



January 5, 2016

Sylvia Mathews Burwell
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

We are writing to express our support for the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's (Committee) proposal for public comment: Redesigning Liver Distribution, and to address concerns about the proposal raised in a recent letter¹ from Members of Congress. This proposal acts on a longstanding legal obligation that allocation policies "[s]hall not be based on the candidate's place of residence or place of listing."² Moreover, as highlighted by 68 Members of Congress in a recent letter (see Appendix I), this proposal "reflects the careful balance of input from a diverse assortment of stakeholders" and would bring tremendous benefit to the thousands of patients who suffer due to the current inequitable distribution scheme.

Opponents of liver distribution reform – most of whom benefit from the inequities in the current system – have worked tirelessly to stonewall the scientifically rigorous process for developing an updated policy. These opponents have attempted to smear this process through baseless allegations of conflict of interest. Even though they have openly criticized the process, they have taken advantage of its deliberative nature by making repeated, eleventh hour requests for additional modeling just before the next phase of the process begins – requests that they know will cause delay and take months or years to complete.

Despite their criticism of the Committee's work, those who oppose distribution reform have yet to propose a workable alternative. Indeed, despite the gaping inequity in access to transplant, it is unclear that those who oppose liver distribution reform even recognize the need to update current policy. Their stated position, website testimonials, and efforts to engage Congress on this issue indicate that they would prefer the *status quo* – a situation in which patients in their regions continue to have access to transplants while those in neighboring regions suffer and die at the hands of our current scheme.

Instead of proposing legitimate policy alternatives that actually address equality, they prefer to obfuscate the scientific debate at hand. They focus attention on arguments about increasing transplant rates – an

¹ Rep. Kevin Yoder et. al., letter to Secretary Sylvia Mathews Burwell, 19 Dec. 2016. TS.

² 42 CFR 121.8.

issue which enjoys consensus from across the transplant stakeholder community, but does nothing to address the inequity in how organs are distributed. Their ill-intention is further demonstrated through inaccurate, protectionist rhetoric designed to turn one region against another, flying in the face of our shared national values.

In reality, the Committee's pending proposal to reduce then number of transplant regions could save hundreds of lives over the next five years and generate nearly \$250 million in savings from transplantation-related expenses. As an organization dedicated to equity in liver distribution, CODE supports the Committee's work to reach consensus on a proposal, and appreciates your commitment to encouraging the transplantation experts at OPTN/UNOS to reach an expeditious conclusion.

THE NEED FOR REFORM

Contrary to clearly stated federal policy, patients in certain places have had to wait to get very sick or in some cases die before they could get a transplant, while candidates in other areas are able to obtain transplant when they are much less sick.³ Recognizing this ongoing disparity, and pursuant to the OPTN Board's charge to establish a disparity metric, the Committee decided upon variance in MELD score at the time of transplant. In our current system, across donation service areas (DSAs), research has established that the variation in MELD score at transplant can be as high as 10 points.⁴ More recent OPTN data has found regional disparity to be as high as a 12-point difference in median MELD at transplant. The policy put forth by the Committee's proposal directly addresses this extreme difference in the sickness of candidates at the time of transplant by reducing the current local and regional variation in MELD at transplant.

Further, under the current local distribution system, research indicates that there is wide disparity in a candidate's chances of receiving a liver.⁵ For example, one study found that for patients who were equally sick, 90-day transplant rates ranged from 18% to 86% across DSAs.⁶ That study also highlighted that among candidates with MELD scores between 21 and 34, the probability of transplant within 90 days for candidates with the same score varied widely across OPOs, ranging from under 30% to over 90%.⁷

Additional evidence of the ongoing disparity can be seen through the higher overall death rates in places where patients have to wait longer to receive a life-saving transplant.⁸ For patients with very high MELD

³ Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.

⁴ Yeh H, Smoot E, Schoenfeld DA, Markmann JF. Geographic inequity in access to livers for transplantation. *Transplantation*. 2011; 91(4):479–486.

⁵ Koizumi N, Ganesan R, Gentili M, et al. Redesigning Organ Allocation Boundaries for Liver Transplantation in the United States. *Proceedings of the International Conference on Health Care Systems Engineering / Andrea Matta, Jingshan Li, Evren Sahin, Ettore Lanzarone, John Fowler, editors International Conference on Health Care Systems Engineering* (2013 : Milan, . 2014;61:15-27. doi:10.1007/978-3-319-01848-5_2.

⁶ Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.

⁷ Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.

⁸ Yeh H, Smoot E, Schoenfeld DA, Markmann JF. Geographic inequity in access to livers for transplantation. *Transplantation*. 2011; 91(4):479–486.

scores, findings indicate a 90-day probability of waitlist death, ranging widely from 14% in some DSAs to 82% in others.⁹ Patients who have to wait longer to receive a transplant also have a higher chance of dying after the procedure, as pre-transplant MELD score have been demonstrated to correlate inversely with post-transplant survival.¹⁰ These staggering statistics demonstrate that the costs of waiting in some areas have indeed been high, lowering patients' chances of survival both before and after transplant.

Every candidate for a life-saving liver transplant should have an equal shot at getting one. Federal policy intends that livers for transplant from deceased donors be allocated equitably across the entire nation based on need. Despite this noble purpose, evidence clearly demonstrates that critical gaps in our current distribution policy hinder realization of these goals. As the well-documented disparities in liver distribution linger, our shared values of equality in access to organ transplant cannot be achieved, and patients in some places must continue to wait a long time, get too sick, or die before they can receive a transplant.

ADDRESSING CONCERNS

While the merits of liver distribution reform have been well documented, some in Congress have advanced inaccurate and misguided criticisms that do an injustice to the professionals who have long contemplated these reforms. Per their December 19, 2016 letter, we think it is important to address many of the concerns cited in their correspondence:

“The proposal has been circulated without considering larger efforts addressing the need to increase the number of donors and the performance of organ procurement organizations in underperforming regions.”

The Liver Committee has repeatedly recognized the importance of a parallel aim to increase the number of organs donated, and the claim that liver distribution reform fails to address the necessity to increase organ donation willfully ignores that fact. The proposal in question specifically seeks to make sure people everywhere in the U.S. can have a similar chance of receiving an organ based on need rather than their place of residence. It does not have to do with – nor intend to address – the number of livers donated or the places where livers are donated.

CODE is highly supportive of the Committee's efforts to increase the total number of transplants. The overall availability of organs is an important and closely related issue, but the Committee's work in this instance addresses unfairness in the way we deal with the current shortage. Federal policy dictates that organs for transplant are a resource to be distributed fairly across the entire country.¹¹ Rather than rewarding one area at the expense of another, we believe this policy seeks to make sure that patients

⁹ Massie AB, Caffo B, Gentry SE, Hall EC, Axelrod DA, Lentine KL, et al. MELD Exceptions and Rates of Waiting List Outcomes. *Am J Transplant*. 2011; 11(11):2362–2371.

¹⁰ Habib, S., Berk, B., Chang, C.-C. H., Demetris, A. J., Fontes, P., Dvorchik, I., Eghtesad, B., Marcos, A. and Shakil, A. O. (2006), MELD and prediction of post-liver transplantation survival. *Liver Transpl*, 12: 440–447. doi:10.1002/lt.20721.

¹¹ See, Final Rule, ACOT Recommendation, POC Recommendation, UNOS/OPTN Strategic Plan, UNOS/OPTN Board Resolution.

nationwide who are most in need will have a better chance of accessing organs for transplant no matter where they live.

“The projected 2 percent decline in the number of liver transplants significantly outweighs the alleged current geographic disparity... Because the UNOS proposal will increase cost and reduce the number of transplants performed, some transplant programs will (or are likely to) close, harming the people they were created to serve.”

Modeling conducted under the proposal projects a two percent reduction in transplants overall. However, a small projected reduction in overall transplants does not compare to the projected hundreds of lives saved under the policy or the rampant current geographic inequity. As the Committee has asserted, we believe strongly that the two percent reduction modeled by the proposal will be offset by behavioral changes and logistical improvements. For example, the Committee highlights that predictive modeling relied upon, while able to project the direction of large-scale changes, is unable to account for behavioral changes, especially acceptance behavior.¹²

While any policy that redistributes organs over a broader area can reasonably be anticipated to raise transport time, distance, and the amount of organs flown, the current proposal minimizes each of these metrics compared to any other potential option.¹³ The hypothetical (and modest) reduction in overall transplants modeled under the proposal should not prevent adoption of a policy that would reduce significant disparity inherent in our current system and save lives.

“Congress created the OPTN to support reasoned, expert-based and consensus driven decisions in organ allocation policy. This proposal contradicts that expectation as evidenced by its unpopularity among members of the transplant community and the general public... “There are also several procedural shortcomings that demand further examination.”

Those who support the status quo have criticized *any* proposal that would change the current system of liver distribution. Although these critics have decried the process for procedural shortcomings, there is scant evidence to defend these claims – including those alleging conflicts of interest in the policymaking process. In 2009, the NIH awarded a challenge grant to reduce geographic disparities in transplant access to a multi-disciplinary and multi-institutional team led by Krista Lentine (nephrologist, Saint Louis University) that included Sommer Gentry (mathematician, U.S. Naval Academy), Dorry Segev (transplant surgeon, Johns Hopkins), David Axelrod (transplant surgeon, Dartmouth), and Mark Schnitzler (health policy researcher, SLU).¹⁴ This grant funded Gentry’s initial work on redistricting U.S. liver allocation, which eventually resulted in development of the redistricting concept that is currently under consideration by the Liver Committee.

Stated plainly, this proposal withstands the highest levels of scientific scrutiny. Many members of the transplant community have co-authored, peer-reviewed, or responded to numerous publications about

¹² OPTN/UNOS Public Comment Proposal: Redesigning Liver Distribution (August, 2016). Available at: https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf.

¹³ Id.

¹⁴ https://projectreporter.nih.gov/project_info_description.cfm?aid=7825537&icde=0.

redistricting in the academic medical literature (see Appendix II). They respond directly to concerns raised by the transplant community about the cold ischemia time required to transport livers, about the relationship between OPO performance and liver transplant access, about the technical aspects of simulation and optimization involved in designing the districts, and about the OPTN's policy development process.

Moreover, we would like to express disappointment with comments suggesting the proposal reflects any conflict of interest. In fact, each region has a representative on the Committee responsible for specific issues pertaining to that area. Allegations of conflict of interest are unfounded, and amount to a baseless effort to smear the integrity of the Committee and its members – not to mention delay life-saving reforms. These efforts to subvert a needed and required reform are especially harmful, aside from being disrespectful, to the thousands of patients who bear the burden of the current inequity.

CONCLUSION

CODE respectfully encourages HHS and HRSA to hold OPTN accountable to their directive to “develop evidence-based allocation policies which are not determined by arbitrary administrative boundaries.”¹⁵ At a recent meeting of the HHS Advisory Committee on Organ Transplantation, HRSA Division of Transplantation Director Melissa Greenwald confirmed that the agency is setting a new goal to present a final proposal to the OPTN Board in December 2017. After years of careful consideration and countless delays in this process, it is essential that OPTN be strictly held to this pending deadline. Further delay in implementing a fair policy after so many years of injustice is not only inconsistent with federal statutes, but legally and morally indefensible.

Sincerely,

A handwritten signature in black ink, appearing to read "Harriet Melvin". The signature is fluid and cursive, with the first name "Harriet" being more prominent than the last name "Melvin".

Harriet Melvin
Executive Director, CODE

¹⁵ Advisory Committee on Organ Transplantation Recommendation 51 Available at: <http://www.organdonor.gov/legislation/acotreccs51.html>.

Congress of the United States
Washington, DC 20515

September 30, 2016

Sylvia Mathews Burwell
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

We write to voice our support for proposed changes to the current United States model of distributing livers for transplant. We thank the Department of Health and Human Services (HHS) for its demonstrated commitment to addressing geographic disparities in access to livers for transplant, and encourage the Department to maintain that commitment while considering these proposed changes.

As you know, under current policies, livers from deceased donors are given to the sickest person in that particular United Network for Organ Sharing (UNOS) region, even if there are sicker patients in greater need of a transplant elsewhere in the nation. As a result, patients' chances of survival while waiting for transplantation are determined by their zip codes, not medical need. A study of more than 100,000 patients on the Organ Procurement Transplant Network (OPTN) liver transplant waiting list found that one-year mortality rates vary tremendously across regions, ranging from 34 percent to 60 percent.¹

We commend the Health Resources and Services Administration (HRSA) and the OPTN for their efforts to reduce these disparities by proposing an alternative distribution model and were pleased that, after lengthy consideration and extensive stakeholder input, UNOS posted this proposal for public comment on August 15, 2016.²

The proposal in question would reduce the number of transplant regions – a change that could save more than 500 lives over the next five years and generate nearly \$250 million in savings from transplantation-related expenses.³ In the wake of the successful White House Organ Summit, wherein the goal of ending waitlist-related deaths was broadly embraced, we urge you to remain vigilant in the effort to improve the liver distribution process and save lives.

¹ M. D. Voigt, L. G. Hunsicker, J. J. Snyder, A. K. Isranib, and B. L. Kasiske. Regional Variability in Liver Waiting List Removals Causes False Ascertainment of Waiting List Deaths. *American Journal of Transplantation* 2013; 13: 369–375, available at <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12000/full>

² Redesigning Liver Distribution, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (August 15, 2016), available at https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf

³ Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (June, 2014), available at https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf

This proposal reflects a careful balance of input from a diverse assortment of stakeholders, and we urge you to ensure the public comment process on the proposal, and subsequent consideration by OPTN, is not delayed.

We recognize that equality in access to organs continues to be a priority for the Department and applaud the serious discussions and analyses that have been underway to address existing disparities. Thank you for your consideration and attention to this important issue.

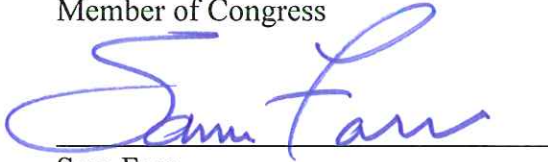
Sincerely,



Eliot L. Engel
Member of Congress



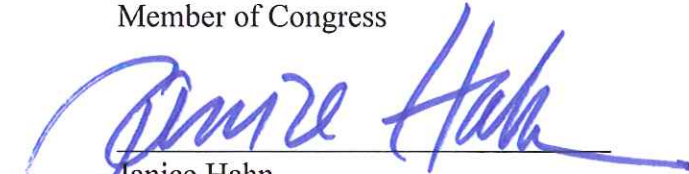
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Sam Farr
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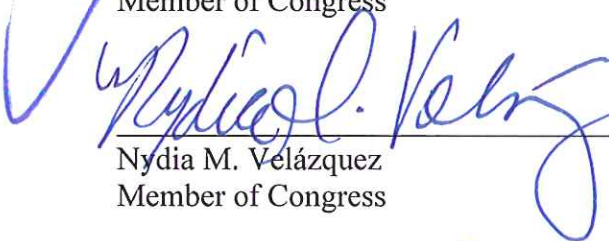
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Nydia M. Velázquez
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Jerrold Nadler
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Grace F. Napolitano
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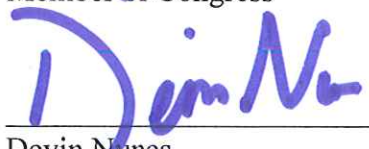


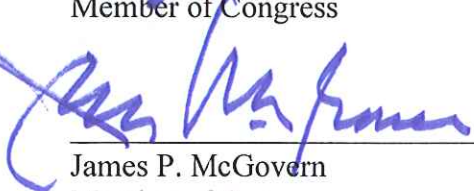
Steve Israel
Member of Congress

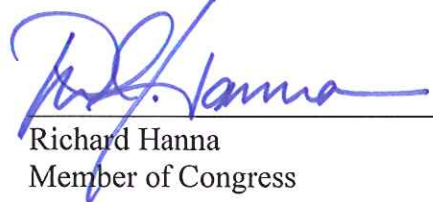



Paul Tonko
Member of Congress

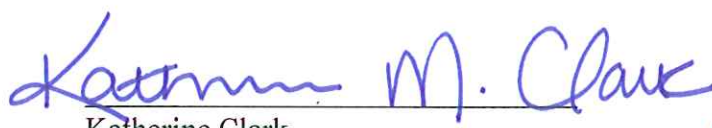

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Devin Nunes
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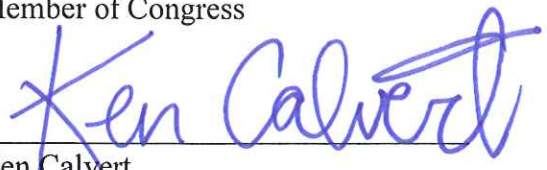

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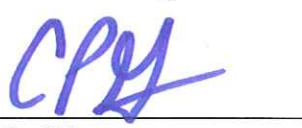

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Member of Congress

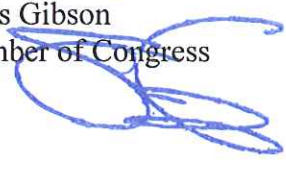

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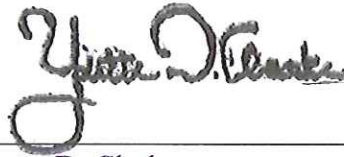

Kathleen M. Rice
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Chris Gibson
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Sean Patrick Maloney
Member of Congress



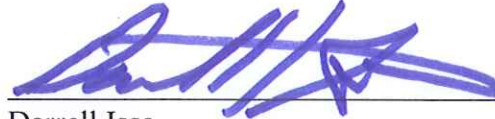
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Yvette D. Clarke
Member of Congress



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Member of Congress



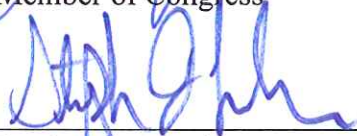
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Member of Congress



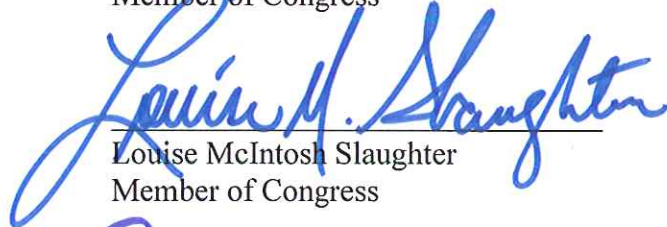
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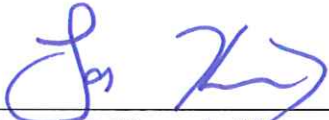
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Member of Congress



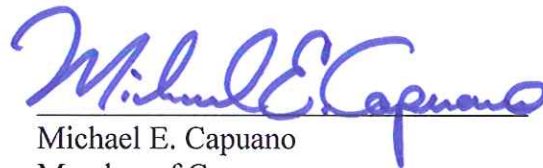
Stephen F. Lynch
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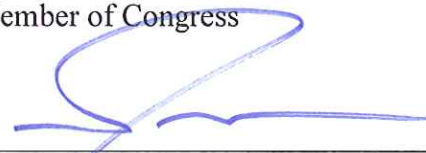
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Julia Brownley
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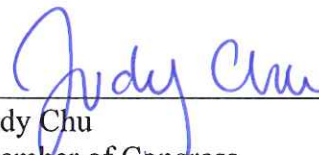
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Tom Reed
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Dan Donovan
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Judy Chu
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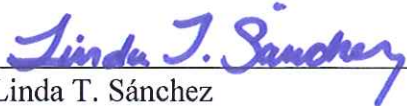
Ted Lieu
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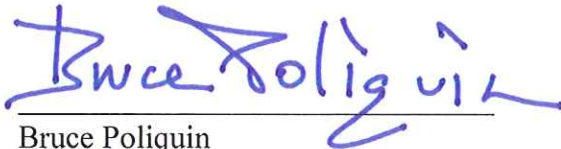
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Member of Congress



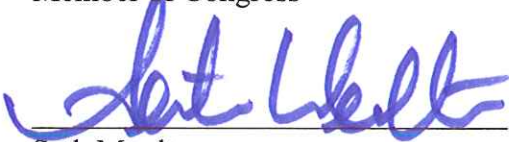
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Lee Zeldin
Member of Congress



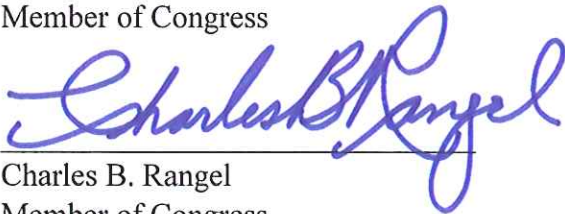
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Seth Moulton
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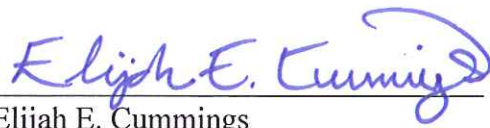
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Member of Congress



Elijah E. Cummings
Member of Congress



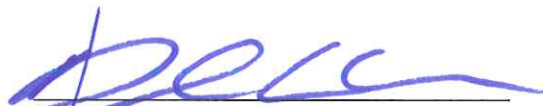
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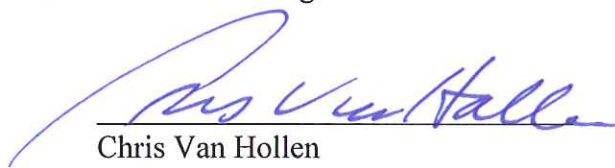
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Alan Lowenthal
Member of Congress



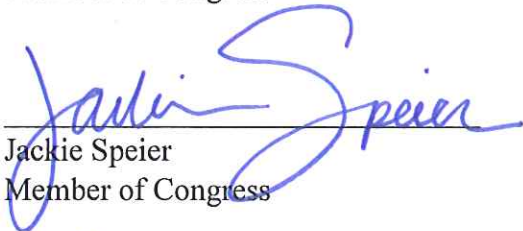
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Chris Van Hollen
Member of Congress



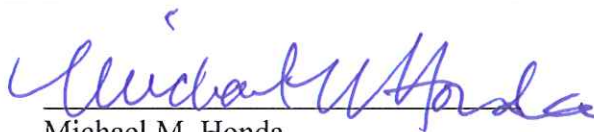
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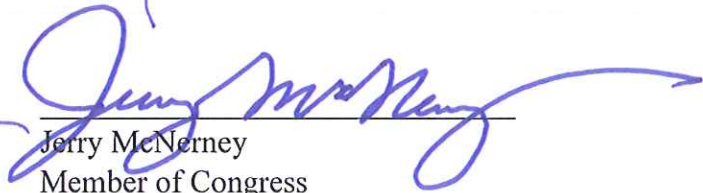
Jackie Speier
Member of Congress



Joe Courtney
Member of Congress



Michael M. Honda
Member of Congress



Jerry McNerney
Member of Congress

CC: The Honorable Harold Rogers
Chairman
House Committee on Appropriations
H-305, the Capitol
Washington, D.C. 20515

The Honorable Nita M. Lowey
Ranking Member
House Committee on Appropriations
1016 Longworth House Office Building
Washington, D.C. 20515

APPENDIX II – BIBLIOGRAPHY OF REDISTRICTING-RELATED PUBLICATIONS

- 1: Chow EK, Massie AB, Luo X, Wickliffe C, Gentry SE, Cameron AM, Segev DL. Waitlist Outcomes of Liver Transplant Candidates Reprioritized Under Share-35. *Am J Transplant*. 2016 Jul 26. doi: 10.1111/ajt.13980. [Epub ahead of print] PubMed PMID: 27457221.
- 2: Gentry SE, Hirose R, Mulligan D. Resolving Misconceptions About Liver Allocation and Redistricting Methodology. *JAMA Surg*. 2016 Jun 22. doi: 10.1001/jamasurg.2016.1315. [Epub ahead of print] PubMed PMID: 27333440.
- 3: Hirose R, Gentry SE, Mulligan DC. Increasing the Number of Organs Available to Transplant Is Separate From Ensuring Equitable Distribution of Available Organs: Both Are Important Goals. *Am J Transplant*. 2016 Feb;16(2):728-9. doi: 10.1111/ajt.13577. Epub 2016 Jan 12. PubMed PMID: 26757240.
- 4: Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL, Axelrod DA. The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients. *Am J Transplant*. 2016 Feb;16(2):583-93. doi: 10.1111/ajt.13569. Epub 2016 Jan 18. PubMed PMID: 26779694.
- 5: Gentry SE, Segev DL, Kasiske BL, Mulligan DC, Hirose R. Robust Models Support Redistricting Liver Allocation to Reduce Geographic Disparity. *Transplantation*. 2015 Sep;99(9):e159-60. doi: 10.1097/TP.0000000000000834. PubMed PMID: 26308421; PubMed Central PMCID: PMC4576715.
- 6: Gentry SE, Chow EK, Massie A, Luo X, Shteyn E, Pyke J, Zaun D, Snyder JJ, Israni AK, Kasiske B, Segev DL. Liver sharing and organ procurement organization performance under redistricted allocation. *Liver Transpl*. 2015 Aug;21(8):1031-9. doi: 10.1002/lt.24171. PubMed PMID: 25990089; PubMed Central PMCID: PMC4516652.
- 7: Massie AB, Chow EK, Wickliffe CE, Luo X, Gentry SE, Mulligan DC, Segev DL. Early changes in liver distribution following implementation of Share 35. *Am J Transplant*. 2015 Mar;15(3):659-67. doi: 10.1111/ajt.13099. PubMed PMID: 25693474.
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