, and no clear lines of accountability were ever drawn. The result was inevitable: MDTL slipped through the cracks.

121. SickKids should have appreciated that others would rely on its reputation and ensure that customers and other users of MDTL's hair tests, including participants in the justice system, received the "substance" behind that reputation. SickKids failed to live up to its reputation and obligations.

F. INDEPENDENT REVIEW CONFIRMS MDTL'S ANALYTICAL METHODS WERE INADEQUATE AND UNRELIABLE

122. An independent review was initiated by the Province of Ontario in response to controversy concerning the scientific reliability for forensic purposes of hair tests performed by MDTL (the "Independent Review"). That controversy arose in the context of a criminal appeal in the Court of Appeal in *R v. Broomfield*, 2014 ONCA 725.

123. On October 14, 2014, the Court of Appeal for Ontario allowed the appeal of Tamara Broomfield from two criminal convictions on charges that she had administered cocaine to her two-and-a-half-year-old child over a 14-month period. Ms. Broomfield had been convicted, in part, on the basis of evidence from Koren about the results of MDTL hair tests performed on her child.

124. The Court of Appeal admitted fresh evidence from the deputy chief toxicologist in the Office of the Chief Medical Examiner of Alberta, who criticized MDTL's hair-testing methodology and its interpretations of the hair results. The Court of Appeal concluded that there was a "genuine controversy" about the science and the methodology used by MDTL and quashed two of Ms. Broomfield's cocaine-related convictions. The Court of Appeal ordered a new trial. In keeping with the joint submissions of the Crown and the defence, however, the Court stayed the new trial as

not being in the interest of justice for several reasons, including that Ms. Broomfield had already served the equivalent of a 49-month sentence.

125. On November 26, 2014, the cabinet of the Government of Ontario established the Independent Review and appointed The Honourable Susan Lang as the Independent Reviewer.

126. On April 22, 2015, the mandate of the Independent Review was expanded and the Independent Reviewer was directed to conduct a review and provide a report of her findings and recommendations respecting, amongst others:

- (a) the adequacy and reliability of the hair-strand drug and alcohol testing methodology utilized by MDTL between 2005 and 2015 for use as evidence in child protection and criminal proceedings;
- (b) the extent to which the operation of the MDTL laboratory between 2005 and 2015 was consistent with internationally recognized forensic standards; and,
- (c) whether the use of evidence derived from MDTL's hair-strand drug and alcohol testing had implications in criminal and child protection proceedings.

127. On December 15, 2015, following an extensive investigation, the Independent Reviewer made the following findings:

- (a) the hair-strand drug and alcohol testing used by MDTL between 2005 and 2015 was inadequate and unreliable for use in child protection and criminal proceedings;
- (b) between 2005 and 2015, MDTL operated in a manner that did not meet internationally recognized forensic standards;
- (c) SickKids did not provide meaningful oversight over MDTL; and,

- (d) the use of MDTL hair-testing evidence in child protection and criminal proceedings has serious implications for the fairness of those proceedings.

G. THE PLAINTIFF'S EXPERIENCE

128. The plaintiff was involved in a custody dispute with the father of her daughter. The father made false allegations of alcohol abuse against the plaintiff. As a result, the Catholic Children's Aid Society Toronto (the "Children's Aid Society") investigated and they retained the defendants to conduct the hair test analysis for alcohol abuse. The defendants conducted a hair test analysis and a false-positive result was obtained.

129. Knowing that she was not abusing alcohol, the plaintiff commissioned an independent test from an accredited laboratory which retested her hair for determining consumption of alcohol (the "Independent Test"). The Independent Test concluded that she was negative for alcohol abuse.

130. The Children's Aid Society presented the defendants' analysis at the custody trial. The laboratory manager rather than the author of the Independent Test attended in court to give evidence on behalf of the plaintiff. As a self-represented individual, the plaintiff was unable to qualify the laboratory manager as an expert. The judge refused to admit the Independent Test as evidence because the author was not present in court. As a result, the false-positive result obtained from the defendants was relied upon and used to strip custody of her daughter away from the plaintiff.

H. THE NEGLIGENCE OF SICKKIDS AND MDTL

131. SickKids created, planned, established, set up, initiated, operated, financed, supervised, controlled, and regulated MDTL during the class period.

132. SickKids, by promoting, advertising, marketing, selling, collecting hair samples, and utilizing the test to allegedly establish use of drugs of abuse and alcohol created a duty to use a reasonable degree of care to avoid erroneous test results.

133. The plaintiff and the other Class Members were the intended test subjects and the defendants knew or had reason to know that their custody of their children and, in the case of criminal proceedings, their liberty could be in jeopardy if they tested positive.

134. The plaintiff and other Class Members relied on the validity of the defendants' hair-tests, to which they either voluntarily or otherwise subjected themselves, with the goal that they could provide MDTL, the courts and other interested parties with evidence of their abstinence.

135. Because of the serious and devastating consequences of reporting that the results were positive, the defendants had to exercise their standard of care to the foreseeable Class reasonably and appropriately.

136. At all material times, SickKids owed, and consequently breached, its common law duties to the Class and the Family Class, which include but are not limited to:

- (a) adequately, properly and effectively supervising the environment of MDTL and the conduct of its employees;
- (b) ensuring that proper forensic procedures were employed by MDTL;
- (c) ensuring that MDTL maintained standard operating procedures and contemporaneous documentation in connection with the hair-strand test carried out by MDTL;
- (d) ensuring that incorrect and unreliable hair-strand tests conducted by MDTL did not occur, regardless of their intended use;
- (e) ensuring that MDTL were providing adequate and reliable hair-strand drug and alcohol testing for use in child protection and criminal proceedings;
- (f) ensuring that the operation of MDTL was consistent with internationally recognized forensic standards;

- (g) ensuring that MDTL was staffed with persons with formal training, experience and expertise in forensic toxicology;
- (h) ensuring that meaningful oversight was provided to MDTL;
- (i) ensuring that MDTL was not representing its services for improper or unqualified purposes;
- (j) preventing the serious implications that inadequate and unreliable hair-testing results would have in the fairness of child protection and criminal proceedings;
- (k) ensuring that children's aid societies were not using or relying on inadequate or unreliable hair testing in child protection proceedings;
- (l) ensuring that Crown prosecutors were not using or relying upon inadequate or unreliable hair testing in criminal proceedings; and,
- (m) ensuring that proper and qualified accreditation was afforded to MDTL.

137. As a result of these breaches, the Class Members and the Family Class Members suffered damages as set out below and the administration of justice fell into disrepute.

I. VICARIOUS LIABILITY

138. SickKids was responsible, for amongst other things:

- (a) for the construction, operation, maintenance, ownership, management, financing, staffing, administration, supervision, inspection, auditing and representing of MDTL, and all activities that took place therein, during the class period;
- (b) for decisions, procedures, regulations, policies, operations and actions taken by MDTL, its employees, servants, officers and agents during the class period; and,

- (c) for full and frank reporting with respect to conditions, adequacy, reliability, and competence at MDTL.

139. SickKids is vicariously liable for the harms perpetrated upon the Class Members and the Family Class Members by virtue of, but not limited to, its power, control and discretion over its employees, representatives, servants, officers and agents at all material times during the class period.

140. SickKids maintained an employer-employee relationship with the individual defendants, Koren and Gareri, during the class period, whereby Koren and Gareri were operating within the course and scope of employment at all material times.

J. DAMAGES SUFFERED BY THE CLASS

141. The defendants knew, or ought to have known, that as a consequence of their negligent operation and supervision of MDTL, the Class Members and the Family Class Members would suffer significant monetary and non-monetary damages, including but not limited to:

- (a) protracted and more complex legal proceedings, resulting in increased legal costs, including the need for expert responding evidence;
- (b) loss of custody of a child(s), be it temporary or permanent, on false pretenses, resulting in loss of dignity and interference with familial relations;
- (c) requirement of supervised visitation of a child(s) on false pretenses, resulting in loss of dignity and interference with familial relations;
- (d) deprivation of liberty on account of criminal convictions based on false pretenses;
- (e) exacerbation of depression, anxiety, emotional distress and mental anguish, leading to impairment of mental and emotional well-being;

- (f) a loss of self-esteem and feelings of humiliation and degradation;
- (g) pain and suffering;
- (h) destruction of credibility, character and trustworthiness;
- (i) impaired ability to participate in normal family affairs and relationships;
- (j) loss of friendship and companionship;
- (k) a sense of isolation and separateness from their community;
- (l) an impaired ability to obtain and sustain employment, resulting either in lost or reduced income and ongoing loss of income; and,
- (m) the loss of general enjoyment of life.

142. At all material times, the defendants knew, or ought to have known, that ongoing delay in failing to rectify the institutional failures at MDTL would continue to aggravate and contribute to the Class Members' and the Family Class Members' injuries and damage.

143. The plaintiff pleads that the defendants are strictly liable in tort for damages enumerated herein as they were aware, or should have been aware, that their operation, management, oversight and control, or lack thereof, of MDTL was in breach of all forensic laboratory industry standards and in breach of the duties they owed to the Class Members and the Family Class Members.

K. PUNITIVE DAMAGES

144. The high-handed and callous conduct of the defendants warrants the condemnation of this Honourable Court. The defendants conducted their affairs with wanton and callous disregard for the Class Members' and the Family Class Members' interests and well-being.

145. The loss of a child, or the deprivation of liberty, on account of a false-positive test, in addition to the anxiety, depression, insult to character and mental anguish to which the plaintiff and Class Members and Family Class Members were exposed, has grossly violated their rights and severally altered the paths of their lives.

146. In these circumstances, the plaintiff, the Class and the Family Class request punitive damages to demonstrate to other laboratories and hospitals that such willfully irresponsible and tortious behaviour will not be tolerated and will act as a deterrent to other laboratories and hospitals in Canada that are in the position of providing forensic hair-strand tests for drugs of abuse and alcohol consumption.

147. Her Majesty the Queen in Right of the Province of Ontario will be added as a defendant after the 60 day notice is given under section 7(1) of the *Proceedings Against the Crown Act*. Notice of this action was provided to Her Majesty, the Queen in Right of Ontario, on December 22, 2015.

148. This action is commenced pursuant to the *Class Proceedings Act, 1992*.

149. The plaintiff pleads and relies on the common law and the *Family Law Act*, R.S.O. 1990, c. F.3.

150. The trial of the action should take place in the city of Toronto, in the Province of Ontario.

January 20, 2016

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Court File No.: CV-15-54325900CP

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Toronto

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM
(Notice of action issued on December 22, 2015)

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