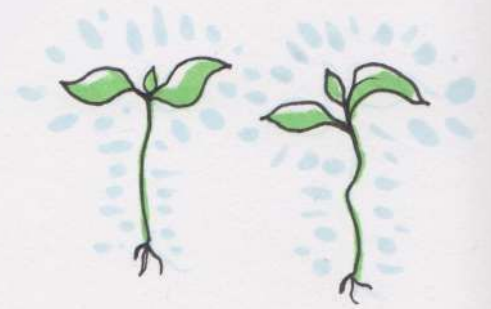


Why



Bioethics?

Weds 8/28/2019

Ann Fink, Ph.D.

BioS 10/ BioS 90: Bioscience in the 21<sup>st</sup> Century

Why  
Bioethics?

What is  
Bioethics?

We can ask scientific AND ethical questions about biology.



What is Bioethics?

What do these questions look like?

For example:

- What is a scientific question about genetics?
- What is an ethical question?



## Some basic terms

- **“Morality”**: Questions about what is “right” and “wrong”
- **“Ethics”**: How do we *decide* what is “right” and what is “wrong”

How do we evaluate our knowledge about the world around us?

- **Metaphysics**: (the study of “what is”)
- **Epistemology**: how knowledge is created and organized

# Ethics: What “ought” to be? How do we decide?

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**Many different types of questions:**

**Research ethics:** How is scientific knowledge created? Who creates it? What methods are used to obtain that knowledge?



**Use of scientific knowledge:** Technology resulting from scientific knowledge? Development of medical treatments / drugs? Scientific basis for policy? Who benefits from science?



## Some primary *Western*\* theories of ethics:

- **“Virtue ethics”** – Aristotle
- **Deontological ethics** – Kant
  - Duty-based
  - Humanity (reason, free will, autonomy)
  - Universalisability
- **Consequentialism**
  - Utilitarianism – Mill, (Greatest happiness for the greatest number)

*\*\* (What aspects of moral reasoning might be common across cultures? What aspects might vary?)*

Beauchamp and Childress: 4 Principles  
*Principles of Biomedical Ethics, 1985*

- **Non-maleficence**
- **Beneficence**
- **Respect for Autonomy**
- **Justice**

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- **Respect for Autonomy** – Respect for the rights of individuals to make free decisions
- **Justice** – Fairness and equity in research and medical applications.

*Principles are both widely applied and continuously debated...*

# Deontology vs. consequentialism... the trolley problem.

(Small spoiler for “The Good Place” / brief depiction of violence)

<https://www.youtube.com/watch?v=vfIdNV22LQM>

## The trolley / patient problem

- If you could save seven patients by killing one person and redistributing their organs, would you?
- Why?

# Sneak preview: Neuroethics

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How “ought” we to consider, research, and treat  
brains in health and illness?

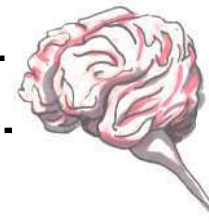
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How should we study



??

Who should do the  
studying of



??

Whose  should we study??

*How should we use the  
knowledge that we gain  
from brain research?*

# Neuroethics: some of the issues

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## Mental health and illness

- How should we define a “disorder” (e.g. addiction, anxiety, autism, schizophrenia)?
- Ethics of experimental and invasive treatments (e.g. deep-brain stimulation for Parkinsons or depression)?

## Socioeconomic variables and the brain:

- e.g. What duties arise from understanding how childhood adversity affects the brain?



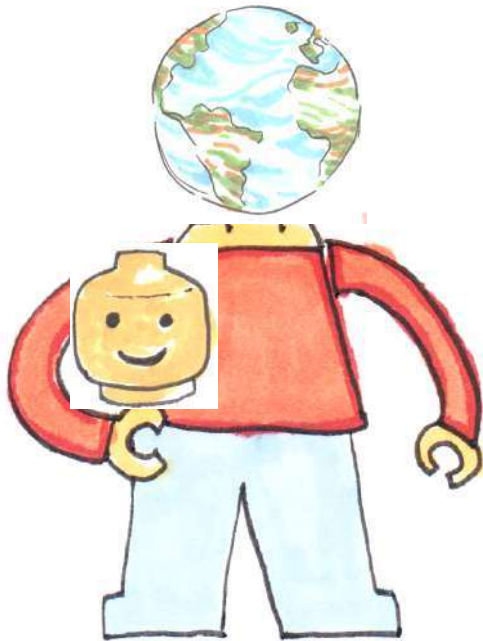
## Cognitive enhancer drugs?

- Should people be allowed to use these?
- In what situations?

**Why do we care so much about these questions?**

# Ethics and Biology: asking bigger questions

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Through the study of ethics, we continually evaluate our values, our science, and our responsibilities.

This allows us to understand relationships between people and the natural world in more complex ways.

*Thank you!*



# **BIOMEDICAL ETHICS**

- 1. Organ Needs**
- 2. Drug Pricing**
- 3. Start-up Companies**

**Neal G. Simon, Ph.D.  
Dept. of Biological Sciences  
August 28, 2019**

# ORGAN PROCUREMENT AND TRANSPLANT NETWORK WAITLIST\*

## Dept. of Health and Human Services

All Organs	Kidney	Liver	Pancreas	Kidney / Pancreas	Heart	Lung	Heart / Lung	Intestine	Abdominal Wall	Head & Neck: Craniofacial	GU: Uterus
124,309	102,941	13,289	853	1,711	3,776	1,449	44	226	3	5	8

➤ ***20 people die every day waiting for an organ transplant***

\*as of August 26, 2019

**Organ Wait List: United States**  
**August 27, 2019**

**All Organs                      124,309**

**Kidney                              102,941**

**Number of Transplants (2018)**

**All Organs                      36,526**

**Kidney                              21,167**

**Number of Donors (2018)**

**Total                      17,568**

**Deceased                      10,721**

# Desperation & Cultural Prohibition

- **Should people be allowed to sell their organs?**
- **What about cultural/religious prohibitions?**
- **National Policy: Opt-in or Opt-Out?**
- **UNOS decision rules**

## The NY TIMES Editorial Board: August 20,2019

### **She Beat Cancer. Now, She's in Another Fight for Her Life.**

Twenty Americans die each day waiting for organs. Here's how to change that.



- Erika Zak beat Stage IV metastatic colon cancer. She survived more than 70 rounds of chemotherapy
- She's stayed alive more than two years despite liver failure after a botched surgery

***Is Ms. Zak a candidate for a liver transplant?***

## Erika Zak Update



- The insurance company had repeatedly declined to cover the liver transplant that Ms. Zak's doctors say she will die without
- Last year it agreed to cover the cost after Ms. Zak made an impassioned plea, *but...*
- UNOS had refused to grant her an emergency exception that would significantly increase her chances of receiving the liver transplant

***You are on the 5 person UNOS Board, would you approve or not approve Ms. Zak? Why?***

## Social Responsibility, Altruism, & Philanthropy

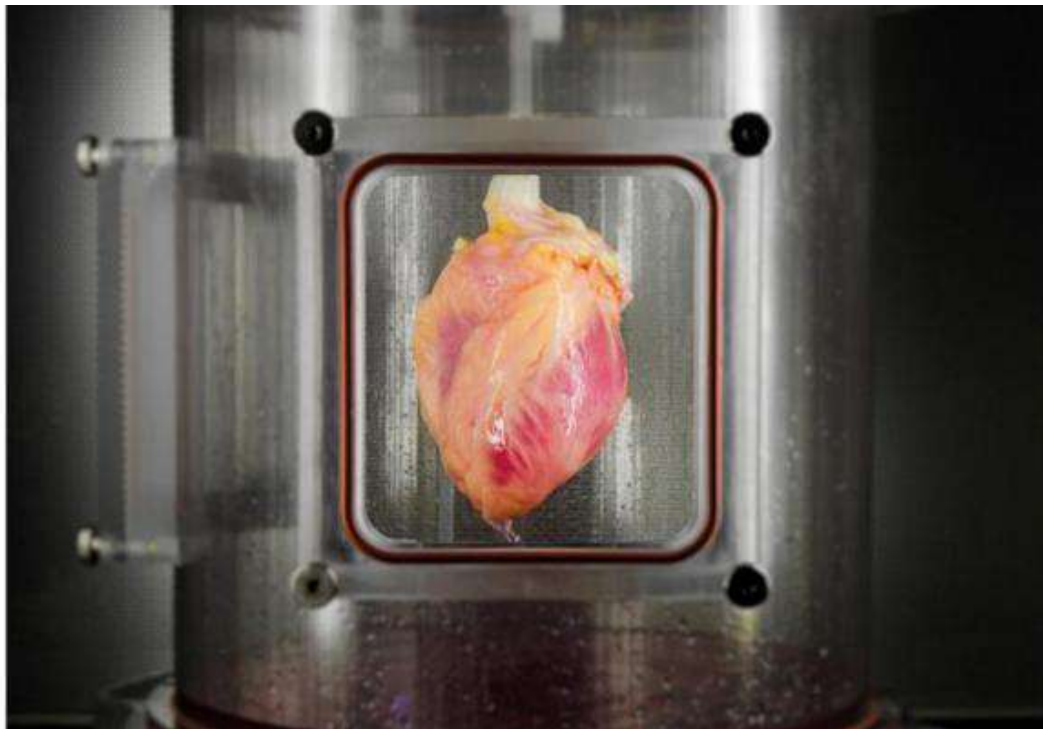


Liang Yaoyi, age 11, had a dying wish to donate his organs so others could live. He lost his battle with brain cancer on Friday. As his body was wheeled from the surgery room to harvest his organs, the medical team bowed to honor him and the lives he saved.

# The Future of Meeting Need



Genetically engineered piglets free of retroviral sequences may provide safer organs for human transplant (Niu et al. (2017) Science)



A partially recellularized human whole-heart cardiac scaffold, reseeded with human cardiac cells derived from induced pluripotent stem cells, being cultured in a bioreactor that delivers a nutrient solution and replicates some of the environmental conditions around a living heart (Guyette et al (2016))



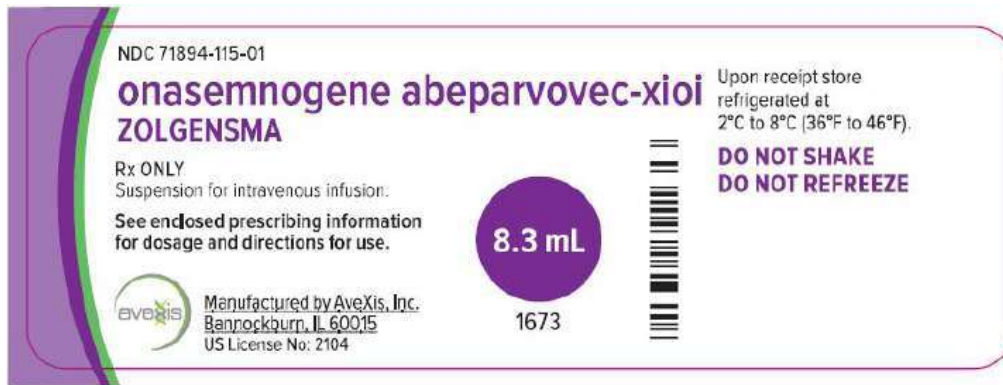
# **DRUG PRICING & MARKETING**



# SPINAL MUSCULAR ATROPHY

- A rare, autosomal recessive neuromuscular disease characterized by degeneration of alpha motor neurons in the spinal cord, resulting in progressive proximal muscle weakness and paralysis.
- Occurs in 1:6000 to 1:10,000 births
- Caused by a defective or missing *SMN1* gene. Infants with SMA lose the motor neurons responsible for muscle functions such as breathing, swallowing, speaking and walking.
- SMA type 1 is the most common type of SMA and is also a severe form of the disease. Infants with SMA type 1 experience severe weakness before 6 months of age and never sit independently. Muscle weakness, lack of motor development and poor muscle tone are the major clinical manifestations Intelligence is normal. Most affected children die before two years of age.
- The onset of weakness in SMA type 2 patients is usually between 6 and 12 months. Affected children can sit independently early in development but are unable to walk even 10 feet independently. Those with SMA type 2 are usually not able to sit independently by the mid-teens or later.

# ZOLGENSMA FOR SPINAL MUSCULAR ATROPHY



NOVARTIS



## Vas Narasimhan, MD

### CEO, Novartis

#### ➤ **On the price of Zolgensma**

.... Novartis was quick to point out that the price comes out to \$425,000 per year for five years, which is also far less—50%—than the 10-year cost of current chronic SMA therapy.

#### ➤ **On data manipulation and reporting**

.... an AveXis scientist stepped up in mid-March to report the manipulated data, which the FDA said was submitted as part of Zolgensma's application for approval. The company launched an internal probe, and by early May had determined the scientist was correct. It didn't tell the FDA about the allegations, however, until June 28, more than a month after Zolgensma won its FDA green light.

#### ➤ **On being CEO**

..... explained the delay as a result of the company wanting to complete an internal investigation to determine what happened prior to notifying the agency. He said he's committed to rebuilding trust.

“We moved quickly to conduct the relevant investigations and to be science-based and patient driven. In our approach, we determined that the potential data issue in question impacted a very small amount of data and did not impact the safety, efficacy or product quality of Zolgensma.”

**START-UP COMPANIES  
THERANOS**

**See Tyler Schultz on September 24**

**Thank you for your time and attention**

## Most Expensive Drugs: United States

- **Actimmune** (Chronic Granulomatous Disease; slows severe, malignant osteopetrosis)\* **\$627,852/patient/year**
- **H.P. Acthar Gel (Multiple Sclerosis)** **\$205,681/patient/year**
- **Cinryze (Hereditary Angioedema)\*** **\$230,826/patient/year**
- **Kalydeco (Cystic Fibrosis)** **\$299,592/patient/year**
- **Naglzyme (Maroteaux-Lamy Syndrome)\*** **\$485,747/patient/year**
- **Soliris (paroxysmal nocturnal hemoglobinuria) \*** **\$536,629/patient /year**

\*orphan indication



# In the News



- Martin Shkreli
- CEO of Retrophin and Turing
- Daraprim: toxoplasmosis
- \$13.50 to US\$750 per pill overnight



- Michael Pearson
- CEO of Valeant Pharmaceuticals
- Nitropress: hypertension: 3-fold
- Isuprel: bradycardia: 6-fold



- Heather Bresch
- CEO of Mylan
- EpiPen: 10-fold increase

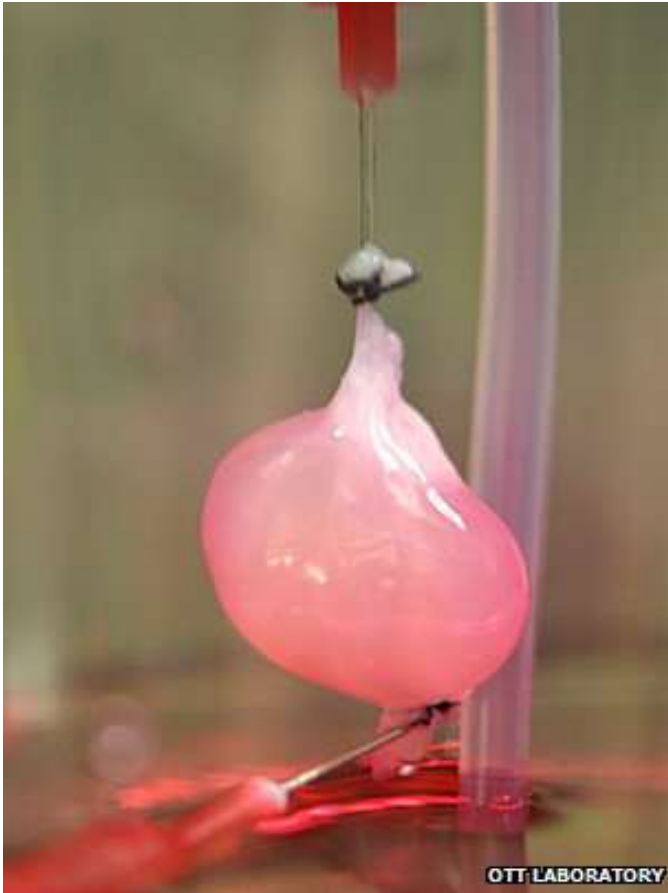
# Where are They Now

**M. Shkreli: charged in securities fraud case, found guilty on multiple counts, not guilty on others. In jail**

**M. Pearson: “all we care about is shareholder value.”  
Price per share was \$262 in August, 2015  
Current price: \$30.30**

**H. Bresch: still CEO  
April 2017: class action suit for racketeering filed based on EpiPen pricing**

# Innovation & Entrepreneurship



H. Ott, 2013, Nature Medicine



M. Little, 2013, Nature Biology

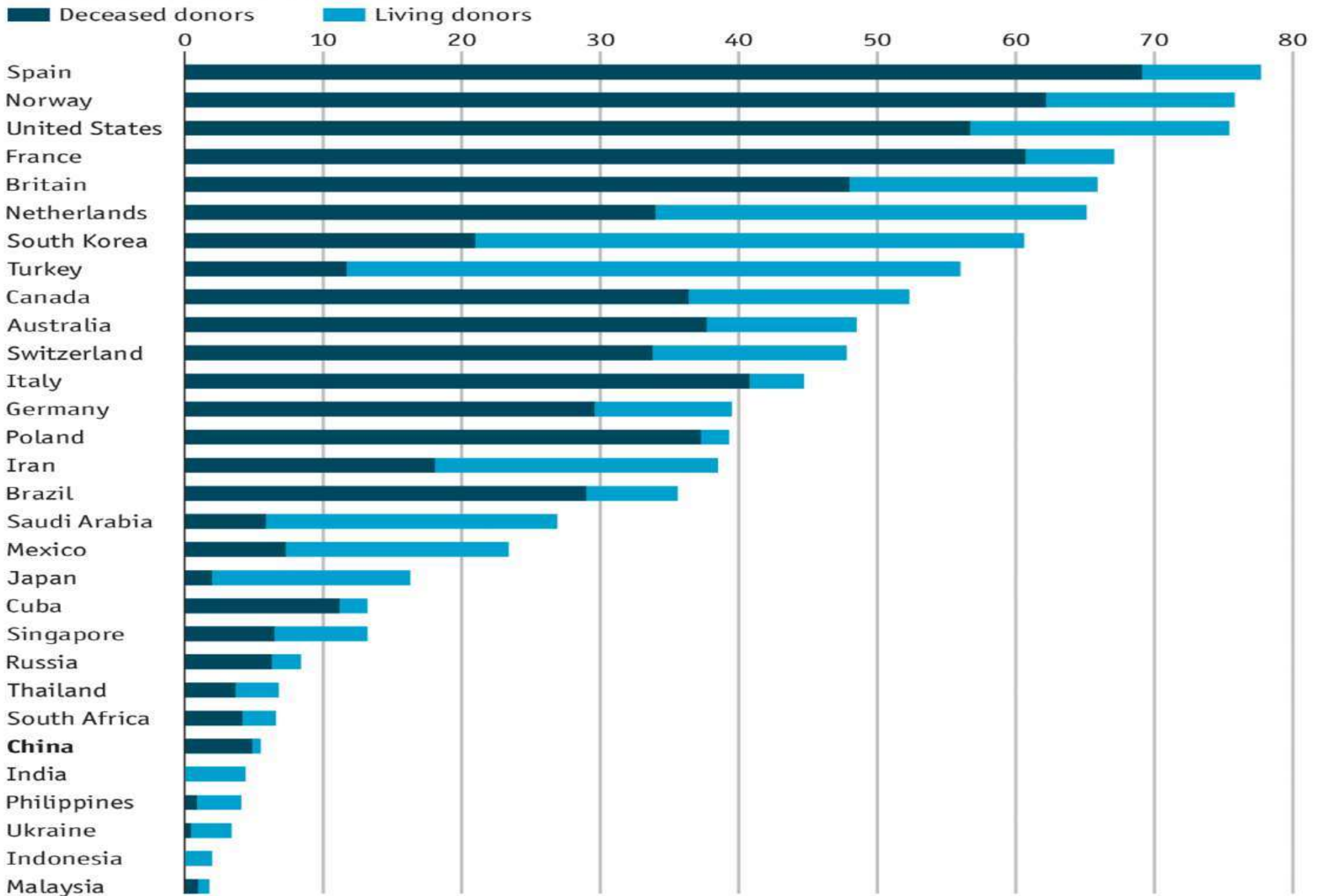
# **Ethics of Access**

**1. Organ Transplants**

**2. Orphan Drugs**

# Transplants\* per million people

Selected countries, 2013 or latest



Sources: Global Observatory on Donation & Transplantation; WHO; ONT

\*Kidney and liver transplants, which comprised almost 90% of all transplants in 2012