

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

B E T W E E N :

~~YVONNE MARCHAND~~-REBECCA GREEN

Plaintiff

- and -

THE HOSPITAL FOR SICK CHILDREN, GIDEON KOREN  
and JOEY GARERI

Defendants

***Proceeding under the Class Proceedings Act, 1992***

**AMENDED STATEMENT OF DEFENCE AND ~~CROSSCLAIM~~  
OF THE DEFENDANT, DR. GIDEON KOREN**

1. Unless otherwise expressly admitted herein, the Defendant, Dr. Gideon Koren (“**Dr. Koren**”), denies each and every allegation contained in the Amended Statement of Claim and puts the Plaintiff to the strict proof thereof.

**Dr. Koren**

2. Dr. Koren is a physician and clinical toxicologist. In 1982, he joined the Hospital for Sick Children (“**SickKids**”) as a fellow, and in 1986 as a clinician scientist.

**Overview of the Motherisk Program and MDTL**

3. The Motherisk Program (the “**Program**”) was founded at SickKids by Dr. Koren in 1985 to study the effect of drugs and other agents on infants in utero and during breastfeeding. One of Dr. Koren’s research goals was to determine if it was possible to ascertain whether or not a mother had used a specific drug during her pregnancy, by conducting studies or testing on the mother’s infant.

4. Over the years, the Program grew to include additional services, such as counseling and clinics for pregnant and breastfeeding women on the use of drugs (including, but not limited to, drugs of abuse) during pregnancy and breastfeeding.

5. The Motherisk Drug Testing Laboratory (“**MDTL**”) was founded as the research laboratory for the Program. The research done at MDTL included meconium testing and hair sample testing for drugs of abuse and, later, alcohol (the “**Hair Tests**”).

6. Dr. Koren did not develop the testing methodologies used at MDTL, nor did he perform the testing.

7. At all material times, Dr. Koren understood and intended the primary role of MDTL to be conducting research that could be used in clinical settings to provide information relevant to the medical care and safety of children.

8. In the late 1990s, MDTL began testing hair samples for the clinical purpose of assisting at-risk children and parents. At all material times, when providing Hair Test results, MDTL advised that the results should be interpreted with other evidence and ought not to be relied upon as the sole or predominant indicator of the best interests of any child.

9. On rare occasions, MDTL staff would be summonsed to testify in court proceedings, as expert witnesses either for criminal or child protection purposes. Dr. Koren himself rarely testified. When Dr. Koren did testify, he did so in his capacity as a clinical toxicologist with expertise in interpreting hair testing results. At all material times, Dr. Koren expressed his honestly held opinion.

10. The hair testing methodologies employed by MDTL were, at all material times, accurate and reliable for their intended purpose. The results and interpretations of hair testing results provided by Dr. Koren were similarly accurate and reliable for their intended purpose.

## **Structure and Supervision of MDTL**

11. MDTL was supervised within SickKids by the SickKids Research Institute (“**RI**”) until 2014, and from mid-2014 onwards by the SickKids Department of Paediatric Laboratory Medicine (“**DPLM**”).

12. Dr. Koren was the founder of the Program and subsequently became the Director of MDTL.

13. Dr. Koren was at all material times the leader of the research team at MDTL; however, Dr. Koren was not, and never purported to be, the technical expert with respect to the development and performance of the Hair Tests.

14. At all material times, day-to-day management of MDTL was appropriately delegated by Dr. Koren to the MDTL laboratory manager.

15. Julia Klein (“**Ms. Klein**”) was the chief technician and MDTL laboratory manager from 1995 to 2005. Ms. Klein was employed by SickKids. Dr. Koren appropriately relied on Ms. Klein’s advice and technical expertise.

16. Ms. Klein had significant expertise in drug detection in hair, and was a member of the Society of Hair Testing (the “**SoHT**”). Ms. Klein established MDTL’s relationship with SoHT and was responsible for representing MDTL at SoHT with respect to protocols and testing standards and relaying information from her participation in SoHT workshops and conferences to Dr. Koren and MDTL.

17. Ms. Klein was responsible for the technical development of the tests that MDTL used in its research, including the enzyme-linked immunosorbent assay (“**ELISA**”) method of testing hair samples that MDTL used.

18. Ms. Klein’s employment at MDTL was terminated in 2005. Upon her departure, Joey Gareri (“**Dr. Gareri**”) became the MDTL laboratory manager. Dr. Gareri also took over Ms. Klein’s role as MDTL’s principal member of the SoHT.

19. Dr. Gareri was employed by SickKids. Dr. Koren appropriately relied on Dr. Gareri's advice and technical expertise.

20. Shortly after Dr. Gareri began as laboratory manager at MDTL, he advised Dr. Koren that many laboratories were using a gas chromatography-mass spectrometry ("GC/MS") method of hair testing for drugs of abuse, including cocaine, in addition to using ELISA as a screening index.

21. At Dr. Gareri's recommendation, Dr. Koren and the MDTL team took steps to transition the hair testing at MDTL to the GC/MS method. This was completed in 2010. In 2014, MDTL further upgraded to a liquid chromatography tandem mass spectrometry ("LC-MS/MS") method of testing.

22. In or around 2005, SickKids requested that MDTL become accredited as a clinical laboratory; however, SickKids later decided to postpone accreditation until 2010-2011. At SickKids' direction, Dr. Koren undertook the necessary steps to obtain clinical laboratory accreditation for MDTL and, in 2011, MDTL became accredited as a clinical laboratory.

23. In two accreditation rounds (2011 and 2014), the MDTL methodologies of hair testing were thoroughly reviewed and examined by the accrediting body, and passed without any requests for changes. The accrediting body noted MDTL to have high standards of quality assurance.

24. At all material times, Dr. Koren had no knowledge that the Inquiry into Pediatric Forensic Pathology in Ontario and the subsequent report authored by the Honourable Stephen T. Goudge and released on October 1, 2008 (the "**Goudge Report**"), or of any of the recommendations in the Goudge Report, were relevant to his role as Director of MDTL.

25. At all material times, Dr. Koren acted appropriately and in accordance with the applicable standard of care of a similarly situated laboratory director.

### **MDTL's Analytical Methods for Hair Testing were Adequate and Reliable**

26. Dr. Koren denies that the Hair Tests used by MDTL to test for drugs of abuse were inadequate or unreliable. Contrary to paragraphs 23 and 53-61 of the Statement of Claim, Dr. Koren specifically denies that the Hair Tests used by MDTL created a material risk of false positive results.

27. At all material times, the Hair Tests used by MDTL to test for drugs of abuse were accurate and reliable. For example:

- (a) The ELISA method of hair testing used by MDTL to detect cocaine use from January 2005 to August 2010 had a false positive rate of virtually zero (if not zero). In 2010, MDTL compared 163 test results of hair samples originally tested under the ELISA method by MDTL with results gleaned by testing under the GC/MS method. There were no false positives using the ELISA method;
- (b) In instances where the Hair Test results were disputed by the subject, samples were sent to a reference laboratory for further testing and confirmation. In no case did this further testing identify a false positive result;
- (c) From 2010-2014, MDTL used GC/MS, an accepted forensic methodology, to confirm ELISA results for drugs of abuse;
- (d) From 2014-2015, MDTL used LC-MS/MS to confirm ELISA results for drugs of abuse. LC-MS/MS is an internationally recognized forensic method of testing.

28. Dr. Koren also denies that the Hair Tests used by MDTL to test for alcohol were inadequate or unreliable. Contrary to paragraphs 67-71 of the Statement of Claim, Dr. Koren specifically denies that the Hair Tests used by MDTL to test for alcohol created a material risk of false positive results.

29. At all material times, the Hair Tests used by MDTL to test for alcohol were adequate and reliable. For example:

- (a) In 2006, Dr. Katrina Aleksa, a research associate at MDTL, attended training in the FAEE method of testing for alcohol with the inventor of the test, Professor Pragst, at the Institute of Legal Medicine and Forensic Sciences in Berlin. She brought her understanding of the method back for use at MDTL;
- (b) MDTL used the solid phase micro-extraction (“SPME”) technique to analyze samples for Fatty Acid Ethyl Esters (“FAEE”) analysis to test for alcohol, which was validated against accepted clinical standards;
- (c) MDTL washed all hair samples before testing for alcohol;
- (d) From February 2011 until 2015, MDTL sent all samples that were above the SoHT cut-off for FAEEs to a second laboratory for Ethyl Glucuronide (“EtG”) detection. EtG is an additional internationally recognized method of testing for alcohol.

30. Dr. Aleksa was employed by SickKids. Dr. Koren appropriately relied on Dr. Aleksa’s advice and technical expertise.

31. Dr. Koren further denies that the interpretations and opinions given by himself and others at MDTL with respect to the Hair Tests for drugs of abuse or alcohol were unreliable or inaccurate.

32. Dr. Koren specifically denies the findings of the Independent Review of the Honourable Susan Lang referred to at paragraph 127 of the Statement of Claim and states that these findings cannot be relied upon and are inadmissible in this proceeding.

**Ms. Green Ms. Marchand**

33. Dr. Koren specifically denies that Ms. Green’s Hair Tests produced unreliable and inaccurate results and/or interpretations of those results, as alleged at paragraph 9 of the Amended Statement of Claim. Dr. Koren further denies that Ms. Green was at any time

denied custody of her son as a result of the results/interpretations of her Hair Tests. Assuming Ms. Green's son was apprehended by the Toronto Children's Aid Society ("TCAS") from hospital after his birth in August 2009, and Ms. Green did not undergo any Hair Tests until October 2009, after her son had already been removed from her care, Ms. Green's Hair Tests did not cause her to lose custody of her son. Ms. Marchand's Hair Tests produced a false positive result, as alleged at paragraph 9 of the Statement of Claim.

34. Samples of Ms. Green's hair were tested by MDTL from October 2009 to February 2012, at the request of the TCAS. Samples of Ms. Marchand's hair were tested by MDTL in September 2011 and again in April 2012, at the request of the Catholic Children's Aid Society of Toronto ("CCAS").

35. Ms. Green was advised by SickKids and/or Dr. Gareri that it was recommended that the use of any hair-care product containing ethanol be avoided for three months prior to any hair testing.

36. In October 2009, Ms. Green's Hair Test was positive for cocaine and benzoylecgonine, a cocaine metabolite using the ELISA method of hair testing. In May 2010, Ms. Green's Hair Test was positive for cocaine, and negative for benzoylecgonine using the ELISA method of hair testing. In December 2010, Ms. Green's Hair Test was positive for cocaine (trace), and negative for benzoylecgonine using the ELISA method of hair testing, and these results were confirmed using the GC/MS method of hair testing. Hair Tests performed in May 2011, November 2011, and February 2012 were all negative for cocaine. No testing for benzoylecgonine was carried out as part of these Hair Tests given the negative results for ng for alcohol. Assuming Ms. Green used cocaine in 2009 through to part of 2010, the results of Ms. Green's Hair Tests from October 2009 through to February 2012 are consistent with such use.

37. In October 2009, May 2010, December 2010, May 2011, and November 2011, Ms. Green's Hair Tests were positive for alcohol markers using the FAEE method of hair testing. In May 2011 and November 2011, Ms. Green's hair samples were sent by MDTL to the United States Drug Testing Laboratories ("USDTL") for confirmation of the positive

alcohol results. On both occasions, the USDTL confirmed the positive alcohol results through the EtG method of testing.

~~35. In both instances, Hair Tests for alcohol and cannabis were performed. In both September 2011 and April 2012, the Hair Tests were positive for both alcohol and cannabis. Ms. Marchand disputed the results of the Hair Tests. On both occasions, Ms. Marchand's hair samples were sent by MDTL to the United States Drug Testing Laboratories ("USDTL") for confirmation of the positive alcohol results. On both occasions, the USDTL confirmed the positive alcohol results.~~

38. In August 2011, Dr. Gareri provided a report to the TCAS that explained the results of Ms. Green's May 2011 Hair Test. The TCAS was also advised by Dr. Gareri and/or SickKids that the results of Ms. Green's Hair Tests should be interpreted in conjunction with other evidence and should not be relied upon as the sole or predominant indicator of the best interests of Ms. Green's child or children. The TCAS was also advised specifically by Dr. Gareri and/or SickKids that it was not advisable to use the results of hair testing for alcohol markers in isolation from other evidence pertaining to alcohol consumption. At the request of the CCAS, Dr. Gareri provided a written report to CCAS that explained the results of Ms. Marchand's Hair Tests, and responded to an expert toxicologist report that Ms. Marchand relied upon. The CCAS was advised by Dr. Gareri and/or SickKids that the results of Ms. Marchand's Hair Tests should be interpreted in conjunction with other evidence and should not be relied upon as the sole or predominant indicator of the best interests of Ms. Marchand's child or children.

39. ~~37.~~ Dr. Koren had no involvement whatsoever in the testing of Ms. Green's Ms. Marchand's hair or in the interpretation of results of Ms. Green's Ms. Marchand's Hair Tests.

## **Summary**

40. ~~38.~~ Dr. Koren denies any liability to Ms. GreenMs. Marchand. Dr. Koren similarly denies any liability to the proposed class members.



41.39. Dr. Koren denies the existence of any contractual relationship with Ms. Green ~~Ms. Marchand~~ or any of the class members.

42.40. Dr. Koren denies that he owed the representative plaintiff, Ms. Green, ~~Ms. Marchand~~, or any of members of the proposed class, a duty of care.

43. Dr. Koren denies that he is strictly liable in tort to Ms. Green or the proposed class members.

44.41. Dr. Koren has complete immunity at common law and under statute from the imposition of a duty of care with respect to Ms. Green ~~Ms. Marchand~~ and the proposed class.

45.42. Dr. Koren pleads and relies on the *Child and Family Services Act*, R.S.O, 1990, c C.11., (“CFSA”) pursuant to which children’s aid societies owe a duty to children, and a duty to the public at large to take into account relevant considerations and conduct appropriate analysis and investigations prior to making any decision that could affect the interests, liberties, and rights of a child. ~~Pursuant to the CFSA, no duty was owed by any children’s aid society to Ms. Marchand or any members of the proposed class.~~

46.43. Pursuant to the CFSA, children’s aid society officers and employees are immune for acts done in good faith in the execution or intended execution of their duties or for alleged neglect or default in the execution of good faith of their duties. Dr. Koren states that he is immune from the claims of Ms. Green ~~Ms. Marchand~~ and the proposed class as a result of the immunity provided to children’s aid society officers and employees under the CFSA.

47.44. Any assistance provided by Dr. Koren in court proceedings respecting the Hair Tests is subject to absolute privilege and immunity from suit. Dr. Koren’s opinions regarding the Hair Tests were confined to interpreting the results of testing conducted by MDTL. This assistance was provided in good faith. Dr. Koren gave these opinions as a witness during the course of criminal, child protection, or custody proceedings. As a result, Dr. Koren states that his opinions, having been provided as a witness in judicial hearing, are

subject to absolute privilege and immunity from suit. Dr. Koren also pleads and relies upon s. 142 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43.

48.45. It was not reasonably foreseeable that the actions or inactions of Dr. Koren could cause legally compensable harm to Ms. Green ~~Ms. Marchand~~ or members of the proposed class.

49.46. In the alternative, if Dr. Koren owed any members of the proposed class a duty of care, Dr. Koren acted at all times in accordance with the applicable standard of care. Dr. Koren denies that he was negligent in any manner whatsoever.

50.47. Dr. Koren denies that Ms. Green ~~Ms. Marchand~~ or any of the proposed class members suffered any of the damages alleged in the Statement of Claim. Moreover, and in any event, Dr. Koren denies that any actionable act or omission on his part caused or materially contributed to any damages suffered by Ms. Green ~~Ms. Marchand~~ or any of the proposed class members.

51.48. In the alternative, if Ms. Green ~~Ms. Marchand~~ or any of the proposed class members suffered any loss or damage whatsoever, which is denied, it was not caused by any positive Hair Test result for drugs of abuse and/or alcohol performed by MDTL, or by Dr. Koren.

52.49. In particular, without restricting the generality of the foregoing, Dr. Koren asserts that any loss or damage suffered by Ms. Green ~~Ms. Marchand~~ or any of the proposed class was caused or materially contributed to by the claimants' own behaviour, including, but not limited to, use of drugs of abuse, alcohol abuse, and/or failure to take adequate care of children in their care, and that any loss of custody or visitation rights respecting a child that was suffered by Ms. Green ~~Ms. Marchand~~ or any of the proposed class members would have occurred regardless of the Hair Tests performed by MDTL.

53.50. In the alternative, the damages claimed by Ms. Green ~~Ms. Marchand~~ and the proposed class members are excessive, too remote, and/or not otherwise recoverable in law.

54. In the further alternative, Dr. Koren states that any damages suffered by Ms. Green and the proposed class members were as a result of the acts or omissions of others, and Dr. Koren has no several liability.

55.54. Dr. Koren denies that a class proceeding is an appropriate or preferred manner of proceeding with this litigation.

56.52. Dr. Koren states that the actions of Ms. Green ~~Ms. Marchand~~ and the proposed class are statute-barred pursuant to sections 4 and 5 of the *Limitations Act, 2002*, S.O. 2002 c. 24, Schedule B. In particular, Dr. Koren states that this action was not commenced within two years of Ms. Green's ~~Ms. Marchand's~~ and the proposed class' discovery of their alleged claims or the date they ought to have been discovered through reasonable diligence.

57.53. Dr. Koren denies that this is an appropriate case for the award of punitive damages.

58.54. Dr. Koren also pleads and relies upon the provisions of the *Negligence Act*, R.S.O. 1990, c. N.1.

59.55. Dr. Koren requests that this action be dismissed against him with costs.

### **CROSSCLAIM**

~~56.— If Ms. Marchand and/or the proposed class have suffered any damages, which is denied, and if they were caused or contributed to by the negligence of SickKids and/or Dr. Gareri as alleged by Ms. Marchand, then Dr. Koren is entitled to contribution and indemnity.~~

~~57.— If Dr. Koren is found liable to Ms. Marchand and/or the proposed class, he claims against SickKids, including its agents, employees, and anyone else for whom SickKids is in law responsible for, and Dr. Gareri for:~~

- ~~(a) — contribution and indemnity for any and all amounts found to be owing by Dr. Koren to Ms. Marchand and the proposed class;~~
- ~~(b) — interest on such amounts pursuant to the provisions of the *Courts of Justice Act*, R.S.O. 1990, c.C.43;~~
- ~~(c) — his costs of this action and this Crossclaim; and~~
- ~~(d) — such further and other relief as this Honourable Court may deem just.~~

~~58.— Dr. Koren repeats and relies upon the allegations contained in his Statement of Defence and pleads and relies upon the provisions of the *Negligence Act*, R.S.O. 1990, c.N.1 as amended, with respect to this Crossclaim.~~

59. — ~~Dr. Koren asks that this Crossclaim be tried with the Main Action herein.~~

~~June 17, 2016~~ December 2, 2016

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Proceeding commenced at Toronto

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