

LIBERTY COUNSEL



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REPLY TO FLORIDA

February 16, 2022

VIA EMAIL ONLY

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RE: Deactivation of Transplant Candidate Katie Shier on Heart Transplant Waiting List
and Denial of her Religious Exemption Request

Dear Ms. Morgenstern, Ms. Schilling and Dr. Runge:

Liberty Counsel is a national non-profit litigation, education, and public policy organization with an emphasis on First Amendment liberties, and a particular focus on religious freedom and the sanctity of human life. Liberty Counsel has engaged in extensive litigation in the last year regarding civil rights violations ostensibly justified by “COVID-19,” and have had great success holding both government entities and private actors accountable. *See, e.g., Harvest Rock Church, Inc. v. Newsom*, 141 S. Ct. 1289 (2021) (permanent injunction granted and \$1,350,000 in attorney’s fees awarded in *Harvest Rock Church, Inc. v. Newsom*, No. 2:20-cv-06414, C.D. Cal.,

May 17, 2021); *Harvest Rock Church, Inc. v. Newsom*, 141 S. Ct. 889 (2020); *Elim Romanian Pentecostal Church v. Pritzker*, 962 F.3d 341 (7th Cir. 2020); *Maryville Baptist Church, Inc. v. Beshear*, 957 F.3d 610 (6th Cir. 2020).

I. Background

We are writing on behalf of our client, Katie Shier, who was notified by the Transplant Team at the University of Michigan Health System (UMHS) in a letter dated June 29, 2021, that she was accepted as a Heart Transplant candidate and her name “was placed on the United Network for Organ Sharing (UNOS) national transplant waitlist as of 06/29/2021.” Following the 2021 notification, Ms. Shier has continued to make herself available for the labs, tests, and other requests made by UMHS.

Notwithstanding her 2021 acceptance into the UMHS program and placement on its active Heart Transplant Waiting List, Ms. Shier was contacted by the Michigan Medicine Transplant Center (MMTC) in a letter dated December 7, 2021 (addressed to all patients on the waiting list for transplant or being evaluated for transplant at the University of Michigan Transplant Center) which advised: “*We want to inform you of our decision to require COVID vaccination in order to be active on the waitlist at our Center, and to undergo transplant surgery.*” *Id.* This letter also included the **Michigan Medicine Transplant Center COVID-19 Vaccination Requirement for Transplant Candidates on the Waitlist** statement and Frequently Asked Questions (FAQs).

This FAQs portion specified,

Patients currently on our waiting list who are not vaccinated against COVID-19 have until February 1, 2022 to complete vaccination. As of February 1, 2022, patients who decline COVID-19 vaccination will be made inactive on the waiting list (“placed on hold”) until they complete the COVID vaccine sequence. In other words, unvaccinated individuals will not be eligible for organ offers and transplant surgery as of February 1, 2022.

The FAQs also addressed the issue of whether a transplant patient who had a prior Covid-19 infection would still be required to receive a COVID-19 vaccination providing, in part,

In general, COVID-19 infection provides lower rates of protection from future infection with COVID-19 than vaccination. To best protect our patients, we require vaccination regardless of previous COVID-19 infection.

See attached 12/07/2021 letter from MMTC.

After learning UMHS would change her status to inactive unless she agreed to receive a COVID vaccination, Ms. Shier responded by letter dated January 16, 2022, explaining why she must decline the vaccine:

This is my formal request to Michigan Medicine to claim a religious exemption from the requirement to receive a Covid-19 vaccine in order to remain active on the heart transplant waitlist.

I have been praying and researching and watching this vaccine issue unfold ever since they first came out. The more I research and pray, the more the Holy Spirit leads my heart **away** from receiving the shot. I have come to the conclusion that not only I *will not* comply, I *cannot* comply. Doing so would be against my conscience. I have a strong and well-formed conscience rooted in the doctrine and tradition of the Roman Catholic Church. According to *The Catechism of the Catholic Church*, the conscience is a judgment of reason that informs a person as to what is morally right and wrong. The conscience is built on deeply held personal beliefs. It is an essential part of human dignity, and no one may be forced to act against it.^[1] There are three major issues about accepting the vaccine that would violate my conscience.

First, I have always been pro-life and believe in the sanctity of all human life from conception to natural death. Knowing that all three brands of the Covid-19 injection available in the US used aborted fetal cells in the testing and development process,^[2] I cannot receive them in good conscience. The Catholic Church prohibits participating in the evil of abortion, however remote.

Second, I firmly believe that the body is a temple, which must be treated with respect. It would be morally wrong to intentionally do harm to my body. I have recently recovered from Covid and now have natural immunity. Getting a shot now would confer no benefit, and carry many risks. Among these risks are blood disorders and heart problems, which I already have an increased risk of. I believe this vaccine is contraindicated for my current state of health. To receive it would be to put myself at an unnecessary risk.

If I get a transplant I will be immunosuppressed. Being vaccinated will not help any more than my natural immunity if I cannot make antibodies. Early treatment with safer, proven therapies^[3] will be the best possible option if I should come down with Covid post-transplant.

Third, I see this drug as part of an amoral experiment on humanity. As the death toll rises from the experimental vaccines, it is only pushed harder. There are over one million adverse events and 20,000 deaths reported to VAERS^[4] from these vaccines in the United States. Worldwide, there have been nearly 3 million adverse reactions reported.^[5] And these are only a sliver of reality, as there has only been a 1% reporting rate historically.^[6] These drugs were rushed to market and are still being tested on the public. This and the active blocking of effective therapies in order to increase vaccine uptake is a crime against humanity^[7] and my conscience will not allow me to be a part of it.

These three issues are unacceptable. I will not be complicit in these sins against the unborn, of my own health and safety, and the human race by partaking in the Covid-19 vaccine. I therefore ask that I be exempted from the Covid-19 vaccine requirement so that my conscience remains clear and my body stays healthy as I remain active on the heart transplant waitlist. Thank you for your patience and understanding.

Sincerely,
Katie Shier

References

[1] The Catechism of the Catholic Church p. 1780-1782, 1798

[2]https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf

[3] <https://c19early.com/>

[4] Openvaers.com

[5] <http://vigiaccess.org/>

[6] <https://openvaers.com/images/r18hs017045-lazarus-final-report-20116.pdf>

[7]<https://amgreatness.com/2021/09/24/over-3000-doctors-and-scientists-sign-declaration-accusing-covid-policy-makers-of-crimes-against-humanity/>

See attached January 16, 2022, letter from Ms. Shier.

Not long after, UMHS *denied* her request for a religious exemption from the COVID-19 vaccine requirement providing, in part,

A group of Transplant Center leaders and your transplant physicians have reviewed your request for an exemption from this vaccine requirement and determined that you are not eligible for an exemption.

UMHS further advised,

As of February 1, 2022 any patient who is not fully vaccinated against COVID cannot be active on our waitlist for transplant. If you choose to seek care at another transplant center, we will help facilitate transfer of your medical records and other information to that center. While we are not able to offer you a transplant in your present unvaccinated status, we remain fully committed to your health, and will continue to work with you to provide our best care for your organ failure, short of transplantation.

See attached UMHS January 25, 2022 letter.

We write this letter to persuade UMHS to grant Ms. Shier's religious exemption request. Simply put, the COVID-19 pandemic does not justify violations of fundamental individual, economic and religious liberties. These include the rights of personal autonomy and bodily integrity, and the right to accept or reject the various COVID vaccines based on religious belief. UMHS may not condition participation in its transplantation programs on the taking a COVID vaccine.

That all three of the currently available COVID-19 vaccines are produced by, derived from, manufactured with, tested on, developed with, or otherwise connected to aborted fetal cell lines is no longer controvertible. There can be no reasonable debate regarding the accuracy of this statement. Consider the following sources:

- The North Dakota Department of Health, in its literature for those considering one of the three, currently available COVID-19 vaccines, notes the following: “[t]he non-replicating viral vector vaccine produced by Johnson & Johnson *did require the use of fetal cell cultures, specifically PER.C6, in order to produce and manufacture the vaccine.*”¹

¹ See North Dakota Health, COVID-19 Vaccines & Fetal Cell Lines (Apr. 20, 2021), available at https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19_Vaccine_Fetal_Cell_Handout.pdf (bold added).

- The Louisiana Department of Health likewise confirms that the Johnson & Johnson COVID-19 vaccine, which used PER.C6 fetal cell line, “is a retinal cell line that was *isolated from a terminated fetus in 1985.*”²
- The same is true of the Moderna and Pfizer/BioNTech mRNA vaccines. The Louisiana Department of Health’s publications confirm that aborted fetal cells lines were used in the “proof of concept” phase of the development of their COVID-19 mRNA vaccines.³
- The North Dakota Department of Health, in its handout literature on COVID-19 vaccines, notes: “[e]arly in the development of mRNA vaccine technology, *fetal cells were used for ‘proof of concept’ (to demonstrate how a cell could take up mRNA and produce the SARS- CoV-2 spike protein) or to characterize the SARS-CoV-2 spike protein.*”⁴

Based on the foregoing scientific authorities, there is irrefutable evidence that the COVID vaccines are associated with fetal tissue cell lines. *Thus, individuals who believe God is the creator of life have the right to reject them.*

A. UMHS, Alone, Removed Ms. Shier from Its Active Heart Transplant Waiting List.

During the evaluation process, UMHS provided Ms. Shier with information on two organizations which assist hospitals and patients with the organ transplantation and procurement process: (i) *the Organ Procurement and Transplantation Network (OPTN)* and (ii) *the United Network for Organ Sharing (UNOS)*. Generally, the relationship between OPTN and UNOS is described as follows:

The nation’s transplant system, the OPTN, is *managed* under federal contract by the United Network for Organ Sharing (UNOS), which is a non-profit charitable organization. The OPTN helps create and define organ sharing policies that make the best use of donated organs. ... All transplant programs and organ procurement organizations throughout the country are OPTN members and are obligated to follow the policies the OPTN creates for allocating organs.

Based upon the UMHS’s communications with Ms. Shier and the OPTN and UNOS policies, it is clear that UMHS, alone, made the decision to change Ms. Shier from active to *inactive* on the Heart Transplant Waiting List. Thus, UMHS, alone, bears responsibility for this decision to delay her access to lifesaving healthcare.

² Louisiana Department of Public Health, You Have Questions, We Have Answers: COVID-19 Vaccine FAQ (Dec. 12, 2020), available at https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf (bold added)

³ Louisiana Department of Public Health, You Have Questions, We Have Answers: COVID-19 Vaccine FAQ (Dec.12, 2020, available at https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf

⁴ See North Dakota Health, COVID-19 Vaccines & Fetal Cell Lines (Apr. 20, 2021), available at https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19_Vaccine_Fetal_Cell_Handout.pdf (bold added).

UMHS's role in this decision is confirmed on the UNOS's *Transplant Living* website which advises patients that *hospitals* (not OPTN or UNOS) determine whether organ transplant recipients have to receive a COVID vaccine:

Is a COVID-19 vaccination required in order to receive an organ transplant?

Each transplant hospital makes its own decisions about listing candidates according to the hospital best clinical judgments, including whether or not any specific vaccination is part of their eligibility criteria. If you have any questions about listing criteria at your transplant hospital, we encourage you to contact the hospital directly. (emphasis added).

See <https://www.transplantliving.org/covid/>.

By removing her from the active Heart Transplant Waiting List, UMHS made a life-or-death decision for Ms. Shier – without her consent. UMHS forced Ms. Shier to choose between her life and her religious beliefs. Such coercion by a hospital violates federal and state laws.

B. UMHS's Requirement That Ms. Shier Receive A COVID Vaccine Violates the American Society of Transplantation's Ethics Statement.

Hospitals and transplant centers have reached no consensus on whether COVID vaccines must be taken by transplant recipients. In fact, many simply test for COVID. "Transplant providers and centers serve as *gatekeepers* to transplant waiting lists." *The Limits of Refusal: An Ethical Review of Solid Organ Transplantation and Vaccine Hesitancy*, Olivia Kates et al, Am J Transplant 2021; 21:2637-2645 (12/23/20) (emphasis added).⁵ Any hospital removing/deactivating recipients or donors for not taking a COVID vaccine runs afoul of the "Ethics Statement" espoused by the American Society of Transplantation (AST) expressly acknowledges the significance of the religious beliefs of candidates/recipients, as set forth below:

AUTONOMY

*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.

Ethics Statement - Revised and Approved by the AST Board of Directors on December 6, 2012 (emphasis added).

In fact, "[t]he Department of Health and Human Services acknowledges that "it and the Organ Procurement and Transplant Network have not 'set any specific guidance on vaccination status

⁵ AJT is the official journal of the American Society of Transplantation and the American Society of Transplant Surgeons.

for organ recipients nor living organ donors.” *Id.* In sum, the federal government has not imposed a COVID mandate on organ transplant recipients, but UMHS has.

Hospitals forcing organ recipients and donors to violate sincerely held religious beliefs to receive/donate an organ vitiates the respect owed to the participants in the transplantation process. Certainly, for a hospital to impose such an outcome, the patient would be entitled to, at a minimum, ample objective data demonstrating the inevitable benefit to her. Because “[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.*” *The Limits of Refusal: An Ethical Review of Solid Organ Transplantation and Vaccine Hesitancy*, Olivia Kates et al, *Am J Transplant* 2021; 21:2637, 2641 (emphasis added). *Despite her religious objections to the COVID vaccines and the novelty of the COVID vaccines and the unforeseeable impact on Ms. Shier because of her health condition, UMHS failed to provide Ms. Shier with data showing that the anticipated outcome for unvaccinated recipients is vastly inferior to vaccinated ones.* Yet, UMHS wanted her to concede to receive the COVID vaccine with no objective proof it would benefit her. Notably, in *The Limits of Refusal*, chief among the reasons for *not* mandating COVID vaccines for organ recipients is their novelty:

For new vaccines, such as those currently in development for SARS-CoV-2, a *demonstrated track record of safety and efficacy must be established* before these vaccines will be included in ACIP [Advisory Committee on Immunization Practices] recommendations. In addition, as with other new agents, safety and efficacy should be demonstrated for patients with end-stage organ dysfunction or organ transplants, and any theoretical risk for immunostimulation must be considered prior to updating vaccine requirements specific to transplant candidates.

Id. at 2641 (emphasis added). UMHS failed to provide Ms. Shier with links to COVID data involving transplant candidates.

Given these pressing ethical and moral issues, it is not surprising that “[a]s of late April, [2021] *fewer than 7 percent of transplant programs nationwide reported inactivating patients who were unvaccinated or partially vaccinated against COVID-19*, according to research by Dr. Krista Lentine, a nephrologist at the Saint Louis University School of Medicine.” www.bangordailynews.com/2021/10/11/news/nation/organ-centers-tell-transplant-patients-to-get-a-covid-shot-or-move-down-on-waitlist (last viewed on 12/24/21) (emphasis added). Yet, UHMS has chosen a punitive road for some of its sickest patients.

C. UMHS Violated OPTN Policy by Failing to Provide Written Notification to Ms. Shier About the Impact of Her Deactivation on Her Waiting Time.

Patients who have been removed from a waiting list by a transplant center or hospital are entitled to be advised – in writing – of the reasons for the deactivation or removal. *See* OPTN Policies Section 3.4.E (“If the candidate is temporarily unsuitable for transplant, then the candidate’s transplant program may classify the candidate as inactive and the candidate will not receive any organ offers.”) The written notification of removal from the active list is to provide, at a minimum, information about what happens to the candidate’s position on the *waiting list*. Yet, Ms. Shier received *no such information*. The OPTN policies dictate that “[c]andidates accrue waiting time while inactive according to” a table provided in its policies. *See* OPTN Policies Sections 3.5 and 3.6 and

Table 3-3 (effective date 10/07/2021). Because Ms. Shier was *not* notified in writing of how her deactivation impacted her waiting time, UMHS has *violated* OPTN policy.⁶

D. COVID Patients Have Been Receiving Transplants Since *Before* The Vaccine Was Available.

In the transplantation community, it is generally understood that “[t]he goal is to treat the most medically urgent cases first.” See *Covid Spawns ‘Completely New Category’ of Organ Transplants*. <https://khn.org/news/article/covid-spawns-new-category-of-organ-transplants> (last accessed on 12/10/21). *In fact, individuals infected with the COVID virus have been receiving organ transplants since 2020, with an increasing number in 2021.* In fact, some experts believe that this will “be a completely new category of transplant patients.” *Id.* (quoting Dr. Tae Song, surgical director of the lung transplant program at the University of Chicago Medical Center.) “The rules don’t necessarily bump Covid patients to the front of the line, experts said, but many become sick enough to require immediate care.” *Id.* *It is curious that recent COVID survivors (whose need for transplants resulted from COVID infection) received donated organs, yet candidates who refuse COVID vaccines, but have no active COVID infections, cannot.* For example, “Mark Buchanan of Roopville, [Georgia] received a double-lung transplant in October, nearly three months after Covid left him hospitalized and sedated, first on a ventilator and then on the last-resort treatment known as ECMO.” *Id.* “While Emory University Hospital in Atlanta, ... advised [his wife] to withdraw treatment and allow him to die peacefully,” Buchanan eventually received a double-lung transplant at University of Florida Shands Hospital on October 28, 2020. *Id.*⁷ In a similar fashion, Al Brown, contracted COVID in May 2020 following which he was diagnosed with congestive heart failure. *Id.* After he continued to deteriorate, in October 2020, he received a heart transplant. *Id.* It is ironic that COVID patients have received transplants, while transplant candidates with natural immunity cannot.

E. Studies at Johns Hopkins University Demonstrate That Organ Transplant Recipients Benefit *Less* from COVID Vaccines.

Johns Hopkins has published two studies in the March and May issues of JAMA in 2021, acknowledging that organ transplant recipients receive *fewer* benefits from COVID vaccines than others. See <https://www.hopkinsmedicine.org/news/newsroom/news-releases/organ-transplant-recipients-remain-vulnerable-to-covid-19-even-after-second-vaccine-dose>. “[T]he number of transplant recipients in our second study whose antibody levels reached high enough levels to ward off a SARS-CoV-2 infection was still well *below* what’s typically seen in people with healthy immune systems,” says study lead author Brian Boyarsky, M.D, a surgery resident at the Johns Hopkins University School of Medicine. *Id.* (emphasis added). https://www.hopkinsmedicine.org/surgery/education/residency/general-surgery/meet_our_residents/pgy-3.html

In a recent article entitled, *Doctors ‘Push the Limit’ with Organ Transplants as Covid-19 Extends Waitlists*, <https://www.mlive.com/public-interest/2021/06/doctors-push-the-limit-with-organ-transplants-as-covid-19-extends-wait-lists.html> (updated September 29, 2021)(last visited 12/10/21),

⁶ Organs for transplant are allocated according to complicated metrics, including how long the patients have been waiting, how ill they are, how likely they are to survive with a transplant and how close they are to donor hospitals.” See *Covid Spawns ‘Completely New Category’ of Organ Transplants*. <https://khn.org/news/article/covid-spawns-new-category-of-organ-transplants> (last accessed on 12/10/21) (emphasis in original).

⁷ In fact, Shands performed the most lung transplants “of any hospital in the country” in 2021. *Id.*

Dr. Marwan Aboujioud, chair of Henry Ford Health System's Transplant Institute was interviewed about how, in the face of COVID, "[the] transplant community start[ed] pushing the limit." *Id.* The article explained Dr. Aboujioud's meaning of the use of the phrase "push the limits":

By 'pushing the limit,' he means using organs from donors who are labeled "increased risk" because of one of a number of factors, including they were old, obese, had diabetes, a history of drug use or were previously incarcerated, among other factors. Instead of simply ruling them out, Aboujioud said there's value in pairing those increased-risk donors with patients who have higher risk of dying on the wait list.

He used the example of a 70-year-old on dialysis with liver or kidney disease and a 25% chance of dying on the waiting list. If there's a 3-5% chance of an 'increased risk' organ not working, and a 1% chance of the patient developing treatable Hepatitis C, is it worth the risk to try the transplant instead of waiting for a healthier donor to come along?

'At 70 years old on dialysis, your risk of dying is really high,' he said. 'Now if I give you a kidney with increased risk, it might not last you 15 years but the statistics say you won't live 15 years ... When I say I can give you five years off dialysis, would you take it? I surely would.'

'It's an area the transplant community has battled with for some time. When I say increased risk, it's for us to manage the risk. We won't give you a bad organ but we'll match a donor with a recipient and redefine expectations.'

Id. (emphasis supplied).

Consistent with the pragmatism espoused by Dr. Aboujioud, a moral and ethical approach to organ transplantation in the COVID era would be to allow organ recipients to determine, with medical advice, the level of risk he/she is willing to take to remain on the active waitlist while remaining free from coerced, novel vaccinations. *Ms. Shier was denied the right to make an informed decision about her medical care and was denied access to the necessary information allowing her to converse intelligently with her physician about the data showing COVID vaccines may be CONTRAINDICATED for her.*

II. LEGAL ANALYSIS

A. **The Federal Emergency Use Authorization Statute Prohibits Mandating That Ms. Shier Take the Currently Available COVID-19 Vaccines.**

As noted above, UMHS did *not* expressly require that Ms. Shier receive one of the COVID vaccines to be approved and placed on the active Heart Transplant Waiting List in June 2021, despite the fact that the COVID vaccines were available. It was not until the December 7, 2021 letter that Ms. Shier was instructed to be vaccinated to remain active on the waiting list. You may not be aware, but the Emergency Use Authorization statute prohibits mandating COVID vaccines. In fact, the United States Code provides,

[S]ubject 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”). 21 U.S.C. § 360bbb-3(a)(1) (emphasis added) [hereinafter EUA Statute].

As an essential part of the explicit statutory conditions for emergency use authorization (EUA), the EUA Statute mandates that all individuals to whom the EUA product may be administered be given the option to accept or refuse administration of the product. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) (requiring that “individual to whom the product is administered are informed . . . of the option to accept or refuse administration of the product” (emphasis added)). The currently available COVID-19 vaccines (Janssen/Johnson & Johnson, Moderna, and Pfizer-BioNTech) are authorized for use under the EUA Statute, alone; they have no general approval under federal law. Thus, the administration of such vaccines *cannot be mandatory* under the plain text of the EUA Statute.

The statutorily required Fact Sheets for each of the EUA COVID-19 vaccines acknowledge that individuals *cannot be compelled* to accept or receive the vaccine. *See* Moderna, *Fact Sheet for Recipients and Caregivers* (June 24, 2021)⁸ (“*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.*” (emphasis added)); Pfizer-BioNTech, *Fact Sheet for Recipients and Caregivers* (June 25, 2021)⁹ (“*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.*” (emphasis added)); Janssen, *Fact Sheet for Recipients and Caregivers* (July 8, 2021)¹⁰ (“*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.*” (emphasis added)).

The recent FDA biologics license application (BLA) approval of the product COMIRNATY, COVID-19 Vaccine, mRNA, manufactured by BioNTech Manufacturing GmbH,¹¹ *does not change the EUA status* of the Pfizer-BioNTech COVID-19 Vaccine that has been available under EUA since December 23, 2020. According to the EUA extension letter issued by the FDA to Pfizer on August 23, 2021,¹² the Pfizer-BioNTech COVID-19 Vaccine and BioNTech’s COMIRNATY, COVID-19 Vaccine, mRNA “are legally distinct” products.¹³ Moreover, the now “approved” COMIRNATY vaccine cannot be 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).”¹⁴

B. UM’s Policies Prohibit Religious Discrimination.

(1) UM’s Nondiscrimination Policy Protects Religious Beliefs.

⁸ <https://www.fda.gov/media/144638/download>

⁹ <https://www.fda.gov/media/144414/download>

¹⁰ <https://www.fda.gov/media/146305/download>

¹¹ BLA Approval Letter for COMIRNATY, COVID-19 Vaccine, mRNA (Aug. 23, 2021), <https://www.fda.gov/media/151710/download>

¹² EUA Extension Letter for Pfizer-BioNTech COVID 19 Vaccine (Jan. 3, 2022); <https://www.fda.gov/media/150386/download>.

¹³ *See* EUA Extension Letter, *supra* note 2, at 2 n.8.

¹⁴ *See* BLA Approval Letter, *supra* note 1, at 2.

UM's *general* nondiscrimination policy forbids discrimination "and harassment on the basis of race, color, national origin, age, marital status, disability, *religion*, height, weight or veteran's status ...". <https://spg.umich.edu/policyu/201.89-1> (last accessed on 2/9/2022) (emphasis added).¹⁵ Thus, students, faculty, and staff are protected from religious discrimination.

Michigan Medicine complies with applicable federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex.

Michigan Medicine does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

<https://www.michigananswers.com/nondiscrimination-notice/> (last accessed on 2/9/2022).

(2) UM's COVID -19 Vaccination Policy Permits Exemptions to the Vaccine.

We understand that, in 2021, UM's COVID-19 Vaccination Policy requested "students, faculty, and staff on the three U-M campuses, including Michigan Medicine" to advise UM of their vaccination or exemption status no later than Aug. 30, 2021. <https://mmheadlines.org/2021/07/required-covid-19-vaccinme-fags/>. Thus, UM permits students, faculty, and staff to take the vaccine or seek an exemption. Yet, UHMS violates UM's general policies. One could ask why UM students, faculty and staff are afforded religious freedoms whereas UMHS's students, faculty, employees and patients are not?

(3) Transplantation Experts Centers Have Begun to Recognize Natural Immunity.

Recently, Drs. Michael Moritz, Patty Liu, and Christine Du, transplant doctors at Lehigh Valley Health Network, authored an article recognizing natural immunity:

To be eligible for transplant, waitlist candidates must have either completed vaccination or *have fully recovered from Covid-19. Fully recovered is defined as having anti-Covid-19 antibodies (a blood test) after recovery, be greater than 60 days from last symptoms of acute infection (fever, cough, GI symptoms, etc.) or greater than 30 days from last symptoms in a negative nasal swab test.* If you had Covid-19 infection we strongly advised to also undergo vaccination, as vaccination boosts the immune response to Covid-19. (emphasis added).

COVID-19 Vaccine: An Update From Our Transplant Doctors, Transplant Times (Summer 2021).

Ms. Shier had COVID in January 2022 and recovered. The superior benefits of natural immunity have been demonstrated in numerous studies and prominent articles. From the NIH's National Institute of Allergy and Infectious Diseases (NIAID),

"The researchers found durable immune responses in the majority of people studied."

"But, promisingly, their levels remains fairly stable over time ...".

¹⁵ "Sex, sexual orientation, gender identity, and gender expression" are protected under a separate policy. <https://spg.umich.edu/policyu/201.89-1>.

“Virus-specific B cells increased over time.”

“Levels of T cells for the virus also remained high after infection.”

<https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19> (January 26, 2021) (last accessed 1/27/2022)(referring to article published in *Science* on January 6, 2021).

From Cleveland Clinic,

A practical and useful message would be to consider symptomatic COVID-19 to be as good as having received vaccine, and that people who have had COVID-19 confirmed by a reliable laboratory test do not need the vaccine.

<https://www.news-medical.net/news/20210608/No-point-vaccinating-those-who-ve-had-COVID-19-Findings-of-Cleveland-Clinic-study.aspx> (authored by Dr. Sanchari Sinha Dutta, Ph.D.)(June 8, 2021).

(B) Michigan Law Prohibits Religious Discrimination.¹⁶

(1) Religious Discrimination Is Illegal in Michigan.

Michigan’s Elliott-Larsen Civil Rights Act (“the Elliott-Larsen Act”) prohibits discrimination by places of public accommodation, which include a healthcare facility (M.C.L.A. §37.2301). Healthcare facilities cannot discriminate in the provision of services, goods, or access on the basis of religion and other enumerated grounds. (M.C.L.A. §37.2302(a)). A claim under the Elliot-Larsen Act requires proof of four element: “(1) discrimination based on a protected characteristic (2) by a person, (3) resulting in the denial of the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations (4) of a place of public accommodation.” *See Haynes v. Neshewat*, 477 Mich. 29, 35, 729 N.W.2d 488, 492 (Mich. 2007). A plaintiff suing under the Elliott-Larsen Act may seek damages and injunctive relief and an award attorney’s fees if the court deems it appropriate. M.C.L.A. §§37.2801(1) and 37.2802.¹⁷

¹⁶ The January 13, 2022, Supreme Court ruling in the CMS mandate case, *Xavier Becerra, Sec. of Health and Human Services vs. Louisiana*, 595 US – (January 13, 2022), does not undermine Ms. Shier’s legal position. In the *CMS* case, the Court highlighted that “[t]he [HHS] rule requires providers to offer medical and religious exemptions”. *Id.* at p. 3. Thus, the *CMS* case cannot be used to posit that all healthcare workers must be vaccinated. The ruling specifically refers to religious and medical exemptions. Additionally, the HHS interim rule at issue specifically references that the religious and medical exemptions available to employees under Title VII of the Civil Rights Act, the Americans With Disabilities Act, the Pregnancy Discrimination Act, and other federal and state laws under which exemptions to the COVID-19 vaccinations could be sought.

¹⁷ M.C.L.A. §37.2302 states: “Except where prohibited by law, a person shall not (a) Deny an individual the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of a place of public accommodation because of **religion**, race, color, national origin, age, sex, or marital status.” (Emphasis added). M.C.L.A. §37.2301 defines “[p]lace of public accommodation” includes a “**health**, or transportation facility, or institution of any kind, whether licensed or not, whose goods, services, facilities, privileges, advantages, or accommodations are extended, offered, sold, or otherwise made available to the public.” (Emphasis added).

In summary, in *Haynes*, a black physician sued the hospital at which he had privileges and its chief of staff for alleged discriminatory treatment. In remanding the case to the trial court to allow the plaintiff to pursue his claim, the Michigan Supreme Court affirmed that defendant hospital was, in fact, a place of public accommodation which would be sued under the Elliott-Larsen Act. *Id.* at 37. Consistent with *Haynes*, Ms. Shier has the right to sue UMHS because her religious objections to the COVID vaccines were ignored, while UM employees, faculty, and students obtained exemptions from the COVID vaccine requirement.

(2) UMHS's Explanation for Requiring Ms. Shier to Receive the COVID Vaccine Is Pretextual.

The generalized information provided to Ms. Shier in UMHS's denial of her religious exemption advised her that UMHS "believe[s] this decision is necessary to best ensure your safety as a future transplant recipient." Under the Elliott-Larsen Act, UMHS must "articulate a legitimate, nondiscriminatory reason for its action." *Allen v. Highlands Hosp. Corp.*, 545 F.3d 387, 394 (6th Cir. 2008). However, UMHS merely advised Ms. Shier that it believes it knows what is best for her. Failing to even discuss her religious objections amounts to a "pretext for discrimination." *Ali v. Advance AM. Cash Advance Ctrs., Inc.*, 110 F. Supp. 3d 754, (E.D. Mich. 2015). Mandating that patients receive a vaccine that is directly contrary to religious beliefs when faculty, staff, and students have been exempted reveals pretext. Indeed, the UMHS's "proffered reason (1) has no basis in fact, (2) d[oes] not actually motivate the defendant's challenged conduct, or (3) [is] insufficient to warrant the challenged conduct." *Id.* (quoting *Pierson v. Quad/Graphics Printing Corp.*, 749 F.3d 530, 539 (6th Cir. 2014)). Indeed, a newly minted policy imposing such a vaccination requirement on transplant patients when no such vaccination requirement is forced on others is, *per se*, pretextual.

D. Other Hospitals Have Granted Religious Exemptions to Organ Transplant Recipients/ Donors.

Like UMHS, in 2021, Vanderbilt University Medical Center began to require COVID vaccination of transplantation candidates. When the plight of a young transplant candidate became well known in early November 2021, Vanderbilt had to *reverse* course. The following is a summary of the events leading up to Vanderbilt's decision to permit *unvaccinated* transplant candidates to undergo transplantation procedures:

Vanderbilt ... deactivated a 23-year-old woman from the transplant list, where she had been waiting since June 2018 on dialysis for a lifesaving kidney transplant, because she isn't vaccinated against COVID-19. *The woman, Codie Samuelson, now has six months to get listed for the transplant at another hospital or be removed entirely.*

See <https://www.dailywire.com/news/Vanderbilt-university-medical-center-takes-woman-off-transplant-list-for-refusing-covid-19-vaccine> (emphasis supplied).

Notably, three Vanderbilt nurses had recommended that the patient (Ms. Samuelson) *not* receive the COVID vaccines, advice which she followed. In 2021, This decision resulted in her "deactivation" by Vanderbilt. *Id.* A Vanderbilt spokesman confirmed that while "unvaccinated individuals may not be eligible for a transplant ... [he] also indicated that *an exemption process was in place for those with medical, religious, or personal objections to the vaccine.*" *Id.* (emphasis added). Since the news account about Vanderbilt's decision in 2021, we have independently

confirmed that Vanderbilt has approved several religious exemptions sought by organ candidates and donors.

In fact, one of our clients received a religious exemption from taking a COVID vaccine in October 2021, as did her brother (the donor). Just last week, Vanderbilt notified a different client that: her “*waitlist status has been reactivated;*” she would “*receive a written notice from her providers to that effect in a communication dated today;*” and her “*accumulated waitlist time at the time of her reactivation will include the time during which her waitlist status was inactive. As such, [her] accumulated waitlist time is wholly unaffected by the time she spent in inactive status.*” Thus, hospitals have begun to protect the rights of transplant candidates’ religious rights.

Fortunately, there are numerous other hospitals which *have not* deactivated patients on waiting lists for organs merely because they have not received a COVID vaccine. For example, *Jackson Health System in Miami and Memorial Healthcare System in Broward* are two Florida hospitals not requiring organ recipients to take a COVID vaccine. <https://nbcmiami.com/news/local/covid-19-vaccine-not-part-of-criteria-for-organ-transplant-at-jackson-health/2568131/>. Also, *UT Southwestern*, in Texas, *Houston Methodist and Baylor University Medical Center* have allowed transplant recipients to receive exemptions from the COVID-19 vaccines. We trust that UMHS will consider all of the relevant laws and policies and grant Ms. Shier’s request for a religious exemption to the COVID vaccine mandate.

CONCLUSION

In summary, we request written assurances from UMHS no later than Wednesday, March 2, 2022:

- (1) That UMHS replaces Ms. Shier on the active *Heart Transplant Waiting List in the position she held* when she was removed in violation of federal law;
- (2) That Ms. Shier receive written notification from UMHS that her active status and position on the *Heart Transplant Waiting List* has been restored;
- (3) That UMHS will not take any adverse action, or otherwise retaliate, against Ms. Shier based on her sincerely held religious beliefs or request for an exemption from receiving any of the COVID vaccines.

Thank you for your consideration and prompt response.

Sincerely,

Deborah A. Catalano

Deborah A. Catalano*
Senior Counsel
Liberty Counsel

*Licensed in Florida

Attachments: UMHS 12/07/21 letter to Ms. Shier
Ms. Shier’s 01/16/22 response to UMHS
UMHS 01/25/22 denial letter to Ms. Shier

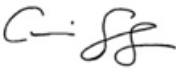

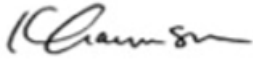
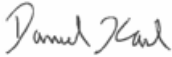

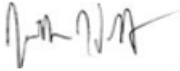
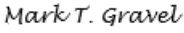


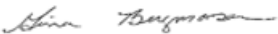



12/7/2021

Dear Katie Shier,

This letter is being sent to all patients on the waiting list for transplant at the University of Michigan Transplant Center, and patients in the process of being evaluated for transplant at our Center. We want to inform you of our decision to require COVID vaccination in order to be active on the waitlist at our Center, and to undergo transplant surgery. We have made this decision after carefully reviewing all available data about the COVID vaccine and the risk of COVID-19 infection among transplant recipients. We believe this requirement is necessary to best ensure the safety of our patients. We have witnessed many of our transplant recipients suffer severe illness and death due to COVID-19 infection. We have also vaccinated hundreds of our patients without severe side effects, and believe the vaccines are safe and remarkably effective at preventing severe illness and death due to COVID-19.

We understand this new requirement may cause concern or questions and we want to hear from you. Please read the key information about this new requirement below. It provides resources and contact information to reach out to us with your concerns. We are committed to providing all our patients the opportunity for the gift of life through transplantation, and to help each of you achieve health and wellness with your new organ. We believe this policy is an important step in increasing the safety of transplantation.

Sincerely,

 Christopher Sonnenday, MD, MHS Transplant Center Director Surgical Director, Adult Liver Program	 Silas Norman, MD Medical Co-Director, Adult Kidney Program	 Keith Aaronson, MD Medical Director, Adult Heart Program
 Daniel Kaul, MD Director, Transplant Infectious Disease	 Mona Doshi, MD Medical Co-Director, Adult Kidney Program	 Jonathan W. Haft, MD Surgical Director, Adult Heart Program
 Mark T. Gravel, RN, CPTC Interim Transplant Center Administrator	 Randall Sung, MD Surgical Director, Adult Kidney Program	 Dennis Lyu, MD Medical Director, Adult Lung Program
 Gina Bergmooser, RN, MSN, CCM, CNML Transplant Center Senior Nursing Director	 Pratima Sharma, MD, MS Medical Director, Adult Liver Program	 Jules Lin, MD Surgical Director, Adult Lung Program
	 Monica Colvin, MD Assoc. Medical Director, Adult Heart Program	

Michigan Medicine Transplant Center COVID-19 Vaccination Requirement for Transplant Candidates on the Waitlist

The COVID-19 pandemic has killed over 750,000 Americans to date. Fortunately, overwhelming evidence demonstrates that the **vaccines developed against COVID-19 are safe and effective in preventing hospitalization, critical illness, and death from COVID-19 infection**. Three vaccines have been approved under emergency use authorization in the United States, and one vaccine has full FDA approval. Over 5 billion COVID-19 doses have been given world-wide with a remarkably consistent record of safety and effectiveness.

People who receive an organ transplant need to take medications that suppress the immune system and make people more vulnerable to infection. In addition, many organ transplant recipients have other medical problems that increase their risk of severe COVID-19. For these reasons, organ transplant recipients have an increased risk of bad outcomes including death if they get COVID-19. The risk of severe illness and death due to COVID-19 among organ transplant recipients is similar to the risks due to COVID faced by elderly individuals aged 80 or older. In addition, many recipients who get COVID-19 can experience failure of the transplanted organ (for example a kidney transplant recipient having to go back on dialysis). While COVID-19 vaccines provide some protection when given after transplantation, **the vaccines appear to work much better when given before rather than after a transplant**.

To best protect our patients from serious disease, loss of the transplanted organ, and even death due to COVID-19, **the Michigan Medicine Transplant Center has determined that COVID-19 vaccination will now be required to be on the waiting list for a transplant**. You will need to have received the COVID vaccine to undergo transplant surgery. Your transplant professional at the Michigan Medicine will be happy to answer any questions you might have about COVID-19 vaccination. In addition, please see the Frequently Asked Questions (FAQ) for more information.

FAQs

I have read a lot about possible side effects of the COVID-19 vaccines, and with my medical problems, I am concerned that the vaccine will harm my health. How do we know the vaccine is safe, particularly for people with health problems?

*While side effects can occur with any medical treatment, the COVID-19 vaccines have been given to millions of Americans and billions of people worldwide and have been shown to be very safe with serious side effects occurring in a very small number of people. Many of the rumors of serious side effects of the vaccine are not true, and **other non-live vaccines have never been shown to cause long-term problems that were not seen soon after administration**. People with serious health problems are at the greatest risk for severe disease if they get COVID-19, and in general benefit from the vaccine more than healthy people. Except for known allergy to components of the vaccine (exceedingly rare) there are essentially no medical reasons not to get*

vaccinated.

Will there be any exceptions to the requirement for COVID-19 vaccinations prior to transplant?

Critically ill patients requiring urgent transplantation may not have time to get vaccinated. In those cases, exceptions to the policy will be considered. Patients with proven severe allergy to ingredients in the vaccine – a very rare situation- will also be considered for exception.

I am already listed for a transplant, will I be removed from the list if I am not vaccinated?

Patients currently on our waiting list who are not vaccinated against COVID-19 have until February 1, 2022 to complete vaccination.. As of February 1, 2022, patients who decline COVID-19 vaccination will be made inactive on the waiting list (“placed on hold”) until they complete the COVID vaccine sequence. In other words, unvaccinated individuals will not be eligible for organ offers and transplant surgery as of February 1, 2022.

When will the requirement for vaccination go into effect, and how do I provide proof of my vaccination if I did not get vaccinated at Michigan Medicine?

We will require proof of COVID-19 vaccination by February 1, 2022. If vaccines were administered in Michigan, we should be able to view that in the electronic medical record. If administered outside of Michigan, other forms of proof such as the CDC vaccine card may be required.

How many COVID-19 shots are required to be considered fully vaccinated?

For the purposes of pre-transplant vaccination, we consider full vaccination 2 doses of mRNA (Pfizer or Moderna) or one dose of Johnson and Johnson. However, most patients with serious medical conditions should strongly consider a third dose of vaccine 6 months after the second dose of an mRNA vaccine (Pfizer or Moderna), or 2 months after the Johnson and Johnson vaccine (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>).

I already had COVID-19, do I still need to get vaccinated?

Yes. In general, COVID-19 infection provides lower rates of protection from future infection with COVID-19 than vaccination. To best protect our patients, we require vaccination regardless of previous COVID-19 infection.

I have more questions about COVID-19 vaccination and the requirement for vaccination prior to being listed for transplant, how do I get more information?

Please message your care team through the Patient Portal or call the Transplant Center at 1-800-333-9013. We have a group of providers with specific training and expertise about the COVID vaccine who will listen to your concerns and provide additional information.

1/16/2022

Dear Pre-Transplant Team,

This is my formal request to Michigan Medicine to claim a religious exemption from the requirement to receive a Covid-19 vaccine in order to remain active on the heart transplant waitlist.

I have been praying and researching and watching this vaccine issue unfold ever since they first came out. The more I research and pray, the more the Holy Spirit leads my heart **away** from receiving the shot. I have come to the conclusion that not only I *will not* comply, I *can not* comply. Doing so would be against my conscience. I have a strong and well-formed conscience rooted in the doctrine and tradition of the Roman Catholic Church. According to *The Catechism of the Catholic Church*, the conscience is a judgment of reason that informs a person as to what is morally right and wrong. The conscience is built on deeply held personal beliefs. It is an essential part of human dignity, and no one may be forced to act against it. ¹ There are three major issues about accepting the vaccine that would violate my conscience.

First, I have always been pro-life and believe in the sanctity of all human life from conception to natural death. Knowing that all three brands of the Covid-19 injection available in the US used aborted fetal cells in the testing and development process ², I cannot receive them in good conscience. The Catholic Church prohibits participating in the evil of abortion, however remote.

Second, I firmly believe that the body is a temple, which must be treated with respect. It would be morally wrong to intentionally do harm to my body. I have recently recovered from Covid and now have natural immunity. Getting a shot now would confer no benefit, and carry many risks. Among these risks are blood disorders and heart problems, which I already have an increased risk of. I believe this vaccine is contraindicated for my current state of health. To receive it would be to put myself at an unnecessary risk.

If I get a transplant I will be immunosuppressed. Being vaccinated will not help any more than my natural immunity if I cannot make antibodies. Early treatment with safer, proven therapies ³ will be the best possible option if I should come down with Covid post-transplant.

Third, I see this drug as part of an amoral experiment on humanity. As the death toll rises from the experimental vaccines, it is only pushed harder. There are over one million adverse events and 20,000 deaths reported to VAERS ⁴ from these vaccines in the United States. Worldwide, there have been nearly 3 million adverse reactions reported. ⁵ And these are only a sliver of reality, as there has only been a 1% reporting rate historically. ⁶ These drugs were rushed to market and are still being tested on the public. This and the active blocking of effective therapies in order to increase vaccine uptake is a crime against humanity ⁷, and my conscience will not allow me to be a part of it.

These three issues are unacceptable. I will not be complicit in these sins against the unborn, of my own health and safety, and the human race by partaking in the Covid-19 vaccine. I therefore ask that I be exempted from the Covid-19 vaccine requirement so that my conscience remains clear and my body stays healthy as I remain active on the heart transplant waitlist. Thank you for your patience and understanding.

Sincerely,
Katie Shier

References

- [1] The Catechism of the Catholic Church p. 1780-1782, 1798
- [2]https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf
- [3] <https://c19early.com/>
- [4] Openvaers.com
- [5] <http://vigiaccess.org/>
- [6] <https://openvaers.com/images/r18hs017045-lazarus-final-report-20116.pdf>
- [7]<https://amgreatness.com/2021/09/24/over-3000-doctors-and-scientists-sign-declaration-accusing-covid-policy-makers-of-crimes-against-humanity/>



MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

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1/25/2022

Katie Shier
2700 Shimmons Rd Lot 76
Auburn Hills MI 48326-2005

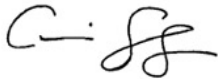
Dear Ms. Katie Shier

The University of Michigan Transplant Center requires COVID vaccination for all adult patients on our waitlist for transplant at our Center. We have made this decision after carefully reviewing all available data about the COVID vaccine and the risk of COVID-19 infection among transplant recipients.

A group of Transplant Center leaders and your transplant physicians have reviewed your request for an exemption from this vaccine requirement and determined that you are not eligible for an exemption. We understand that this decision may be frustrating to you. We believe this decision is necessary to best ensure your safety as a future transplant recipient. We have witnessed many of our transplant recipients suffer severe illness and death due to COVID-19 infection. We have also vaccinated hundreds of our patients without severe side effects, and believe the vaccines are safe and remarkably effective at preventing severe illness and death due to COVID-19.

As of February 1, 2022 any patient who is not fully vaccinated against COVID cannot be active on our waitlist for transplant. If you choose to seek care at another transplant center, we will help facilitate transfer of your medical records and other information to that center. While we are not able to offer you a transplant in your present unvaccinated status, we remain fully committed to your health, and will continue to work with you to provide our best care for your organ failure, short of transplantation.

Sincerely,



Christopher Sonnenday, MD, MHS
Transplant Center Director
Surgical Director, Adult Liver Program



Daniel Kaul, MD
Director, Transplant Infectious Disease

Mark T. Gravel
Mark T. Gravel, RN, CPTC
Interim Transplant Center Administrator



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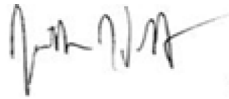
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Surgical Director, Adult Heart Program



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