1. Personal Background

Good Morning. My name is Carlos Marroquin. I am a transplant surgeon and the chief of The University of Vermont Transplant Program. I trained initially in surgical oncology but rapidly found a love for transplantation as, I believe, it is the only field in medicine that truly changes the natural history of disease and offers patients and their families the gift of life. I have learned over the years that the transplant procedure is the easy part. The real challenge is in developing a program that fosters behavioral modification in our patients to help them live a healthy life-style. This is critical as transplant candidates and recipients have multiple co-morbidities that evolve and are often associated with their end organ disease. As such, our greatest challenge is to mitigate co-morbidities that threaten the lifespan and quality of both the transplanted organ and transplant recipient.

Thank you for the opportunity to testify this morning on S. 216 - An act relating to the administration of Vermont's Medical Marijuana Registry.

2. The process for patients becoming eligible and screened for a transplant; Transplant 101

Patients undergo an enormous evaluation before being listed for a potential transplant. The evaluation process involves a multidisciplinary group of professionals. Patients are evaluated clinically by a transplant coordinator, transplant dietitian, transplant pharmacist, transplant financial coordinator, transplant social worker, transplant nephrologist and transplant surgeon. The goal of the evaluation is to be certain patients are physically, emotionally and financially ready and capable of getting to the point of benefiting from a transplant.

Patients are evaluated form head to toe. They are evaluated for many systemic diseases to include heart and lung diseases, cancer, malnutrition and frailty to site a few. Sadly, we must evaluate their ability to obtain, "pay," for medicines that may not be covered by their insurance or medicare. If they re unable to obtain these medicines, it would compromise their transplant outcome, well-being and possibly life. I recently had a patient who had to hide his car so it would not be re-possessed and have had many patient who are evicted and at risk of losing their homes. Patients who are frail are at an increased risk of poor

outcome and death. This global evaluation is critical as transplant recipients have an increased mortality in the first six to 18 months following a transplant. Once they make it past this initial phase, they have a better survival then if they remained on any of the other form of renal replacement therapy.

Patients are presented at a listing committee meeting and everyone has a vote and an opportunity to express their concerns about the candidate's ability to survive and thrive with a transplant. We make an effort to work with patients who are not good candidates initially and follow patients we list with regularity as events do occur that would make proceeding with a transplant unsafe once listed.

We are not telling people not to use marijuana, as it is a decision made with their providers, but we do need to counsel patients about the risks associated with its use. If one understood the pain and suffering that results when a transplant does not go well, they may reconsider the decision to seek a transplant. The consequences of an infection or heart disease following a surgical procedure and the numerous medical co-morbidities associated with immunosuppression such as malignancies are devastating. If one witnessed some of these events, providers would advocate for a better selection process for transplant candidates to minimize potential pain and suffering. When one considers that it is those patients who are doing really well on dialysis and sometimes off of dialysis that are referred for a transplant, some providers may even counsel against undergoing a transplant and risking the good quality of life these patients have independent of a transplant.

Fortunately, patients with end stage renal disease have other options that do not risk their life. In some patients, allowing them to remain on dialysis is the safest and most humane option. As such, it is critically important that we select patients well and "first do no harm."

Once one has seen somebody die and experienced the helplessness of being unable to save a person who is dying prematurely from infectious causes or a malignancy, it is difficult **NOT** to consider the poor outcome and associated suffering may have been avoided if we had not performed the transplant. I have participated in the care of over 1800 transplant recipients and have experienced the misfortune of witnessing the detrimental effects of the combination of an

invasive procedure and immunosuppression. A bad transplant can be devastating to a recipient's family and has the capacity to rob the recipient of many good life years on dialysis. Every candidate comes forward with the expectation a transplant is going to give them back the life they had before they developed end organ disease with no appreciation of the effect the end organ disease has had on their whole body. The only guarantee we can make is that we will change their life; unfortunately, this change can be far worse then the life they have on dialysis.

2a. Immunosuppressive Therapy

It is very important to realize that we can do a great deal of harm with an invasive procedure, like a kidney transplant and needed immunosuppressive medications. While risky, the procedure itself is not the greatest concern. Our greatest concern is the need to utilize immunosuppressive medications that, quite frankly, are toxins and a necessary evil. These medications are necessary as they prevent a given patient's immune system from rejecting the transplanted kidney. Unfortunately, nothing is "free gratis." These medications have enormous side effects. Patients on immunosuppressive medications are prone to infections, cardiovascular complications, and cancer.

3. The quality and regulatory requirements of the transplant program

The University of Vermont Medical Center's transplant program, like all programs in this country, are subject to numerous comprehensive regulatory and credentialing bodies. We must demonstrate that we our program has a robust quality process and ensures internal standards and meets quality metrics. We are expected and must demonstrate patient success after transplant, and any adverse patient experience can have a detrimental impact on our ability to continue to serve Vermonters and run a transplant program in Vermont. These standards have evolved over years and have become very stringent as the demand for transplants has rapidly out paced the supply.

On March 21, 1984, UNOS was incorporated as an independent, non-profit organization, committed to saving lives through uniting and supporting the efforts of donation and transplantation professionals. Also in 1984, the National Organ Transplant Act (NOTA) called for an Organ Procurement and Transplantation Network (OPTN) to be created and run by a private, non-profit organization under federal contract. The federal Final Rule provides a regulatory framework for the structure and operation of the OPTN.

UNOS was first awarded the national <u>OPTN</u> contract in 1986 by the <u>U.S.</u>

<u>Department of Health and Human Services</u>. UNOS continues as the only organization ever to operate the OPTN. As part of the OPTN contract, UNOS has:

- established an organ sharing system that maximizes the efficient use of deceased organs through equitable and timely allocation
- established a system to collect, store, analyze and publish data pertaining to the patient waiting list, organ matching, and transplants
- informed, consulted and guided persons and organizations concerned with human organ transplantation in order to increase the number of organs available for transplantation

This is a necessary undertaking as it is critical to preserve the public trust as it is the public that fosters transplantation through gifts of life-saving organs.

Every ten minutes, someone is added to the national transplant waiting list.

On average, 20 people die each day while waiting for a transplant.

114,830 people need a lifesaving organ transplant (total waiting list candidates). Of those, 74,908 people are active waiting list candidates.

In 2017, there were 19,850 kidney transplants performed of 95,105 candidates.

The supply cannot and does not keep up with the demand for life saving transplants.

4. The issue of substance use – including marijuana – in relation to transplant

The American Association of Pediatrics position paper on legalizing marijuana states the effects of marijuana use is still very much unknown. I am not here to debate the merits of legalization, or whether it is appropriate for patients to be referred to the medical marijuana registry. What I am here to say is, given that we all must acknowledge there is a lack of data on the impacts of long term use, legislating whether or not it should be a factor in determining a patient's suitability for a transplant is a serious mistake.

Let me be perfectly clear: the UVM Medical Center's transplant program does not have a policy regarding marijuana use as it has truly not been a salient issue. Moreover, we have gone forward with candidates after counseling them against its use and we believed they stopped using and took them at their word.

You heard from a colleague, Ms. Caroline Tassey, last week. Ms. Tassey talks about medical marijuana mitigating nausea, vomiting and appetite but there are many other medicines that could be used instead of marijuana. She mentioned using Merinol; we are not opposed to the use of Merinol as an appetite stimulant and its effect on nausea. In fact, the majority of patients go through dialysis and treatment of end stage renal disease without relying on marijuana or Merinol.

We are simply trying to do the safest thing for everyone. We are, by no means, saying that people should not smoke marijuana, but, if they choose to do so, the marginal benefit of smoking marijuana may impose an enormous risk when done in the setting of transplantation and necessary immunosuppression. We do not allow patients to smoke cigarettes because of the known risks of heart disease, peripheral vascular disease and cancer, as these pathologies are accelerated by immunosuppressive medications. The unknown consequences and interactions of marijuana with immunosuppression is the issue we are scared of, as they are unknown.

Before transplant, we talk to patients about the need for behavioral modification and the need for adherence to a healthy lifestyle. Post-transplant, we work very hard to incorporate healthy choices into patients' lives. We discuss the importance of good dietary habits to maintain healthy blood sugars, medical compliance to control blood pressure to mitigate cardiovascular risk, and counsel against using NSAIDS like Motrin and Excedrin as they can cause primary renal injury and the interactions with a class of immunosuppressive agents known as Calcineurin inhibitors can be nephrotoxic. We do not allow liver transplant recipients to drink alcohol regardless of the underlying cause of liver disease. We counsel recipients against riding motorcycles as I have had the misfortune of being asked to recover organs from someone I transplanted following a motorcycle accident. We have also recovered organs from donors who developed respiratory arrest after smoking marijuana. I would equate marijuana use in a category of agents we counsel against using as it has an unknown risk and may potentially be **more harmful** than these other measures we discourage. We do

this only to help patients maximize the benefits of going through a transplant. I do not believe it is medically prudent to equate marijuana use with a sensible, smart medical decision or practice.

5. Closing thoughts

In my opinion as a physician, an educator, and a parent, there are many areas of health and education I would hope our legislators would focus their time and energy on. One example of policies negatively affecting transplant patients involves immunosuppressive medications. Patients under 65 years of age currently lose immunosuppressive medical coverage three years after a successful transplant. I have personally seen young men and women lose a transplant because they had to decide between feeding their children, paying their rent or buying immunosuppressive medications. Securing life-long assistance with immunosuppressive medical coverage and helping us develop a program of preconditioning and nutrition for patients with end organ disease would have an enormous impact in the patients we serve.

In our effort to provide the safest possible care, the question before us is a given patient's right to transplant regardless of any other co-morbidities that may affect the outcome. This is an example of making things that matter least more important than those things that matter most; which in this case is a global medical evaluation to be sure patients undergo a safe transplant.

Finally, one other issue needs to be addressed. Donor families, who have decided to give the gift of life when their loved one ceased to live have demonstrated an incredible sense of selflessness during what must be the hardest moment in their lives deserve we be good stewards of their gifts so that their loved ones may live on in someone else safely. This gift is a privilege with which comes the responsibility of living healthily to honor the gift.

Thank you for your attention and willingness to entertain the notion that our only interest is our patient's safety and well-being.