Opt Out of the Black Market for Organ Transplantation

Sander S. Florman, M.D.

The system for organ transplantation in the United States is in drastic need of reform, and not just because the disparity between supply and demand continues to increase at an alarming rate. More than 105,000 men, women, and children await organ transplantation in the United States, and nearly 20 of them die every day without the opportunity for transplant.

More alarming is that a black market for human organs exists – right here and worldwide. While buying and selling organs is illegal in almost all countries, enforcement of the laws has been weak. In some nations, prisoners are executed and organs are procured for transplantation. In others, impoverished, illiterate, and desperate people sell their organs for a pittance.

MOUNT SINAI SCHOOL OF MEDICINE

The 1984 National Organ Transplant Act established a framework for a national system of transplantation and prohibited the buying and selling of human organs. Before being approved for transplant, living donor candidates must undergo rigorous medical evaluations, and their case must be reviewed by a multidisciplinary committee. Despite the law and the intense approval process, a black market for live-donor organs operates in the United States, undermining the very basis and sanctity of the doctor-patient relationship: honesty and trust. Since donor compensation is illegal, patients must lie to the very medical teams responsible for their lives by denying any financial arrangements.

It is easy to pass judgment on the practice of commercializing body parts, but it is not hard to understand what is behind it. For example, the harsh reality is that of the 83,000 people in the United States awaiting kidney transplantation, most will never get one. For those who do, the benefits are well established. Compared with dialysis patients, transplant recipients enjoy a longer lifespan and a dramatically improved quality of life.

To save and improve many more lives, we need to increase our nation's supply of organs for transplant. Changing our deceased-donor system is one way to do so. Many countries have adopted a "presumed consent" model that considers all citizens to be donors upon death unless they specifically register to "opt out" of donation. In contrast, our current "informed consent" system encourages donation through awareness, primarily by inviting people to "opt in" when they sign their driver's license.

The majority of Americans do support donation, but despite aggressive national appeals, actual donation rates remain low. Whether presumed consent would eliminate a black market is debatable. That such a system increases organ availability has been overwhelmingly proven true: in nations with presumed consent, fewer than 5 percent of citizens register to opt out.

It is clear that our efforts to increase organ availability have not worked. We need innovative ideas and strong legislation that will allow us to save lives, protect donors, and end illegal black market practices. Choosing an "opt out" system for organ donation is a much better solution than allowing ourselves to opt into the black market.

Sander S. Florman, M.D., is Director of the Recanati/Miller Transplantation Institute at The Mount Sinai Medical Center.

One in a series of commentaries by prominent Mount Sinai physicians and scientists.

From: Tom D. Mone [mailto:tdmone@onelegacy.org]
Sent: Wednesday, February 03, 2010 1:17 AM
To: letters@nytimes.com
Subject: Mt Sinai Physician "Op-Ed" Response

Dear Times Op-Ed Page Editor:

I am writing in response to the "Op-Ed" advertisement placed in the February 2, 2010 paper by the Mount Sinai physician. While it is reasonable to assume that the Times does not hold its advertisers to journalistic standards of research and evidence prior to accepting their pieces, the acceptance and Op-Ed page placement of a purchased commentary by Mount Sinai Hospital presents information to readers that assumes they understand that the piece is a paid advertisement and that it is not held to currently accepted standards of journalism, as this piece was clearly not held.

While the doctor was clever enough to engender a sympathetic audience by implying that the piece's intent was to object to a black market for organs for transplant, his recommendation of Presumed Consent was sorely missing the intellectual rigor, factual analysis, and evidentiary support for its adoption as a means to improve the organ donation system in the U.S.

A simple perusal of the2008 international organ donation statistics published in the IRODAT study within the journal "Organs, Tissues, and Cells" shows that no Presumed Consent country in the world exceeds U.S. donation rates, as measured by the international standard of Donors per Million population, with the U.S. at 26 DPM and the closest Presumed Consent country being Belgium at 20 and Austria at 25. Now, some who have read only statutes and not evidence of actual practice might point to Spain, its Presumed Consent laws, and its 34 DPM, but Spain has not relied on the legal right to assume consent and has approached each and every family, shared the benefits of donation, and asked for consent exactly as we do in the US. Thus, even on the surface, Presumed Consent is a poor second choice and has never been proven to perform better than we do in the U.S.

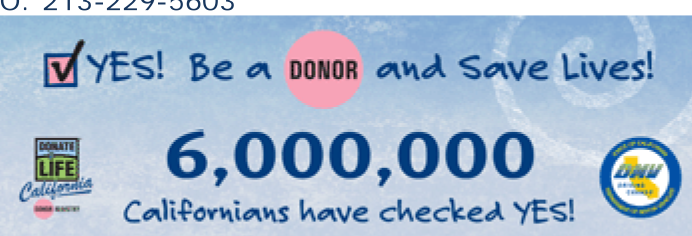
Even more significantly, when international donation rates are adjusted to reflect varying death rates of each country, the U.S performance dramatically exceeds any Presumed Consent country. When adjusted to match California's death rate of 6.2/thousand, Spain's 9.9, Belgium's 10.4, and Austria's 9.9 deaths per thousand reduce their Donors Per Million to 21.3, 14.8, and 12.5 respectively…with the U.S adjusted rate 19.6 and California's, where we are challenged with a highly diverse and substantially immigrant population without years of exposure donation and transplantation, a best practice high of 22.4 DPM.

This American, Spanish, and Californian "Best Practice" performance is the result of coordinated efforts to help hospitals, doctors, caregivers, families, and individuals to recognize the value of donation not just to a recipient whose life is saved but also to the family who creates hope and good from a tragedy and to the healthcare team who helps salvage lives from an unavoidable death. The result of this collaborative effort in the U.S. has been an increase in the organ donation rate from 50% in 2000 to 70% today…a remarkable social change achievement …and if the significance of 70% of people voluntarily agreeing and actually donating (as occurred in 2009 is lost on anyone, perhaps comparing it to blood donation, in which only 7% of those who can actually do donate, helps frame organ donation as a truly remarkable success story in this country.

Of course, a 70% donation rate, as remarkable as it is, is not enough. In fact even if everyone who could donate did so (a 100% consent rate) there would not be enough organs

to save and improve the lives of all who need them because only slightly more than 11,000 people die each year in a way that allows donation. Thus, while we in the organ donation and healthcare communities must continue our constant efforts to raise the donation rate to unprecedented levels, we must also dramatically increase efforts to increase living donation for kidney recipients who make up 80% or the waitlist. His means increasing insurance coverage, time off of work, tax incentives to offset lost wages, and dramatic expansion of paired chain kidney donation exchanges across all of our transplant programs. And we need the self-styled pundits who leap to the mirage of Presumed Consent to drop that mantle and join us in the hard work rather than advocating the discard of the most effective organ donation system in the world.

Thomas Mone
CEO and EVP
OneLegacy
221 S Figueroa Street
Suite 500
C: 424-298-0229
O: 213-229-5603



From: Richard Darling, DDS [mailto:rdarling1@dc.rr.com]
Sent: Saturday, February 06, 2010 7:24 PM
To: 'NY Times--Executive Editor (executive-editor@nytimes.com)'; 'NY Times (letters@nytimes.com)'
Subject: Rebuttal to Tom Mone regarding Mt Sinai MD's support of PC [OPO total revenue & individual compensation figures included]

Cc: Tom Mone; Sander S. Florman, MD, Director: Recanati/Miller Transplant Institute; Financial incentives & PC OD Template Letter Co-signers; Bryan Stewart (bstewart@onelegacy.org); Greg Melkonian, DVM, MD (gregory.melkonian@childrens.harvard.edu);

Dear Times Op-Ed Page Editor:

I am writing in response to my friend, Tom Mone's, submission (included below) that was critical of the "Op-Ed" ad in favor of "Presumed Consent" (PC) placed in the February 2, 2010 paper. That article was written by abdominal organ transplant surgeon Sander Florman, MD, who is Director of the Recanati/Miller Transplantation Institute at Mount Sinai Medical Center.

Tom's descriptions of this eminent surgeon as being "clever" and a "self-styled pundit" are inappropriate, disrespectful and not helpful to this debate. Tom, as Chief Executive Officer (CEO) of our nation's largest organ procurement organization (OPO), OneLegacy, must keep the discourse on a higher level than name calling.

Tom is disdainful of PC, but the truth is that he does not know if PC would work well in the USA, nor do I. That is why many eminent physicians and organ donor advocates have proposed a trial project—pick one of the 50 states and let us try it to see if organ recoveries increase. The American and British Medical Associations and over twenty other countries support the use of PC; perhaps it will work for us.

I suspect that Tom's reply would be that PC may turn people off in that state and the number of organ recoveries would go down.

Let's see, how is "altruism" alone working for us now? Tom states that our system is "truly a remarkable success story in this country," and as a transplant recipient it saved my life, but he does not state or emphasize that altruism is failing miserably *in meeting the overall demand.*

For a half-decade from 2004 to 2008 the USA averaged 14,402 donors per year (living and deceased). In 2009 the number dropped a full 15 percent to 12,186, a startling reduction of 2,215.

Keep in mind, the number of people on the waiting list dying today is 105,652 and that number continues its inexorable rise due to the shortage of organs. Shockingly, another 350,000 patients are on kidney dialysis but not even listed for transplant yet.

The shortage is so acute that donated kidneys are now being rationed by the organization that oversees all organ transplants, UNOS (United Network of Organ Sharing). Such rationing rejects older patients who need a kidney to survive—allowing them to die—in order to save younger patients.

Indeed, we have an organ-donor crisis in this country. There is a death every hour—EVERY HOUR—of a person on the waiting list, or one who was taken off the list because he/she got too sick to be transplanted.

If an administrator was in charge of an emergency room after a catastrophic event and one person was dying every hour, would the administrator say, "What we are doing is

remarkably successful."? Of course not, because if such a statement was uttered, he/she'd be fired.

I applaud Tom for his suggestion that we need to incentivize living organ donation but he omitted important factors and did not offer "financial" incentives which many believe would eliminate the kidney waiting list within a few years and lower the waiting list for all other organs.

In addition, Tom offers nothing to the family of a deceased donor. Why should a living donor benefit but not the family of a deceased donor? This omission is especially perplexing when Tom's non-profit OPO, OneLegacy, and almost all other OPO's derive financial gain from the organs and tissues they take from the deceased and redistribute to the recipient's physician and to others.

In fact, OneLegacy's 2007 IRS Form 990 reports "Program service & organ/tissue revenue of $54,593,691 and total compensation as follows: $487,225 for Tom as Chief Executive Officer, $243,493 for the Chief Financial Officer and in excess of $170,000 for six others.

It should also be noted that companies such as Genzyme Biosurgery, LifeCell, LifeNet Health and others are expected to have gross revenue of over $200 million dollars by 2012. Their business includes providing, for transplant, human cells, tissues and organs that originated from deceased donors.

Is it ethical to allow businesses and OPO's to profit/receive financial gain from patients' cells, tissues and organs, while those same living donors and deceased donor families are not allowed compensation or even a burial expense benefit, having to settle for only a pat on the back?

I implore Tom and all Americans to recognize the suffering of the dying patients and to support trial projects of Presumed Consent and financial incentives for organ donation to determine if these policies can be contributory towards eliminating America's organ-donor crisis.

Richard

Dr. Richard Darling, DDS: Past National Public Citizen of the Year (NASW)
President and CEO: The FAIR Foundation, a national organization with thousands of members and supporters whose goal is to reverse inequities in NIH research funding and to institute new organ-donor policies to reverse America's organ-donor crisis
Founder: The FAIR Foundation Liver Disease & Transplant Support Group
Author: Coma Life, an autobiographical memoir of life "within" coma and survival over hepatitis C induced liver cancer, coma, 3 liver transplants, heart attack, diabetes & Muscular Dystrophy (Myasthenia Gravis)
Address: 78629 Bougainvillea Drive, Palm Desert, CA 92211 Ph: 760-200-2766

From: Tom D. Mone [mailto:tdmone@onelegacy.org]
Sent: Saturday, February 06, 2010 3:24 PM
To: Richard Darling, DDS; LA Times Letters; LA Times Health
Cc: Sander S. Florman, MD, Director: Recanati/Miller Transplant Institute; Financial incentives & PC OD Template Letter Co-signers; Bryan Stewart; Greg Melkonian, DVM, MD; Fred Barden
Subject: RE: Rebuttal to Tom Mone regarding Mt Sinai MD's support of PC [OPO total revenue & individual compensation figures included]

Richard,

My letter was sent to the NY Times, not the LA Times, as the "advertorial" op-ed piece was in the NY Times.

As for the term "Pundit", it is a complimentary term and connotes expertise, but based on the incomplete nature of the research and conclusions, I must disagree in this case with the insinuation of "expert" that an op-ed usually confers. Further, given that the advertisement for Mt. Sinai was masquerading as an Op-Ed, I believe that the term "self-styled" is entirely appropriate. And "clever" I will also stand by because I really liked the headline and found it remarkably smart....and attractive, as a headline should be. I should share with you that another transplant colleague at Mt. Sinai has subsequently asked me to speak their on what has worked in US donation and how best to transfer successes across the country, so I don't think my comments were taken negatively.

Next, your numbers for 2009 donation rates are incorrect because the 2009 data reported by UNOS is incomplete and will be until at least late February (as occurs each year) as OPOs and transplant centers finalize their December and year-end data.

As for incentivizing living donors, we can "remove the disincentives" such as lost wages and travel time etcetera, but we cannot pay them or deceased donors for their organs, per federal NOTA and more importantly, to avoid creating a "donor class" of the poor who would provide organs for the better off...as has happened in every country that allows or puts up with payment for organs. I do understand and agree that if there is a tax credit to offset costs of living donation we need to find some means of aiding families of deceased donations, and maybe there is a way to acknowledge in the federal or state tax codes that such a personal donation benefits our states and country and warrants a tax credit as well. I discussed this with my New York colleague just yesterday and we agree that this deserves a public discussion and is among items that we will be discussing with state and federal legislators.

To the heart of the matter, while meeting overall demand for organs is the ideal, you and I both know that a 100% consent rate would not meet overall demand of even today's waitlist. And with dialysis needs expected to triple, the gap grows impossibly huge. Further, the great unknown is the question of just how many would be listed if there were an unending supply of organs...I would submit that the need is far greater than the current waitlist...as one transplant cardiologist said a few years ago, there may be 250,000 people who would benefit from heart transplantation if it were available to them. For this reason, the American Association of Organ Procurement Organizations has clearly identified that our goal is "to end deaths on the waiting list" not provide organs to all who can benefit....because we need to focus on a theoretically achievable goal and leave the larger problem to medical research which is the only available solution at this time.

So, as for what we can do, I was intentionally making a point that with OPOs having moved from fewer than 5000 deceased donor to 8000 per year and from a 50% consent rate to 70% today as compared to 10 years ago, this HAS been remarkable success in the social marketing of organ donation as a cause that the public has found worth supporting..that few if any social causes can match...as noted only 7% of potential blood donors actually donating by comparison. To assume that the remaining 30% who today decline to donate would not opt-out if given the chance at the DMV is a leap of faith that no social cause that I know of has ever shown to be accomplishable. More importantly, the experiences of the Presumed Consent countries in Europe ranges from poor to abysmal compared to the US and Spain and our voluntary consent systems, so any suggestion of "testing" this in the US risks harming many more lives than it could possibly save base don the unfounded assumption that the US would have a better outcome. Until we can close the gap between the 60-70% of people who choose to NOT register as donors at their DMVs (who would

likely opt-out and never be able to be approached for donation) and the 70% who actually donate at time of death....any opt-out, presumed consent system will most likely reduce organ donation, dramatically.

To this point, while I did not discuss the issue of population differences between the PC countries and the US, it is worth noting that the two leading countries Belgium and Austria are 90% white and Catholic, two social characteristics most highly correlated with high donation rates in the US as well. Those countries do not have to address substantial populations that include substantially non-native speaking immigrants who may come from countries without generations of transplant and donation awareness and education. With a white donation rate in California that is between 85 and 90% currently, and an overall of 70%, the anticipation that the African American (45-55% current consent rate), Asian (35-45%), and Hispanic (60-70%) would be comfortable enough with the idea of donation to NOT opt out is a leap of faith. It is a leap because we know that refusal is often linked to mistrust of the healthcare system, being estranged form societal inclusion, personal religious and cultural beliefs about death that are inconsistent with traditional US beliefs.
Our challenge is to help people address those issues, but that is not done at the DMV counter in which, under PC, one could opt-out forever.

Finally, re PC, given what we have learned in the national debate of healthcare reform, is it reasonable to assume that Americans that do not trust their government to provide healthcare; preferring personal choice, would be willing to adopt a law that said that state has a right to their organs unless they object in advance? I would add, should any state that does not guarantee access to healthcare presume the right to your organs upon your death? In my ethical and legalistic view, it is better to leave this to individuals and families than to make the very successful donation system we have a part of the divisive national debate on healthcare rights, responsibilities, and obligations that has only polarized us.

Before itemizing our specific recommendations in lieu of Presumed Consent, let me address your implication that healthcare professional who are paid for working in organ donation are in some way "profiting" from organ donation in some inappropriate manner. Fundamentally, NOTA allows OPOs and only OPOs to recover organs and be reimbursed the cost of that recovery which includes thousands of highly trained staff working 24/7/365 responding immediately and carrying for families in grief with unique sensitivity, professionalism, and technical expertise as well as thousands of agreements with hospitals and service providers nationwide to make he miracle of transplantation possible. In compensating any and all of our staff, OneLegacy like all health care providers and hospitals, be they profit or not-for-profit, relies on studies of current compensation rates based on role, job requirements, and performance. OneLegacy's salary structure is reviewed annually by our Board and is always developed to ensure that our salaries for each and every position are within the range of Southern California hospital community, not-for-profit healthcare agencies, California business community, and national OPO compensation rates to ensure our ability to recruit and retain staff who are still frequently wooed away to transplant centers and hospital positions. Organ recovery is a complex business with logistical, technical, and communications skills equivalent to or beyond any social service or business venture, and has a 70% "sales success rate" (if you want to speak about it in business terms), greater than just about any business I know of and the staff probably deserve as much or more than their hospital colleagues, but all OneLegacy compensation is kept within the healthcare industry benchmarks I listed.

So while we applaud the intent of Presumed Consent advocates, but recognize the likelihood that it will harm not help donation (based on the relative success of the American donation system, poorer European experience with PC, and the unique needs of our non-donor populations), we must reframe the challenge as not an organ crisis but a transplant crisis. And, this transplant crisis requires not simplistic silver bullets that have failed previously, but rather a series of simultaneous and significant actions if we are to end deaths on the waitlist now and in the next decade.
The actions that we in the California donation community are discussing with the intent of refining and formalizing as recommendations to our individual OPO Boards, the Donate Life California Board and the State of California and the national transplant community include some version of the following; and I would very much appreciate your thoughts on each item:

1) Requiring all drivers when renewing their licenses to either check the box and register in the DLCA registry or check a box saying that they defer this decision to their families or a later date...to

ensure that the registry choice is not skipped (which has been shown in other states to make a positive difference).
2) Adding the chance to register when renewing an automobile registration (which occurs every year rather than every five years with licenses)
3) Requiring donation education in school health classes prior to the 15th birthday
4) Requiring donation education in drivers education and traffic school classes
5) Expanding the DLCA to allow altruistic living donors to register and begin the vetting process (which is timely and costly with a 96% fall-off rate, so needs thousands to make a meaningful difference)
6) Stimulate living donor kidney chain donation by unmatched living donors of kidney recipients (which could allow 1 deceased donor kidney to result in 8, 9, 10 or more people to get transplanted that today depend upon finding an altruistic donor to start a chain)
7) A tax credit to help offset lost wages for living donors (which is tricky to calculate across different income levels, but would be simulative at most any reasonable level)
8) Some type of tax credit for deceased donor families (which would require federal legislation to overcome NOTA restrictions)
9) The creation of a foundation to assist living donor families reduce the costs of donation and potentially to help deceased donor families to cover funeral costs or similar, as allowed by law.
10) Recommending that some portion of State of California bond funds supporting stem cell research be directed toward organ failure treatments (which may include underlying disease cures, organ production, and xenotransplantation)
11) National investment and support for biomechanical assist devices to make kidney dialysis more portable and less debilitating, liver "dialysis" a reality, and heart and lung and pancreas support until transplant more viable.

Thank you for sharing your letter with me.

Sincerely,

Tom Mone
CEO
OneLegacy

From: Richard Darling, DDS [mailto:rdarling1@dc.rr.com]
Sent: Sunday, February 14, 2010 5:45 PM
To: Tom Mone
Cc: Sander S. Florman, MD, Director: Recanati/Miller Transplant Institute; Bryan Stewart (bstewart@onelegacy.org); Greg Melkonian, DVM, MD (gregory.melkonian@childrens.harvard.edu); Financial incentives & PC OD Template Letter Co-signers
Subject: RE: Rebuttal to Tom Mone regarding Mt Sinai MD's support of PC [OPO total revenue & individual compensation figures included]

Tom, please see my responses below each paragraph. You and I have debated these issues in person before on more than one occasion and done so without animus and I want you to know my comments below continue that spirit of positive debate. Indeed, I think you are one of the more enlightened employees at UNOS and wish you well as a nominee to be Vice President of the Board of Directors. Your position as President of the Association of Organ Procurement Organizations and as CEO of our country's largest OPO, OneLegacy, also gives you inroads into the potential for change and evidence by your courageously writing a letter to the LA Business Journal in which you supported limited incentivizing of OD. You wrote:

"...I believe the best way to proceed would be with small-scale pilot programs that offer donors lifetime insurance coverage and see what the effect would be…..If such programs do not indicate that there would be any negative effect on the national organ donation process, then the practice of paying for kidneys through insurance coverage and similar non-cash incentives should be allowed."

We'll have to continue to agree to disagree about PC but we do agree about incentivizing OD; however our group wishes to offer greater incentives that you propose.

From: Tom D. Mone [mailto:tdmone@onelegacy.org]
Sent: Saturday, February 06, 2010 3:24 PM
To: Richard Darling, DDS; LA Times Letters; LA Times Health
Cc: Sander S. Florman, MD, Director: Recanati/Miller Transplant Institute; Financial incentives & PC OD Template Letter Co-signers; Bryan Stewart; Greg Melkonian, DVM, MD; Fred Barden
Subject: RE: Rebuttal to Tom Mone regarding Mt Sinai MD's support of PC [OPO total revenue & individual compensation figures included]

Richard,

My letter was sent to the NY Times, not the LA Times, as the "advertorial" op-ed piece was in the NY Times. Thank you for alerting me to this error. I re-submitted to the NY Times – if they publish either please let us know.

As for the term "Pundit", it is a complimentary term and connotes expertise, but based on the incomplete nature of the research and conclusions, I must disagree in this case with the insinuation of "expert" that an op-ed usually confers. Further, given that the advertisement for Mt. Sinai was masquerading as an Op-Ed, I believe that the term "self-styled" is entirely appropriate. And "clever" I will also stand by because I really liked the headline and found it remarkably smart....and attractive, as a headline should be. I should share with you that another transplant colleague at Mt. Sinai has subsequently asked me to speak their on what has worked in US donation and how best to transfer successes across the country, so I don't think my comments were taken negatively. They were and they created insult in those I shared it with. "Self-styled pundit" sounds accusatory as in "you think you know it all" and "clever" used with that did not imply a compliment. Thank you for clarifying your intent and thoughts here. I'd appreciate it if you'd ask the transplant colleague at Mt. Sinai who invited you to speak if he would like add proper balance to his event by bringing me to speak on the need for pilot projects of new OD policies to "transfer successes across the country."

Next, your numbers for 2009 donation rates are incorrect because the 2009 data reported by UNOS is incomplete and will be until at least late February (as occurs each year) as OPOs and transplant centers finalize their December and year-end data. Well, my numbers came from your (UNOS's site) so it would be appropriate for you to state that their numbers are wrong, not mine. Each OPO knows on 1/1 of each year how many donors they had the previous year. With today's efficient technology there is no reason why UNOS's site should not be updated by 1/7, giving them a week to report on the previous year. Regardless, I would bet my home that the number will not be significantly different that previous years and perhaps lower, either way, it represents failure of altruism to meet the demand of 105,692 today.

As for incentivizing living donors, we can "remove the disincentives" such as lost wages and travel time etcetera, but we cannot pay them or deceased donors for their organs, per federal NOTA and more importantly, to avoid creating a "donor class" of the poor who would provide organs for the better off...as has happened in every country that allows or puts up with payment for organs. I do understand and agree that if there is a tax credit to offset costs of living donation we need to find some means of aiding families of deceased donations, and maybe there is a way to acknowledge in the federal or state tax codes that such a personal donation benefits our states and country and warrants a tax credit as well. I discussed this with my New York colleague just yesterday and we agree that this deserves a public discussion and is among items that we will be discussing with state and federal legislators. When we met you agreed NOTA needed to be changed and you referenced the change that had occurred to allow paired donations. UNOS reported to me (here) that the waiting list started in 1989. NOTA was passed by Congress before that--years earlier when there was no official waiting list. We could afford to be "moralistic" then regarding payment for organs—nothing to lose with no official waiting list—but now with a death every hour (here) we cannot be so moralistic, we must be realistic to save more lives. Regarding creating a "donor class of the poor"…well, if that's the fear then why don't we eliminate welfare, food stamps, Medicaid, etc since many argue that they have created a "poor class." And since NOTA allows the sale of blood and hair, let's stop that too. Is it appropriate for UNOS to take on this somewhat pious psychosocial analysis to protect the poor from their own ability to make decisions for themselves? Let them decide. In addition, your premise that only the poor will jump at the opportunity to receive $50,000 for a kidney is shortsighted and not true. There are thousands of middle-class people today who could use such funds to avoid foreclosure, etc. yet your position deprives them of this opportunity to relieve themselves of something they don't need—a kidney--for a real, financial benefit and to, perhaps, keep their kids in their home. Of course, the benefit would have to be accompanied by coverage of all expenses associated with the transplant, including lifetime follow-up care, replacement of lost wages, travel expenses, etc. You have accused us of recommending "bribery" in the past-a term that I felt was uncalled for but…yes, I'll accept that if it'll save just one life or, indeed, hundreds of thousands of lives.

To the heart of the matter, while meeting overall demand for organs is the ideal, you and I both know that a 100% consent rate would not meet overall demand of even today's waitlist. And with dialysis needs expected to triple, the gap grows impossibly huge. Further, the great unknown is the question of just how many would be listed if there were an unending supply of organs...I would submit that the need is far greater than the current waitlist...as one transplant cardiologist said a few years ago, there may be 250,000 people who would benefit from heart transplantation if it were available to them. For this reason, the American Association of Organ Procurement Organizations has clearly identified that our goal is "to end deaths on the waiting list" not provide organs to all who can benefit....because we need to focus on a theoretically achievable goal and leave the larger problem to medical research which is the only available solution at this time. You lose me here: your goal is to end deaths but not provide organs to all who can benefit?? You state the gap grows "impossibly large." Yes, both of these ideas are posited because you are relying on only altruism. The gap is NOT impossibly large if UNOS would utilize new OD policies, or as we recommend, just test them first. With PC and financial incentives the "gap" would be eliminated and the goal can, indeed, be an organ for every person who needs it, those on the list and those who are being held off the list because they aren't sick enough yet (355,000 on dialysis but not listed according to the renal database).

So, as for what we can do, I was intentionally making a point that with OPOs having moved from fewer than 5000 deceased donor to 8000 per year and from a 50% consent rate to 70% today as compared to 10 years ago, this HAS been remarkable success in the social marketing of organ donation as a cause that the public has found worth supporting..that few if any social causes can match...as noted only 7% of potential blood donors actually donating by comparison. To assume that the remaining 30% who today decline to donate would not opt-out if given the chance at the

DMV is a leap of faith that no social cause that I know of has ever shown to be accomplishable. More importantly, the experiences of the Presumed Consent countries in Europe ranges from poor to abysmal compared to the US and Spain and our voluntary consent systems, so any suggestion of "testing" this in the US risks harming many more lives than it could possibly save base don the unfounded assumption that the US would have a better outcome. Until we can close the gap between the 60-70% of people who choose to NOT register as donors at their DMVs (who would likely opt-out and never be able to be approached for donation) and the 70% who actually donate at time of death....any opt-out, presumed consent system will most likely reduce organ donation, dramatically. I agree efforts that have increased the consent rate from 50 to 70 represent remarkable success but it is very frustrating to hear you and your VP of Communications at OneLegacy, Brian, give conferences in which you boast about this when patients are dying every hour due to the shortage of organs by reliance on altruism alone. The sentence would be factual and honest if stated like this: “We have made remarkable progress but with only altruism as our country’s sole OD policy we are failing to meet the demand. We need to test new OD policies to see if they can help reverse the present crisis.”

To this point, while I did not discuss the issue of population differences between the PC countries and the US, it is worth noting that the two leading countries Belgium and Austria are 90% white and Catholic, two social characteristics most highly correlated with high donation rates in the US as well. Those countries do not have to address substantial populations that include substantially non-native speaking immigrants who may come from countries without generations of transplant and donation awareness and education. With a white donation rate in California that is between 85 and 90% currently, and an overall of 70%, the anticipation that the African American (45-55% current consent rate), Asian (35-45%), and Hispanic (60-70%) would be comfortable enough with the idea of donation to NOT opt out is a leap of faith. It is a leap because we know that refusal is often linked to mistrust of the healthcare system, being estranged form societal inclusion, personal religious and cultural beliefs about death that are inconsistent with traditional US beliefs.
Our challenge is to help people address those issues, but that is not done at the DMV counter in which, under PC, one could opt-out forever.

Finally, re PC, given what we have learned in the national debate of healthcare reform, is it reasonable to assume that Americans that do not trust their government to provide healthcare; preferring personal choice, would be willing to adopt a law that said that state has a right to their organs unless they object in advance? I would add, should any state that does not guarantee access to healthcare presume the right to your organs upon your death? In my ethical and legalistic view, it is better **to leave this to individuals and families** than to make the very successful donation system we have a part of the divisive national debate on healthcare rights, responsibilities, and obligations that has only polarized us. You wish to “to leave this decision [to donate or not] to individuals and families” but you deny them the same right to decide regarding financial incentives. That is not fair, nor respectful of those who would jump at the chance to trade a kidney for a large cash infusion. You may be right in that with the strong hostility toward the government’s desire to take over health insurance that PC is not palatable now. In fact, even if PC was 100% successful, we’d still have the problem now: a rising waiting list, so what is the answer to complete elimination of the waiting list? Financial Incentives.

Before itemizing our specific recommendations in lieu of Presumed Consent, let me address your implication that healthcare professional who are paid for working in organ donation are in some way "profiting" from organ donation in some inappropriate manner. Fundamentally, NOTA allows OPOs and only OPOs to recover organs and be reimbursed the cost of that recovery which includes thousands of highly trained staff working 24/7/365 responding immediately and carrying for families in grief with unique sensitivity, professionalism, and technical expertise as well as thousands of agreements with hospitals and service providers nationwide to make he miracle of transplantation possible. In compensating any and all of our staff, OneLegacy like all health care providers and hospitals, be they profit or not-for-profit, relies on studies of current compensation rates based on role, job requirements, and performance. OneLegacy's salary structure is reviewed annually by our Board and is always developed to ensure that our salaries for each and every position are within the range of Southern California hospital community, not-for-profit healthcare agencies, California business community, and national OPO compensation rates to ensure our ability to recruit and retain staff who are still frequently wooed away to transplant centers and hospital positions. Organ recovery is a complex business with logistical, technical, and communications skills equivalent to or beyond any social service or business venture, and has a 70% "sales success rate" (if you want to speak about it in business terms), greater than just about any business I know of and the staff probably deserve as much or more than their hospital

colleagues, but all OneLegacy compensation is kept within the healthcare industry benchmarks I listed. I structured the sentence with "profit" respective to the for-profits and "producing revenue" for you non-profits. Having said that, UNOS deriving great revenue from "deceased" donors' organs and tissues without compensation to the deceased-donor families is unconscionable. If Congress were to name an ombudsman to evaluate UNOS, the OPO's and their employees' efficacy in reducing the waiting list and/or eliminating the waiting list, what grade would they receive? They would receive a failing grade and those in charge would have to look to new OD policies for a solution or be replaced with others who are willing to look at incentivizing OD as you did in the LA Business Journal article.

So while we applaud the intent of Presumed Consent advocates, but recognize the likelihood that it will harm not help donation (based on the relative success of the American donation system, poorer European experience with PC, and the unique needs of our non-donor populations), we must reframe the challenge as not an organ crisis but a transplant crisis. And, this transplant crisis requires not simplistic silver bullets that have failed previously, but rather a series of simultaneous and significant actions if we are to end deaths on the waitlist now and in the next decade.
The actions that we in the California donation community are discussing with the intent of refining and formalizing as recommendations to our individual OPO Boards, the Donate Life California Board and the State of California and the national transplant community include some version of the following; and I would very much appreciate your thoughts on each item:

1) Requiring all drivers when renewing their licenses to either check the box and register in the DLCA registry or check a box saying that they defer this decision to their families or a later date...to ensure that the registry choice is not skipped (which has been shown in other states to make a positive difference).
2) Adding the chance to register when renewing an automobile registration (which occurs every year rather than every five years with licenses) regarding #1 and this one, Bryan stated at one conference the Donate Life Registry at the DMV is adding 1.5 million new donors a year. With perhaps 30 million adults in California that means 20 years to complete sign-up. Not only is that unacceptable, but as you stated above, even if we have 100% tomorrow, we still don't have enough organs to meet the 105,000+ demand.
3) Requiring donation education in school health classes prior to the 15th birthday **A+**
4) Requiring donation education in drivers education and traffic school classes **A+**
5) Expanding the DLCA to allow altruistic living donors to register and begin the vetting process (which is timely and costly with a 96% fall-off rate, so needs thousands to make a meaningful difference) **A+**
6) Stimulate living donor kidney chain donation by unmatched living donors of kidney recipients (which could allow 1 deceased donor kidney to result in 8, 9, 10 or more people to get transplanted that today depend upon finding an altruistic donor to start a chain) **A+**
7) A tax credit to help offset lost wages for living donors (which is tricky to calculate across different income levels, but would be simulative at most any reasonable level) **A+**
8) Some type of tax credit for deceased donor families (which would require federal legislation to overcome NOTA restrictions) **A+**
9) The creation of a foundation to assist living donor families reduce the costs of donation and potentially to help deceased donor families to cover funeral costs or similar, as allowed by law. **A+**
10) Recommending that some portion of State of California bond funds supporting stem cell research be directed toward organ failure treatments (which may include underlying disease cures, organ production, and xenotransplantation) **A+**
11) National investment and support for biomechanical assist devices to make kidney dialysis more portable and less debilitating, liver "dialysis" a reality, and heart and lung and pancreas support until transplant more viable. **A+**
But after all those A+ grades, we've still got a waiting list rising. So, now let's add $50,000 or 5-10 years of medical insurance for a family to the equation and we'll eliminate the waiting list for all organs in five years. Plus, the "poor" won't be poor any longer and they will have a chance at a better life. A++

Thank you for sharing your letter with me. Same back at you for your thoughts; I think we've exhausted this for now. Hope you'll bring me to a debate as mentioned at Mt. Sinai or elsewhere so proper balance can be presented.
Richard

From: Tom D. Mone [mailto:tdmone@onelegacy.org]
Sent: Thursday, February 18, 2010 1:01 PM
To: Richard Darling, DDS
Cc: Sander S. Florman, MD, Director: Recanati/Miller Transplant Institute; Bryan Stewart; Greg Melkonian, DVM, MD; Financial incentives & PC OD Template Letter Co-signers
Subject: RE: Rebuttal to Tom Mone regarding Mt Sinai MD's support of PC [OPO total revenue & individual compensation figures included]

Richard,

I am all for amicable debate and hereby offer my response to your points:

First, I do believe that a "*small scale pilot project*" makes a good deal of sense, ***if*** people feel completed to employ Presumed Consent (which the data I shared and our donor registry experience has told me since I wrote that comment is a huge risk)….and as we all know, there is nothing about California nor New York that is "small scale", and I was speaking on from the context of the largest OPO and state and to a spokesperson for the second largest OPO. Neither area is a viable testing ground.

Second, I remain an employee of OneLegacy and only OneLegacy, though I did sit on the board of UNOS (an unpaid position for two years) and I have rotated off of that voluntary role.

Third, Alas, I am not a candidate for VP of UNOS. I was one of the two first ever OPO candidates for the role of President a year ago and fortunately the other guy won!

Fourth, as noted, I do not work for UNOS and their numbers are in their database, not OneLegacy's, I do not manage them and they haven't even posted OneLegacy's December numbers (for reasons I am calling them to investigate) as of this date….For the record, OneLegacy recovered 382 deceased donors in 2009 not the 352 UNOS reports as of today at 2:00 PM.

Fifth, I agree that the 2009 numbers will be lower than 2008 and in fact, the country as a whole has been declining in deceased donors since our high in 2006; despite an increase in consent and conversion rates. My research lays the blame for this on two factors: 1) a measurable decline in ICU deaths due to neurological injury that is secondary to a 10% decline in highway fatalities and a significant decline in homicides (LA County reports a 34% decline this year) and 2) a significant shift to a conservative medical practice by centers that are seeking to avoid CMS (Medicare) and UNOS audit performance measures and to capture private insurer center of excellence contracts and thereby patients. This is a huge problem because centers that would previously seek an 80-85% 1 year graft survival rate, concluding it is better than continued dialysis or death, are uniformly seeking 90-95% 1 year graft survival performance and are therefore turning down organs and donors they accepted 3 years ago. A tragedy is that 16% of our families that consent cannot do so because the medical condition of the donor, as assessed by the transplant surgeons and their staff, decline the donors; as compared with only 13% in 2006. More troubling is the increase in specific organs declined or discarded…here are two examples: in 2002 liver surgeons used 80% of the livers we recovered at OneLegacy, in 2005 it was 79%, in 2009 it was only 73%....so, despite families saying "Yes" and the OPO's offering livers, fewer are transplanted. The there is the tragedy of kidneys…in 2005 OneLegacy's kidney discard (due to surgeon medical assessment) rate was 13%, in 2009 it was 20%....this is a tragedy that is driven more by fears of arbitrarily defined measures and an allocation system that favors declining kidney offers and waiting for the next and likely better organ.

Sixth, **The 4 OPOs in California have recommended to the Governor that a state tax credit be established to offset the costs and lost wages associated with living organ donation**. This could be somewhat complex to administer and assess what the right amount is to offset for each

person. **Therefore, I am recommending that we propose that the fee that offsets living donor expenses be set equivalent to the average of the four California OPO kidney fees (currently approximately $35,000), which should remove financial disincentives, motivate many people, and stay within the limits of NOTA and not require changes in federal law. As for medical coverage, I am in FULL agreement with you and as the healthcare reform bill sinks into the sunset, the value of "Lifetime Medicare for living donors or the consenter of a deceased donor is a valuable incentive and tool we =should pitch vigorously.**

Seventh, I completely agree that revisions in the organ allocation system (which is what I believe you mean by "new OD policies") will save lives and reduce deaths on the waiting lists IF they focus on broader sharing across the inappropriate and boundaries of an OPO territory (Donation Service Area). Additionally other changes, such as adding an "old for old" policy will reduce the number of kidneys discarded as older waiting recipients and their MDs turn down and discard viable organs while waiting for the next, younger donor organ. As for "impossibly large", I meant that only re the deceased donor pool, which cannot ever meet the need of those who could benefit from transplant…even if 100% said Yes, not today's 70%. However, I fully agree that stimulating living donation changes this math, primarily for kidney recipient but also to some extent for liver and even lung recipients. Unfortunately, heart recipients will need to hold on to other hopes, as there have not been too many living heart donors and I don't think any of us see this as a viable option!

Eighth: The strategy of celebrating the improvement from 50% to 70% consent and donation rate is a conscious strategy, not to self-congratulate, but rather to position deceased organ donation as the norm, as a commonplace, and as a very positive thing worth celebrating….and we spend far more time celebrating and promoting the individual decision via floragraphs and riders on a Rose Parade float, and by news stories retelling those individual stories…the numbers are simply a contextual benchmark that says that the vast majority of people get it and it's OK for them and it's OK for you…And, we share this number to keep people and politicians from taking inappropriate actions that would actually reduce that rate of donation because far too many think that most people say no.

Ninth, while UNOS receives revenues from listing fees paid by transplant centers, it receives no funds related to organs recovered and transplanted and makes no profits from its organ allocation and oversight activities as it is a not-for-profit. Further, its staff compensation are well within and often below national average compensation rates for such staff with their duties, education , and skill requirements. But, as noted, I am not nor never have been a UNOS employee, so what I share is publically available information that can be found on Guidestar.org. In point of fact, when registrations dropped precipitously last year, the UNOS staff, from top to bottom took a 10% pay cut in order to reduce the losses it was facing. Running its oversight and allocation system is fairly expensive and …by the way, there is a governmental overseer who attends every board meeting and holds the organization to strict contract compliance…..and that governmental oversight agency has recently put the brakes on UNOS work to expand living donation, so please contact the HHS/HRSA/Division of Transplantation if you want to see UNOS do more to promote living donation.

Here's to our future success on the many items we agree on!

Tom

Thomas Mone
CEO and EVP
OneLegacy
221 S Figueroa Street
Suite 500

C: 424-298-0229
O: 213-229-5603