

Patients For Stem Cells

www.patientsforstemcells.org

It is our right to access our own stem cells for potential life saving therapies

Our mission is to create awareness about the violation of our basic human rights to access our own stem cells for potential life saving therapies, through vetting media sources and enlightening the research community and public of our plight.

One Man's Reluctant Tour For Adult Stem Cells

Forbes, [John Farrell](#), Contributor science and technology. 2/21/2013
<http://www.forbes.com/sites/johnfarrell/2013/02/21/one-mans-reluctant-tour-for-adult-stem-cells/>

- *My symptoms started 8 years ago, in my late 40s. 57 now.*
- *CEO / Co-founder Software Company*
- *Approved Treatments*
- *Trails – Did Not Qualify*
- *Forced Overseas*

What Are The Experts Saying?

Arnold I. Caplan, PHD, Professor of Biology, Professor of General Medical Sciences (Oncology)

Case Western Reserve University in Cleveland, Ohio

Pioneering work on MSCs and refers to their action as “hit and run” healing

“ If I had MS, I would be getting this therapy. I’d probably go offshore.”

Stem cells in Texas: Cowboy culture Nature, Feb 2013

Patents

2008 President-George Daley-Children's Hospital

Creating Embryonic Stem Cells for Mass production-PCT/US2007/019935

Method for Enhancing Proliferation of Stem Cells-PCT/US03/29185

Proprietary Kit to see if an iPS Cell is Correctly Manufactured-PCT/US09/57849

Method to Create iPSC's (artificial stem cells)-PCT/US08/12532

2010 President-Irving L. Weissman-Stanford University

Method for Isolating a Stem cell Type-Issued Patent-[US7592174](#)

Regenerating a Liver with a certain Stem Cell Type-US 2001/0049139 A1

Method for Culturing Embryonic Stem Cells-US 2006/0172414 A1

A Method for Concentrating Stem Cells of the same Type-Patent Number US 5087570

A Device for Isolating Stem Cells-US 2004/0038316 A1

Methods to Isolate and Culture Certain Blood Stem Cells-US 2009/0191164 A1

2011 President-Elaine Fuchs-Rockefeller University

A Method for Changing Skin Stem Cells-US 2012/0034616 A1

A Method for Isolating a new Stem Cell Type-US Patent 7829336

A Method for Modulating Hair Growth-US 2009/0203574 A1

A Method for Isolating Hair Stem Cells-US 2008/0213882 A1

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Patents = Conflict

2012 President-Fred Gage-Salk Institute for Biological Studies

A Method and Device for Extracting Stem Cells-US 2007/0190649 A1

A Method to turn Stem Cells into Nerves-US 2010/0166710 A1

A Stem Cell Therapy to treat Brain Diseases-US Patent number: 6451306

A Method for Culturing Stem Cells from Deceased Patients-US 2002/0098584 A1

A Method to use a Centrifuge to Isolate Nerve Stem Cells-US Patent number: 6767738

A Method to use IGF-1 to turns Stem cells into Certain Nerve Cells-US 2005/0148069 A1

A Patent on using a Molecular Switch to turn Stem Cells to nerve Cells-US 2006/0234378 A1

2013 President-Shinya Yamanaka- Center for IPS Cell Research & Application

A Method for Producing Induced Pluripotent Stem Cells-US 2011/0250692 A1

Another Method for Producing Induced Pluripotent Stem Cells-US 2009/0227032 A1

A Method for Improving the Efficiency of Induced Pluripotent Stem Cells-US 2011/0039338 A1

Reprogramming Factors to create iPS Cells-US Patent number: 8058065

Yet Another Method for Producing Induced Pluripotent Stem Cells-US 2011/0003365 A1

A Method to create Nerve Cells from Stem Cells-US 2011/0183350 A1

A Method of treating Nerve Problems with Stem cells-US 2009/0208465 A1

Another Method for reprogramming Cells to Stem cells-US 2010/0279404 A1

A Method to create Platelets from iPS Cells-US 2011/0053267 A1

A Method to find Substances that will Reprogram Cells to iPS Cells-US 2008/0274914 A1

A Gene only expressed in Embryonic Stem Cells-US 2008/0299548 A1

How Safe Are Stem Cells?

Conflicted scientists have claimed that cultured stem cells are potentially dangerous.

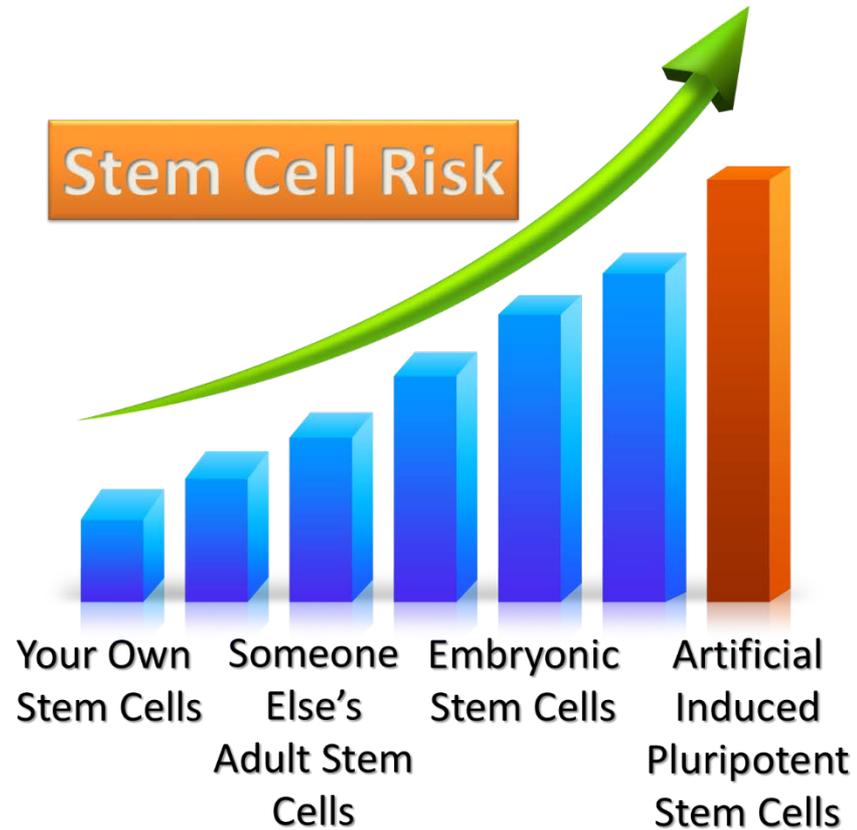
What data exists showing safety?

Stem Cell Risk

The risk of a stem cell therapy generally increases as the source changes.

The safest cells are your own adult stem cells.

Newer induced Pluripotent Stem Cells (iPSC), are artificial stem cells manufactured in a lab and as such are considered the most dangerous.



What's financially at stake for scientists, universities, drug companies, and the FDA?

MONEY. Much of the stem cell risk cry wolf has been sponsored by vested financial interests to protect markets.

Patients access to their own stem cells for therapy is bad business for those trying to produce patented FDA stem cell drugs.



**YOUR
ADULT
STEM CELLS**

**SOMEONE
ELSE'S STEM
CELLS**

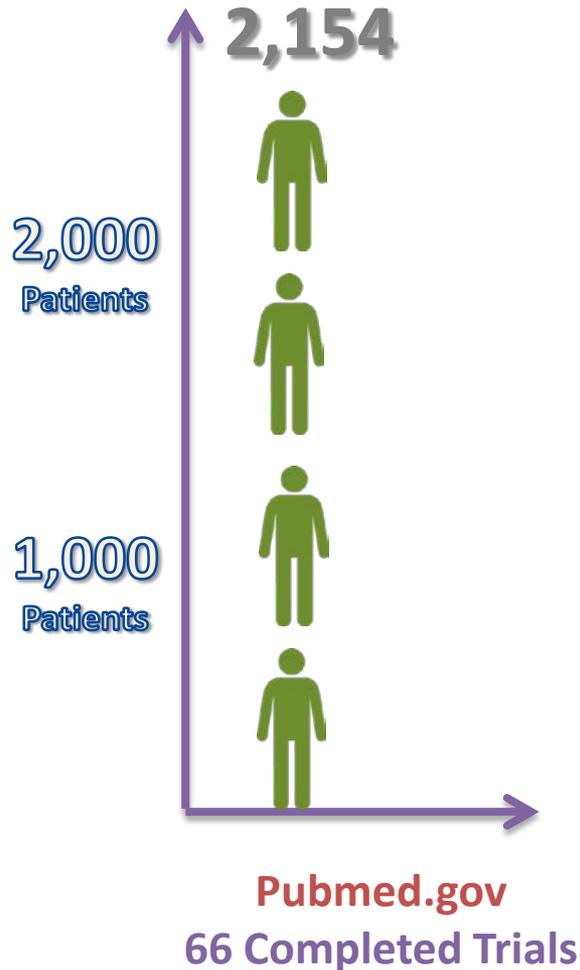
**EMBRYONIC
STEM
CELLS**

IPS

So if the media surrounding risk is being generated by financially conflicted parties, what's the real risk?

In the U.S. national library of medicine or published FDA trials, how many patients have been treated with expanded MSCs *without serious complications?*

Over 2000 Patients!



PubMed search of US National Library of Medicine Feb 14, 2013:

Search terms "expanded mesenchymal stem cells"
-and clinical trials
-and safety
-and complications

Number of completed studies seen in this search=66

Search of ClinicalTrials.gov Feb 15, 2013:

Number of ongoing and completed studies seen in this search=54

**How many patients are currently
being treated with autologous stem
cells in research studies listed on
ClinicalTrials.gov?**

1,630

What Are The Experts Saying

“I think patients would be happy to take the risk of using their own cells given the choice,” Gurdon told a press conference in London, criticizing the US Food and Drug Administration for placing *“immense conditions on approval”*.

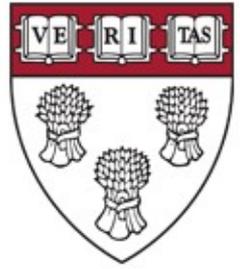
- *Sir John Gurdon, winner of the 2012 Nobel Prize
for stem cell research*

[Good choice but will cures come soon?](#) New Scientist, Oct 2012



Bill of Health

Examining the intersection of law and health care, biotech & bioethics
A blog by the Petrie-Flom Center and friends



Our Bodies, Our Cells: FDA Regulation of Autologous Adult Stem Cell Therapies

Posted on [June 2, 2013](#) by [Katharine Van Tassel](#) By [Mary Ann Chirba, J.D., D.Sc., M.P.H.](#) and [Alice A. Noble, J.D., M.P.H.](#)

- The restrictive FDA regulatory framework, as it exists today, is a significant driver in building 'stem cell tourism.
- **..it makes no sense to deprive patients of autologous therapies** because their physician lacks the resources – and patients lack the time – to satisfy the pre-marketing requirements that oppress even Merck and Johnson & Johnson.
- the FDA should re-examine its regulations especially as applied to physicians treating patients with their own cells. Extracting a patient's cells for subsequent reinjection undoubtedly carries risk – but so does banking one's own blood or freezing eggs for later use.

Stem Cells and the Lawsuit That May Shape Our Medical Future

Chris Centeno M.D., Medical Director of Regenerative Sciences

Forbes, [PHARMA & HEALTHCARE](#), 2/10/2012

<http://www.forbes.com/sites/gerganakoleva/2012/02/10/stem-cells-and-the-lawsuit-that-may-shape-our-medical-future/>

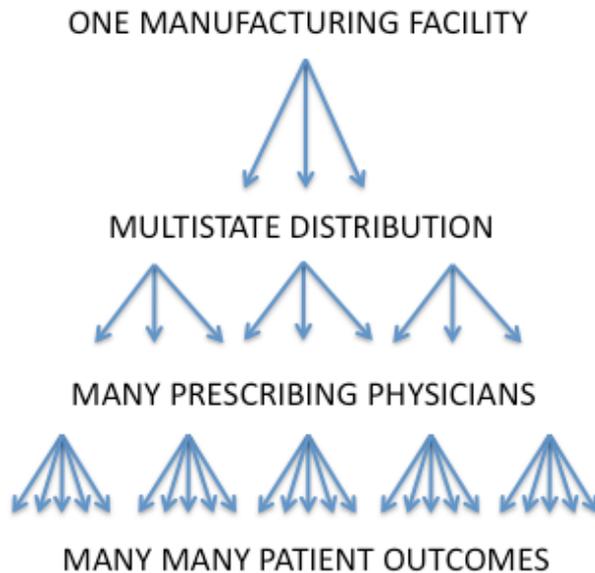
United States (FDA) v. Regenerative Sciences

“We see this lawsuit as a 21st century civil rights issue that will define what control you have about the use of your own cells and tissue.

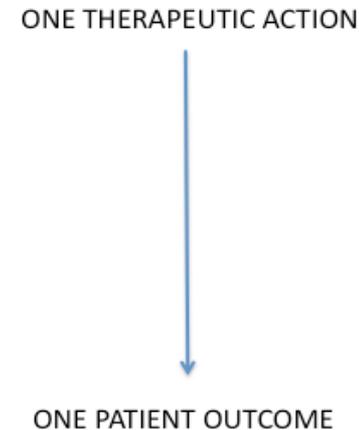
“If a loved one is dying in intensive care and a well done study shows that the patient’s own cells can be used to help, does the patient get to decide to use those cells, or is that a decision for the FDA?”

What is the science behind regulating a medical procedure the same as a mass produced drug?

Mass Drug Manufacture



Doctor-Patient interaction



One procedure is discussed with one patient who is informed of the risks

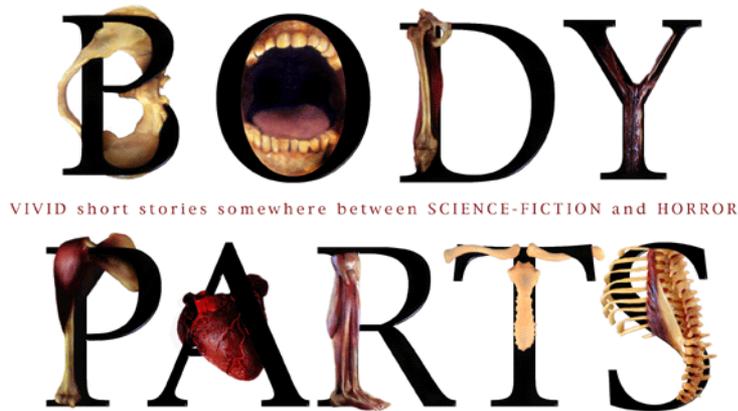
One “bad batch” of mass produced cells can make millions sick

Cells taken from one patient and injected back into the same patient is NOT a public health issue

Body Parts or Drugs

- Surgeons transplant hearts and other body parts;
- regulated as “medical procedures”
- In Vitro Fertilization (IVF) involves using sperm cells from one person, egg cells from another person and manipulation in a lab to create a third person - regulated as a “medical procedure.”
- Taking MY cells, manipulating them (expanding to therapeutic dose), injecting them back into MY body – FDA wants to regulate as a “drug”?

Are autologous stem cells body parts or drugs?



vs.



Excessive Regulations have Prohibited
Doctors from Trying to Cure Patients

4X Regulation

- State Medical Board
- Hospital Privileges / Board Regulation
- Public Health Department
- Professional Societies clinical guidelines
- College of American Pathologists (CAP) program accredits labs
- Board certification through ABMS
- State medical boards provide licensure

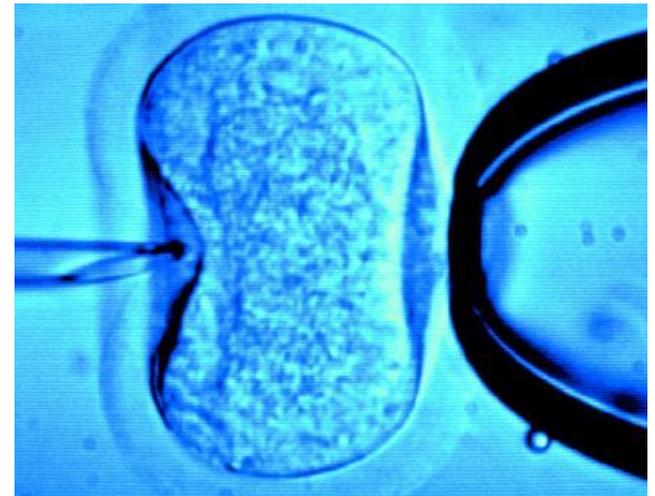
- Civil Tort (Malpractice)

Do we need more?

EXTRA SLIDES

If FDA doesn't regulate physicians culturing cells, who will?

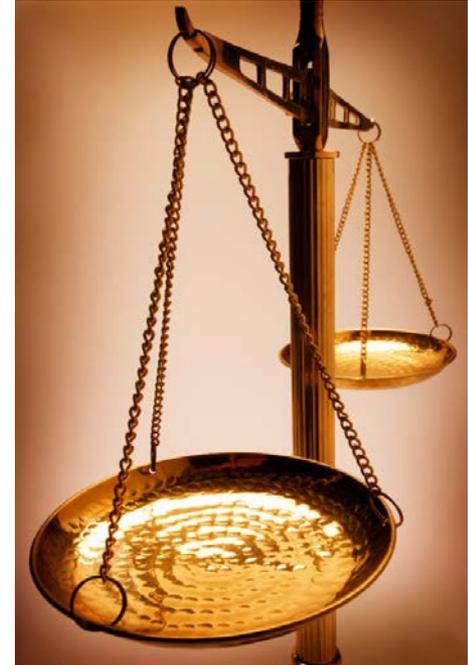
- In-vitro fertilization / Assisted Reproductive Techniques
 - Professional societies have promulgated clinical guidelines
 - College of American Pathologists (CAP) program accredits labs
 - CDC monitors fertility rates
 - Board certification through ABMS
 - State medical boards provide licensure



If heart transplants had been held to these new regulatory standards, they would never have become standard practice of medicine.

The legal controversy (RS claims in part):

- For FDCA to apply there must be **interstate distribution**
- 21 CFR 1271 is *ultra vires*
- FDA's definition of "minimal manipulation" is **arbitrary**
- FDA is **prohibited from involvement in medical practice**



Cells That Heal Us From Cradle To Grave: A Quantum Leap in Medical Science Nocera, Dr. Roger (2011-02-15)

We can now effectively predict the clinical outcome of a stroke by measuring the Healing Cell blood count.

If a high enough Healing Cells blood count (CD34+ adult stem cell blood count) has not been achieved by one month after any stroke, we can now use that objective information to predict that the patient will not recover from the stroke neurologically.

This has now been proven.

Cells That Heal Us From Cradle To Grave: A Quantum Leap in Medical Science

Nocera, Dr. Roger (2011-02-15)

We have done the initial work, inconveniently overseas, demonstrating “proof of concept” of Healing Cells

Once our FDA stops denying our nation’s capable physicians their civil right to focus upon it., then Healing Cell treatments will rapidly revolutionize healthcare in a manner that will reduce costs to a fraction of the current system and drastically improve the health of our citizens.

Autologous MSC for MS Trail

The mesenchymal stem cells in multiple sclerosis (MSCIMS) trial protocol and baseline cohort characteristics: an open-label pre-test: post-test study with blinded outcome assessments

Published: 2 March 2011

<http://www.trialsjournal.com/content/12/1/62>

Corresponding author: Peter Connick pc349@cam.ac.uk

Dept. of Clinical Neurosciences, University of Cambridge, UK

MSCIMS is a phase IIA study of autologous mesenchymal stem cells (MSCs) in secondary progressive MS.

The MSCIMS trial established safety and feasibility of autologous intravenous mesenchymal stem cell therapy in multiple sclerosis

Common Sense

- Autologous therapies do not represent a public health risk in the same sense as a mass-produced drug, but rather, represent a risk more akin to a surgery than a drug;
- It is neither cost-effective nor feasible to expect the same manufacturing quality controls for autologous therapies as those in place for mass-produced allogeneic therapies (just as one would not expect the same quality control burden in an operating room as in a device manufacturer's clean room);
- The risks associated with the delivery of adult, autologous cells (i.e., cancer, cell aggregation-induced embolism or stroke, ectopic tissue formation, disease transmission), while not zero, is exceptionally low in practice and largely theoretical at this point;
- With the exception of maintaining sterility, the risks associated with short-term expansion (through p5) are relatively low and can be managed effectively through the use of closed loop systems or modest QA programs;
- While efficacy may vary with cell purity or dosing, there is little risk from a safety perspective in delivering a mixed population of autologous cell types across a wide range of dosages. Similarly, there does not appear to be a safety issue associated with cell-viability;

One patient and one doctor deciding what's best for the individual patient

Off track in America

- *Adult stem cells are confused with embryonic stem cells.*
- *Religious and financial interests slow progress*
- *Adult stem cells can't be patented, limiting the financial incentive.*
- *Few conflicted stem cell "experts" – ESC & iPSC researchers, spreading misinformation about adult stem cells.*
 - *Creating their "Stem Cell Expert" Brand*
 - *Adult Stem Cell are Safe – no rejection*
 - *ESC cause cancer*
- *Result: FDA oversteps "minimally manipulated" threshold*
 - *authority over a medical procedure.*
 - *This is a crime against ill people who can't afford to travel overseas for treatment.*
- *America should be fast tracking this treatment, not slowing the adoption process to the crawl involved in drug approval.*

What are cultured stem cells?



- A mesenchymal stem cell (MSC) is a cell that can become other cells or help repair damaged tissue.
- MSCs are usually harvested from bone marrow or adipose tissue, but only a small quantity.
- To create enough for an effective dose, they are grown in culture and expanded

Congress and the courts have prohibited FDA's involvement in medical practice

- *U.S. v. Evers* - "...if a doctor must prescribe and treat only within "federally sanctioned" methods, this would result in medical stagnation at the best, as physicians await ... FDA approval.
- A free, progressive society has an enormous stake in recognizing and protecting this right of the physician."



Patients For Stem Cells

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Our basic human rights are being violated

Many People are suffering

*America should be fast tracking this treatment,
not slowing the adoption process to the crawl involved in
drug approval.*

This is my body! These are my Cells!
It is between Me & my Doctor

Conflicted Scientists & FDA needs to back off.. Anything
less is criminal!

What Needs to Happen?

LEGAL

No. 17 September 2013



THE FDA'S MISGUIDED
REGULATION OF
STEM-CELL PROCEDURES:
How Administrative
Overreach Blocks
Medical Innovation

CENTER FOR LEGAL POLICY
AT THE MANHATTAN INSTITUTE
Published by Manhattan Institute
No. 17 September 2013
Legal Policy Report