

Allison Kindle Pejovic | B.A., L.L.B., L.L.M

[REDACTED]
[REDACTED]
[REDACTED]

WITH PREJUDICE

April 14, 2023

Via Email: [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

Dear Sirs,

Re: Sheila Annette Lewis and Results of Blood Test For Natural Immunity to Covid-19

We write in respect of Sheila Annette Lewis, who as you know from our ongoing litigation is a patient in the Alberta Health Services' [REDACTED] transplant program at the [REDACTED] Hospital. As you also know, your clients removed Ms. Lewis from the high priority transplant list ("Status 2") to a list where she is not currently eligible for a transplant ("Status 0") because she refused their demands that she take two Covid-19 vaccines prior to her transplant surgery.

Although your clients refused to test Ms. Lewis for natural immunity to Covid-19, Ms. Lewis recently had her blood tested to determine whether she has antibodies to Covid-19. On March 28, 2023, she provided a report from Kinexus Labs to the [REDACTED] transplant team and to AHS via email. According to this report, which was authored by scientific expert and PhD Dr. Steven Pelech, who has published a peer reviewed study on natural immunity to Covid-19, Ms. Lewis has extremely high levels of antibodies to Covid-19.

The report states:

*So far, our clinical study results have demonstrated that most of the healthy, unvaccinated participants that we have tested, do, in fact, already have antibodies against SARS-CoV-2. This indicates previous exposure to SARS-CoV-2 or to other endemic coronaviruses that elicit cross-reactivity to and immunity against SARS-CoV-2, thereby mitigating the development of COVID-19 illness. **We have determined that***

SARS-CoV-2 antibody levels are sustained for at least two years after initial infection for the vast majority of those participants with natural immunity.

...

*The test of the Participant's blood sample was performed on a blood sample processed at our facility that was obtained around March 1, 2023. **The Participant was likely infected with SARS-CoV-2 originally around September 17, 2021 based on her COVID-19-like symptoms at that time. However, it is evident that she has been further infected since then and has extremely high levels of antibodies against SARS-CoV-2. Weaker signals on our test reflect the duration in time since her SARS-CoV-2 infection, but still clearly demonstrates **establishment of natural immune memory in the B cells that produce these antibodies.**** [Emphasis added]*

A copy of this report is attached to this letter.

On April 3, 2023, the [REDACTED] transplant team spoke with Ms. Lewis and advised her that, despite the results from this report showing that she has natural immunity to Covid-19, they would still not permit her to get a [REDACTED] transplant without receiving Covid-19 vaccines. Dr. [REDACTED] justified this, now seemingly arbitrary, rule on that basis that natural immunity only lasts two years. This despite the fact that: 1) Ms. Lewis will enjoy natural immunity for approximately another five months from the September 17, 2021, infection; 2) Ms. Lewis will enjoy natural immunity for two years from her more recent infection; 3) Ms. Lewis would currently enjoy no immunity whatsoever had she received two vaccinations in 2021; and 4) Ms. Lewis has at least twice been infected and has fully recovered from Covid-19. Your clients are effectively ignoring this information.

Your clients' position is indefensible and completely unacceptable. Their patient Ms. Lewis is dying, and in our view your clients are simply turning their back, both, on their patient, and on reliable evidence of her natural immunity to Covid-19 which negates the need for her to receive the Covid-19 vaccines prior to her transplant.

In this April 3, 2023, phone call, Dr. [REDACTED] also referenced the need for Ms. Lewis to get a booster dose of a Covid-19 vaccine, despite her natural immunity. That was the first time Ms. Lewis has ever been advised that she would need more than two Covid-19 vaccines to get a [REDACTED] transplant, and she was only advised of this after she provided proof that she is naturally immune. If your clients are changing the parameters of the requirements for a [REDACTED] transplant upon learning of Ms. Lewis's natural immunity, this would be evidence of bad faith and would, of course, constitute medical malpractice.

It is impossible for Ms. Lewis to know whether the policy has been changed, because although she has repeatedly asked in writing to review a written Covid-19 vaccine policy so she can understand what is required of her to get a [REDACTED] transplant, your clients have steadfastly refused to provide it.

Please provide a response to these questions immediately:

- What is the current Covid-19 vaccine policy in place in order for Ms. Lewis to get a [REDACTED] transplant? Please forward it to us.
- Has the policy been amended at any time since Ms. Lewis was accepted as a patient and, if so, provide all earlier versions of the policy.

In the litigation between the parties related to your clients' earlier removal of Ms. Lewis from the Status 2 transplant list, AHS' witness in cross examinations in 2022 admitted, under oath, that the [REDACTED] Hospital has completed its written Covid-19 vaccination policy for transplant candidates.

We remind your clients that Ms. Lewis, in fact, asked Dr. [REDACTED] twice in mid-2022 to test her blood to see if she had antibodies to Covid-19. He refused to do so. Dr. [REDACTED] admitted in cross-examination that the [REDACTED] transplant team does not test patients for natural immunity to Covid-19, and that she never considered doing so.

Without ever having tested Ms. Lewis to see if she had infection-induced immunity to Covid-19 from a previous Covid-19 infection, despite her repeated requests for the [REDACTED] transplant physicians to do so, they removed her from the [REDACTED] transplant Status 2 list to Status 0 in the fall of 2022, with threats to remove her from the [REDACTED] transplant program altogether because she has refused to get the Covid-19 vaccine.

In sworn evidence before the Alberta Court of King's Bench, your clients stated that the reason that the Covid-19 vaccine is required is that patients need to be protected from Covid-19 in order to maximize the benefit from a scarce resource – i.e. a [REDACTED] – and that too many transplant patients who got Covid-19 passed away.

Ms. Lewis has now demonstrated to the [REDACTED] transplant physicians, the [REDACTED] Hospital, and AHS, that she is protected from Covid-19 today. She has had natural immunity to Covid-19 since September 2021 when she was first infected with Covid-19. According to her bloodwork, she was recently reinfected with Covid-19, and has strong antibodies to it. So far as we can tell, and based on your clients' own justification for the vaccine mandate, there is absolutely no medically defensible reason to deny her a transplant now that she is able to demonstrate that she is protected from Covid-19.

Your clients knew in early 2022 from the sworn evidence tendered in Ms. Lewis's case against them, that natural immunity provided protection against Covid-19. AHS's own expert on immunity, Dr. Michael Houghton, and the physicians' expert in ethics Dr. Olivia Kates, both admitted in cross-examination that it would be reasonable to test Ms. Lewis to see if she is naturally immune to Covid-19. Yet, inexplicably, your clients refused to do so even though Ms. Lewis asked them to in June 2022.

We assume your clients are aware that by August 2022, the U.S. Centre for Disease Control ("CDC") accepted that natural immunity from a previous Covid-19 infection provides

protection against serious illness and death. In the CDC's Morbidity and Mortality Weekly Report from August 19, 2022 entitled, "[Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems – United States, August 2022](#)," the CDC recognized that natural immunity from a previous Covid-19 infection has played a role in reducing the risk for severe illness and death due to Covid-19:

As SARS-CoV-2, the virus that causes COVID-19, continues to circulate globally, high levels of vaccine- and **infection-induced immunity** and the availability of effective treatments and prevention tools **have substantially reduced the risk for medically significant COVID-19 illness (severe acute illness and post-COVID-19 conditions) and associated hospitalization and death** (1). These circumstances now allow public health efforts to minimize the individual and societal health impacts of COVID-19 by focusing on sustainable measures to further reduce medically significant illness as well as to minimize strain on the health care system, while reducing barriers to social, educational, and economic activity (2). Individual risk for medically significant COVID-19 depends on a person's risk for exposure to SARS-CoV-2 and their risk for developing severe illness if infected (3). Exposure risk can be mitigated through nonpharmaceutical interventions, including improving ventilation, use of masks or respirators indoors, and testing (4). **The risk for medically significant illness** increases with age, disability status, and underlying medical conditions but **is considerably reduced by immunity derived from vaccination, previous infection**, or both, as well as timely access to effective biomedical prevention measures and treatments (3,5).

COVID-19 remains an ongoing public health threat; however, **high levels of vaccine- and infection-induced immunity** and the availability of medical and nonpharmaceutical interventions **have substantially reduced the risk for medically significant illness, hospitalization, and death from COVID-19**.

We likewise assume your clients know that a February 2023 [study](#) published in the prestigious *The Lancet* journal found that infection-acquired immunity cut the risk of hospitalization and death from a Covid reinfection by 88% for at least 10 months, and the immunity generated from an infection was found to be "at least as high, if not higher" than that provided by two doses of an mRNA vaccine.

Despite the CDC and a recent meta-analysis published in the top journal *The Lancet's* recognition of natural immunity as steadfast protection against Covid-19, and Ms. Lewis's recent bloodwork result (report from Kinexus labs) showing that she has strong immunity to Covid-19 which should last until **at least** September 2023, your clients continue to refuse to reinstate Ms. Lewis to Status 2 on the [REDACTED] transplant waitlist which would enable her to receive a potentially life-saving [REDACTED] transplant.

We see no excuse, scientific, or medical reason for your clients to continue to deny Ms. Lewis a [REDACTED] transplant because she refuses to take the Covid-19 vaccine. She is currently immune to Covid-19. Every day that passes is a wasted opportunity for Ms. Lewis's life to be saved. Your clients accepted Ms. Lewis into the [REDACTED] transplant program and were prepared to

perform a life-saving transplant for her, until she refused the Covid-19 vaccine and for no other reason. Now that she has protection equivalent to or superior to the Covid-19 vaccine, they still refuse to permit her to have the life-saving surgery she so desperately needs. They are depriving her of that chance to survive, with no apparent medical reason for doing so, and have needlessly caused her months of stress and emotional harm.

If Ms. Lewis does not get her transplant, she will not survive, and her family will lose years of time with their mother, wife, and grandmother.

This record suggests very strongly that your clients are negligent in failing to test Ms. Lewis for natural immunity and in failing to reinstate her to Status 2 upon discovering her robust natural immunity.

Please be aware that Ms. Lewis has indicated her family's interest in pursuing a future wrongful death lawsuit against your clients if she passes away due to medical malpractice including failure to reinstate her to Status 2--which is almost certainly a death sentence.

If your clients do not reverse course and reinstate her to Status 2 by **April 21, 2023**, Ms. Lewis is considering initiating further legal proceedings.

On Ms. Lewis's behalf we hereby demand that your clients immediately reinstate her to Status 2 on the [REDACTED] transplant list.

We look forward to hearing from you.

Yours Sincerely,



Allison Kindle Pejovic, L.L.M., L.L.B., B.A

Encl. (1)



24 March 2023

Re: Attestation of Clinical Study Enrollment for SARS-CoV-2 Antibody Testing for Ms. Sheila Annette Lewis

Please be aware that Ms. Sheila Annette Lewis (hereinafter referred to as “Clinical Study Participant”) has been formally enrolled in a clinical study, entitled “Identification of SARS-CoV-2 Viral Protein Epitopes for Antibodies from Recovered COVID-19 Patients, Healthy and Vaccinated Individuals”, being conducted by Kinexus Bioinformatics Corporation. Our clinical study has received Independent Review Board (IRB) approval. The first phase of our clinical study was ongoing with IRB approval until May 20, 2022, and we are now continuing a second phase in the study.

The primary objective of our clinical study was to identify the most immunogenic sequences in SARS-CoV-2 viral proteins that have been found to successfully elicit antibody production in people who have recovered from COVID-19. These are likely to be protective antibodies in view of their recovery. A secondary objective of our clinical study is to investigate whether immunity to SARS-CoV-2 is conferred in individuals with prior exposure to other endemic coronaviruses. This is a minimally invasive clinical study in which small volumes of blood will be collected by finger-prick on repeated occasions to evaluate and monitor the presence and persistence of natural immunity. The study involves monitoring the antibodies against SARS-CoV-2 that are present in the participant’s blood to check for their binding to membranes that feature, within spots, custom arrays of chemically synthesized peptides that are patterned after the amino acid sequences in the viral proteins. The presence of a spot indicates that the participant has antibodies that will recognize that specific portion of the target SARS-CoV-2 virus protein and likely offer protection against the virus.

To date, Kinexus has monitored over 4000 COVID-19 patients and healthy, unvaccinated controls with our SARS-CoV-2 antibody tests. Our current CCS test utilizes 41 different markers that cover the spike protein as well as 9 additional SARS-CoV-2 viral proteins. These 41 markers were selected from over 8000 potential SARS-CoV-2 markers that we originally screened using serum samples from over 200 fully recovered COVID-19 patients who were confirmed with PCR-positive genetic tests. Our preliminary results have been formally published in the *Journal of Clinical Investigation (JCI) Insight*, which is the peer-reviewed, flagship journal for the American Society for Clinical Investigation (Majdoubi *et al.* (2021) *JCI Insight*. 6(8): e14631 (<https://doi.org/10.1172/jci.insight.146316>). In the *JCI Insight* study, which included serum samples from 276 participants, the Kinexus SARS-CoV-2 antibody test results were cross-validated with another SARS-CoV-2 antibody test developed and marketed by the U.S. company MesoScale Devices. The Kinexus SARS-CoV-2 antibody test is likely one of the most sensitive and accurate serological antibody tests in the world for monitoring immunity to SARS-CoV-2.

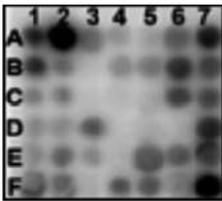
So far, our clinical study results have demonstrated that most of the healthy, unvaccinated participants that we have tested, do, in fact, already have antibodies against SARS-CoV-2. This indicates previous exposure to SARS-CoV-2 or to other endemic coronaviruses that elicit cross-reactivity to and immunity against SARS-CoV-2, thereby mitigating the development of COVID-19 illness. **We have determined that SARS-CoV-2 antibody levels are sustained for at least two years after initial infection for the vast majority of those participants with natural immunity.** Almost all of our vaccinated participants have also been found to have natural immunity, acquired either before or after their vaccination.

The results of the clinical study will enhance our understanding of the prevalence and durability of natural immunity, and whether it is associated with broader coverage against SARS-CoV-2 viral proteins, enhanced immune memory, and a more favourable antibody isotype response (e.g., IgG, IgA, and IgM) compared with current COVID-19 vaccines. As well, the clinical study results may contribute to the development of:

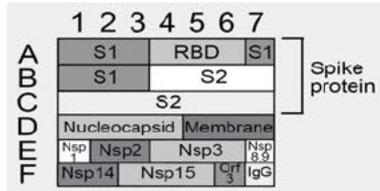
- (i) SARS-CoV-2 vaccines that could offer broader and longer-lasting protection than those currently available;
- (ii) More rapid, sensitive, and accurate serological blood and saliva antibody tests for determining whether an individual has immunity to SARS-CoV-2; and
- (iii) Next-generation antibody treatments for people actively infected with SARS-CoV-2.

The initial results obtained from the testing of the Clinical Study Participant is shown below in the left most image, and clearly supports the presence of SARS-CoV-2 immunoreactivity in her blood sample, as found in many of our other trial participants that have recovered from COVID-19 as confirmed by PCR testing in those cases. A negative control immunoblot image of a person that did not have COVID-19 is shown in the right-most image for comparison. The test of the Participant’s blood sample was performed on a blood sample processed at our facility that was obtained around March 1, 2023. The Participant was likely infected with SARS-CoV-2 originally around September 17, 2021 based on her COVID-19-like symptoms at that time. However, it is evident that she has been further infected since then and has extremely high levels of antibodies against SARS-CoV-2. Weaker signals on our test reflect the duration in time since her SARS-CoV-2 infection, but still clearly demonstrates establishment of natural immune memory in the B cells that produce these antibodies.

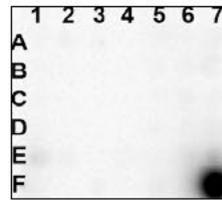
Participant Blot



Map of SARS-CoV-2 proteins tracked



Negative COVID-19 Blot



Please feel free to contact me directly if you have any questions or concerns.

Sincerely,

Dr. Steven Pelech, Ph.D.



KINEXUS