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VIA FEDERAL EXPRESS

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Re: Tanner Donaldson – Denial of Kidney Transplant

Dear Sir or Madam:

We write in regard to our unanswered correspondence to Director Jankowski¹ at Cleveland Clinic (the “**Hospital**”) on behalf of Tanner Donaldson (“**Tanner**”) and his father, Dane Donaldson (“**Mr. Donaldson**”), (collectively, “**the Donaldsons**”), dated January 13, 2022, urging the Hospital to reconsider its denial of Tanner’s kidney transplant surgery. As previously stated, the Donaldsons hold sincere religious beliefs contrary to the COVID-19 vaccine and as such, are unable to meet the Hospital’s COVID-19 vaccine requirement (the “**Policy**”). This letter serves as a final pre-litigation opportunity for the Hospital to rectify its actions against the Donaldsons for its wrongful denial of treatment.

I. FACTUAL DEVELOPMENTS

Since the January 13, 2022 letter, Tanner’s physical condition has worsened severely, with an emergency room visit on March 16, 2022 for severe stomach issues and vomiting related to his kidney disease. After this visit, there has been zero communication from the Hospital regarding Tanner’s condition, not even from Tanner’s nephrologist, Dr. Bobrowski. The behavior of the physicians at the Hospital has forced Mr. and Mrs. Donaldson to remove Tanner from the Hospital’s care and seek other options. Because of this, Tanner is currently without a nephrologist and is left with only his pediatrician to maintain his care until other accommodations can be made. The lack of concern for Tanner, after nine years of treating his condition, further reveals the present attitude of the Hospital in prioritizing political narratives over patient care.

¹ Attachment 1 (Siri & Glimstad Letter Dated January 13, 2022).

II. PHYSICIANS COMPLICIT IN ENFORCING THE POLICY RISK DISCIPLINARY ACTION ON THEIR MEDICAL LICENSES

Regardless of hospital policy, a physician must adhere to Ohio law governing the medical profession. In refusing to treat patients on the basis of their vaccination status for COVID-19, physicians at the Hospital are potentially in violation of the following provisions of the Ohio Revised Code and risk disciplinary action against their medical license, up to and including revocation.²

A) **VIOLATIONS OF MEDICAL ETHICS**

The Hospital's Policy violates both the American Medical Association's ("**AMA**") Code of Medical Ethics³ and the American Society of Transplantation's ("**AST**") Ethics Statement.⁴ More importantly, any physician imposing such a requirement on his or her patients violates the Ohio Revised Code governing the medical profession.⁵ Specifically, subsection (B)(18) states,

(B) Except as provided in division (P) of this section, the board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend a license or certificate to practice or certificate to recommend, refuse to issue a license or certificate, refuse to renew a license or certificate, refuse to reinstate a license or certificate, or reprimand or place on probation the holder of a license or certificate for one or more of the following reasons:

(18) Subject to section 4731.226 of the Revised Code, violation of any provision of a code of ethics of the American medical association, the American osteopathic association, the American podiatric medical association, or any other national professional organizations that the board specifies by rule. The state medical board shall obtain and keep on file current copies of the codes of ethics of the various national professional organizations. The individual whose license or certificate is being suspended or revoked shall not be found to have violated any provision of a code

² Ohio Rev. Code §4731.22.

³ See *AMA Code of Medical Ethics*, American Medical Association (revised Jun. 2001), available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf>.

⁴ *American Society of Transplantation Ethics Statement* (last updated Dec. 6, 2012), available at <https://www.healthytransplant.com/about-ast/who-we-are/strategic-plan-our-mission/ast-statement-ethics-organ-transplantation>.

⁵ See Ohio Rev. Code §4731.22 (outlining all actions that will be deemed actionable violations against an Ohio medical professional's license).

of ethics of an organization not appropriate to the individual's profession.⁶

The AMA's Code of Ethics⁷ states in relevant part,

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.⁸

Any physician found to have refused to treat a patient due to their noncompliance with the Policy violated each of the above provisions. First, conditioning a life-saving treatment on the receipt of another that violates the sincere religious beliefs of the patient disrespects the patient's dignity and rights to personal autonomy and informed consent. Second, by failing to advocate on behalf of his or her patient's individual needs, and rather, blindly conforming to the Hospital's Policy, a physician violates provision III. Third, in refusing to provide life-saving treatment because of adherence to the Policy without providing adequate exemptions for individualized circumstances, a physician fails to "regard responsibility to the patient as paramount."⁹ Lastly, and most obviously, acting in concert with a policy that denies access to medical care for any person violates provision IX.

Furthermore, consistent with established ethical obligations of patient autonomy and informed consent, the AST expressly acknowledges the importance of respecting the religious beliefs of transplant candidates and recipients. In its *Statement on Ethics in Organ Transplantation*¹⁰ the AST places autonomy first and foremost, stating that:

I. AUTONOMY

⁶ *Id.* at (B)(18).

⁷ See *AMA Code of Medical Ethics*, American Medical Association (revised Jun. 2001), available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf>.

⁸ *Id.*

⁹ *Id.*

¹⁰ American Society of Transplantation (last updated Dec. 6, 2012), available at <https://www.healthytransplant.com/about-ast/who-we-are/strategic-plan-our-mission/ast-statement-ethics-organ-transplantation>.

All participants in solid organ transplantation (donors, recipients, providers, investigators) should be respected as autonomous individuals whose interests may not always coincide.

Healthcare providers, recipients (or candidates) and living donors bring personal, philosophical, and religious beliefs that should be respected.

All participants must be fully informed of the risks and benefits of all procedures.

Privacy and confidentiality are the norm for both donors and recipients.¹¹

The Hospital's conditioning Tanner's life-saving treatment on receiving a medical product that violates his and his father's sincerely held religious beliefs contravenes the aforementioned ethical principles. Moreover, in its failure to provide long-term data to fully apprise Tanner of the risks associated with the COVID-19 vaccine,¹² it also errs in abiding by the ethical requirements of informed consent. As stated in *The Limits of Refusal: An Ethical Review of Solid Organ Transplantation and Vaccine Hesitancy*:

[v]accine refusal differs by racial, ethnic, socioeconomic, or religious groups . . . and . . . is, so far, uncommon, the difference in transplant outcomes between vaccinated and non-vaccinated recipients would have to be substantial to justify excluding vaccine-refusing patients on the basis of overall utility.¹³

¹¹ *Id.*

¹² It is worth noting that all 3 COVID-19 vaccines allowed their clinical trial participants to “unblind” and choose to receive the active product if they were in the placebo control cohort. Manipulating and diluting the placebo control group ultimately undermines any legitimate analysis of long-term effects associated with the vaccine because the control group has been tainted. See *Long-Term Studies of COVID-19 Vaccines Hurt by Placebo Recipients Getting Immunized*, NPR.org (Feb. 19, 2021), available at <https://www.npr.org/sections/health-shots/2021/02/19/969143015/long-term-studies-of-covid-19-vaccines-hurt-by-placebo-recipients-getting-immuni> [https://perma.cc/627d-hh5e]; see also *A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Assess the Efficacy And Safety of AD26.CoV2.S for the Prevention of SARS-CoV-2-Mediated Covid-19 in Adults Aged 18 Years And Older*, Janssen Vaccines & Prevention B.V. Clinical Protocol (Dec. 14, 2020), available at <https://www.jnj.com%2fcoronavirus%2fensemble-1-study-protocol>; see also *Q&A for SPIKEVAX (COVID-19 Vaccine mRNA)*, U.S. Food & Drug Administration (Feb. 8, 2022), available at <https://www.fda.gov/vaccines-blood-biologics/qa-spikevax-covid-19-vaccine-mrna> [https://perma.cc/h8l4-nz9r] (“After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Moderna COVID-19 vaccine to placebo participants.”); see also *Vaccine Transition Option Covid-19 Vaccine Study*, Pfizer (last visited Feb. 23, 2022), available at <https://www.covidvaccinestudy.com/participants> [https://perma.cc/ac2t-wprx] (giving Pfizer-BioNTech clinical trial placebo recipients option to unblind and receive active vaccine).

¹³ Olivia S. Kates, et al., *The Limits of Refusal: An Ethical Review of Solid Organ Transplantation and Vaccine Hesitancy*, Am J Transplant (Jan. 23, 2021), available at <https://pubmed.ncbi.nlm.nih.gov/33370501>.

Such deprivation of human rights and dignity contravenes the clear ethical guidelines under which Ohio physicians must adhere, or risk disciplinary action on their licenses under O.R.C. §§4731.22(B)(18).

B) FALSE, FRAUDULENT, DECEPTIVE, OR MISLEADING STATEMENTS

Ohio law prohibits medical professionals from making false or misleading statements to patients in the course of the practice of medicine. Subsection (5) makes the following actionable against a practitioner's license:

(5) Making a **false, fraudulent, deceptive, or misleading statement** in the solicitation of or advertising for patients; **in relation to the practice of medicine and surgery**, osteopathic medicine and surgery, podiatric medicine and surgery, or a limited branch of medicine; or in securing or attempting to secure any license or certificate to practice issued by the board.¹⁴

In requiring the COVID-19 vaccine for all transplant patients and donors, without exception, the Hospital assured its patients that it had sufficient data underlying its decision to impose such an inflexible requirement. The truth is, however, that there were no clinical trial cohorts including persons either in need of organ transplant, or recently having received one.¹⁵ In fact, one of the most critical concerns for transplantation candidates, inflammation, has been almost entirely ignored by scientists in evaluating effects of the COVID-19 vaccine, leaving no data for physicians to properly be forcing the vaccine on their patients.¹⁶

C) FAILING TO PROVIDE THE MINIMUM STANDARD OF CARE

Tanner's physicians are similarly liable under §4731.22(B)(6) for failing to meet the minimum standard of care. Section (B)(6) places a physician's medical license at risk when there is, "[a] departure from, or the failure to conform to, minimal standards of care of similar

¹⁴ Ohio Rev. Code §4731.22(B)(5) (emphasis added).

¹⁵ See *Acute Kidney Rejection After Anti-Sars-Cov-2 Virus-Vectored Vaccine—Case Report*, Nature Partner J. (Mar. 2, 2022) available at <https://www.nature.com/articles/s41541-022-00445-5> ("Individuals who have undergone kidney transplants have been identified as high-risk populations and prioritized for vaccination, but have been excluded from major severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine clinical trials.").

¹⁶ See *The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory*, iScience (Dec. 17, 2021) available at <https://doi.org/10.1016/j.isci.2021.103479> ("The human clinical trials of the Pfizer/BioNTech and Moderna vaccines have reported side effects such as pain, swelling, fever, and sleepiness. Under the presumption that this vaccine platform is noninflammatory, some of the clinicians and public health communicators interpreted these reported acute side effects as the vaccine being potent and generating an adaptive immune response. These side effects, however, are more in line with acute inflammatory responses induced by the vaccine. Still, no studies have been undertaken to characterize the immediate innate inflammatory reactions induced by this vaccine platform that could potentially cause the local and systemic side effects. Therefore, in this study, we took a systematic approach, focusing our attention on the injection site and analyzing the inflammatory reactions caused by the LNPs used for preclinical vaccine studies.") (internal citations omitted).

practitioners under the same or similar circumstances, whether or not actual injury to a patient is established...”¹⁷

The Ohio Supreme Court has defined the minimum standard of care test as:

...whether the physician, in the performance of his service, either did some particular thing or things that physicians and surgeons, in that medical community, of ordinary skill, care and diligence would not have done under the same or similar circumstances, or failed or omitted to do some particular thing or things which physicians and surgeons of ordinary skill, care and diligence would have done under the same or similar circumstances.¹⁸

The protections afforded physicians under the Public Readiness and Emergency Preparedness (“PREP”) Act¹⁹ do not protect against patient abandonment and the refusal to provide a lifesaving surgery. The PREP Act makes immune from suit “...all claims for loss caused by, arising out of, relating to, or resulting from **the administration to or the use by an individual of a covered countermeasure**....”²⁰ Nothing in the statutory language protects a physician for refusal to treat a patient on the basis of his refusal to receive a covered countermeasure. In fact, several cases brought for negligence, wrongful death, and other state law tort claims against healthcare workers have been found to not fall within the protections of the PREP Act due to the cause of death or harm arising from the failure to act, rather than from the use of covered countermeasures.²¹ Therefore, any physician’s reliance on the PREP Act to shield his or her failure to adhere to the minimum standard of care is misplaced, and continued adherence to the Hospital’s

¹⁷ Ohio Rev. Code §4731.22(B)(6).

¹⁸ *Bruni v. Tatsumi*, 46 Ohio St. 2d 127, 129 (1976).

¹⁹ See 42 USCA § 247d-6d (targeted liability protections for pandemic and epidemic products and security countermeasures).

²⁰ *Id.* at (a)(1)(emphasis added).

²¹ See *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271 (D. Kan. 2021)(“Claims for negligence and wrongful death brought by surviving child of care facility resident who contracted and died of COVID-19 at facility did not fall within scope of Public Readiness and Emergency Preparedness (PREP) Act, and thus, PREP Act could not serve as basis for federal-question jurisdiction under doctrine of complete preemption in order to support removal of action against owners and operators of facility; claims did not arise from administration or use of covered countermeasures, but rather alleged failure to act in face of threat of COVID-19 altogether.”); *Lutz v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2316-HLT-JPO, 2020 WL 4815100 (D. Kan. Aug. 19, 2020)(“Public Readiness and Emergency Preparedness Act (PREP Act) did not preempt state law negligence claims asserted by survivors of residents of rehabilitation facility who contracted and died of COVID-19 against owners and operators of the facility; there was no clear allegation that any injury or claim of loss was caused by the administration or use of any covered countermeasure, let alone that the loss arose out of, related to, or resulted from the same.”); *Dupervil v. All. Health Operations, LCC*, 516 F. Supp. 3d 238 (E.D.N.Y. 2021)(“State law claims brought against nursing home by son of nursing home resident who contracted and died of COVID-19 did not fall within scope of Public Readiness and Emergency Preparedness (PREP) Act, and thus son's claims were not preempted; son claimed that resident died due to failures to take certain steps such as separating residents, enforcing social distancing among residents and staff, and timely restricting visitors, and none of son's allegations involved administering, prioritizing, or purposefully allocating, a drug, biological product, or device to an individual within meaning of PREP Act.”).

policy that has deprived Tanner of critical care will be subject to disciplinary charges against his or her license consistent with §4731.22(B)(6).

III. THE HOSPITAL'S REFUSAL TO TREAT TANNER VIOLATES OHIO'S ANTI-DISCRIMINATION STATUTE FOR PLACES OF PUBLIC ACCOMMODATION

The Hospital's Policy imposes a substantial burden on those who hold sincere religious beliefs precluding them from the COVID-19 vaccination, ultimately resulting in disparate treatment and unequal enjoyment of the Hospital's services. The Hospital's blanket refusal to provide accommodations to any person holding religious beliefs contrary to the Policy further evidences discriminatory animus by the Hospital against people of faith, in contravention of state law. In addition, any non-religious exemption to the Policy given to other patients at the Hospital further points to intentional discrimination on the basis of religion. Ohio's anti-discrimination statute prohibits discrimination in places of public accommodation based on race, color, religion, or national origin, providing that, it is unlawful for:

any proprietor or any employee, keeper, or manager of a place of public accommodation to deny to any person, except for reasons applicable alike to all persons regardless of . . . religion . . . the full enjoyment of the accommodations, advantages, facilities, or privileges of the place of public accommodation.²²

The statute defines "places of public accommodation" as:

any inn, restaurant, eating house, barbershop, public conveyance by air, land, or water, theater, store, other place for the sale of merchandise, or any other place of public accommodation or amusement of which the accommodations, advantages, facilities, or privileges are available to the public.²³

As articulated in the Ohio Administrative Code, when used in the context of §4112, a "place of public accommodation" also includes dispensaries, clinics, and hospitals.²⁴ Thus, the Hospital classifies as a place of public accommodation under §4112 and must provide "full enjoyment of the accommodations, advantages, facilities, [and] privileges"²⁵ to all persons regardless of their religious beliefs.

Tanner and Mr. Donaldson availed themselves of §4112's protections when Mr. Donaldson informed the Hospital that both he and Tanner had religious objections to the COVID-19 vaccine and were thus unable to comply with the Policy. If the Hospital were found to have granted exemptions to the Policy for non-religious reasons, while denying all requests for religious accommodation, the Hospital's defense of an equally applicable Policy evaporates. In refusing to

²² Ohio Rev. Code § 4112.02.

²³ Ohio Rev. Code § 4112.01.

²⁴ Ohio Admin. Code § 4112-5-02.

²⁵ Ohio Rev. Code § 4112.02.

operate on the Donaldsons due to their noncompliance with the Policy, while exempting others from the Policy for secular reasons, the Hospital has discriminated against the Donaldsons in violation of state law.

IV. FEDERAL LAW PROHIBITS THE HOSPITAL FROM MANDATING THE CURRENTLY AVAILABLE COVID-19 VACCINES

In addition to its violation of state law, the Hospital also violated federal law by requiring Tanner to receive a vaccine that is not fully approved by the FDA. The Emergency Use Authorization (“EUA”) statute²⁶ under which all the currently available COVID-19 vaccines are administered prohibits the mandate of any products authorized thereunder. This is because EUA authorization is an emergency exception to the standing regulatory framework for drugs, devices, and biologics. As such, it requires that all individuals offered an EUA product have the option to accept or refuse it.²⁷

Despite the FDA’s approval of Pfizer and Moderna’s biologics license applications (“BLA”) for its COMIRNATY COVID-19 Vaccine²⁸ and Moderna’s SPIKEVAX COVID-19 vaccine,²⁹ neither are available to the general public. The only available vials of Pfizer or Moderna’s COVID-19 vaccines are those lots authorized under the EUA Statute.³⁰ The COMIRNATY vaccine cannot be legally distributed for use until BioNTech submits “final container samples of the product in final containers together with protocols showing results of all applicable tests” and BioNTech receives “a notification of release from the Director, Center for Biologics Evaluation and Research (“CBER”).”³¹ To date, there has been no public announcement

²⁶ See 21 U.S.C. § 360bbb-3(a)(1) (“EUA Statute”) (stating that “subject to the provisions of this section, the Secretary (of the Department of Health and Human Services) may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).”).

²⁷ See 21 U.S.C. § 360bbb-3(e)(1)(A)(jj)(III) (requiring that “individual to whom the product is administered are informed . . . of the option to accept or refuse administration of the product.”). The statutorily required Facts Sheets for each of the COVID-19 vaccines with EUA status echo this sentiment. See *Fact Sheet for Recipients and Caregivers*, Moderna (Jan. 31, 2022), available at <https://www.fda.gov/media/144638/download> (“It is your choice to receive or not to receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.”); see also *Fact Sheet for Recipients and Caregivers*, Pfizer-BioNTech (Jan. 31, 2022), available at <https://www.fda.gov/media/153716/download> (“It is your choice to receive or not to receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.”); *Fact Sheet for Recipients and Caregivers*, Janssen (Jan. 31, 2022), available at <https://www.fda.gov/media/146305/download> (“It is your choice to receive or not to receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.”).

²⁸ *BLA Approval Letter for COMIRNATY, COVID-19 Vaccine, mRNA* (Aug. 23, 2021), available at <https://www.fda.gov/media/151710/download>.

²⁹ See *BLA Approval Letter for SPIKEVAX, COVID-19 Vaccine, mRNA* (Jan. 31, 2022), available at <https://www.fda.gov/media/155815/download> (“You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).”).

³⁰ See *BLA Approval Letter for COMIRNATY*, *supra* note 28 (“You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).”). See also *BLA Approval Letter for SPIKEVAX*, *supra* note 29.

³¹ *BLA Approval Letter for COMIRNATY*, *supra* note 28, at 2.

of the requisite notification of release for either Pfizer or Moderna. In fact, the FDA stated, “[a]lthough COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA.”³² The notification of release requirement also applies to Moderna’s SPIKEVAX vaccine.³³

Moreover, the FDA’s BLA approvals of COMIRNATY and SPIKEVAX do not change the EUA status of the Pfizer-BioNTech or Moderna COVID-19 Vaccines that have operated under EUA since December 23, 2020, and are currently in circulation.³⁴ According to the EUA extension letter initially issued by the FDA to Pfizer on August 23, 2021,³⁵ and subsequently re-issued on January 3, 2022,³⁶ the Pfizer-BioNTech COVID-19 Vaccine and BioNTech’s COMIRNATY, COVID-19 vaccine, mRNA “are legally distinct” products.³⁷ Because the FDA-approved vaccines are unavailable for distribution to the public, the Hospital cannot require that Tanner receive an EUA authorized vaccination as a pre-requisite to a life-saving operation.

V. THE HOSPITAL’S COVID-19 POLICY VIOLATES THE OPTN CHARTER

As a transplant hospital, the Hospital is required to maintain an active membership with the Organ Procurement and Transplantation Network (“OPTN”).³⁸ OPTN is a public-private partnership created by the National Organ Transplant Act³⁹ to regulate organ donation and transplantation nationwide. All hospitals that conduct organ transplant surgeries in the United States must join OPTN. To maintain status within the network and continue conducting transplant surgeries, all members are subject to the OPTN Policies and Bylaws.⁴⁰ The OPTN charter states that:

³² See *EUA Expansion Letter from FDA to Pfizer, Inc.*, at 10 fn. 19 (Jan. 3, 2022), available at <https://www.fda.gov/media/150386/download>.

³³ See *BLA Approval Letter for SPIKEVAX, COVID-19 Vaccine, mRNA* (Jan. 31, 2022), available at <https://www.fda.gov/media/155815/download> (“You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).”).

³⁴ *Updated EUA Extension Letter for Pfizer-BioNTech COVID-19 Vaccine* (Jan. 3, 2022), available at <https://www.fda.gov/media/150386/download>.

³⁵ *EUA Extension Letter for Pfizer-BioNTech COVID-19 Vaccine* (Aug. 23, 2021), available at <https://www.fda.gov/media/151710/download>.

³⁶ *Updated EUA Extension Letter*, *supra* note 34.

³⁷ *EUA Extension Letter*, *supra* note 35, at 2 n. 8.

³⁸ See Article IV, *Charter*, Organ Procurement and Transplantation Network (OPTN), available at <https://optn.transplant.hrsa.gov/about/final-rule/>; See also 42 C.F.R. §121.

³⁹ See 42 U.S.C. 273 et seq.; see also <https://optn.transplant.hrsa.gov/about/>.

⁴⁰ See 42 C.F.R. §121.1(d) (“In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.”).

By accepting membership in the OPTN, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.; OPTN Final Rule, 42 CFR Part 121; this Charter; the OPTN Bylaws; and OPTN policies as in effect from time to time. The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with OPTN policies. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), to operate the OPTN (OPTN Contract).⁴¹

By removing patients from the transplant list for failure to receive the COVID-19 vaccine, the Hospital directly violates the OPTN charter, the National Organ Transplant Act, its accompanying federal regulations,⁴² and the OPTN Policies and Bylaws.⁴³ Section 121.8 of OPTN's underlying regulations state that the OPTN Board of Directors shall develop "policies for the equitable allocation of cadaveric organs among potential recipients" and that "[s]uch allocation policies [] shall be based on sound medical judgment."⁴⁴ Neither OPTN nor the Department of Health and Human Services ("HHS") has promulgated any federal rules or regulations requiring transplant recipients to receive the COVID-19 vaccine to remain active on the List. Although OPTN's policies allow member hospitals to "classify the candidate as inactive" if it finds "the candidate is temporarily unsuitable for transplant,"⁴⁵ nothing in the OPTN's guidelines or requirements for qualifying transplant candidates references a COVID-19 vaccination requirement.⁴⁶

In fact, OPTN has continued to promulgate rules and policy throughout the pandemic.⁴⁷ For example, on December 2, 2021, OPTN published its *Updated Refusal Codes*,⁴⁸ including direction on pandemic-related issues for transplant candidates:

⁴¹ See Article IV *supra* note 38.

⁴² 42 C.F.R. §121 *et seq.*

⁴³ *OPTN Policies* (last updated Feb. 10, 2022) available at <https://optn.transplant.hrsa.gov/policies-bylaws/policies/>; *OPTN Bylaws* (last updated Dec. 26, 2021) available at <https://optn.transplant.hrsa.gov/policies-bylaws/bylaws/>.

⁴⁴ 42 C.F.R. §121.8 (emphasis added).

⁴⁵ *OPTN Policies*, *supra* note 43, at 3.4E.

⁴⁶ See sources cited *supra* note 43.

⁴⁷ See *OPTN Notices of Implemented Actions* (last visited Mar. 4, 2022), available at <https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/> (listing notices of updated policy throughout 2020, 2021, and as recent as Feb. 10, 2022).

⁴⁸ *OPTN Updated Refusal Codes* (Dec. 2, 2021), available at https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf.

Transplant hospitals should use this refusal when refusing an organ offer due to a candidate related epidemic/pandemic reason (e.g., COVID-19). This may include reasons such as the candidate has a potential exposure, is symptomatic, is being tested, or has a positive test result. Do not use this code if the candidate is refusing all organ offers at this time due to the pandemic.

Transplant hospitals should use this refusal code when refusing an organ offer due to a donor related epidemic/pandemic reason (e.g., COVID-19). This may include reasons such as donors with high exposure risk, no testing available, positive or indeterminate test results, or if a different specimen type is preferred.⁴⁹

The rejection codes, written specifically to address COVID-19 issues, do not provide the candidate's vaccination status as a COVID-19 reason for refusing an organ. Thus, any argument that the Policies and Bylaws did not account for the COVID-19 pandemic is misplaced. The Hospital must abide by the Policies and Bylaws as they stand and cannot rely on the pandemic as a scapegoat for its discriminatory actions. Moreover, nowhere in the OPTN Policies for live organ donation does it allow for OPTN hospitals to refuse to conduct a transplant surgery from a private donor based on his COVID-19 vaccine status, or the status of the donor.⁵⁰

If the Hospital does not grant Tanner and his father a religious exemption, allowing the transplant surgery to go forward, the Donaldsons plan to file a grievance with OPTN. OPTN is obligated to investigate all grievances for noncompliance. If OPTN determines that the Hospital is noncompliant, it may suspend or remove the Hospital from its network, rendering it incapable of conducting organ transplantation or procurement surgeries and participating in the Center for Medicaid Services ("CMS") programs.⁵¹ The Hospital's actions, if not remedied, could reasonably result in severe financial consequences to the hospital's operating revenue.

VI. THE HOSPITAL'S COVID-19 POLICY PLACES ITS CMS CERTIFICATION AT RISK FOR REGULATORY NONCOMPLIANCE

The Hospital's treatment of Tanner violates CMS's regulatory requirements that protect patient rights for all hospitals participating in or receiving funding from CMS-related programs.

⁴⁹ *Id.* at 3.

⁵⁰ See *OPTN Policy 14* (last updated Feb. 10, 2022) available at <https://optn.transplant.hrsa.gov/policies-bylaws/policies/>.

⁵¹ See 42 C.F.R. §482.72 ("A transplant program must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.").

Specifically, under 42 C.F.R. §482.13, any CMS participating hospital must inform and protect patients' exercise of the following rights:

(a) Standard: Notice of rights.

(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(b) Standard: Exercise of rights.

(1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(c) Standard: Privacy and safety.

(1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.⁵²

A) THE HOSPITAL DID NOT PROVIDE THE DONALDSONS INFORMED CONSENT

By imposing the COVID-19 vaccine requirement on Tanner and Mr. Donaldson, as a condition to receive life-saving treatment, the Hospital deprived Tanner and his father of their federally protected right to "make informed decisions" regarding their care, and removed their "right to request or refuse treatment."⁵³ On a basic level, informed consent requires no undue influence placed upon the decisionmaker. However, Tanner's life hinges upon the ability to receive an organ transplant, and the Hospital is forcing him and his father to "choose" between receiving this life-saving treatment or receiving a vaccine that violates their religious faith. This "choice" is entirely illusory and a coercive violation of the fundamental principles of informed consent.

⁵² See 42 C.F.R. §482.13(a)(1), (b)(1)-(2), (c) (emphasis added).

⁵³ *Id.* at (b).

Additionally, the Hospital failed to provide Tanner or Mr. Donaldson with written notice that the COVID-19 vaccine requirement was a factor in the transplant evaluation process. As stated above, not only did the Hospital fail to provide this information in a timely manner, but it also approved both Tanner and Mr. Donaldson for transplant without his having received the COVID-19 vaccine.⁵⁴ The Hospital then sought to apply subsequent additional terms to the previously consented requirements. The Hospital's actions are antithetical to informed consent.

B) THE HOSPITAL FAILED TO INFORM THE DONALDSONS OF THEIR RIGHT TO FILE A GRIEVANCE

The Hospital is required by CMS regulations to “establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.”⁵⁵ Section 482.13(a) states in relevant part:

At a minimum:

- (i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.
- (ii) The grievance process must specify time frames for review of the grievance and the provision of a response.
- (iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.⁵⁶

Thus, the Hospital must exempt the Donaldsons from its Policy and conduct the transplant surgery. Otherwise, the Donaldsons **will report the Hospital's CMS violations to the Office of the Inspector General for HHS**. We note that the Terms & Conditions governing the \$431,032,935.00 it received from the HHS Provider Relief Fund⁵⁷ requires that the Hospital “be and remain in good standing with Medicare, Medicaid, and other Federal health care programs.”⁵⁸ Noncompliance could require the Hospital to repay the entire lump sum to HHS.⁵⁹

⁵⁴ The Hospital approved Tanner and Mr. Donaldson for transplant and live donation in 2017.

⁵⁵ 42 C.F.R. §482.13(a)(2).

⁵⁶ *Id.*

⁵⁷ <https://data.cdc.gov/Administrative/HHS-Provider-Relief-Fund/kh8y-3es6/data>.

⁵⁸ See e.g., <https://www.hrsa.gov/sites/default/files/hrsa/provider-relief/terms-and-conditions-phase-4-general-distribution-relief-fund.pdf>.

⁵⁹ *Id.* (“Non-compliance with the Terms or Conditions is grounds for HHS to recoup or collect some or all of the payments or take other actions pursuant to 45 CFR § 75.371 – Remedies for non-compliance.”).

VII. MORE DATA AND CONSIDERATIONS FOR THOSE WHO HAVE NATURAL IMMUNITY TO COVID-19

In addition to the several studies referenced in our January 13, 2022 letter, even more evidence has come to light to underscore the absurdity of the Hospital requiring the Donaldsons, who already have natural immunity to COVID-19, to receive the vaccine in order for the procurement and transplant surgeries to go forward.

A) UNKNOWN CLINICAL SIGNIFICANCE OF HYBRID IMMUNITY

In addition to the science on natural immunity from the January 13, 2022 letter, there are unknown questions as to the risks and benefits to those who acquire hybrid immunity. Numerous studies suggest that hybrid immunity, often referred to as “super immunity,” may protect against future infections better than natural immunity alone.⁶⁰ These studies commonly isolate IgG from serum and measure the antibody neutralization titers in vitro to the spike protein antigen.⁶¹ However, SARS-CoV-2 is a respiratory pathogen, not a blood-born pathogen. Antibody levels in the blood (serum) play a clinically relevant role predominantly during periods of severe COVID-19 disease, not in the early stages of infection, and they have little impact on attenuating reinfection.⁶² Therefore, mucosal immunity of the respiratory track plays an important role in protecting an individual from reinfection, primarily via secretory IgA (“SIgA”), which neutralizes previously encountered pathogens.⁶³ A recent study found that salivary IgA from natural infection is produced early during SARS-CoV-2 infection and can neutralize SARS-CoV-2 spike protein-expressing virus, unlike salivary IgG.⁶⁴ This suggests that mucosal IgA plays a protective role limiting disease severity and/or reinfections.

Scientists from Mount Sinai School of Medicine assessed the ability of COVID-19 vaccines to elicit production of secretory IgA in the saliva. They collected saliva samples from 30 individuals, 60% of whom recovered from COVID-19 prior to vaccination, and measured anti-spike SIgA levels over a period of 200 and 372 days.⁶⁵ Their results suggest, “that the level of mucosal SIgA responses induced by mRNA vaccination depend on pre-existing immunity”. In other words, SARS-CoV-2 native individuals who become vaccinated do not generate SIgA. Unlike serum IgG, SIgA levels in the saliva fall between 49- and 73-days post-SARS-CoV-2

⁶⁰ <https://www.nature.com/articles/d41586-021-02795-x>.

⁶¹ Chen, Y. et al., *Differential antibody dynamics to SARS-CoV-2 infection and vaccination*, MedRxiv (Sep. 10, 2021), available at <https://www.biorxiv.org/content/10.1101/2021.09.09.459504v1>; See also, Wang, Z. et al., *Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection*, Nature (Jun. 14, 2021), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8277577/#MOESM2>.

⁶² Renegar, K., et al., *Role of IgA versus IgG in the control of influenza viral infection in the murine respiratory tract*, J. Immunol (Aug. 1, 2004), available at <https://pubmed.ncbi.nlm.nih.gov/15265932/>.

⁶³ Corthesy, B., et al., *Multi-faceted functions of secretory IgA at mucosal surfaces*, Front Immunol (Jul. 12, 2013), available at <https://www.frontiersin.org/articles/10.3389/fimmu.2013.00185/full>.

⁶⁴ Sterlin, D. et al., *IgA dominates the early neutralizing antibody response to SARS-CoV-2*, Sci. Transl. Med. (Jan. 20, 2021) available at <https://www.science.org/doi/10.1126/scitranslmed.abd2223>.

⁶⁵ Sano et al., *Efficient mucosal antibody response to SARS-CoV-2 vaccination is induced in previously infected individuals*, MedRxiv (Dec.11, 2021), available at <https://www.medrxiv.org/content/10.1101/2021.12.06.21267352v1.full.pdf>.

infection but can be rapidly recalled following re-exposure.⁶⁶ Therefore, the fact that SIgA levels are only detected in the saliva from naturally immune individuals after vaccination is likely attributed to the recall of SARS-CoV-2 memory from previous infection.

The other weakness of hybrid immunity studies is that they narrowly focus on the immune response to a single antigen, the spike protein. Those with natural immunity, however, acquire an adaptive immune response, consisting of memory B and T lymphocytes, that recognizes numerous antigens including the S protein. Therefore, hybrid immunity studies cannot conclude that a more robust immune response to a single spike protein antigen, among the hybrid immune, is superior to natural immunity alone. Therefore, it has yet to be demonstrated that additional antibodies with higher affinity against the spike protein alone prevents reinfection.

Thus, it is likely that vaccination will not protect the Donaldsons from infection following organ transplantation because the vaccine does not generate a protective mucosal immune response. Preexisting mucosal immunity is arguably most important during reinfection because this SIgA will be least impacted by immunosuppressive drugs which work by limiting immune cell activation and cytokine production.⁶⁷

B) THE COVID-19 VACCINES ARE INEFFECTIVE AGAINST CURRENT VARIANTS

Critically, the current COVID-19 vaccines are not effective against the present variants. The vaccines were engineered from an isolated SARS-CoV-2 sample collected from an infected patient in Wuhan, China, on December 26, 2020 (Wuhan-Hu-1).⁶⁸ This means that the genetic code upon which both the mRNA and viral vector vaccines were developed was that of the parental strain, which has been replaced by the Alpha, Beta, Gamma, Delta, and now the Omicron variant of the virus.⁶⁹ Each variant of the virus has become more genetically distinct from the original strain, therefore substantially weakening vaccine efficacy with each new variant.⁷⁰ The present variant, Omicron, was first reported to the World Health Organization on November 24, 2021.⁷¹ The variant has “considerable escape from vaccine elicited immunity” due to a large number of

⁶⁶ Sterlin, D. *et al.*, *IgA dominates the early neutralizing antibody response to SARS-CoV-2*, *Sci. Transl. Med.* (Jan. 20, 2021), available at <https://www.science.org/doi/10.1126/scitranslmed.abd2223>.

⁶⁷ Suthanthiran, M. *et al.*, *Immunosuppressants: Cellular and Molecular Mechanisms of Action*, *Journal of Kidney Disease* (August 1996), available at <https://www.sciencedirect-com.webproxy2.ouhsc.edu/science/article/pii/S0272638696902978?via%3Dihub>.

⁶⁸ Jackson, L. *et al.*, *An mRNA Vaccine against SARS-CoV-2 – Preliminary Report*, *N Engl J Med* (Nov. 12, 2020), available at https://www.nejm.org/doi/10.1056/NEJMoa2022483?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed.

⁶⁹ <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>.

⁷⁰ See Cele, Sandile *et al.*, *SARS-CoV-2 Omicron has extensive but incomplete escape of Pfizer BNT162b2 elicited neutralization and requires ACE2 for infection*, *medRxiv* (Dec. 17, 2021), available at <https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v3>; See also Lu Lu, *et al.*, *Neutralization of SARS-CoV-2 Omicron variant by sera from BNT162b2 or Coronavac vaccine recipients*, *Oxford Academic* (Dec. 16, 2021), available at <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab1041/6463504>.

⁷¹ *SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021*, *Morbidity and Mortality Weekly Report (MMWR)* Vol. 70, No. 50 (Dec. 17, 2021), available at <https://www.cdc.gov/mmwr/index2021.html>.

mutations in the spike (the “S”) protein and elsewhere on the virus.⁷² Furthermore, a collection of recent scientific studies demonstrate that vaccine-derived antibodies have a 15-to-127-fold reduced ability to prevent SARS-CoV-2 cell entry.⁷³ The accumulation of the S protein mutations renders the current vaccines largely ineffective in neutralizing the Omicron variant.⁷⁴

Most importantly, the lack of severity of disease for the Omicron variant, when combined with its powerful cross-protective immune response it generates from a full recovery, makes the mandate of an obsolete vaccine even more erroneous.⁷⁵ In terms of severity of illness, the most common symptoms reported were cough, fatigue, congestion, or runny nose.⁷⁶ New data from South Africa corroborates United States data showing reduced severity of Omicron compared to other variants.⁷⁷ Of note, of the 43 reported COVID-19 Omicron variant cases in the United States as of December 17, 2021, 79% occurred in individuals who had received the primary series of an FDA-authorized COVID-19 vaccine, and 32% had received a booster dose of a vaccine.⁷⁸ The data as it stands highlights exactly why the Hospital’s mandate of a vaccine for a strain of the virus it can no longer protect against, at best, evidences negligence, or at worst, malicious intent for imposing a policy so counter to the best interests of its patients.

C) STUDIES AT JOHN HOPKINS UNIVERSITY SHOW THAT ORGAN TRANSPLANT RECIPIENTS BENEFIT LESS FROM COVID-19 VACCINES

The Hospital’s justification for refusing Tanner’s transplant surgery ignores current and relevant science. For example, antibody levels post two doses of the mRNA SARS-CoV-2 vaccine in solid organ transplant recipients were well below that observed in immunocompetent

⁷² *Cele, supra* note 70.

⁷³ See, e.g., Wilhelm, Alexander *et al.*, *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies*, medRxiv (Dec. 7, 2021), available at <https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v2.full.pdf>; Ikemura, Nariko *et al.*, *SARS-CoV-2 Omicron variant escapes neutralization by vaccinated and convalescent sera and therapeutic monoclonal antibodies*, medRxiv (Dec. 13, 2021), available at <https://www.medrxiv.org/content/medrxiv/early/2021/12/14/2021.12.13.21267761.full.pdf>.

⁷⁴ Wilhelm, Alexander *et al.*, *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies*, medRxiv (Dec. 7, 2021), available at <https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v1>.

⁷⁵ Khan, Khadija, *et al.*, *Omicron infection enhances neutralizing immunity against the Delta variant*, medRxiv (Dec. 27, 2021), available at <https://www.medrxiv.org/content/10.1101/2021.12.27.21268439v1.full.pdf> (Study supported by the Bill and Melinda Gates Foundation and the National Institutes of Health, among others, found that infection with the Omicron variant resulted in neutralization of the Delta variant, meaning that Omicron infection results in the production of a cross-protective immune response to the Delta variant).

⁷⁶ *Id.*

⁷⁷ Beaumont, Peter, *South African data suggests Omicron outbreak has caused less severe disease*, The Guardian (Dec. 22, 2021), available at <https://www.theguardian.com/world/2021/dec/22/data-appears-to-support-claims-that-omicron-is-less-severe-in-south-africa>.

⁷⁸ SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021, Morbidity and Mortality Weekly Report (MMWR) Vol. 70, No. 50 (Dec. 17, 2021), available at <https://www.cdc.gov/mmwr/index2021.html>.

vaccinees.⁷⁹ In an earlier study of immunogenicity of the first dose of the mRNA SARS-CoV-2 vaccine among solid organ transplant recipients, the majority of participants did not mount appreciable anti-spike antibody responses.⁸⁰ In this study, only 17% produced detectable antibodies against COVID-19.⁸¹ This data suggests that even if Tanner received the COVID-19 vaccine before his kidney transplant, he could still contract COVID-19. The Hospital's position that the vaccine mandate is necessary to protect Tanner from future infection and severe illness is unsupported by the available scientific data.

D) CONTINUED INCREASE IN HARM AND QUESTIONS OF SCIENTIFIC LEGITIMACY OF FDA APPROVAL

In the two months since our prior letter, the CDC's Vaccine Adverse Event Reporting System ("VAERS") reported an additional 4,639 deaths, 30,503 hospitalizations, and 183,266 adverse events following the administration of the COVID-19 vaccines.⁸² In addition, through its recent disclosure of internal documents, Pfizer reported that as of February 28, 2021, the company knew of 158,893 reported adverse events after the administration of its COVID-19 vaccine.⁸³

VIII. CONCLUSION

The Hospital must provide Tanner and Mr. Donaldson the opportunity for a religious exemption and conduct the procurement and transplant surgeries for all the reasons stated herein. We request a response by 5 PM EST on March 30, 2022, Tanner and Mr. Donaldson reserve all rights.

The firm's contact person for this matter is Attorney Elizabeth A. Brehm⁸⁴ who is reached at ebrehm@sirillp.com and (212)-532-1091.

Sincerely,



Elizabeth A. Brehm, Esq.
Laura M. Carroll, Esq.

⁷⁹ Brian J. Boyarsky, MD, PhD, *et al*, *Antibody Response to 2-Dose SARS-CoV-2 mRNA Vaccine Series in Solid Organ Transplant Recipients* (May 5, 2021), available at <https://jamanetwork.com/journals/jama/fullarticle/2779852>.

⁸⁰ Brian J. Boyarsky, MD, PhD, *et al.*, *Immunogenicity of a Single Dose of SARS-CoV-2 Messenger RNA Vaccine in Solid Organ Transplant Recipients* (Mar. 15, 2021), available at <https://jamanetwork.com/journals/jama/fullarticle/2777685>.

⁸¹ *Id.*

⁸² <https://vaers.hhs.gov/data.html>.

⁸³ See 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021, Worldwide Safety – Pfizer (Apr. 30, 2021), available at <https://phmppt.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 own reporting “the magnitude of underreporting is unknown.”).

⁸⁴ Elizabeth A. Brehm is licensed in New York and will seek pro hac vice admission if this matter proceeds to trial.

cc: VIA FEDERAL EXPRESS ONLY

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ATTACHMENT 1

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:

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 COVID-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

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-arthritis, 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

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://phmp.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

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://aaron Siri.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-program-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

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EXHIBIT A

MP-Univ Gastroenterology-Parma

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

Patient: DONALDSON, DANE

Age/Sex/DOB:

EMRN:

OMRN:

Home:

Work:

Results

Lab Accession #

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 Asymptomatic

Stage: Final

Result 10/21/2021 8:51:00AM Raad, Dany

Annotations: patient was called

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

Test

Coronavirus 2019, PCR

SOURCE: Nasal, Nasopharyngeal

Reference Range: Not Detected

Result

DETECTED

Units

Flag Reference Range

A See Below

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