Research Advocacy

Dorry Segev, MD, PhD
Professor of Surgery and Epidemiology
Associate Vice Chair
Dept of Surgery
Johns Hopkins Univ
Motivating HOPE

• Poor outcomes of HIV+ patients on kidney and liver waiting lists
• Encouraging outcomes with NIH HIV trial
• Encouraging outcomes with HIV-to-HIV in South Africa
42 U.S.C. 274(b) Section 372(b)

"...including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome"

(National Organ Transplant Act, 1984/88)
• >7,000 bills before Congress
• < 5% become law
From Bench to Bill: How a Transplant Nuance Became One of Only 57 Laws Passed in 2013

Brian J. Boyarsky, BA,* and Dorry L. Segev, MD, PhD*†


“I’m just a bill, yes I’m only a bill, and I’m sitting here on Capitol Hill.
Well, it’s a long, long journey to the capital city,
It’s a long, long wait while I’m sitting in committee,
But I know I’ll be a law someday...
At least I hope and pray that I will, but today I am still just a bill.”
(Schoolhouse Rock)

Annals of Surgery, 2016
Getting Congress to Do Something

• How many people are we talking about?
• What will be the benefit if we do this?
  – How many lives will be saved
  – How much money will it cost (or save)
• What is the political benefit/risk?
  – Will our constituents benefit?
  – Will our constituents be harmed?
Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States

B. J. Boyarsky\textsuperscript{a}, E. C. Hall\textsuperscript{a,b}, A. L. Singer\textsuperscript{a}, R. A. Montgomery\textsuperscript{a}, K. A. Gebo\textsuperscript{c,d,e} and D. L. Segev\textsuperscript{a,d,*}

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\textsuperscript{e} HIV Research Network, Baltimore, MD
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2011
February.  
March.  
        AJT study published
April.  
July.  
August.  
November.  

2012
March.  
June.  

2013
February.  
March.  
June.  
November.  

HIVMA & major AIDS groups position established
NYT coverage of study
ASTS, AST, UNOS, AOPO position established
First meeting on Capitol Hill
AMA endorsement

Lead sponsors established
Draft legislative language
Meet with HHS/ONAP
Congressional briefing

HOPE Act introduced
CBO scoring
Senate HELP passes HOPE Act
Senate passes HOPE Act
House E & C passes HOPE Act
House passes HOPE Act
Obama signs HOPE Act
A Push to Let H.I.V. Patients Accept Organs That Are Infected

By PAM BELLUCK

David Aldridge of Los Angeles had a kidney transplant in 2006, but he will soon need another. Like many people living with H.I.V., he suffers from kidney damage, either from the virus or from the life-saving medications that keep it at bay.

Until recently, such patients did not receive transplants at all because doctors worried that their health was too compromised. Now they can get transplants, but organ-donor waiting lists are long. And for Mr. Aldridge, 45, and other H.I.V. patients, a potential source of kidneys and livers is off limits, because it is illegal to transplant organs from donors who test posi-

other experts are calling for repeal of the provision that bans such transplants, a 23-year-old amendment to the National Organ Transplant Act.

“The clock is ticking more quickly for those who are H.I.V.-positive,” said Dr. Dorry Segev, transplant surgery director of clinical research at Johns Hopkins and a co-author of a new study indicating that 500 to 600 H.I.V.-infected livers and kidneys would become available each year if the law were changed. “We have a huge organ shortage. Every H.I.V.-infected one we use is a new organ that takes one more person off the list.”

The ban on transplanting or
2011
February.  AJT study published
March.    HIVMA & major AIDS groups position established
April.    NYT coverage of study
July.     ASTS, AST, UNOS, AOPO position established
August.   First meeting on Capitol Hill
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March.    Senate HELP passes HOPE Act
June.     Senate passes HOPE Act
November. House E & C passes HOPE Act
          House passes HOPE Act
          Obama signs HOPE Act
Our Effort Inside the Beltway

• Congress
  – US Senate
  – US House of Representatives

• The Obama Administration
  – National AIDS Strategy
  – HHS/HRSA

• Professional group endorsements
  – Transplantation
  – HIV/AIDS
  – General medical
  – Patient advocacy
Official Endorsements

AIDS Community Research Initiative
AIDS Foundation of Chicago
AIDS Law Project of Pennsylvania
AIDS Project Los Angeles
AIDS Treatment News
AIDS United
American Academy of HIV Medicine
American Association of Kidney Patients
American Medical Association
American Sexual Health Association
American Society of Nephrology
AST
ASTS
American Transplant Foundation
amfAR, The Foundation for AIDS Research
Association of Nurses in AIDS Care
AOPO
Birmingham AIDS Outreach
Cascade AIDS Project
Center for HIV Law and Policy
Community Access National Ntwk
Dialysis Patient Citizens
Eye Bank Association of America
Fenway Health/Fenway Institute
Gay & Lesbian Medical Association
Gay Men's Health Crisis
HealthHIV
HIV Dental Alliance
HIV Medicine Association
Human Rights Campaign
Infectious Diseases Society of America
Lambda Legal
Latino Commission on AIDS
Mendocino County AIDS/Viral Hepatitis Network
Moveable Feast
NATCO
National Minority AIDS Council
Okaloosa AIDS Support
RAIN Oklahoma
Renal Physicians Association
San Francisco AIDS Foundation
Sisterhood Mobilized for Research & Treatment
Texas Transplant Society
The AIDS Institute
Transplant Recipients International
Treatment Action Group
UNOS
US Positive Women's Network
VillageCare
Warren Clinic for Pediatric Infectious Diseases
Congressional Briefing
Increasing Organ Donation
Repeal of the 1980s federal ban on transplanting organs from HIV+ donors to benefit HIV+ recipients

HIV Medicine Association • amfAR, The Foundation for AIDS Research
Human Rights Campaign • AIDS United • Treatment Action Group

Invite you to a Congressional Briefing held in collaboration with the offices of

Wednesday, June 27, 2012
12:00 - 1:00 pm
Room SVC 201-00

* Lunch will be provided *

Joel Newman
Professor of Medicine
Johns Hopkins School of Medicine
Assistant Director, Communications
United Network for Organ Sharing (UNOS)

Thomas Lane
Kidney Transplant Recipient

Kindly RSVP by June 25 to bjb@jhmi.edu
Congressional Briefing in June 2012

• Moderated by ABC journalist
• > 100 legislative aides
  – Standing room only
  – Facts and emotions
• Very positive write up in CQ & feedback from staff
• BEFORE we had a bill introduced
## Senate Co-Sponsors

<table>
<thead>
<tr>
<th>Blue</th>
<th>Red</th>
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<tbody>
<tr>
<td>*Boxer, Barbara [D-CA]</td>
<td>*Coburn, Thomas [R-OK]</td>
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<td>*Baldwin, Tammy [D-WI]</td>
<td>*Paul, Rand [R-KY]</td>
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<td>Warren, Elizabeth [D-MA]</td>
<td>Enzi, Michael [R-WY]</td>
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<td>Feinstein, Dianne [D-CA]</td>
<td>Burr, Richard [R-NC]</td>
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<td>Blumenthal, Richard [D-CT]</td>
<td>Kirk, Mark [R-IL]</td>
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<td>Landrieu, Mary [D-LA]</td>
<td>Blunt, Roy [R-MO]</td>
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<td>Schatz, Brian [D-HI]</td>
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<td>Levin, Carl [D-MI]</td>
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<td>Pryor, Mark [D-AR]</td>
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## House Co-Sponsors

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<tr>
<th>*Capps, Lois [D-CA24]</th>
<th>Rush, Bobby [D-IL1]</th>
<th>Harris, Andy [R-MD1]</th>
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<tr>
<td>Cummings, Elijah [D-MD7]</td>
<td>Takano, Mark [D-CA41]</td>
<td>Burgess, Michael [R-TX26]</td>
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<td>Schiff, Adam [D-CA28]</td>
<td>Maloney, Sean [D-NY18]</td>
<td>McKinley, David [R-WV1]</td>
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<td>Huffman, Jared [D-CA2]</td>
<td>Titus, Dina [D-NV1]</td>
<td>Harper, Gregg [R-MS3]</td>
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<td>Loebssack, David [D-IA2]</td>
<td>Carson, André [D-IN7]</td>
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<td>Polis, Jared [D-CO2]</td>
<td>Levin, Sander [D-MI9]</td>
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<td>Norton, Eleanor [D-DC0]</td>
<td>Cohen, Steve [D-TN9]</td>
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<td>Costa, Jim [D-CA16]</td>
<td>Pocan, Mark [D-WI2]</td>
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<td>Michaud, Michael [D-ME2]</td>
<td>Christensen, Donna [D-VI0]</td>
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<td>Ruiz, Raul [D-CA36]</td>
<td>Schwartz, Allyson [D-PA13]</td>
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<td>Cicilline, David [D-RI1]</td>
<td>Chu, Judy [D-CA27]</td>
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<td>Maloney, Carolyn [D-NY12]</td>
<td>Himes, James [D-CT4]</td>
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<td>Schakowsky, Janice &quot;Jan&quot; [D-IL9]</td>
<td>Lipinski, Daniel [D-IL3]</td>
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S330/HR698: Progress

• Introduced **Feb 14, 2013**

• Senate:
  – HELP Committee: 3/20/13
  – Floor Vote: Unanimous 6/17/13

• House:
  – E&C Committee: 7/17/13
  – Suspension: 11/12/13

• **Obama: 11/21/13**
Hopkins Begins Nation's First HIV-Positive Organ Transplants

Johns Hopkins performs first transplants between donors, recipients infected with HIV

In a medical first, HIV-infected organs are transplanted into HIV-positive patients

There used to be a longstanding ban on the use of HIV-infected organs in transplantation.
Dear Dr. Segev:

I wanted to take a moment to extend my congratulations on all you’ve done to successfully increase access to life-saving organ transplants.

I was proud to sign the HOPE Act into law in 2013 as part of the effort to expand the national supply of organs for all those in need. Through your team’s actions—including performing the first-ever transplants between HIV-positive donors and recipients in the United States—the intent of this legislation has been realized and will continue to be for generations to come.

Again, congratulations. You and your colleagues have my very best.

Sincerely,
• R01AI120938: Unlocking the potential of HIV-infected deceased donors for organ transplantation

• R34AI123023: HOPE in Action: HIV-to-HIV solid organ transplantation in the US

• U01AI134591: HOPE in Action: A clinical trial of HIV-to-HIV kidney transplantation

• U01AI138897: HOPE in Action: A clinical trial of HIV-to-HIV liver transplantation
Kidney Exchange: Paradigm

Donor

A

O

Recipient

O

A

ABO Incompatible

Positive Crossmatch
42 U.S.C. 274(e)

"It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation..."

(National Organ Transplant Act, 1984/88)
Kidney Paired Donation and Optimizing the Use of Live Donor Organs

Dorry L. Segev, MD
Sommer E. Gentry, MS
Daniel S. Warren, PhD
Brigitte Reeb, MFA
Robert A. Montgomery, MD, DPhil

- How many pairs?
- How best to match them?
- How many lives would be saved?
- How much money would Medicare save?
Each Patient has 1-4 Potential Donors

Medical and Psychosocial Workup

Donor

ABO & XM test

Patient

Eligible

Failed

Check other donors For eligibility

Incompatible

Compatible

Direct Donation

Check other donors for compatibility
If none are compatible:
Join KPD

Keep simulating patients until live directed donors are found

(Segev, JAMA, 2005)
Kidney Exchange: IP Optimization

Pair 1: Donor: A, Recipient: B  
Pair 2: Donor: O, Recipient: A  
Pair 3: Donor: B, Recipient: A  
Pair 4: Donor: A, Recipient: O

-objective function-
\[ \text{max}(335x_1 + 200x_2 + 275x_3) \]

-subject to constraints-
\[ x_1, x_2, x_3 \in \{0,1\} \]
\[ x_1 + x_2 \leq 1 \]
\[ x_1 + x_3 \leq 1 \]

(Segev, JAMA, 2005)
The Kidney Connection

DORRY SEGEV & SOMMER GENTRY

The couple tweaked a decades-old algorithm to develop a better way to match kidney donors and patients. Their optimized matching system could save hundreds of lives each year.
A BILL

To amend the National Organ Transplant Act to clarify that kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,
3 SECTION 1. SHORT TITLE.
4 This Act may be cited as the “Living Kidney Organ
5 Donation Clarification Act of 2007”.

SEC. 2. AMENDMENT TO THE NATIONAL ORGAN TRANSPLANT ACT.

Section 301(a) of the National Organ Transplant Act (42 U.S.C. 274e(a)) is amended by adding at the end the following: “For purposes of this section, kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.”.
Title: A bill to amend the National Organ Transplant Act to clarify that kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.

Sponsor: Sen Levin, Carl [MI] (introduced 2/1/2007)  
Cosponsors (10)

Related Bills: H.R.710


COSPONSORS (10), BY DATE [order is left to right]: (Sort: alphabetical order)


H.R.710
Title: To amend the National Organ Transplant Act to clarify that kidney paired donation does not involve the transfer of a human organ for valuable consideration.
(29)
Related Bills: S.487

COSPONSORS(29), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date)

Kidney Exchange in the US: >5000

(SRTR Data)
16% of Live Donor Transplants

(SRTR Data)
Learn the policy
Think from the trenches

Learn the science
Publish for the policymakers

Make media connections
Learn how to talk to media

Learn how congress works (Fellowship?)
Work with advocacy groups, societies, LAs