

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

VACCINE CHOICE CANADA (VCC), [REDACTED]

Plaintiff

- and -

**HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO, THE ATTORNEY GENERAL
OF ONTARIO, THE MINISTER OF HEALTH AND LONG TERM CARE, THE
MINISTER OF EDUCATION, AS REPRESENTED BY THE ATTORNEY GENERAL
OF ONTARIO**

Defendants

STATEMENT OF DEFENCE OF THE DEFENDANTS

Admissions and denials

1. The Defendants admit the allegations contained in paragraphs 7, 8, 9 (except for the words “and enforcement of enrollment, suspension, and expulsion of pupils, and otherwise to give effect to the statutory, constitutional and international law rights to education for every child”), 30 (but only the first sentence, and except for the words “compulsory” and “all”), 31 (except for the words “the pupil and”), 32 (but only the last sentence), subparagraph (c) of the second paragraph numbered 35, subparagraph 41(m), subparagraph 58(a) (except for the words “and are less likely to be ‘up to date’ with their vaccinations”), subparagraph 58(g) and 59 (but only the first sentence) of the Statement of Claim.
2. The Defendants deny the allegations contained in paragraphs 29, 30 (but only the word “compulsory” and the second sentence in parentheses), 31(a) (but only the words “the pupil”), 32 (except for the last sentence), 33, 34, the first paragraph numbered 35 (that

includes the words “when and where vaccinations are administered by private general physicians”), subparagraphs (a), (b), (d) and (e) of the second paragraph numbered 35, 36, 37, 38, 40 (but only the words “VCC has noted, uncovered, and researched certain established facts as set out below”), subparagraphs 41(a)-(l) and (o)-(s), 42, subparagraphs 43(a), (c), (d) and (f), subparagraphs 44(a)-(c) and (e)-(j), 45, 46-57, subparagraph 58(a) (but only the words “and are less likely to be ‘up to date’ with their vaccinations”), (b)-(f) and (h), 59 (except for the first sentence) and 60-62 of the Statement of Claim, as they are inaccurate, incomplete, irrelevant and/or argumentative. The Defendant’s statement of the material facts on which it relies is set out below.

3. The Defendants have no knowledge of the allegations contained in paragraphs 4-6, 10-28, 39, 40 (except for the words “VCC has noted, uncovered, and researched certain established facts as set out below”) and subparagraph 41 (n) of the Statement of Claim.

Immunization serves important public health goals

4. The goal of Ontario’s immunization policy is to reduce the burden of vaccine-preventable diseases. Immunization programs are an important foundation of Ontario’s health system.
5. Infectious diseases can spread among children and adolescents at school who are not vaccinated. Vaccine-preventable diseases can kill or seriously harm children and others. Vaccines save lives and prevent serious illnesses, including many that are easily spread in schools and child care centres. They also reduce health care costs.
6. Immunization directly protects individuals who receive vaccines. Through community (or herd) immunity, immunization against many diseases also prevents the spread of infection in the community and indirectly protects newborns who have not yet received all of their vaccines, people who cannot be vaccinated for medical reasons such as people who have allergies, or who have had an organ transplant or are undergoing treatment for cancer or other illnesses, and people who may not adequately respond to immunization such as the elderly.
7. Comprehensive information about vaccines, immunization practices and vaccine safety is provided to health care practitioners, vaccine program administrators and the public (including parents) by the Public Health Agency of Canada in the *Canadian Immunization*

Guide, which is available online at <https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>.

Vaccine safety is carefully monitored

8. The medical evidence overwhelmingly demonstrates that vaccinations are safe, that their most common side effects are mild pain, swelling and redness where the injection was given, and that serious side effects, while possible, are rare.
9. In Canada, regulatory oversight is in place to ensure that all phases of vaccine testing and production are done in accordance with rigorous standards. Vaccine safety assessment and monitoring exist throughout all phases of the vaccine product 'life cycle', from discovery through market authorization and beyond.
10. Health Canada is the regulatory authority in Canada responsible for working to maximize the quality, safety, and efficacy of all biologic drugs, including vaccines for human use. Vaccines are authorized for sale by Health Canada only after undergoing rigorous reviews to maximize their quality, safety, and efficacy. If there is insufficient evidence to support safety, efficacy or quality claims, Health Canada will not authorize the vaccine, and the product cannot be sold in Canada.
11. The safety of vaccines is carefully monitored, starting early in the product development and continuing for as long as the vaccine is being used. Part of the process for monitoring and assessing vaccine safety involves surveillance and assessment of adverse events following immunization (AEFIs). An AEFI is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine.
12. In Ontario, health professionals are required to report AEFIs to their local public health unit. Public health units investigate AEFIs and provide support to immunizers, individuals, and their families.
13. The actual cause of an AEFI could be related to a variety of factors, including those that are not vaccine-related. There are several challenges involved in determining whether or not there is a causal association between a vaccine and an adverse event, and sometimes the root cause cannot be exactly determined. Using scientific and epidemiological methods,

an assessment can be undertaken to assess causality between the vaccine and adverse event.

14. Vaccine safety monitoring in the form of AEFI surveillance is a joint effort of provincial/territorial and federal public health partners. AEFI surveillance is conducted through passive reporting (e.g. reports to local public health by a healthcare provider, client or caregiver) and active reporting (via the Immunization Monitoring Program ACTIVE-IMPACT, a national pediatric hospital-based surveillance network with designated nurse monitors actively searching client records for AEFIs).
15. Ontario has its own AEFI reporting system, and, like the other provinces and territories, contributes to the national surveillance system by submitting reports of AEFIs to the Canadian Adverse Event Following Immunization (CAEFI) database.

The *Immunization of School Pupils Act*

16. The purpose of the *Immunization of School Pupils Act*, RSO 1990, c I.1 ("the *ISPA*") is to protect children from certain designated diseases, including diphtheria, measles, mumps, poliomyelitis, rubella, tetanus and any other disease prescribed by the Minister of Health.
17. To achieve this objective, s. 3 (1) of the *ISPA* imposes a duty on parents of children who attend private school or a school as defined in the *Education Act*, RSO 1990, c E.2 in Ontario to ensure their children complete a prescribed program of immunization. The *ISPA* does not apply to parents whose children are home schooled. The immunization requirement is subject to two exceptions: one for medical reasons and one based on conscience or religious belief.
18. The exception based on religion or conscience is set out in s. 3(3) of the *ISPA*, which states that the duty to cause a child to complete the prescribed program of immunization does not apply to parents who have completed an immunization education session with a medical officer of health (or their delegate) and who have filed a statement of conscience or religious belief with the proper medical officer of health.
19. Section 4 of the *ISPA* creates an offence for parents who contravene s. 3. The penalty upon conviction of an offence under s. 4 is a fine of up to \$1,000. Imprisonment is not a possible penalty upon conviction.

20. Section 6 of the *ISPA* states that a medical officer of health may, by written order, require a school to suspend a pupil from attendance at the school under the circumstances outlined in s. 6(2) are met. Those circumstances are limited to when the medical officer of health has not received proof of compliance with s. 3 of the *ISPA*, including the requirements for either exception, and is not satisfied that the pupil has or will complete the prescribed program of immunization. A suspension ordered by the medical officer of health under s. 6 is for a period of twenty school days.
21. Section 12 of the *ISPA* also gives a medical officer of health the authority to order that any pupil who has not completed the prescribed program of immunization, or for whom the prescribed program of immunization is unnecessary by reason of past infection or laboratory evidence of immunity, be excluded from school where there is an outbreak, or an immediate risk of an outbreak, of a prescribed disease at the school the pupil attends.

The Child Care and Early Years Act, 2014 and regulations

22. Ontario Regulation 137/15 promulgated pursuant to the *Child Care and Early Years Act, 2014*, SO 2014, c 11, Sch 1 ("the *CCEYA*") establishes immunization requirements for children attending licensed child care centres and home child care premises.
23. Section 35 of O.Reg 137/15 requires every licensee to ensure that before a child is admitted to a child care centre or premises where home child care is provided the child is immunized as directed by the local medical officer of health.
24. Pursuant to s. 35(2) of O. Reg 137/15, the immunization requirements do not apply where a parent objects to immunization on the basis of sincerely held convictions of the parent's religion or conscience, or where a medical practitioner provides medical reasons why the child should not be immunized. The application of s. 35(2) is not subject to a parent attending an immunization education session.
25. Section 35(3) requires that any objections and medical reasons in accordance with s. 35(2) be submitted in the approved form.
26. Contravention of s. 35 of O. Reg 137/15 does not constitute an offence for parents of unimmunized children. While a licensee could be found to be not in compliance with a provision under the regulation, the provision does not impose requirements on parents.

Education sessions under the ISPA

27. On September 1, 2017 amendments to the *ISPA* came in effect, including the requirement for the completion of an immunization education session before a religious or conscientious exception can be granted. This requirement supports parents in making informed decisions about immunizing their children if they are considering a non-medical exemption. Completion of the immunization education session is not a requirement for parents seeking a medical exception.
28. The requirements that apply to the immunization education session described in s. 3(3) of the *ISPA* are set out in s. 4 of Ontario Regulation 645 promulgated under the *ISPA*.
29. Subsection 4(2) of O. Reg. 645 provides that the immunization education session must provide information **on the benefits and risks of immunization**, as well as vaccine safety.
30. Subsection 4(3) of O. Reg. 645 requires that an immunization education session be delivered by a medical officer of health (or delegate). The local medical officer of health (or their delegate) who delivers the education session is a professional who works within a local public health unit and who has received **training in immunization**.
31. Subsection 4(4) of O. Reg. 645 states that a certificate of completion must be provided to every parent who completes an immunization education session. O. Reg 645 does not establish standards for achievement or evaluation of parents who complete the immunization education session.
32. The content of the immunization education sessions and any information sheets, tools or resources that are provided during the session by local public health units **are evidence-based and factual**. They discuss potential side effects, both minor and major, of vaccines as well as the benefits of immunization in protecting children from vaccine preventable diseases.
33. In any event, while the challenged legislation sets out minimum requirements for the education sessions as detailed above, **the Defendants are not responsible in law for the conduct of the medical officers of health or the public health units in delivering the education sessions. Medical officers of health and boards of health, as defined in the *ISPA***

and the *Health Protection and Promotion Act*, RSO 1990, c H.7, are not agents of the Defendants.

34. Contrary to the Plaintiff's assertion at paragraph 33 of the Statement of Claim, the immunization education sessions are not designed to "brow-beat" parents to accept vaccination. Instead, by providing parents with information about benefits and risks of immunization and information about vaccine safety, immunization education sessions assist parents in making informed decisions about their children's health.

Statement of conscious or religious belief exemption forms

35. The form entitled "Statement of Conscience or Religious Belief – *Immunization of School Pupils Act*", dated July 2017 and available through the website of the Government of Ontario Central Forms Repository, is the prescribed form for a statement of conscience or religious belief under the *ISPA* ("*ISPA* Statement Form").
36. The *ISPA* Statement Form is not intended to provide comprehensive information about the risks and benefits of immunization, or to be a parent's sole source of information on these topics. The information provided on the *ISPA* Statement Form is not and does not purport to be a replacement for the product monograph for specific vaccines, or for a thorough and personalized discussion with a doctor or other health care provider. Unlike the immunization education session, the *ISPA* Statement Form is also not intended to educate parents about the risks and benefits of immunization and about vaccine safety.
37. Rather, the *ISPA* Statement Form is designed to be completed by parents who have already had the opportunity to receive information and education about immunization through the immunization education session provided by their local public health unit and their own physician or other trusted health care provider, and who have made the decision to obtain an exemption from Ontario's immunization requirements for their children. In this context, there is no obligation on the Defendants to provide further information about the risks and benefits of immunization on the *ISPA* Statement Form.
38. The information section on the *ISPA* Statement Form furthers the important public health objective of protecting children from vaccine-preventable diseases by highlighting the evidence-based benefits of vaccination and the risks of denying or delaying vaccines.

39. Contrary to the Plaintiffs' assertion at paragraph 33 of the Statement of Claim, the *ISPA* Statement Form's statement that "With the decision to delay or refuse vaccines, you are accepting responsibility that you are putting your child's health and even life at risk" is not an "acknowledgement" by the signatory and does not purport to represent the opinion or belief of the person completing the form. This statement does not form part of the Affidavit sworn or affirmed by the person seeking the exemption. Rather, it is information provided by the Government of Ontario.
40. The Plaintiffs' allegations at paragraphs 33 and 37(b) of the Statement of Claim that the *ISPA* Statement Form could provide "a basis for future criminal prosecution" for "failure to provide the necessities of life" is wholly speculative and hypothetical. The Plaintiffs do not allege that they or any other identified individuals have been exposed to criminal investigation or prosecution because of anything in the *ISPA* Statement Form. In any event, any actual criminal investigation or prosecution in a particular case would take into account all of the relevant circumstances.
41. The form entitled "Statement of Conscience or Religious Belief for Child – *Child Care and Early Years Act, 2014*", dated May 2016 and available through the website of the Government of Ontario Central Forms Repository, is the prescribed form for a statement of conscience or religious belief under the *CCEYA*. The Statement of Conscience or Religious Belief for Child form under the *CCEYA* does not include information on the risks of not being vaccinated.

Orders for the suspension of a student

42. Where the grounds in s. 6(2) of the *ISPA* have been met, it is the medical officer of health, not school officials operating under the *Education Act*, who has the authority to make a written order requiring a person who operates a school to suspend a student for a term of twenty school days.
43. Pursuant to s. 8(3) of the *ISPA*, orders for suspension of a student under s. 6 may be repeated from time to time where the circumstances specified in s. 6(2) still exist.

44. Contrary to paragraph 32 of the Statement of Claim, the *ISPA* and its regulations do not grant anyone the authority to expel a student from school or refuse to enroll a student in school.
45. Under s. 12 of the *ISPA*, a medical officer of health may also make a written order requiring a school operator to exclude a student who has received an exemption from the immunization requirements based on conscientious or religious belief from school when there is an outbreak or an immediate risk of an outbreak of a designated disease at the school the child attends. Orders excluding students from school under s. 12 of the *ISPA* remain in force until they are rescinded in writing, which must occur as soon as the medical officer of health is satisfied that the outbreak or immediate risk of the outbreak of the designated disease has ended.

Administration of vaccines in schools

46. None of the legislative provisions challenged in the Statement of Claim provide for school-based immunization programs. School vaccination clinics are authorized under the *Health Protection and Promotion Act*, RSO 1990, c H.7 ("the *HPPA*") and Ontario Regulation 570 and are delivered by local public health units, not by the Defendants. Nor are the Defendants responsible for any actions taken by school boards, private school operators, child care licensees or any of their employees.
47. Prior to the date of a school vaccination clinic, students are given a consent form and information sheet for their parents. These documents contain contact information for the public health unit and encourage parents to contact the public health unit with any questions or concerns prior to the school vaccination clinic.
48. The vaccine information sheets also contain information about who should not receive the specific vaccine(s) to be administered at the clinic for medical reasons. The consent forms ask specific questions about a child's health status to help determine whether a given vaccine may be contraindicated.
49. Vaccines at school vaccination clinics are administered by trained health care providers. Health care providers administering vaccinations at school vaccination clinics are required to conduct an assessment of the student's health status to identify any risk factors and will

not provide the vaccine if their assessment indicates the vaccine may not be safe for the student to receive.

Administration of vaccines by private physicians or other health care providers

50. In Ontario, regulated health professionals must comply with legislative, professional and ethical guidelines.
51. Pursuant to the *Health Care Consent Act*, SO 1996, c 2, Sch A, health care practitioners in Ontario are required to obtain informed consent before administering any treatment, including vaccination. Informed consent to any form of medical treatment is obtained through the provision of information about: the nature of the treatment, expected benefits of the treatment, material risks of the treatment, material side effects of the treatment, alternative courses of action, and the likely consequences of not having the treatment.
52. No individual physician or other health care professional is named as a defendant in this proceeding. The Plaintiff has not pleaded any particular facts concerning an act or omission by a specific health care provider.
53. Nothing in the challenged legislation gives the Defendants the legal authority to require health care professionals to do or not to do anything in their exercise of clinical judgment. Physicians and other health care providers administering vaccines are not agents of the Defendants, and the Defendants are not liable for the acts or omissions of any individual health care provider.

Vaccine Choice Canada has no standing

54. Vaccine Choice Canada does not have standing to bring this action. Vaccine Choice Canada is not a natural person and is not directly affected by the challenged provisions. Therefore, Vaccine Choice Canada has no standing to plead this action or to seek a remedy.
55. Vaccine Choice Canada has not pleaded that it seeks public interest standing, and in any event has pleaded no facts to establish that the court should in its discretion grant it public interest standing.

No infringement of the *Charter*

56. The Defendants expressly deny that ss. 3(1), 3(3) or 6 of the *ISPA* or s. 35 of Ontario Regulation 137/15 under the *CCEYA* (“the challenged provisions”) infringe sections 2(a), 2(b) or 7 of the *Canadian Charter of Rights and Freedoms* and put the Plaintiffs to the strict proof thereof.
57. The Statement of Claim fails to disclose an adequate factual foundation for the claim that the challenged provisions infringe the Plaintiffs’ rights under s. 2(a) of the *Charter*.
58. The challenged provisions strike a constitutionally-valid balance between respect for Ontarians’ religious or conscientious beliefs and the important public and individual health benefits of immunization. Rather than limiting the Plaintiffs’ rights under s. 2(a) of the *Charter*, the challenged provisions facilitate the exercise of the Plaintiffs’ religious or conscientious beliefs by permitting religious and conscientious exemptions.
59. The Statement of Claim fails to disclose an adequate factual foundation for the claim that the challenged provisions infringe the Plaintiffs’ rights under s. 2(b) of the *Charter*.
60. None of the challenged provisions, the immunization education session or the *ISPA* statement form have the purpose or effect of limiting the ability of the Plaintiffs’ or anyone else to express any message. Nor do the challenged provisions, the immunization education session or the *ISPA* Statement Form constitute compelled speech or expose the Plaintiffs’ or anyone else to criminal liability or in any way remove the presumption of innocence.
61. The Defendant denies the allegation that the immunization education sessions offer a “distorted” presentation of the risks of vaccinating or not vaccinating. The information provided in the immunization education sessions is factual and evidence-based.
62. Ontario’s immunization scheme under the *ISPA* and *CCEYA* furthers the purposes of freedom of expression, which include seeking and attaining truth, by providing factual, evidence-based information on the benefits and risks of immunization, and thereby promoting informed consent to medical treatment. The decision to obtain an exemption to the immunization requirements under the *ISPA* and *CCEYA* is one that carries significant risk for individual children and others and, as a result, the information included in the *ISPA*

statement form is relevant and important information to highlight for parents at the time when they are requesting an exemption.

63. The Statement of Claim fails to disclose an adequate factual foundation for the claim that the challenged provisions infringe the Plaintiffs' rights under s. 7 of the *Charter*.
64. Section 7 of the *Charter* is not engaged by any of the allegations pleaded in the Statement of Claim. Parents remain free to exempt their children from the requirements under the *ISPA* and *CCEYA* for either medical reasons or based on conscientious or religious belief.
65. Moreover, the Plaintiffs and any other Ontarians who choose not to comply with the immunization or exemption requirements may avoid the application of the challenged provisions by opting to home-school their children so that they do not attend either public or private school or licensed child care centres.
66. In the alternative, if the challenged provisions infringe any of sections 2(a), 2(b) or 7 of the *Charter*, which is denied, the Defendants plead that they constitute a reasonable limit on the Plaintiffs' *Charter* rights that is demonstrably justified under section 1 of the *Charter*. Protecting children, and indeed all Ontarians, from vaccine-preventable diseases is a pressing and substantial objective. Ontario's immunization program, as set out in the *ISPA*, *CCEYA* and their regulations, is rationally connected to these objectives. The challenged provisions are necessarily minimally impairing, including because they provide for individual exemptions. The salutary effects of Ontario's immunization program, including furthering public health goals of saving lives and reducing vaccine-preventable diseases, are proportionate to any deleterious effects.
67. The declaratory relief sought at paragraphs 1(e), 1(f), 1(g) and 1(h) is vague, diffuse and not justiciable. It fails to disclose any judicially recognizable or manageable standard and seeks sweeping judicial pronouncements unconnected to the validity of any particular legislative provisions.

Prerogative remedies are within the exclusive jurisdiction of the Divisional Court

68. Pursuant to ss. 2(1) and 6(1) of the *Judicial Review Procedure Act*, the prerogative remedies of prohibition and *mandamus* in civil matters are within the exclusive jurisdiction

of the Divisional Court and thus are not available in this proceeding which has been commenced as an action in the Superior Court of Justice.

Conclusion

69. The Defendants plead and rely on:
- a) The *Immunization of School Pupils Act*, RSO 1990, c 1.1 and its regulations;
 - b) The *Education Act*, RSO 1990, c E.2 and its regulations;
 - c) The *Child Care and Early Years Act, 2014*, SO 2014, c 11, Sch 1 and its regulations;
 - d) The *Health Care Consent Act, 1996*, SO 1996, c 2, Sch A and its regulations;
 - e) The *Health Protection and Promotion Act*, RSO 1990, c H.7 and its regulations;
 - f) The *Regulated Health Professions Act, 1991*, SO 1991, c 18 and its regulations;
 - g) The *Medicine Act, 1991*, SO 1991 c 30 and its regulations;
 - h) Sections 1, 2 and 7 of the *Canadian Charter of Rights and Freedoms*;
 - i) The *Judicial Review Procedure Act*, RSO 1990 c J. 1; and
 - j) The *Courts of Justice Act*, RSO 1990 c C.43.
70. The Defendants respectfully request that the Plaintiff's claim be dismissed with costs.

December 31, 2019

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Court File No.: CV-19-006298100000

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STATEMENT OF DEFENCE OF THE DEFENDANTS

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