October 1, 2020

Stevan Gonzalez, MD, Chair
OPTN Living Donor Committee
Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS)
700 North 4th Street
Richmond, VA 23218

RE: Modify Living Donor Policy to Include Living VCA Donors.[1]

Dear Dr. Gonzalez:

The National Catholic Bioethics Center, the Catholic Medical Association, the National Association of Catholic Nurses, USA, and the National Catholic Partnership on Disability, wish to respond to the call for comment concerning the *Proposal: Modify Living Donor Policy to Include Living VCA Donors*, hereafter, *Proposal.*

The National Catholic Bioethics Center is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for transplantation. The Center has 2100 members throughout the United States and provides consultations to hundreds of institutions and individuals seeking its opinion on these and other matters as they pertain to the appropriate application of Catholic moral teaching to the common good.

The Catholic Medical Association is a non-profit national organization comprised of over 2,000 members representing physicians and other health care providers in over 75 medical specialties. The Association helps to educate the medical profession and society at large about issues in medical ethics, including ethics involved in human transplantation impacting the best interest of those entrusted to their care. The Association accomplishes this through its annual conferences, local Guilds, its quarterly

[1] OPTN Living Donor Committee. *Proposal: Modify Living Donor Policy to Include Living VCA Donors*, OPTN/UNOS (August 4, 2020). Accessed: https://optn.transplant.hrsa.gov/media/3929/modify_ld_policy_include_living_vca_donors_pc.pdf.

award-winning bioethics journal, *The Linacre Quarterly*, and its other programs, publications, and web communications.

The National Association of Catholic Nurses, U.S.A. (NACN-USA) is the national professional organization for Catholic nurses in the United States representing a membership of hundreds of nurses. Nursing plays an integral role in the process of organ donation and transplantation. In that role, nurses advocate for patients, protect the vulnerable, and promote human dignity and, thus, have a great interest in this policy.

The National Catholic Partnership on Disability is a non-profit agency that affirms the dignity of every person, working collaboratively to ensure meaningful participation of people with disabilities in all aspects of the life of the Church and society. As an organization that advocates for policies respectful of all persons, especially those with disabilities, the National Catholic Partnership on Disability wishes to express its concern for any government sanctioned program that fosters the creation of a disability, even for the laudable cause of providing organs for transplant, thus, violating society's obligation to the human person.

As we have shared with you in the past, the Catholic Church encourages organ donation as providing a gift of life to those in need. In terms of both living and deceased donors, the same generosity of donors is recognized, if there is respect for true informed consent, donor and recipient safety and wellbeing, and human physical and psychosocial integrity. Therefore, we hope that our comments contained herein will be helpful in securing the public safety that we all are hoping to protect.

Overall, we wish to reiterate that, despite the fact that the U.S. Dept. of Health and Human Services had precluded the authority of OPTN/UNOS to prevent living donations of vascularized composite allografts (VCAs), there is the authority of OPTN/UNOS to restrict living donations as rigorously as possible. We urge such an approach.

As you know the Secretary of the U.S. Department of Health and Human Services expanded the definition of human organs and added VCA to the covered list of human organs for transplant under the OPTN.[2] The OPTN *Final Rule* of July 2020 expanded the definition of organ as follows:

> Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such

[2] Department of Health and Human Services, Final rule, "Organ Procurement and Transplantation Network, 42 CFR Part 121," Federal Register 78, No. 128 (July 3, 2013). https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf.

organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels.[3]

VCAs are defined to include:

Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid); Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis); Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder); Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap); Glands (including, but not limited to adrenal or thymus); Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior lateral thigh flaps, or toe transfers); Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap); Spleen.[4]

This *Proposal* will provide eligibility for all the aforementioned organs for donation by a living donor. The vastness of such a listing of living donor options is rife for potential abuses of vulnerable populations due to family pressures for donation, necessitating the most stringent informed consent policies and medical evaluation, not reflected in this current *Proposal*. Recovery hospitals are given great latitude in determining donor eligibility. Furthermore, consent policies cannot justify permitting self-mutilating acts, which will occur with the donation of many of these "organs." We recognize there is an ethical option for the donation of some organs from a living donor, such as one of paired organs for a proportionate reason. However, a number of examples of VCA donation, e.g., face, limb, and womb, even if paired, clearly create a disability for the living donor with a loss of a function. The *Proposal* elevates consent above donor wellbeing, thus, ignoring the mandate to "do no harm."

We understand there are two categories of VCA donations: "restorative" transplants, introduced in 1998 following the first hand transplant in France; and non-"restorative" VCA transplants, exemplified by womb transplants, thirty-one of which have been done in the United States since 2016, and nineteen of these were from living donors. Each of these examples, if from living-donors, represents a deliberate irreversible mutilation of the donor, and in some cases creates a permanent disability. The *Proposal* states: "Non-restorative VCA, such as uterine transplantation, repairs lost or missing non-essential function (i.e. reproductive) to an otherwise healthy individual." [*Proposal*, Background] However, at the same time it creates the same loss in the living donor. The Americans with Disabilities Act defines "disability" to include a significant

[3] 5 OPTN Final Rule, 42 CFR § 121.2 (July 20, 2020).
[4] *Proposal*, Overview of Proposal, Informed Consent.

impairment to reproductive functions[5] The very foundational principle of organ donation is that there be no harm done to the donor, which is being violated by such donations. The stated need to "improve waitlisted patient, living donor, and transplant recipient outcomes," does not justify such harm to the donor. [*Proposal*, Background] Despite the fact that death is less likely after VCA living donation, since the potential for compromise to vital organ function is lower, there is no denying that loss of a uterus or a limb would constitute a serious and irreparable impairment to the donor. In contrast, the procedure for the recipient is only life-enhancing, not life-saving; and, since in virtually all cases, the benefit of living donation to the recipient is merely a shorter waiting time for a deceased donor, this is clearly insufficient to justify such massive harm to the donor.

We note that the *Proposal* considers reproductive organs, including testes and the womb "non-essential." Granted they are not essential to life, but clearly essential to psycho-social, physical wellbeing of a man or woman, who may later regret this substantial loss. Data support that 28% of American women aged 25 to 45 years of age regret their tubal ligation.[6] A number of women seek reversals. Removal of reproductive organs is not reversable. Thus, the elective removal of such a healthy organ is mutilating to the human person and should not be allowed; and if it is to occur requires the most rigorous informed consent processes. This *Proposal* does not provide for this basic right of the donor to full informed consent. Presenting as the solitary psychosocial risk for a Genitourinary donor, "Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome," does not truly inform the donor. [*Proposal, Overview* of Proposal: Psychological Risks] Documented scientific data on outcomes of such transplants for donor and recipient need to be presented, not just the risks, e.g., the nature of reproductive processes (invitro fertilization), data on death of embryos with such processes, and miscarriages, and womb rejection, and the unknown impact on the unborn child. There needs to be a clear statement that there are no long term studies of the impact of such transplants on the mother or child, or even the donor, who similar to women who have undergone tubal ligations may experience irremediable regret and depression.

The lack of exclusion criteria for womb donation is of great concern. There is no minimum age, except one must be an adult, nor history of childbearing required. Because of the impact of infertility on the extended family, emotions run high, placing emotional burdens on fertile relatives who have healthy uteruses. Any signs of donor coercion should prevent the donation. However, the *Proposal* only excludes living donation (for any organ) if there is a "high suspicion" of donor coercion. [Medical Evaluation Requirements for Living Donors, #14.4 E] The *Proposal* contains the same criteria for illegal financial exchange between donor and recipient: "high suspicion." The potential for organ trafficking is significant. Furthermore, living donation of any organ

[5] 42 U.S.c. § 12102 (1)(A) & (2)(B).
[6] Karina M. Shreffler, Ph.D., Arthur L. Greil, Ph.D., Julia McQuillan, Ph.D., and Kami L. Gallus, Ph.D., "Reasons for tubal sterilisation, regret and depressive symptoms," *Jo. Reproductive Infant Psychology* 34(3): 304–313.

represents a loss, regardless of the functional impact, which the *Proposal* allows. There needs to be a clear prohibition against any donation that decreases physiologic function. Also, the exclusion criterion of having an "uncontrolled diagnosable psychiatric conditions requiring treatment before donation" is inadequate. This would allow a person who has a history of engaging in self-mutilating behaviors, but is temporarily medicated, to donate a limb, a face, or any other organ, when confronted with a family member's need.

The *Proposal* defines "genitourinary organs," as "including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder." [*Proposal,* Overview of Proposal, Informed Consent] As proposed, VCA living donation will allow the creation of an irreversible mutilation of healthy function to the living donor. It also represents potential hazards to recipients and their future offspring from certain provisions it contains. In fact, the unborn child is treated as an expendable commodity due to such risks. Engendering is accomplished by in vitro fertilization, a process that usually results in numerous offspring, with only some deemed suitable for implantation, with the expectation that some implanted may not gestate. This is an unacceptable violation of human dignity. In terms of informed consent these hazards remain completely unaddressed by the *Proposal.* Thus, while we do not support such donations, to minimize the risk to the living donors, the recipients, society, and the children engendered through such donations, more substantial evidenced-based data needs to be presented related to these aforementioned concerns.

The National Catholic Bioethics Center, the Catholic Medical Association, the National Association of Catholic Nurses, USA, and the National Catholic Partnership on Disability are agencies of the largest provider of non-governmental, non-profit health care, education, and social services: The Catholic Church. The Catholic Church encourages organ donation as providing a gift of life to those in need. In terms of both living and deceased donors, the same generosity of donors is recognized, if there is respect for true informed consent, donor and recipient safety and wellbeing, and human physical and psychosocial integrity. Many of those with whom we collaborate are providers or consumers of transplant services. They advocate for true informed consent and the principle to "do no harm." Allowing living donation of vascularized composite allographs compromises these principles. While there could be envisioned cases in which such a donation serves a proportionate good for the recipient without harming the donor, those specific cases and criteria need to be clearly identified, with very specific exclusion criteria. Informed consent requires that risks to the donor in terms of human functioning, as well as psychosocial wellbeing need to be clearly and specifically identified, and if human functioning or wellbeing is compromised by the donation, the donation should not be allowed. The risks to the donor and recipient, and in the case of the donated womb the risks to the unborn child cannot be allowed, and, if unfortunately they are, must be presented to the donor. Most VCA donations are not essential to human life. Thus, if the donation creates a disability or diminished functioning for the

donor it is not proportional. This is clearly the case with womb donations. Informed consent cannot justify a procedure that is mutilating to the human person.

Sincerely yours,

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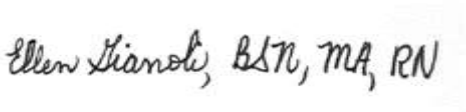

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