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200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

VIA FEDERAL EXPRESS AND EMAIL January 13, 2022

Jane Jankowski, DPS
Interim Director
Cleveland Clinic Center for Bioethics
9500 Euclid Avenue
Cleveland, OH 44195
jankowj@ccf.org

Re: *Tanner Donaldson – denied kidney transplant*

Dear Director Jankowski:

We write on behalf of the Donaldson family to respectfully request reconsideration of Cleveland Children's Hospital's (the "Hospital") refusal to conduct what could be a life-saving kidney transplant for a 9-year-old boy suffering from chronic kidney disease. Tanner Donaldson, a lively and sweet 9-year-old boy, has spent years of his life bearing the burden of chronic illness that has kept him from living a 'normal' childhood. Unlike many in need of organ transplants, who are forced to pray and hope that an organ becomes available for them in time, Tanner was blessed with a miracle. His father, Dane, is a perfect match to donate one of his kidneys to Tanner. In any other year, Tanner would already be on the road to recovery post-operation, but thanks to the Hospital's COVID-19 vaccine policy, Tanner is being refused the surgery on the grounds that his donor has not been vaccinated.

The Hospital's primary concern should be patient care and that care should be science-driven. As the Director of Bioethics, your job is to weigh the ethics of a given situation. Presently, it appears the Hospital is operating under a psychosis of flawed morality in choosing to sacrifice the health and wellness of its 9-year-old patient in exchange for what it perceives to be the "greater good." The Hospital's expectation, that the Donaldsons should ignore their legitimate questions and concerns regarding a novel therapy for the prevention of disease, particularly when the entire family has already contracted and recovered from the disease,[1] goes against one of the most fundamental tenets of medical ethics – informed consent. Given your role, we believe that such a disregard of core ethical conventions warrants your immediate attention and concern.

[1] See Exhibit A (Mr. Donaldson's positive COVID-19 PCR Test Results dated October 21, 2021).

I. Tanner's Medical Journey

Tanner was born with a rare birth defect, posterior urethral valves (PUV), that caused irreversible kidney damage in utero and resulted in stage 4 chronic kidney disease (CKD), as well as bladder and urinary dysfunctions. Even before Tanner's birth, the Donaldsons spoke with numerous specialists that indicated a kidney transplant would inevitably be in their son's future due to the unavoidable kidney damage from the PUV. On June 13, 2017, Tanner was approved for a pre-emptive (pre-dialysis) kidney transplant by the Kidney Transplant Program at the Hospital. In October of the same year, both Jennifer and Dane underwent a battery of invasive tests to determine whether either of them could potentially be a living donor for their son. Doctors had told the Donaldsons that if a family member were to be a match for Tanner, this would be the optimal scenario for a positive transplant outcome. In early 2018, Dane was found to be a match for Tanner and the Hospital approved the transplant.

At 8 months old, Tanner's doctors prescribed a program of intermittent catheterization and overnight catheterization to preserve what kidney function he did have, for as long as possible. The Donaldsons have worked tirelessly over the years to maintain Tanner's catheterization regimen, which has allowed him to live life with some sense of normalcy. Jennifer and Dane would do just about anything for their son. While awaiting the time of transplant, the Donaldsons have complied with monthly lab work, quarterly follow-up visits, and annual transplant testing. In 2018, Dane went so far as to completely alter his diet and lifestyle to lose the weight required to meet the requirements to be a living donor for his son. Altering decades of diet and exercise habits to dramatically lose weight is no easy feat, yet Dane did whatever he had to do so that his son would get the kidney he needs to have not only the childhood, but the *life* he deserves. Although he is presently stable, Tanner's kidney function continues to decline by the day. There is no question that his condition could become life-threatening at any moment. From these circumstances alone, it should be clear to see that Dane's decision to decline the COVID-19 vaccine comes from a place of serious contemplation and concern regarding his sincere religious beliefs, as well as the safety and efficacy of the vaccine, particularly for someone with robust natural immunity to the disease.

II. Mandating Vaccination for the Naturally Immune is Irrational, Arbitrary, and a Violation of the Hippocratic Oath.

All physicians swear an oath to "Do No Harm." By conditioning medical treatment upon receipt of the COVID-19 vaccine, the Hospital violates this very principle and places doctors into the role of judge and jury rather than a facilitator of patient autonomy and informed consent. It is not the job of a doctor, or hospital for that matter, to influence a person's autonomous choice over healthcare decisions for their body. Dane's medical objections to the vaccine are not fleeting or speculative; they are grounded in verifiable scientific data regarding both natural immunity to the disease, as well as the number of known and unknown risks associated with the vaccine. For the reasons stated below, forcing Dane Donaldson to receive the COVID-19 vaccine in order for his child to receive a kidney transplant lacks any scientific basis and evidences ulterior motives on the part of the hospital for mass vaccination.

a. Those with natural immunity pose less risk of spreading COVID-19 than the vaccinated.

CDC's Director, Dr. Walensky, has acknowledged that the COVID-19 vaccines do not "prevent transmission."[2] In contrast to this failure of the vaccines, as conceded by the CDC on November 5, 2021, there has yet to be one documented case of a person who "(1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."[3] In fact, several independent studies confirm that reinfections for COVID-19 are exceedingly rare and reaffirm the durability of natural immunity:

- The Cleveland Clinic measured cumulative incidence of SARS-CoV-2 infection among 52,238 vaccinated and unvaccinated health care workers over a five-month period and found that none of the 1,359 previously infected who remained unvaccinated contracted SARS-CoV-2 over the course of the research despite a high background rate of COVID-19 in the hospital.[4]

- Researchers from Ireland conducted a review of 11 cohort studies involving over 600,000 total recovered COVID-19 patients who were followed up with for over 10 months and found that that reinfection in all studies was "an uncommon event" and explained that there was "no study reporting an increase in the risk of reinfection over time."[5]

- Researchers from Qatar analyzed the population-level risk of reinfection based on whole genome sequencing, tracking 43,044 individuals for up to 35 weeks, and found that just .02% experienced reinfection (an estimated risk of reinfection of 0.66 per 10,000 person-weeks). Notably, there was no evidence of waning immunity during the over seven-month follow-up period.[6]

On the other hand, the rate of breakthrough cases in the vaccinated are multiple times higher than the rate of reinfection for the naturally immune. The following studies affirm the superiority of natural immunity to vaccine-derived immunity:

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[2] The Situation Room, CNN (August 5, 2021) available at https://twitter.com/CNNSitRoom/status/1423422301882748929.

[3] *Final Response Letter to September 2, 2021 FOIA Request*, Center for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) (November 5, 2021) *available at* https://www.sirillp.com/wp-content/uploads/2021/11/21-02152-Final-Response-Letter-Brehm-1.pdf [https://perma.cc/8P3W-7EML].

[4] Nabin K. Shrestha, *et al.*, *Necessity of COVID-19 vaccination in previously infected individuals*, medRxiv (June 19, 2021) https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.

[5] Eamon Murchu, *et al.*, *Quantifying the risk of SARS-CoV-2 reinfection over time*, Reviews of Medical Virology (May 27, 2201) https://pubmed.ncbi.nlm.nih.gov/34043841/.

[6] Laith J. Abu-Raddad, *et al.*, *SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy*, EClinical Medicine (April 28, 2021) https://pubmed.ncbi.nlm.nih.gov/33937733/.

- A comparison of 42,000 naturally immune individuals with 62,000 fully vaccinated individuals found that the fully vaccinated individuals were **6 to 13 times more likely to get infected than the naturally immune**.[7] Additionally, **the risk of symptomatic COVID-19 was 27 times higher among those vaccinated than those previously infected** and the risk of hospitalization was 8 times higher.[8] The study concluded that, "natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [Pfizer] two-dose vaccine-induced immunity."[9]

- The Israeli Health Ministry found that the vaccinated had 6.72 times the rate of infection as compared to those that had contracted COVID-19.

  With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with SARS-CoV-2.

  By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection.[10]

- A nation-wide study of over 6 million individuals in Israel found that vaccine immunity had an efficacy of 92.8% for documented infection, 94.2% for hospitalization, and 94.4% for severe illness, but that the naturally immune had a higher rate of protection in all three of these categories.[11]

- An outbreak of SARS-CoV-2 infected 24/44 (55%) employees of a gold mine in French Guiana. The attack rate was 15/25 (60.0%) in fully vaccinated miners, 6/15 (40.0%) in those partially vaccinated or with a history of COVID-19 (none of the partially vaccinated with a history of COVD-19 were positive), and 3/4 (75%) in those not vaccinated. The attack rate was 0/6 among persons with a previous history of COVID-19 versus 63.2% among those with no previous history.[12]

Notably, a study from researchers at the CDC and at Wisconsin's Department of Health Services evaluated the shedding of infectious SARS-CoV-2 in 36 counties in Wisconsin and

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[7] Sivan Gazit, *et al., Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

[8] *Id.*

[9] *Id.*

[10] https://www.israelnationalnews.com/News/News.aspx/309762.

[11] Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (April 24, 2021) https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

[12] Nicolas Vignier, *et al., Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinated Gold Miners, French Guiana, 2021*, Emerging Infectious Diseases (July 21, 2021) https://pubmed.ncbi.nlm.nih.gov/34289335/.

observed high viral load in 68% of the fully vaccinated and in 63% of the unvaccinated.[13] This reflects that the vaccinated will shed virus and will do so at the same rate as the unvaccinated. On the other hand, **this study did not identify anyone with prior natural infection that had any viral load.** It is also noteworthy that among those who were asymptomatic, 29% of the unvaccinated had high viral load while 82% of the fully vaccinated had high viral load.

b. Risks of the COVID-19 vaccine far outweigh any benefit for those with natural immunity

Receiving the COVID-19 vaccine poses significant and unnecessary health risks to someone who has robust natural immunity. A population-based study involving 2.5 million Israelis from a single, centralized medical database found that the naturally immune were 99.74% protected from reinfection for COVID-19, while the naturally immune who also chose to subsequently vaccinate saw a miniscule .12% increase in protection from the disease.[14] Data from the UK suggests that for the naturally immune, 1 out of 11 who subsequently vaccinate will have a clinically significant adverse event, with the most common including fever, fatigue, myalgia-arthralgia, and lymphadenopathy.[15] A policy rooted in public health in mandating the vaccine is illogical and unethical to force upon someone who poses no risk to the public health, and likely less risk, than those similarly situated who are vaccinated.

c. The COVID-19 vaccines are novel therapies with both known and unknown risks

Contrary to the mainstream narrative, the COVID-19 vaccines are unlike any other vaccine on the market. The vaccines utilize gene therapies never before administered in human beings for the purpose of vaccination against disease.[16] As of December 3, 2021, the CDC's own VAERs database reported 21,002 deaths, 110,609 hospitalizations, and 1,000,227 total adverse events linked to the administration of the COVID-19 vaccines.[17] Pfizer, through its own recent disclosure of internal documents, reported that as of February 28, 2021, the company knew of 158,893 internally reported adverse events after administration of its COVID-19 vaccine.[18] This troubling

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[13] Kasen K. Riemersma, DVM, PhD, *et al.*, *Shedding of Infectious SARS-CoV-2 Despite Vaccination* https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf.

[14] Sivan Gazit, *et al.*, *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

[15] Rachael Kathleen Raw, *et al.*, *Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination*, The Journal of Infection (May 29, 2021) https://pubmed.ncbi.nlm.nih.gov/34062184/ .

[16] Hinori Nakagami, *Development of COVID-19 vaccines utilizing gene therapy technology* (September 25, 2021) https://pubmed.ncbi.nlm.nih.gov/33772572/ ("For rapid development, RNA vaccines and adenovirus vector vaccines have been urgently approved, and their injection has already started across the world. These types of vaccine technologies have been developed over more than 20 years using translational research for use against cancer or diseases caused by genetic disorders but the COVID-19 vaccines are the first licensed drugs to prevent infectious diseases using RNA vaccine technology").

[17] https://vaers.hhs.gov/data.html.

[18] *See 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021*, Worldwide Safety – Pfizer (April 30, 2021) https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf (reporting data containing cases of adverse events in response to the Pfizer COVID-19 vaccine that were all submitted voluntarily to Pfizer through various means. By its

lack of timely disclosure comes in the midst of the FDA's aggressive legal efforts to block public access to the data underlying Pfizer's BLA Licensure Application for the Comirnaty COVID-19 Vaccine **until the year 2096.**[19]

At any other time in history, mass vaccination protocols under these same circumstances *at a minimum* would have been paused to conduct further testing and analysis, as well as investigate related cases of reported adverse health events and deaths. In 1976, the H1N1 (Swine Flu) vaccination program was halted after just 3 deaths and 94 instances of paralysis (Guillain Barre Syndrome) associated with administration of the Swine Flu vaccine.[20] On December 16, 1976, the Secretary of Health, Education and Welfare, (now Health and Human Services, or HHS), suspended the nationwide vaccination program stating, "in the interest of safety of the public, in the interest of credibility, and in the practice of good medicine" the program needed to be halted.[21] Now in January 2022, twelve months of mass vaccination on an unprecedented scale has resulted in over 20,000 deaths and over 35,000 permanently disabled Americans. There is a shocking lack of concern from both the medical and public health establishment to align public health policy with the true morbidity and mortality of these products.[22] In fact, institutions such as the Hospital seem to be in a separate reality, not only aggressively pushing COVID-19 vaccines onto patients but are coercing consent through withholding necessary medical treatment for those who choose to remain unvaccinated.

d. The Hospital refuses to provide supporting data to justify its stance and is unwilling to work together to alleviate its liability concerns

The Donaldsons have continued to request that the Hospital provide the data to support their policy and have been refused this information. Moreover, the Donaldsons are open to any and all suggestions on mitigating risk. If the Hospital's concerns regarding Dane's vaccination status are due to the potential to transmit the SARS-CoV-2 virus to Tanner, all could be alleviated by simply testing Tanner for various markers of natural immunity to the disease in addition to continuing to test them both for COVID-19 up until the point of transplant. Lastly, if the Hospital fears litigation, the Donaldson's could waive their right to sue the hospital for any COVID-19-related complications. There are plenty of reasonable options in play to both mitigate the risk of COVID-19 and achieve a successful surgery for Tanner, but the Hospital refuses to come to the table. It is entirely unethical to refuse treatment to Tanner because the Hospital believes it is more

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own reporting "the magnitude of underreporting is unknown.").

[19] *See FDA Doubles Down: Asks Federal Judge to Grant it Until at Least the Year 2096 to Fully Release Pfizer's' COVID-19 Vaccine Data*, Injecting Freedom by Aaron Siri (Dec. 7, 2021) https://aaronsiri.substack.com/p/fda-doubles-down-asks-federal-judge (citing Second Joint Report, *PHMT v. FDA*, No. 4:21-cv-01058 (Nov. 11, 2021) *available at https://www.sirillp.com/wp-content/uploads/2021/11/020-Second-Joint-Status-Report-8989f1fed17e2d919391d8df1978006e.pdf* [https://perma.cc/859D-92VS]).

[20] *See Swine Flu Program is Halted in 9 States as 3 Die After Shots*, The New York Times (Oct. 13, 1976) *available at* https://www.nytimes.com/1976/10/13/archives/swine-flu-progrm-is-halted-in-9-states-as-3-die-after-shots.html [https://perma.cc/ZSL6-V4SV].

[21] *Swine Flu Program Suspended in Nation; Disease Link Feared*, The New York Times (Dec. 17, 1976) *available at https://www.nytimes.com/1976/12/17/archives/swine-flu-program-suspended-in-nation-disease-link-feared-94-cases.html* [https://perma.cc/VK33-8SCH].

[22] https://vaers.hhs.gov/data.html.

of a risk to Tanner's health that he *might* contract COVID-19 from the transplant rather than the real, actual impending danger of renal failure due to Stage 5 kidney disease.

III. Conclusion

To conclude, the Donaldson family has been on a grueling 4-year journey that has resulted in Tanner now entering Stage 5 kidney disease which will only continue to worsen by the day. Now, due to an unexplained and unjustified policy outside of his control, not only have Tanner's hopes of a "normal life" been shattered, but his chance at even living a *full adult life* is at risk by way of an unethical practice being embraced by the Hospital administration. Dane and Jennifer love their son more than anything in the world and would do anything to keep him safe. Now, not only is the Hospital seeking to coerce Dane and Jennifer into compromising their principles and religious beliefs, but it is forcing them to make an impossible choice between known harm and likely harm by those who swear an oath to "Do no harm." Query whether the Hospital is performing any transplants on patients from donors, living or dead, who are either unvaccinated or whose vaccination status may be unknown in emergent situations.

On behalf of the Donaldson family, we request that the Hospital reconsider its stance on its refusal to operate on Tanner Donaldson absent his father receiving the COVID-19 vaccine and forthwith respond to the points raised herein.

Regards,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

cc: VIA FEDERAL EXPRESS ONLY

Alvin Wee, MD
Cleveland Clinic Main Campus/Transplant Center
Mail Code R3
9500 Euclid Ave
Cleveland, OH 44195

Charles Kwon, MD
Pediatric Nephrology/Transplant Center
Mail Code R3
9500 Euclid Ave.
Cleveland, OH 44195

Katherine Dell, MD
Cleveland Clinic Main Campus/Pediatric Nephrology
Mail Code R3
8950 Euclid Ave
Cleveland, OH 44106

Amy Bobrowski, MD
Cleveland Clinic Main Campus/Pediatric Nephrology
Mail Code R3
9500 Euclid Ave.
Cleveland, OH 44195

Charles Foster, MD
Cleveland Clinic Main Campus/Pediatric Infectious Disease
Mail Code R3
9500 Euclid Ave.
Cleveland, OH 44195

EXHIBIT A

MP-Univ Gastroenterology-Parma

6707 Powers Boulevard, MAC2 - Ste 309
Parma,OH 44129
(440) 886-5558

Patient: DONALDSON, DANE [redacted]

Age/Sex/DOB: [redacted]
EMRN:
OMRN:
Home:
Work:

Results

Lab Accession # [redacted]
Ordering Provider: Raad, Dany
Performing Location: UHC
11100 Euclid Avenue
Cleveland, OH 44106

Collected: 10/20/2021 9:20:00AM
Resulted: 10/20/2021 9:12:00PM
Verified By: Raad, Dany
Auto Verify: N

Coronavirus 2019 RNA by PCR, Screening Asymptomtic **Stage:** **Final**

Result Annotations: 10/21/2021 8:51:00AM Raad, Dany
patient was called [redacted]

COVID Called- RB to STEPHANIE FERTEL , 10/21/2021 09:25

Test	Result	Units	Flag	Reference Range
Coronavirus 2019, PCR	DETECTED		A	See Below

SOURCE: Nasal, Nasopharyngeal
Reference Range: Not Detected

This assay is designed to detect the N, ORF1ab and/or S genes of SARS-CoV-2 via nucleic acid amplification. A Negative (NOT DETECTED) result does not preclude 2019-nCoV infection since the adequacy of sample collection and/or low viral burden may result in presence of viral nucleic acids below the clinical sensitivity of this test method. Negative (NOT DETECTED) result should not be used as the sole basis for treatment or other patient management decisions. Rather negative results should be combined with clinical observations, patient history, and epidemiological information to make patient management decisions.

Fact sheet for providers: https://www.fda.gov/media/136111/download
Fact sheet for patients: https://www.fda.gov/media/136114/download

This test has received FDA Emergency Use Authorization (EUA) and has been verified by University Hospitals Cleveland Medical Center (UHCMC). This test is only authorized for the duration of time that circumstances exist to justify the authorization of the emergency use of in vitro diagnostic tests for the detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

University Hospitals Cleveland Medical Center is certified under CLIA-88 as qualified to perform high complexity testing. Testing is performed in the UHCMC laboratories located at 11100 Euclid Ave Cleveland, OH 44106.
COVID Called- RB to STEPHANIE FERTEL , 10/21/2021 09:25