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**Court File No.:**

**FEDERAL COURT**

**B E T W E E N :**

**PHOEBE MIKE**

**Applicant**

**- and -**

**THE ATTORNEY GENERAL OF CANADA**

**Respondent**

**APPLICATION UNDER SECTION 18.1 OF THE *FEDERAL COURTS ACT***

**NOTICE OF APPLICATION**

**TO THE RESPONDENT:**

**A PROCEEDING HAS BEEN COMMENCED AGAINST YOU** by the Applicant. The relief claimed by the Applicant appears below.

**THIS APPLICATION** will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at Toronto, Ontario.

**IF YOU WISH TO OPPOSE THIS APPLICATION**, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must file a notice of appearance in Form 305 prescribed by the [Federal Courts Rules](#) and serve it on the Applicant's solicitor or, if the applicant is self-represented, on the applicant, **WITHIN 10 DAYS** after being served with this notice of application.

Copies of the [Federal Courts Rules](#), information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

**IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.**

**October 7, 2024**

**Issued by:** \_\_\_\_\_

**Address of local office:** 200-180 Queen Street W.  
Toronto, ON M5V 3L6

**TO: THE ATTORNEY GENERAL OF CANADA  
DEPARTMENT OF JUSTICE**  
Ontario Regional Office  
400-120 Adelaide Street West  
Toronto, ON M5H 1T1

## APPLICATION

This is an application to quash the decision of the Minister of Health, by and through his delegate, Epiq Class Action Services Canada Inc. (“**Epiq**” or the “**CTSSP Administrator**”), to deny the Applicant's application for financial support through the Canadian Thalidomide Survivors Support Program (“**CTSSP**”).

**The Applicant makes an application for:**

- (a) An Order quashing the decision of the Minister of Health, through his delegate, the CTSSP Administrator, dated December 11, 2023, denying the Applicant's eligibility to participate in the CTSSP (the “Decision”);
- (b) An Order declaring that the Applicant is a Thalidomide survivor in accordance with Order-in-Council 2019-0271 and entitled to compensation under the CTSSP;
- (c) in the alternative to (b), an Order setting aside the Decision and referring it back to the CTSSP Administrator or the Minister of Health for determination in accordance with such directions as this Honourable Court considers to be appropriate;
- (d) An Order declaring that the Minister of Health or his delegate acted unreasonably and unlawfully in denying the Applicant's application to the CTSSP;
- (e) Costs of this application on solicitor and client basis; and
- (f) Such further and other relief as this Honourable Court deems just.

**The grounds for the application are:**

**Background**

1. Thalidomide was originally developed and sold as a non-addictive sedative drug.
2. In the 1950s and 1960s, Thalidomide was found to be effective in combatting morning sickness in pregnant women and was widely prescribed off-label for that purpose. Millions of samples of Thalidomide were distributed to pregnant women during this period.
3. Thalidomide was subsequently found to cause miscarriages and birth defects when taken during the first trimester of pregnancy. The drug was recalled on April 10, 1962.
4. In May 1990, Canada established an *ex gratia* payment for "Thalidomide Victims" under the Extraordinary Assistance Plan ("**EAP**"), which was created by a May 10, 1990 Order in Council. To qualify under the EAP, individuals had to provide evidence that they had received a settlement from a drug company or that there had been maternal ingestion of Thalidomide in Canada during the first trimester of pregnancy or listing on a government registry of Thalidomide victims.
5. In 2015, Canada announced a new program for Canadian Thalidomide Survivors known as the Thalidomide Survivors Contribution Program ("**TSCP**"). The TSCP established two classes of eligible recipients – those who had previously received payments under the EAP and those who submitted applications before May 31, 2016, and who met one of the criteria applied in the EAP.
6. However, unlike the EAP, the TSCP imposed a stringent evidentiary barrier, requiring documentary proof of maternal ingestion of Thalidomide in Canada during the first trimester of pregnancy.
7. As a result of the onerous evidentiary requirements, many applicants seeking recognition and support as Thalidomide survivors had their applications under the TSPC denied.

## The Canadian Thalidomide Survivors Support Program

8. In November 2018, the Federal Court of Appeal certified a class judicial review seeking to challenge the TSCP evidentiary criteria and documentary proof requirements ("**Wenham Class Proceeding**").
9. On April 5, 2019, Canada established the CTSSP by Order in Council I.C. 2019-0271 (the "**OIC**").
10. The CTSSP introduced a revised version of the TSCP, providing payments to Thalidomide survivors under less exacting evidentiary standards.
11. The terms of the OIC describe the eligibility requirements of the CTSSP as follows:
  - 3 (1) Any person who meets any of the following conditions is eligible under the Program:
    - (a) they were determined to be eligible under the 1991 Extraordinary Assistance Plan for victims of thalidomide or under the Thalidomide Survivors Contribution Program (2015);
    - (b) they were not determined to be eligible under the 1991 Extraordinary Assistance Plan for victims of thalidomide or under the Thalidomide Survivors Contribution Program (2015) but they are listed on a Canadian government registry for thalidomide victims and that registry exists on the day on which this Order is made; or
    - (c) they are determined by the third-party administrator to be eligible.
12. Epiq was appointed to act as the third-party administrator of the CTSSP referred to in paragraph 3(1)(c) of the OIC.
13. Pursuant to the OIC, Epiq acts as the delegate of Health Canada and exercises the authority of the Minister of Health in respect of eligibility determinations under the CTSSP.
14. Paragraph 3(5) of the OIC prescribes a three-step process that Epiq must follow when determining whether a person is eligible under the program. Paragraph 3(5) provides:

(5) For the purposes of paragraph (1)(c), the third-party administrator must determine whether a person is eligible under the Program by using the following three-step process:

(a) it must conduct a preliminary assessment of the person's eligibility based on the following criteria:

(i) the date of birth of the person in Canada falls within the period beginning on December 3, 1957 and ending on December 21, 1967,

(ii) the person's date of birth or any other information available is consistent with maternal ingestion of thalidomide in the first trimester of pregnancy, and

(iii) the nature of the person's congenital malformations is consistent with known characteristics of congenital malformations linked to thalidomide ("**Step 1**");

(b) if the third party administrator considers that it is likely, based on the preliminary assessment, that the person's congenital malformations are the result of maternal ingestion of thalidomide in the first trimester of pregnancy, it must assess the probability that the person's congenital malformations are consistent with known patterns of thalidomide embryopathy using a diagnostic algorithm for thalidomide embryopathy that it has selected ("**Step 2**"); and

(c) if the diagnostic algorithm for thalidomide embryopathy shows that it is probable that the person's congenital malformations are consistent with known patterns of thalidomide embryopathy, the third-party administrator must refer the person's application to a multi-disciplinary committee of medical and legal experts (the "**MDC**") that it has selected, and the committee must provide the third-party administrator with its recommendation on whether the person should be eligible under the Program ("**Step 3**").

15. Pursuant to paragraph 3(5)(b), the CTSSP Administrator selected and employs the "ValiDATE" diagnostic algorithm to assess whether applicants' malformations are consistent with known patterns of Thalidomide embryopathy.
16. On May 8, 2020, the Federal Court approved a settlement in the Wenham Class Proceeding (the "**Wenham Settlement**"). Under the Wenham Settlement, Canada was required to

implement enhanced procedural safeguards for class members in the Wenham Class Proceeding and ultimately all applicants to the CTSSP, including the Applicant.

17. The enhanced procedural safeguards under the Wenham Settlement include:
  - (a) The Respondent's confirmation that the standard of proof to be applied by the CTSSP Administrator is the balance of probabilities;
  - (b) An opportunity for class members whose applications are denied at Step 3 to provide written submissions and/or to participate in an oral reconsideration hearing with the CTSSP Administrator and at least one representative of the Multi-Disciplinary Committee;
  - (c) The oral reconsideration hearings are to be conducted by teleconference, or videoconference, or in person at the applicant's own expense, if requested: and
  - (d) A class member may seek reconsideration at any time within the five years of the operation of the CTSSP, which ceases on June 3, 2024.

### **The Applicant's Experience**

18. The Applicant has sought to be recognized as a Thalidomide survivor since 2016. She is a class member in the Wenham Class Proceeding.
19. The Applicant first applied to be recognized as a Thalidomide survivor under the TSCP in 2016. Her application was denied on the basis that she could not provide documentary proof of maternal ingestion during the first trimester.
20. The Applicant filed a complete application with supporting documentation to the revised CTSSP.
21. On December 6, 2019, the CTSSP Administrator issued its Step 1 Decision Letter stating that the Applicant's profile was consistent with known characteristics of Thalidomide, and therefore met the three criteria at Step 1.

22. The Applicant completed and returned the required Step 2 Probability Assessment Application with supporting documentation.
23. On August 28, 2020, the CTSSP Administrator returned the Applicant's Step 2 ValiDate Algorithm result, yielding a "Probable/Possible" result. The CTSSP Administrator informed the Applicant that her application would advance to Step 3 for consideration by the MDC.
24. On June 30, 2022 the CTSSP Administrator issued its Step 3 Determination denying the Applicant's eligibility under the CTSSP. The CTSSP Administrator did not give reasons for the denial. The CTSSP Administrator provided the text of the MDC's recommendation stating that it adopted and "concur[red] with the MDC's recommendation."
25. The Applicant submitted a Step 3 Request for Reconsideration in writing October 2022. The Applicant raised numerous grounds for reconsideration, supported by additional information and documents.
26. On December 11, 2023, the CTSSP Administrator issued its Step 3 Reconsideration Determination, denying the Applicant's eligibility. The CTSSP Administrator did not issues independent reasons, and again adopted the MDC's recommendation in full.
27. The CTSSP Administrator's Step 3 Reconsideration Determination did not inform the Applicant of her right to apply for judicial review of the decision.

**The CTSSP Administrator's Step 3 decision is unreasonable and unlawful**

28. The CTSSP Administrator's decision to deny the Applicant's application to the CTSSP is unreasonable, unlawful, and contrary to the principles of procedural fairness and administrative justice.
29. The CTSSP Administrator fettered its discretion and abdicated its role under the OIC by adopting the MDC's recommendation on Step 3, without independent reasons and contrary to its own prior determinations on Steps 1 and 2.

30. Upon being asked to reconsider its decisions, the CTSSP Administrator unlawfully permitted the MDC to reconsider its recommendations contrary to the OIC.
31. The CTSSP Administrator failed to give reasons justifying its decision to deny the Applicant's application.
32. The CTSSP Administrator was required to give reasons, and was not entitled to adopt the MDC's recommendation as its own, due to:
  - (a) the deeply personal nature of the decision being made;
  - (b) the long and demanding process that the Applicant was required to follow;
  - (c) the importance of the decision to the Applicant, who has sought to be recognized as Thalidomide survivor for 8 years of sustained effort;
  - (d) the structure of CTSSP process as dictated by the OIC; and
  - (e) the substantive inconsistency between the MDC's Step 3 recommendation and CTSSP Administrator's prior determinations at Steps 1 and 2.
33. In the alternative, to the extent the CTSSP Administrator was entitled to adopt the MDC's recommendation as its own, the CTSSP Administrator failed to apply a balance of probabilities standard to the entirety of the Applicant's file.
34. The CTSSP Administrator failed to adequately instruct, train and/or supervise the MDC on the balance of probabilities standard to be applied to its assessment to the entirety of the Applicant's file.
35. The CTSSP Administrator, adopting the MDC's recommendation, applied a heightened standard of medical certainty, a standard of proof beyond a reasonable doubt, or a standard greater than the balance of probabilities standard.
36. By adopting the MDC's recommendation on Step 3, the CTSSP Administrator's determination on Step 3 is contradictory and internally inconsistent with its prior determinations on Steps 1 and 2, for among other reasons:

- (a) At Step 1, the CTSSP Administrator accepted that there was sufficient evidence that the Applicant's mother had ingested Thalidomide in the first trimester of pregnancy. However, at Step 3 and on Step 3 Reconsideration, the CTSSP Administrator, by adopting the MDC's reasons, unreasonably ignored the same evidence of maternal ingestion;
  - (b) At Step 1, the CTSSP Administrator found that the nature of the Applicant's congenital malformations was "consistent with known characteristics of congenital malformations linked to Thalidomide." However, at Step 3, the CTSSP Administrator unreasonably concluded that the Applicant's malformations were not consistent with malformations linked to Thalidomide;
  - (c) At Step 2, using the ValiDATE Algorithm, the CTSSP Administrator determined that it was "Probable/Possible" that the Applicant's congenital malformations were linked to Thalidomide. However, on Step 3, the CTSSP Administrator unreasonably concluded that the Applicant's malformations were not consistent with malformations linked to Thalidomide; and
  - (d) At Step 2, the CTSSP Administrator represented to the Applicant that the ValiDATE Algorithm was based on the "best available" science regarding Thalidomide embryopathy. However, at Step 3, the CTSSP Administrator unreasonably disregarded the ValiDATE results, contrary to the OIC, and, through its adoption of the MDC's recommendation, stated that the ValiDATE algorithm was unreliable.
37. The CTSSP Administrator unreasonably preferred the MDC's Step 3 recommendations over its prior determinations at Steps 1 and 2. The CTSSP Administrator was not entitled to abandon the Step 1 and Step 2 results without clear and compelling reasons, which it did not provide.
38. Further, the CTSSP Administrator acted unreasonably by adopting the MDC's recommendations, which failed to assess the evidence on a balance of probabilities, and which were made without regard to the nature and object of the overall CTSSP scheme.

39. The CTSSP Administrator accepted the MDC's recommendation which, by applying a heightened standard of proof, misapprehended the documentary and scientific evidence:
- (a) Despite evidence indicating that the Applicant's mother had ingested Thalidomide samples in the first trimester, the MDC and the CTSSP Administrator unreasonably required "direct evidence or proof" of maternal ingestion of Thalidomide and corroboration of such evidence, including the timing and dose;
  - (b) After having already determined that maternal ingestion of Thalidomide in the first trimester had been made out on a balance of probabilities, the CTSSP Administrator, adopting the MDC's reasons, unreasonably disregarded their own determination in favour of the restrictive standard applied by the MDC;
  - (c) After having already determined that maternal ingestion of Thalidomide in the first trimester had been made out on a balance of probabilities, the CTSSP Administrator, adopting the MDC's reasons, failed to provide reasons as to why it disregarded its own determination in favour of the restrictive standard applied by the MDC;
  - (d) Having found that maternal ingestion of Thalidomide, including the dose and timing, were uncertain, the CTSSP Administrator, adopted the MDC's reasons that concluded that regular exposure to Thalidomide, which the Applicant mentioned, would have resulted in more severe damage to the Applicant. It was not open to the MDC and CTSSP Administrator to find, simultaneously, that there was insufficient evidence of maternal ingestion, including the dose and timing, but then determine that the Applicant's mother took Thalidomide "regularly", which should have resulted in more severe effects on the Applicant. The CTSSP's determination, adopting the reasons of the MDC, was internally inconsistent and unreasonable;
  - (e) The CTSSP Administrator, by adopting the MDC's reasons, unreasonably disregarded numerous first-hand examinations and observations of the Applicant, conducted by her own physicians, and a geneticist who determined the Applicant's malformations were not consistent with a genetic disorder, on the basis that such

physicians were unqualified to make such determinations, without knowledge or assessment of those physicians' qualifications;

- (f) The CTSSP Administrator, adopting the MDC's reasons, failed to cite the applicable scientific evidence upon which it relied, and misapprehended the scientific literature generally.

40. The CTSSP Administrator conducted a cursory review of the Applicant's file on Reconsideration and failed to give due wight to the Applicant's submissions.

**Costs**

41. A costs award on a solicitor-and-client basis is an appropriate remedy in the circumstances, given the excessive delays.

**This application will be supported by the following material:**

- 1. The affidavit of Phoebe Mike, to be sworn;
- 2. The affidavit of Heather Cabral, to be sworn; and
- 3. Such further and other evidence as the Applicant may submit and this Honourable Court may permit.

**October 7, 2024**



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