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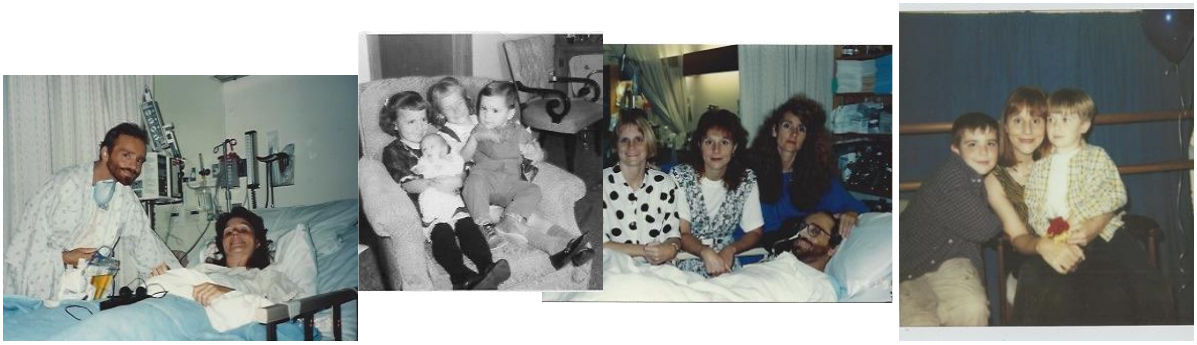
Diabetes, Kidney Failure, Living Organ Donation, and Medicare: Observations of a Fallen Angel

I am a living kidney donor (1991), mother, chronic kidney disease (CKD) patient, former member of the Living Donor Committee & Living Donor Data Task Force for the United Network for Organ Sharing & Organ Procurement Transplant Network (2007-2009), and a licensed clinical social worker proudly guided by the National Association of Social Workers Code of Ethics, which emphasizes advocacy for the public good, specifically for disadvantaged and exploited groups.

This is written in memoriam of my three siblings, each a patient pioneer impacted by genetic kidney disease and organ transplantation: Robin (1956-2007), 19 years-old when she became a living-related kidney donor; Jim (1961-2004), a dialysis patient for three decades and the recipient of three disastrous kidney transplants, and Pam (1963-2013), a dialysis patient for seven years and recipient of one deceased donor transplant that served her for twenty-seven years until her death involving medical error.



Also, I wish to acknowledge the taxpaying public who fund treatment for kidney failure, whether dialysis or transplantation and regardless of patient age, through the Medicare End Stage Renal Disease Program (1973).

Although only 1% of Medicare patients have kidney failure, their treatment accounts for 7% of the Medicare budget. The Medicare budget is 12% of the entire federal budget.

Diabetes is the leading cause of kidney failure in the United States and is responsible for the ever-lengthening national kidney transplant waitlist, the need for donor organs, and increasing public expenditures for dialysis and transplantation. In the U.S., every 24 hours 170 people with diabetes begin treatment for kidney failure or, stated another way, 62,000 people a year.

Living organ donors are often referred to as “heroes” and “life-saving angels.” Unfortunately, their altruism does not make them immune from surgical and medical complications. And often -- if they ask hard questions, tell the truth, expect the truth to be told, have medical complications, or lodge complaints -- they are quickly shape-shifted into ‘fallen angels’ who are viewed as confused, self-centered, ignorant, a nuisance, or worse. Once saints but now sinners, their questions and concerns are too often misconstrued as lacking compassion for the suffering of organ failure patients. Such is my lived experience.

My intention here is to benefit everyone who is impacted by diabetes and kidney disease by advocating for (a) the inclusion of diabetes and living organ donation as qualifying conditions for Medicare regardless of patient age, (b) donor education, medical evaluation, informed consent, and follow-up that takes place independently of those who benefit commercially, professionally, and personally from living organ donation, and (c) the mitigation of self-enriching commercial interests that adversely impact those with renal failure and pillage the Medicare budget.

The National Organ Transplantation Act (1984)

Historically, federal regulation over organ transplantation has been weak, intentionally made so through the 1984 National Organ Transplantation Act (NOTA) enacted during the Reagan Presidency, known for dislike of ‘big government’ and the embrace of free market principles.

NOTA authorizes the Organ Procurement and Transplantation Network (OPTN) to be managed in the private sector. At the time of its enactment legal scholars described its impact:

> The most striking aspect of the legal environment surrounding the procurement and transplantation of human organs is the virtual absence of federal regulation…and reflects an apparent congressional consensus to defer significant federal regulation of organ procurement and transplantation…It is likely that the government’s role in

these matters will continue to be limited to creating conducive environments for private sector initiatives." (The Journal of Legal Medicine (1986))

The Journal of Corporation Law (1994) reported, "Congress …created the OPTN as a private monopoly, funded by taxpayer dollars and user fees, and required that it be operated only by organizations working exclusively in transplant."

For nearly forty-years the OPTN has been managed by the United Network for Organ Sharing (UNOS). In a moment of alarming candor, UNOS former and long-time director, Walter Graham, explained to a 2009 DHHS Blood Safety and Advisory committee, "… patient safety … is not specified in the contract … and so it hasn't been a major part of our charter." (See "U.S. Public Health Service Advisory Committee on Blood Safety and Availability, Thirty-Seventh Meeting." Thursday, Nov.19, 2009.)

In July (2023) President Biden signed into law the *Securing the U.S. Organ Procurement and Transplantation Network Act,* which allows HRSA to break-up the management of the OPTN by issuing contracts to multiple organizations based upon the expertise needed to manage its various functions, instead of contracting only with one organization.

Going forward, will HRSA emphasize patient safety, ethics, and public trust as top priorities for new organ transplantation contractors? Or, will it follow the dangerous free market path created by NOTA, one that led to a blazing wildfire within the Medicare budget? Is it possible for HRSA to resist pressure from commercial interests and its 'mite makes right' self-enriching orientation?

And, will CMS protect the public or pander to industry?

In March (2024), HRSA extended the contract with UNOS for nine months in order to preserve continuity of care for organ transplant patients.

The following represent my observations, thoughts, and recommendations structured into nine sections and an addendum:

1. **Diabetic kidney failure, legislation to cap the cost of insulin, *The Living Donor Protection Act (2023)* and the *Charles Norwood Inslee Act (2007)***
2. **The exploitation of human beings who become living organ donors in the United States**
3. **Living kidney donors need and deserve publicly funded long-term medical care**
4. **Vulnerable kidney failure patients and questionable kidney transplantation reform proposals**
5. **The cost of kidney transplantation**
6. ***Executive Order to Advance American Kidney Health* (2019)**
7. **The selection of contractors of the Organ Procurement and Transplantation Network**
8. **Is U.S. citizenship or residency a requirement for placement on the wait list and in the assignment of organs?**
9. **Conclusion**
10. **Addendum**

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1. Diabetic kidney failure, legislation to cap the cost of insulin, *The Living Donor Protection Act (2023)* and *The Charles Norwood Inslee Act (2007)*

"Important realities are often the ones that are hardest to see and talk about."
David Foster Wallace

On the surface, legislation intended to decrease the prevalence of insulin rationing by capping the cost of insulin, such as the ***Inflation Reduction Act (2023)*** and the ***Insulin for All Act of (2023),*** and legislation pertaining to living organ donation (such as the ***Charles Norwood Inslee Act (2007***) and the ***Living Donor Protection Act of 2023)***, as presented to the public, appear to be unrelated. But, in fact, diabetes is the single greatest cause of kidney failure in the U.S., driving the "organ shortage" and the need for transplantable kidneys.

In 2016, diabetes led to 47% of the new cases of kidney failure, the majority (90 to 95%) from Type 2 diabetes, a disease rooted in socially determined

factors that include inadequate health insurance, toxic stress, food insecurity, air pollution, and other causes of environmental pollution.

Each year 1.4 million Americans receive a new diabetes diagnosis. An estimated 37% of adults with diabetes also have diabetic nephropathy, a type of kidney disease. Consequently, a rise in the incidence of diabetic kidney failure is to be expected.

Thirty-four million U.S. adults have diabetes (approximately 10.5% of the population), and its prevalence is predicted to increase to 54.9 million by 2030, with medical and societal costs increasing 53% to $622 billion annually.

Racial and ethnic-minorities are disproportionately afflicted with diabetes beginning in young adulthood. Applying the standard diabetes screening age of 35 for White adults, the equivalent age threshold for diabetes screening should be 21 for Black adults, 23 for Asian adults, and 25 for Hispanic adults.

The lives of a multitude of young people are impacted by diabetes, with too many ending up on the national kidney transplant wait list when their poorly controlled diabetes leads to kidney failure. Almost 60 percent come from minority communities – African, Hispanic, Asian/Pacific Islander, and Native Americans.

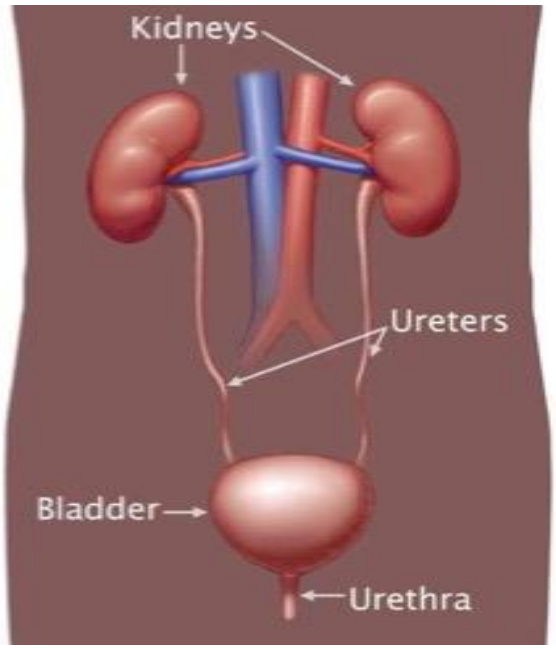
Black Americans are diagnosed with kidney failure 3.2 times more frequently than White and they have higher rates of diabetic-related amputation and blindness. Asian Americans, Native Americans and Hispanics American are 1.5 times more likely to have kidney failure than White Americans.

While a cap on the cost of insulin is long overdue and welcomed by patients with diabetes, it will not advance the use of state-of-the art continuous glucose monitors that mimic the work of a pancreas, remediate food insecurity and/or food deserts, eliminate environmental contamination, eliminate variations in commercial health insurance plans that impact how and when patients access medical care, achieve consistent and equitable medical care for diabetic patients, alleviate the stigma associated with Medicaid, or help patients who are uninsured (individuals mostly between the ages of 18 -64 years of age). Nearly 20 million lower-income

people have lost their federal health insurance since the provision that kept states from disenrolling people from Medicaid during COVID-19 ended in March 2023.

***The Living Donor Protection Act* (2023**) is meant to remove barriers to living donation by extending FMLA for living donor surgery and prohibiting exclusion from disability and life insurance policies on the basis of having been a living organ donor.

Yet, as put before Congress, this bill fails to provide information about the many health risks associated with living organ donation. If passed, this omission will imply that Congress has determined medical risks for living organ donors are minimal when, in fact, long-term risks have been a concern for decades.



Kidneys are two, bean-shaped organs. They hold approximately 25% of the body's blood at all times. Each has more than 1 million nephrons comprised of glomeruli and tubules. Glomeruli serve to filter toxins while tubules discharge waste and extra fluid in the form of urine. Kidneys make hormones to help regulate electrolytes. Kidneys make erythropoietin, which stimulates bone marrow to make red blood cells. Kidneys also regulate blood pressure.

Myth: The donor's remaining kidney grows; new cell growth occurs.

Facts: All donors permanently lose 25 to 40% of kidney function at donation.

Cells of the remaining kidney swell to compensate for the extra blood flow. Greater blood flow increases pressure on the remaining kidney, widens blood vessels, and increases pressure on plasma (the liquid part of blood). An increase in Single Nephron Glomerular Filtration Rate (SNGFR) is called ***"hyper-filtration"***; increased plasma pressure is called ***"glomerular hypertension."*** Both hyper-filtration & glomerular hypertension are symptoms of illness – as in diabetes or kidney disease -- and can lead to kidney damage.

The following is a small sampling of published research related to living kidney donors between 1997 and 2016:

- Partial ablation of renal mass initiates a cycle of progressive glomerular injury in the remnant. This process is associated with glomerular hypertrophy, hyperfiltration and systemic hypertension. (Brenner BM, Mackenzie HS. Nephron mass as a risk factor for progression of renal disease. Brenner BM, Mackenzie HS. Kidney Int Suppl. 1997 Dec;63:S124-7. PMID: 9407439. https://pubmed.ncbi.nlm.nih.gov/20150537/

- Prior to donation 2% of donors had a DSM-IV psychiatric diagnosis. Perioperatively 15% had an Axis I disorder at 12 months. (*Surman O, Fukunishi, I, Allen, T, Hertl, M (2005) Live Organ Donation: Social Context, Clinical Encounter, and the Psychology of Communication. Psychosomatics 46:1, January- February.*

- Fifteen percent of kidney donors are on antidepressants three months after donation. *(McCune, 2006 Live Organ Donor Registry and Donor Insurance Policy.)*

- Twenty-eight percent of kidney donors experienced complications that included medical, psychiatric, and financial problems. *"The Impact of Living-Related Kidney Transplantation on the Donor's Life." Transplantation,* 81(9):1268-1273, May 15, 2006.

- Reduced GFR alone in previous kidney donors is associated with increased insulin resistance. "Susceptibility to Insulin Resistance after Kidney Donation: A Pilot Observational Studyz' , American J of Nephrology, 2009;30(4):371-6.doi: 10.1159/000232577. Epub 2009 Jul 31.

- Forty living kidney donors were followed over 5 years. The most important change was 1,25-dihydroxycholecalciferol deficiency in 57.5% patients after nephrectomy… A decreased serum IGF-1 concentration was observed in 17.5% of donors…however, decreases in both serum IGF-1 and 1,25(OH)2D3 concentrations were observed in 12.5% of donors. (Bieniasza, et al, Serum Concentration of Vitamin D and Parathyroid Hormone After Living Kidney Donation, Transplantation Proceedings, Volume 41, Issue 8, Pages 3067-3068 October 2009.

- Ron Herrik, the first living kidney donor (1954) became diabetic, had a stroke in 2002, developed kidney failure by 2007 and was a dialysis patient when he died in 2010 at age 79. He refused offers of organs from his wife and nephew. (Living Donors are People Too, January 28, 2013)
- The procedure-related complication rate for living donors is approximately 8 to 22%, and is similar to the rate in patients undergoing appendectomy and cholecystectomy. *(Comorbidity Burden and Perioperative Complications for Living Kidney Donors in the United States. CJASN, 2013)*

- Kidney donors have 11.4 times increased risk of ESRD, 1.4 times increased risk of cardiovascular death, 1.3 times increased risk of death from any cause (*Charnow, Jody. "Kidney Donors Face Higher ESRD Risk." Renal and Urology News, July 11, 2014)*

- Kidney donors experience an immediate reduction in GFR … unilateral nephrectomy in healthy subjects is associated with structural and functional cardiovascular abnormalities within 1 year. (Moody, W. Ferro, C, Cardiovascular Effects of Unilateral Nephrectomy in Living Kidney Donors, Hypertension, 2016; 67)

The central mission of the OPTN was to ensure an equitable system for the distribution of transplantable **deceased** donor organs. But, in 2001, living organ donation transplantation surpassed deceased donor surgeries for the first time in history.

This led to increased interest in living organ donation. In 2006, UNOS/OPTN requested increased authority in matters of living organ donation and DHHS granted this request, despite the industry's historic neglect and abandonment of living donors.

A new standing committee of UNOS/OPTN was formed, The Living Donor Committee, charged with the mission to create policies about living organ donation for the first time, over half-a-century (52-years) after the first living donor transplant had taken place in 1954 and twenty years after UNOS was awarded its first contract to manage the OPTN.

I served on this committee and can attest that policy proposals meant to enhance the care of living organ donors met with substantial resistance from transplant centers.

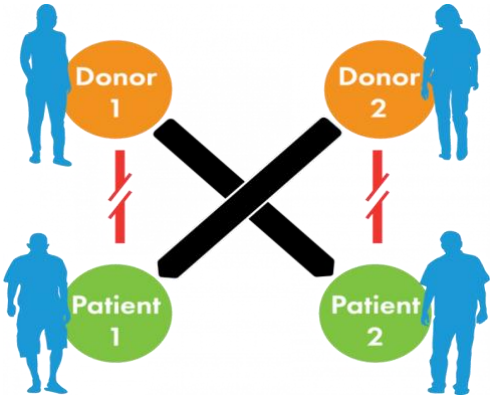
Transplant surgeons do not have the motivation or expertise to develop policy to promote the best interest of living organ donors in the short or long-term. Their motivation is simply to increase the number of organs available for transplantation.

While on the Living Donor Committee, I was asked to travel from Portsmouth, NH to Richmond, VA to have my picture taken at the Deceased Donor Memorial, as if my experiences and needs as a living organ donor are akin to those who became donors at death. I declined. Only one surgeon on "the call" expressed embarrassment when this request was made by the staff liaison to the Living Donor Committee.

Jane, a living organ donor

Donor Memorial at UNOS headquarters in Richmond, Virginia. ***A place of remembrance and tribute to those who have donated an organ at death.***

The Charles Norwood Inslee Act (2007) removed legal obstacles to living organ donation by establishing that paired donation (organ swaps between incompatible pairs) is not in violation of NOTA, which prohibits valuable consideration in organ acquisition.



It also requires Congress to be updated annually regarding the progress made towards understanding the long-term effects of living organ donation. Tellingly, the language is carefully crafted to avoid an obligation to report what is understood, instead emphasizing "progress towards" increasing "understanding":

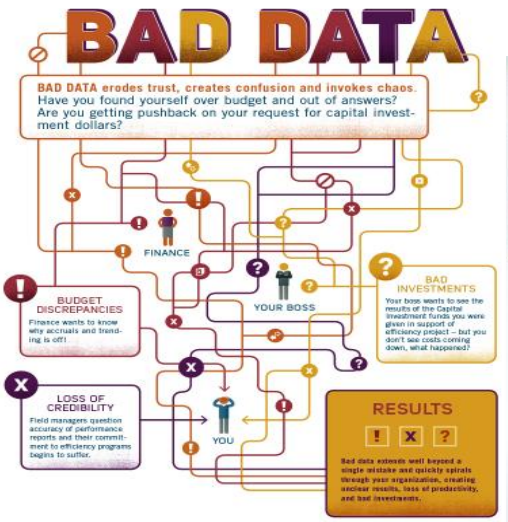
> Not later than 1 year after the date of enactment … and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation. (The Charles Norwood Inslee Bill, 2007)

It is imperative that Congress be informed of what is currently understood about the long-term risk of living kidney donation before passing legislation to remove barriers to it, and Congress should not consider allowing payments to living people for their body parts to incentivize living donation. Instead, Congress should act to protect living donors from exploitation and should immediately establish a program for their long-term medical care through Medicare.

2. The exploitation of human beings who become living organ donors in the United States

"Without data you're just another person with an opinion."
Edwards Deming, Statistician

Evidence of the exploitation of human beings for their vital organs is abundant; (1) three decades of UNOS/OPTN useless living donor data collection and inadequate informed consent, (2) a high percentage of donors lost to follow-up, (3) uninformed long-term medical care for donors due to useless data, (4) inconsistent, unreliable, and inequitable medical care for donors who are dependent upon their organ recipient's health insurance in the short-term and their own insurance long-term, and (5) the incessant and misleading marketing of living organ donation as minimal risk for the donor.




Susan Crichton, 62, of Rochester, recently donated a kidney to Paul Elkins, 54, of Portsmouth, and both are doing fine.

Beyond generous

Woman donates kidney for 'no-brainer' transplant

CHRONIC KIDNEY DISEASE FACTS

BY CHARLES MCMAHON

Although he was diagnosed with kidney disease nearly five years ago, Elkins said

Twenty years ago the *American Journal of Transplantation* (AJT) published, "Data sources and its structure" (2003) which describes the prevalence of irregular and inaccurate data reported by transplant centers tasked with collecting the Social Security Numbers (SSN) of living donors since 1994. The authors found:

> …more than half of SSN matches to the Social Security Death Master File (SSDMF)" were "highly improbable (based on review of names and implausible relationships among birth dates, death dates, and dates of organ recovery), indicating that there is probably significant inaccuracy in these identifiers even when they are available.

Inexplicably, centers had also been given credit for data submission simply by marking the donor as "lost to follow-up." For example, in 2000, one-year follow-up forms were filed for 90% of donors, with 42% of these living donors coded as "lost to follow-up." The authors wrote, "This means that even when complying with requirements for data submission, centers do not know what has happened to these patients."

In 2008, UNOS/OPTN created a Living Donor Data Task Force to analyze its donor data and to identify alternative sources of collection, finding UNOS/OPTN national data "useless for the purposes of research and informed consent." (Consensus Report of the Living Donor Data Task Force, 2009.)

But informed consent is an essential pre-condition for the freedom to make the gift of organ donation. Without data -- or at least an understanding of its absence and potential effects -- there can be no informed consent or "free" act of giving.

The Nuremberg Code

- Voluntary informed consent
- Likelihood of some good resulting
- Based on prior research (animal models)
- Avoidance of physical or psychological injury or harm
- Benefits should outweigh risks
- Proper experience of researcher
- Right to withdraw consent
- Research must stop if harm is resulting

(no specific mention of children, unconscious people, or others who may not be competent to give consent)

The New York Times

The Opinion Pages

OP-ED CONTRIBUTOR

Why Selling Kidneys Should Be Legal

By ALEXANDER BERGER

Published: December 5, 2011

"I have no concerns because my remaining kidney will grow"

If transplant centers had submitted complete and accurate data beginning in 1994, knowledge of the long-term effects of living organ donation would have been guided by ten-years of data in 2004, twenty-years in 2014, and thirty-years in 2024.

Yet, unbelievably, in 2014, the UNOS/OPTN Membership and Professional Standards Committee felt it necessary to create a policy proposal to clarify data submission requirements, explaining:

> Some members… noted that the policy does not state the data must be accurate. Staff often have to explain to these members that the need for accurate data is implied with the policy. In addition, staff oftenj have to make multiple requests for documentation before members submit information.

From a 2018 opinion piece published in AJT, we learn, "UNOS… longitudinal data are…frequently incomplete, as evidenced by the challenges of even meeting new UNOS thresholds for living donor follow-up…"

In April (2023), the UNOS/OPTN Living Donor Committee was told that through "external sources" approximately 1,776 verified living donor deaths have been identified since 1994 and to expect monthly updates of verified deaths. These 1,776 verified deaths occurred, on average, only 18.5 years after donation. These data were not disaggregated by gender, race, and ethnicity, or organ type donated (e.g., kidneys, liver, or lung), nor was an analysis provided of the most common cause(s) of death. It is unclear if the vital status of donors whose SSNs, birthdays, and death dates were not accurately reported to the OPTN can be determined.

Incomplete and inaccurate living donor data is a signature failure of UNOS/OPTN, which has (a) robbed many trusting and generous people of a robust informed consent, (b) tarnished the reputation of transplant medicine, (c) put many prior living donors at risk, and (d) hampered the efforts of community-based medical professionals tasked with caring for living donors after their hospital discharge.

3. Living kidney donors need and deserve publicly funded medical care

> **"Never awake me when you have good news to announce, because with good news nothing presses; but when you have bad news, arouse me immediately, for then there is not an instant to be lost."** *Napolean Bonaparte*

In November 2022, Mjoen & Jenssen published a book chapter, "Long-term Outcomes for Living Kidney Donors," in Living Kidney Donation. Their review of research on living kidney donors found significant flaws due to selection bias, inappropriate control groups, and inadequate length of time of follow-up, and concluded their analysis with this paragraph:

> Current evidence indicates that kidney donors face increased long-term risk of end-stage kidney disease and probably also earlier cardiovascular mortality and all-cause mortality. With present knowledge there are now strong incentives to select older donors over their younger counterparts. With evidence-based knowledge it is crucial to give potential donors adequate information regarding all risks related to kidney donation to enable them to make an informed decision whether they should donate a kidney.

Posts by prior living kidney donors on social media sites and information published in peer-reviewed research on living donors reveal complications from surgery, such as death, hemorrhage, lymphatic injury, infection, hernias, chronic pain, and testicular injury, as well as post-surgery complications, such as weight gain, declining kidney function, hypertension, pre-eclampsia, adrenal insufficiency, insulin resistance, elevated homocysteine, family problems, depression, and suicidality.

Nearly one in seven donors experience an adverse event related to their donation, often occurring many years after the OPTN two-year requirement for donor data reporting. Donors can experience renal failure without intermediate events; complications immediately after donation are not predictive of long-term outcomes.

African American living kidney donors have increased risk. A study conducted by the Scientific Registry of Transplant Recipients found a 17% higher risk for systolic hypertension among Black donors compared with White donors. Others have reported that Black and Hispanic donors have about a 50% increased relative risk of developing hypertension post donation.

Twice the Love, New York Daily News, March 15, 2015

"Down the line, what if he needed a kidney?" "But the doctors explained if he does, he'd be at the top of the list, and that he could function forever with one."

Other researchers have found that African American donors develop kidney failure more quickly and more often than white donors. At the time of the study (2010), African Americans constituted 12% of living kidney donors but represented 43% of prior donors in need of a kidney transplant.

In the same study, suicide was 1.5 times more frequent among living donors than in the general population. (However, cause of death was not reported for 56% of the data, so is likely higher.)

When pregnant, kidney donors have double the rate of preeclampsia as non-donors.

Nature Communications (2023), reported research aimed to advance the use of optical coherence tomography (OCT) to measure future kidney function decline by utilizing data on living kidney donors due to their decreased renal mass and function. Note that the donors are not listed in the category of "healthy volunteers";

> We enrolled patients with pre-dialysis CKD, patients with kidney failure undergoing kidney transplantation, living kidney donors, and healthy volunteers into a series of prospective cross-sectional and longitudinal studies … kidney donors rapidly lose eGFR when they undergo a nephrectomy. ..Twenty-two kidney donors underwent OCT scanning prior to kidney donation and then at fixed intervals post-donation…Following this acute loss of functional kidney mass, the choroid thickened in the first week post-kidney donation before showing a tendency to thinning over the longer term ….healthy individuals who donate a kidney and lose kidney function, gradually develop choroidal thinning and, in those with CKD, a thinner retina and choroid seen on a single point-in-time OCT scan independently associate with future eGFR decline.

Those in pursuit of transplantable organs have Intolerable conflicts-of-interest in living organ donors. Consequently, the public is confused by conflicting information about the safety of living kidney donation and conflicting recommendations.

For example, the ***Executive Order Advancing American Kidney Health (2019***) includes incentivizing living kidney donation, yet the Center for Organ Recovery and Education provides the following cautionary statement:

> Usually, a donor's life returns to normal within four to six weeks after the surgery, but because of all the effects on donors, particularly unknown long-term effects, the federal government does not actively encourage any individual to make a living donation…

Meanwhile, The American Society of Transplantation (AST) has initiated the Living Donor Circle of Excellence, meant to recognize employers who create policies to support lost wages when an employee undergoes organ donation surgery; this raises new concerns about workforce safety, undue influence, and amplifies existing inequities in the experience of living organ donors.

Traditionally there is a disproportionate number of women who become living organ donors. For potential donors considering pregnancy, The AST Living Donor Toolkit offers this confusing recommendation:

> "Donating a kidney may make you more likely to have problems during pregnancy than women who haven't donated a kidney… The most common problem is preeclampsia, which is a type of high blood pressure during pregnancy. 12% of donors had preeclampsia in a later pregnancy in one study…It may be best to donate before becoming pregnant, but it is possible to donate after having a baby." (Italics mine.)

Many donors have reported that their transplant centers deny responsibility for short-term complications, and this often occurs in a context where recipients' health insurance cannot be depended upon.

Financially incentivizing individuals to become living organ donors by paying them for their organs, or removing barriers to living organ donation as with ***The Living Donor Protection Act,*** may help to get more donors to the operating room but will do nothing to enhance their informed consent, prevent long-term complications, or provide medical care in the short or long-term.

It is well past time for a unified program of health insurance for living kidney donors to establish:

a) a national registry;
b) a mechanism to fund their medical care; and,
c) a source of high quality, complete, prospective health data to significantly improve informed consent and guide donors' medical care short and long-term.

The protection of living organ donors also requires the establishment of an independent program for their evaluation, selection, informed consent, and medical follow-up to mitigate the conflict-of-interest inherent among those whose mission includes acquiring organs for transplantation or facilitating matching donors and recipients.

4. Vulnerable kidney failure patients and questionable kidney transplantation reform proposals

"Marketing is no longer about the stuff you make, but about the stories you tell."
Seth Godin

In 2022, recommendations to "reform" the U.S. "kidney transplant eco-system" were presented by the Senior Vice President, Head of Transplant Medicine and Emerging Capabilities, Fresenius Medical Care North American, in a response to a Request for Information from the Centers for Medicare and Medicaid (CMS) and in an opinion piece published in *MEDPAGE TODAY*.

Far from positive for patients, the proposed changes include 1) expanding the wait list by adding medically vulnerable candidates, 2) expanding the use of kidneys of inferior quality, 3) financially incentivizing high-risk kidney transplants (and the care of those with socially determined vulnerability), 4) making transplant center performance outcomes a matter of "confidential peer review" and "no longer… a component of public data reporting," 5) and, adopting mere 90-day and one-year patient and graft survival as part of the "composite metric…approved by the OPTN/UNOS Board of Directors."

If instituted, these reforms will not only increase the number of high-risk kidney transplants, but will also shield outcome data necessary for informed consent and the selection of a transplant center.

Ironically, withholding outcome data from the public effectively eliminates patient/consumer choice, making the recommended reforms inconsistent with free market values, the very values that underpin the 1984 ***National Organ Transplantation Act*** (NOTA.)

Additionally, the recommended reforms would set a very low-bar for the definition of a "successful transplant." Mere one-year graft success and patient survival are described as a "sky high" standard, revealing a disregard for the actual clinical benefit to individual patients. As explained to CMS:

> If transplant centers expand access to the waiting list and are more aggressive in organ acceptance behaviors, *transplant outcomes can be expected to worsen* but outcomes for the general population with ESRD (*kidney failure*) can be expected to improve. *(Italics mine*)

But, in *MEDPAGE TODAY*, with a monthly readership approaching two million, the "reforms" are pitched as a reflection of patient preference:

> Quality outcomes for transplant programs should be pegged to the patient outcome that really matters: Receiving a successful kidney transplant in the shortest period of time. A recent survey of patients with kidney disease regarding tradeoffs between being transplanted earlier and waiting for a "better organ" confirm that a wide majority of patient prioritize being transplanted sooner.

Yet, it's unclear is these surveyed patients understand that both one-and five-year kidney transplant patient survival rates have recently decreased and that kidney transplantation confers comorbidities – including cancer, infection, cardiovascular disease, depression, PTSD, and diabetes.

Death with a functioning graft (DWF), or stated another way, death with a working transplanted organ, is a major cause of graft loss after renal transplantation.

A 2009 analysis found that 4563 people died each day in the U.S. with working transplants -- 12.2 per day based on 1, 3, and 5-year statistics. For the 50-64 age cohort the risk of dying after transplantation is 9% at 1 year, 20% at 3 years and 35% at 5 years. (Weiss, M. "When Altruism Isn't Enough: The Case for Compensating Kidney Donors, March 2009, unpublished paper.)

Additionally, patients are usually not aware that a poorly performing or failed transplant is emotionally and physically debilitating and multiple organ transplants heighten immune sensitivity, making future organ matching increasingly difficult.

Finally, patient acceptance criteria, waiting time, and mortality vary significantly by program, thus underscoring the necessity for transparency about program factors that may influence patient program selection.

Currently, a third of wait listed patients are ineligible for an organ transplant because they are too sick or not sick enough. A 2008 analysis of the wait list by the Washington Post found:

> The large number of inactive patients on the list may signal that potential recipients are languishing…too long…could mislead potential donors, recipients and policymakers about the magnitude of the need…Others noted that the size of the list is often used in lobbying efforts to seek funding or to change organ procurement policies. (*The Washington Post*, "A Third of Patients on Transplant List Are Not Eligible," March 22, 2008)

The *British Medical Journal* (2020) reported that kidney transplant recipients with Type 2 diabetes are more likely to receive a high-risk deceased donor organs and experience worse outcomes as first-time kidney transplant recipients.

Is Fresenius Medical Care North America recommending that organs once considered unsuitable for transplantation are now suitable for extremely vulnerable patients, perhaps those with diabetes, jeopardizing their already fragile existences and unrealistically raising their expectations for an improved quality of life, all to be funded by CMS?

"When someone shows you who they are, believe them the first time." *Maya Angelou*

Fresenius Medical Care is a private, for-profit German organization that began as a for-profit dialysis provider but has pivoted away from its dialysis operations towards transplantation.

In 2019, it settled charges of civil bribery to obtain business in 13 countries by paying $231 million to the United States Department of Justice Department and the U.S. Securities and Exchange Commission.

In 2021, the CEO of Fresenius Kabe, the pharma division of Fresenius, stepped down due to numerous undisclosed challenges, including the need to settle allegations from the US Department of Justice that the company had hidden records from the F.D.A. ahead of an inspection in 2013, which cost Fresenius $50 million.

For decades, Fresenius has also been criticized for poor patient care as a dialysis provider; it was fined $486 million in 2000 for fraudulently billing Medicare for performing unnecessary surgeries on vulnerable dialysis patients.

Is increasing the number of risky organ transplant surgeries for medically fragile patients (many with diabetes), utilizing marginal organs, and shielding outcome data from the public another self-enrichment scheme? Is CMS and Congress poised to allow this?

It's noteworthy that in 2018 President Trump proposed eliminating Medicare rules that penalize transplant centers if too many of their patients die, similar to the 2022 recommendations made by Fresenius Medical Care of North America to CMS.

5. **The cost of kidney transplantation**

> **"All know the influence of interest on the mind of man, and how unconsciously his judgement is warped by that influence."** *Thomas Jefferson*

Government policy is flying in the dark without accurate cost data. Meeting notes of The Advisory Committee on Transplantation (2019) state the annual cost to care for a transplant patient are $30,101 compared to $81,485 for a dialysis patient. Yet, according to the Milliman Research Report, the cost associated with the first six-months following a kidney transplant are $422,000.

Is the cost of a kidney transplant $422,000 and then $30,101 annually?

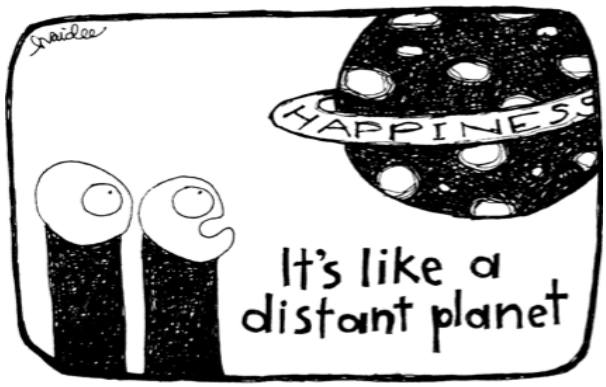
Additionally, when a kidney transplant patient re-experiences kidney failure due to organ rejection, returns to dialysis, needs a second or third transplant, develops cancer, cardiovascular disease, or becomes ill with an infection, additional treatment costs are incurred.

When prior living kidney donors need dialysis or an organ transplant, treatment costs are also incurred. Should these costs be included in the total cost of their recipient's transplant and subsequent treatment? Currently, are costs for caring for these unfortunate donors separated from the cost of care for their recipients?

> **"Ooh, ahh. That's how it always starts. But then later, there's running and screaming."**
> *Malcolm in the film, The Lost World: Jurassic Park*

eGenesis is a gene-editing and genome-engineering company whose mission includes increasing the number of organs available for transplantation through gene edited pig organs.
The growth of eGenesis began in 2017, starting with 38 million dollars for Series A financing. In 2019 Fresenius Medical Care led the efforts to raise 100 million in funds to support eGenesis "on the front lines of end-stage and chronic kidney disease." The proceeds were to help advance eGenesis' kidney xenotransplant into clinical testing and accelerate its development of insulin-producing pancreatic islet cells, livers, hearts, and lungs from other animals. Another $ 125 million was raised for Series C financing in 2021 by multiple investors, including Fresenius Medical Care Ventures "to be used to bring the company's lead programs in kidney and islet cell transplant into human proof-of-concept studies..."

Are high-risk kidney transplant patients to become human subjects for xenotransplantation product development trials, funded by CMS? If so, what should their informed consent entail?



In March (2024) the first organ transplant surgery using a genetically modified pig kidney took place at Massachusetts General Hospital. The patient, Mr. Rick Slayman, is a 62-year old, Black man with diabetes and a failed prior kidney transplant.

Anthropologists documenting the early, experimental days of transplantation, when the "courage to fail" became part of the industry's culture, describe reactions of some early transplant patients, "Often, after entering the experience of great hope, patients for whom transplantation has been a series of setbacks clearly articulate their feelings of betrayal: 'No one ever told me it could be like this." (Leaving the Field, *The Hastings Center Report* Vol. 22, No. 5 (Sep. - Oct., 1992), pp. 9-15)

Historically, projects related to xenotransplantation have been abandoned due to their potential to transmit zoonotic viruses to humans. However coincidental, as eGenesis and Revivicor advanced the field of xenotransplantation, a pandemic emerged.

As reported in STAT (April 8, 2024):

> eGenesis pigs' genomes have been edited to remove the risk that they can pass on porcine viruses to humans, a concern that froze the xenotransplant field for most of the 2000s … But regulators in the U.S. remain worried about the possibility, particularly after a genetically modified pig heart made by a different company, Revivicor, was discovered to have been unknowingly infected with a pig virus …

Consequently, as HRSA prepares to move the OPTN into a new era, what will be the influence of those who have financially invested in xenotransplantation? Who is in charge of overseeing this industry?

Disclosure of investments in product development related to organ transplantation should become an essential requirement of those bidding for contracts to modernize the Organ Procurement Transplant Network and when making policy recommendations to the public and governmental agencies. Why? Because within market-based systems 'duties to shareholders' trump 'duties to stakeholders' -- both patients and taxpayers. Stated another way, moral and financial hazards in

dialysis and transplantation exist due to enhanced conditions for the private sector, with patient and public absorption of their failures.

6. Executive Order to Advance American Kidney Health (2019)

"The kidneys have a very special place in the heart."
President Donald J. Trump (Independent, July 11, 2019)

Obviously, kidneys are not "in the heart." However, as previously noted, they do have a very special place in the Medicare budget through the Medicare End Stage Renal Disease Program.

The Executive Order appropriately promotes home dialysis, but emphasizes transplantation and living kidney donation, with seeming disregard for patient safety.
And although it highlights the importance of prevention of kidney disease, it does not mention diabetes, the leading cause of kidney failure.

The Indian Health Service achieved a 54% reduction in kidney failure by treating kidney disease in the context of diabetes care at established community clinics. Oddly, the Executive Order would establish treatment for diabetes within the context of treatment for kidney disease.

Did the former President opt for an executive order in order to avoid congressional inquiry and a national discussion about the epidemic of diabetes, fearing an onslaught of health-equity, ethical, and programmatic concerns?

7. The selection of new contractors of the Organ Procurement and Transplantation Network

"If we do not change our direction, we are likely to end up where we are headed." *Lao Tzu*

The monopolistic reign of UNOS/OPTN may be ending, but will it move this industry in a positive direction given its cultural legacy of disregard for patient safety, commercialism, corruption, and, multi-organizational development occurring within and alongside it?

The governing boards of those bidding for a role in the organ transplant network merit careful attention, as it's likely there will be overlapping board members among the various organizations, leading to a quasi-monopoly.

For example, a former President of the OPTN and past chair of its Living Donor Committee, is also active as a member of the American Society of Transplant Surgeons and currently serves on the board of the National Kidney Registry and the Board of Donate Life America (both aiming to register living organ donors).

8. Is U.S. citizenship and residency a requirement for placement on the wait list and in assignment of organs?

"Even the most rational approach to ethics is defenseless if there isn't the will to do what is right." *Alexander Solzhenitsyn*

The Declaration of Istanbul (2008) represents the consensus of the international transplant community that each nation develop self-sufficiency in organ procurement and allocation in order to curtail international travel for transplantation, which has led to an international crisis in organ trafficking that involves organs unethically acquired through the exploitation of the imprisoned, poor, or undocumented.

Specifically, the Declaration states, "…treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country's ability to provide transplant services for its own population."

Yet, excerpts from the UNOS/OPTN's, "Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens)" (2011) establish that U.S. citizenship and residency are not a requirement or consideration for placement on the U.S. wait list or in the allocation of organs (see addendum). This is so despite the fact that the U.S. does not demonstrate self-sufficiency in organ procurement as evidenced by the ever-lengthening organ transplant wait list.

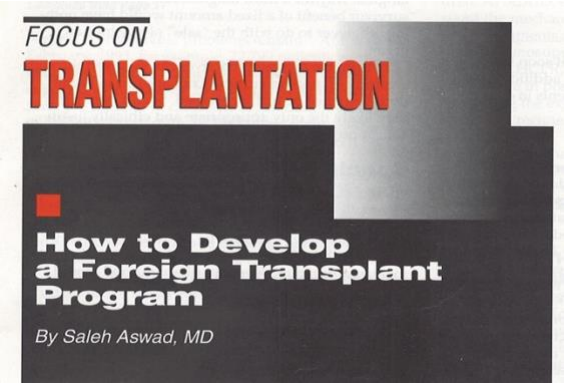
This policy proposal also reveals a shocking disregard for U.S. citizens and residents waiting for an organ despite the privileged role UNOS/OPTN has played as the administrator of the OPTN per the National Organ Transplantation Act (1984). Instead, what is evident is loyalty with international patients and collaborators.

Organ transplantation for foreign nationals in the United States has a long, although somewhat neglected, history. A 1986 report of the Office of the Inspector General found:

> "In the District of Columbia, foreign nationals received about 22 percent of the 181 cadaver kidney transplant performed in 1985. This is especially striking because (1) the incidence of dialysis in the District is more than twice the national average and (2) a major military hospital, which is located in the District and which performs transplants for military personnel and dependents from all over the world, is no longer accepting additions to its transplant waiting list. The shortage of kidneys is cited as a basis for this policy."

The Inspector General's Office also determined that 300 transplants of foreign nationals took place in the United States in 1985. If 275 of them had been for Medicare beneficiaries, 17 million dollars would have been saved over five years. (Department of Health and Human Services, Office of Inspector General, The Access of Foreign Nationals to U.S. Cadaver Organs, Richard P. Kusserow, Inspector General, 1986.)

Below represents the transplant community's interest in foreign nationals in need of an organ transplant.



Contemporary Dialysis & Nephrology • August 1993

Between 2000 and 2004, four Japanese "gangsters" involved with the FBI as informants were able to receive liver transplants at a time when hundreds of patients in the same region died waiting for a new liver.

Securing the Organ Procurement and Transplant Network must involve Congress establishing a system to formally document the following:

- The number of foreign nationals wait-listed for an organ transplant in the U.S. and the criteria justifying their inclusion.
- The countries from which they come.
- The U.S. transplant centers that list them.
- The length of time foreign nationals wait before receiving an organ transplant compared to the wait time of U.S. citizens or residents.
- The financial terms related to the care of foreign national transplant patients.
- Medicare reimbursement for organ acquisition fees related to the care of a foreign national patient.
- The benefit to U.S. transplant centers caring for foreign national patients as compared to caring for U.S. patients.
- The circumstances, if any, that allow foreign national patients to become eligible for Medicare.
- The percentage of foreign national transplant patients lost to follow-up, including those who travel to the United States to become a living organ donor.

Note the characteristics of systems engaged in organ trafficking:

1. Lack of attention to documentation and record keeping, falsified or incomplete data, lost records, and obscured identity of victims.
2. Collaboration between organized crime and political, military, and government agencies.
3. Explicit or implicit endorsement by governments (often destination countries in need of organs).
4. Collaboration with established medical institutions.

5. International networks for the transportation of individuals and/or organs.
6. Involvement of medical professionals whose expertise and complicity are essential.
7. Lack of provision for the medical care of donors and no recourse for those with complications.
8. Deceptive enticement strategies directed at living organ donors.
9. Unusual rapid organ assignment and advancement on a nation's waitlist.
10. Lack of accountability, lax, or corrupt oversight.

The United States Department of Justice should include organ removal in its definition of human trafficking to further protect individuals from the crime of organ trafficking.

9. Conclusion

> **"The only thing that really matters now is whether man can climb up to a higher moral level, to a higher plane of consciousness, in order to be equal to the superhuman powers which the fallen angels have played into his hands. But he can make no progress until he becomes very much better acquainted with his own nature."** *Carl Jung*

The Advisory Committee on Organ Transplantation (ACOT) is to advise the Secretary of Health and Human Services; however, it appears to have stopped meeting in 2020. Perhaps the Public Health Emergency (PHE) prevented ACOT in-person meetings, but virtual meetings were scheduled until they were abruptly announced as "TBD."

To further the goal of securing the Organ Procurement and Transplant Network, the following matters require the immediate attention of ACOT:

1. The impact of diabetes on the Medicare End Stage Renal Disease Program and the "organ shortage"
2. The state of U.S. living donors and long-term data about them per the ***Charles Norwood Inslee Act(2007).***
3. The cost and outcomes of kidney transplantation
4. The status of clinical trials in xenotransplantation
5. Discussion of regulatory features of xenotransplantation, will it fall to the Department of Transplantation and HRSA, industry, the organ transplantation community, or CMS?
6. President Trump's Executive Order on Advancing American Kidney Health (2019)
7. Policy related to the care of foreign nationals at U.S. transplant centers, whether for wait listing, organ assignment, or as a living kidney donor.

Many thanks to artist and patient advocate, Haidee Soule Merritt, who graciously allowed the use of her amazing cartoons.

Addendum

Excerpts from, The UNOS/OPTN Ad Hoc International Relations Committee and Ethics Committee "Proposed Revisions of Policy 6.0 (Transplantation of Non-Resident Aliens) (2011).

"The proposed policy modifications address the "best use" program and the strategic plan goal of the Health and Human Services and OPTN, respectively, and the following constructs in the OPTN: Allocation of organs" (p.1)

"The Committees also recognizes the guidance provided by the Health Resources and Services Administration of HRSA" (p.4)

"The OPTN final rule also does not provide authority for basing such policy upon United States citizenship or residency status. The regulations specify the use of "objective and measurable medical criteria" and **provide no basis for the use of citizenship or residency status in the allocation of organs.**" (42 CFR 121.9 (b) (p.4.)

"The National Organ Transplant ACT (NOTA) requires that OPTN match organs and individuals in accordance with "established medical criteria" and establish "medical criteria for allocating organs." (42 USC 274(b)(2). The plain language of the statute requires that the **OPTN base organ allocation policies on medical criteria and does not provide any authority for basing such policy upon United States citizenship or residency status."** (p.4)

"The proposal clarifies the data collected about the **citizenship and residency of donors and recipients**." (p.1)

"The proposal changes the current definitions by defining residency simply as whether the patient considers the U.S. as the primary place of residence whereas currently the definition in 6.1 is based on legal immigration status." (p.3.)

"Given that neither the OPTN nor its members are likely to have immigration expertise, the Committees also felt that collecting data on legal immigration status should not be part of the wait listing process." (p.3)

"The committee recognizes that self-reporting this type of data has limitations but given that other demographic information is similarly self-reported, the Committees felt this appropriate." (p.3)

"It is important to note that the proposal does not seek to limit or exclude the ability for non-U.S. citizens/non-residents from being listed for transplant." (p.3.), and "The proposed policy changes make no attempt to use citizenship or residency status in the allocation of organs."

"The OPTN will collect these fields along with the country of permanent residence for all non-resident candidates **and living donors**, pending programming." (p.4)

"The AHIRC and the Ethics Committee recognize the dramatic changes that have taken place in the relative availability of transplant services to patients outside of the U.S. since Policy 6 was first adopted," (p.2)

"This proposal is designed to clarify the data collected about the citizenship and residency of transplant recipients in order to evaluate the extent to which patients are traveling to the U.S. for purposes of transplantation…The goal of the data collection, audit, and reporting under this policy proposal is to evaluate and to make publicly transparent the extent of travel to the U.S. for transplant and whether such practices are contributing to transplant tourism by undermining the ability of the U.S. to provide transplantation services for its own people." (p.2)

"The Committees felt that the audit provision was widely misunderstood as a 5% cap on a transplant center's ability to list and transplant non-U.S. citizens...the Committees concluded that providing a percentage about which audit may be triggered was arbitrary and that transparency required that the ability to audit any time a patient who is a non U.S. Citizen/Non-resident is listed and transplanted." (p.4.)

"The proposal also amends the audit trigger policy, allowing the Ad Hoc International Relations Committee to review the circumstances of any transplant on non-U.S. residents/non-U.S. citizens and make a public report." (p. 1)

"To promote an additional goal of enhanced transparency, the proposed policy will allow the Ad Hoc International Relations Committee to review the circumstances of any deceased donor transplant of non-U.S. residents/non-U.S.citizens and to make available to the public a report regarding the extent to which international patients are traveling to the U.S. for deceased donor transplant." (p.2)

"…the Ad Hoc International Relations Committee to review and**, at its discretion**, audit all member transplant center activities pertaining to transplantation of non-U.S. resident/non-U.S. citizen." (p.13)

"**Members may negotiate the terms and conditions** under which any individual candidate would be treated with the understanding that each candidate must be referred on a case-by-case and physician-to-physician." (p .13)

"Members may import deceased donor organs from foreign sources, and in doing so, must adhere to the related policies" Page 14 "Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency or its national government. (p.15)

"State the number of deceased donor organs anticipated for import. And, "Describe the benefits to the foreign and domestic participants." (p.14)

“Delete the policy on ethical practices (6.4.4) because defining the characteristics that constitute ethical practice are subjective and may not be applied consistently within and between professional era, and delete language about the import of an organ for valuable consideration, because to do so is a criminal offense that is under the purview of another federal agency**.”** (p.6.)

The deleted language is**: ~~“6.4.4 Ethical Practices. No member will engage in practices, which might discredit the transplant community. Organs accepted for importation must be from deceased donors and must have been voluntarily donated. Organs imported from living donors and organs for which compensation has been made or promised are not acceptable for exchange.”~~ (p.19)**