

A.J. FARSHCHIAN, MD

- CHIEF SCIENTIFIC OFFICER AND MEDICAL DIRECTOR AT THE CENTER FOR REGENERATIVE MEDICINE
- DIRECTOR TO THE AMERICAN ACADEMY OF STEM CELL PHYSICIANS
- TEAM USA OLYMPIC PHYSICIAN



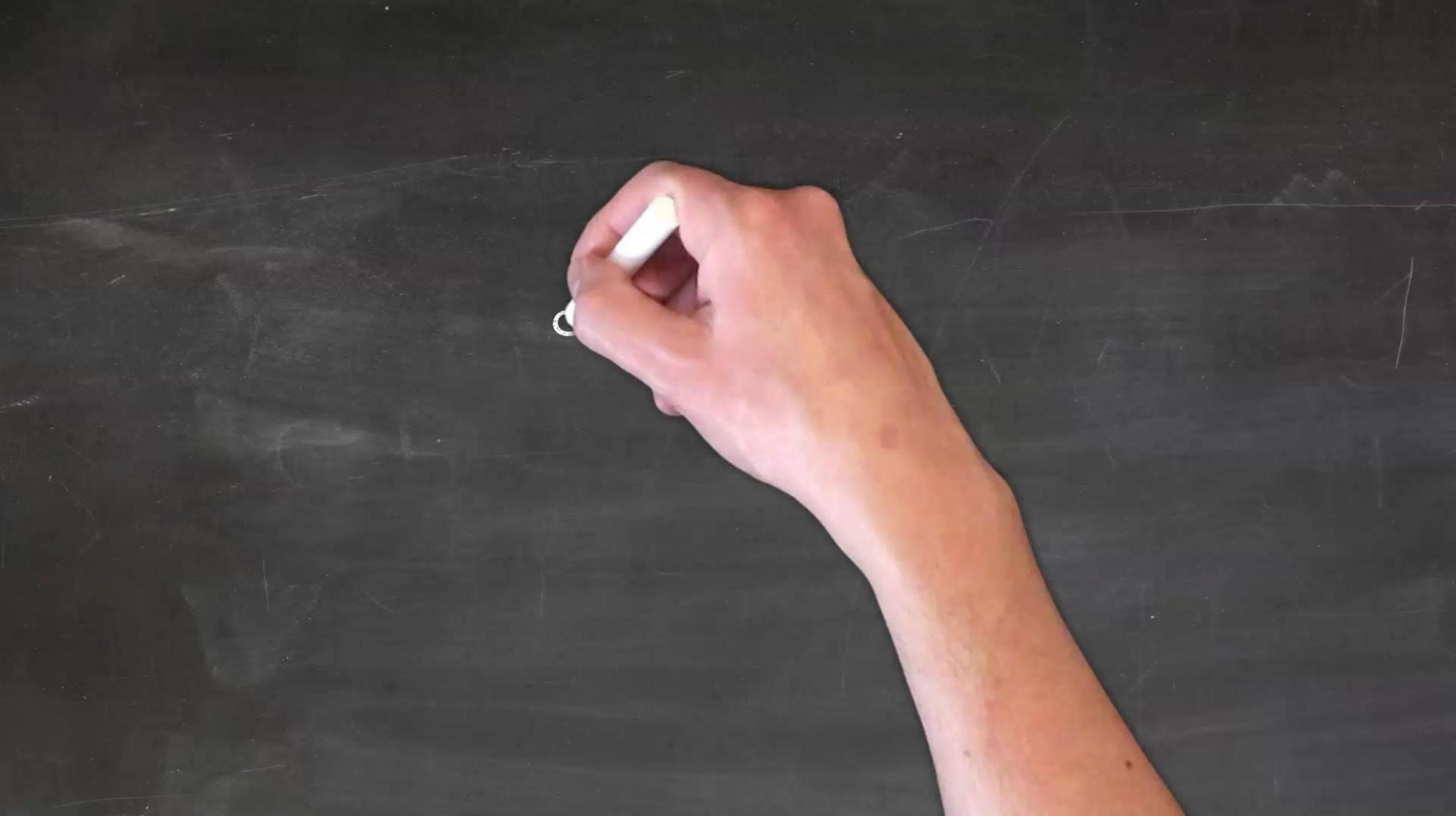
HISTORY OF STEM CELL

the

FDA

Regulations





AAASCP

American Academy of Stem Cell Physicians

We are open to M.D.s, D.O.s, D.C.s, N.D.s, D.P.M.s,
D.V.M.s, D.D.S.s, and D.M.D.s

- 1. Stem cells are just too good not to be shared.**
- 2. As long as your state or your board allows you to practice.**
- 3. So we might as well teach these physicians to reach a level of excellence.**



**To Make Available To
Physicians The
Benefits Of Stem Cell
Therapeutics.**

The image features a central red rectangular overlay with white text. The background is a photograph of a conference room with people seated at a table. The text is written in a white, stylized, cursive font. The overall design is modern and professional, with a blue gradient on the right side and white diagonal lines.

*AMERICAN
ACADEMY OF
STEM CELL
PHYSICIANS
DELEGATES*



American Academy of Stem Cell Physicians

Letter of Guidance

[REDACTED]
[REDACTED]
Miami Beach, FL, 33140

Dear Doctor,

It has come to our attention that you are treating your patients with biologics at your practice. We learned about you from the advertisement that was posted recently for your May 14th, 2019 meeting at the [REDACTED] Marriott.

On your advertisement, you make several claims and comments regarding the nature of your stem cell therapies. These claims are seen as inappropriate and unfounded in scientific research by the FTC, FDA, and Board of Medicine. Our responsibility at the American Academy of Stem Cell Physicians is to ensure that our colleagues are engaging in ethical conduct and maintaining the highest standard of regenerative medical practices.

Our hope is that you will correct this error and change the advertisement to reflect the accepted standard. We will continue monitoring your advertisements and if a change is not made, this letter will be posted onto the internet permanently.

Signed by,

The Ethical Committee

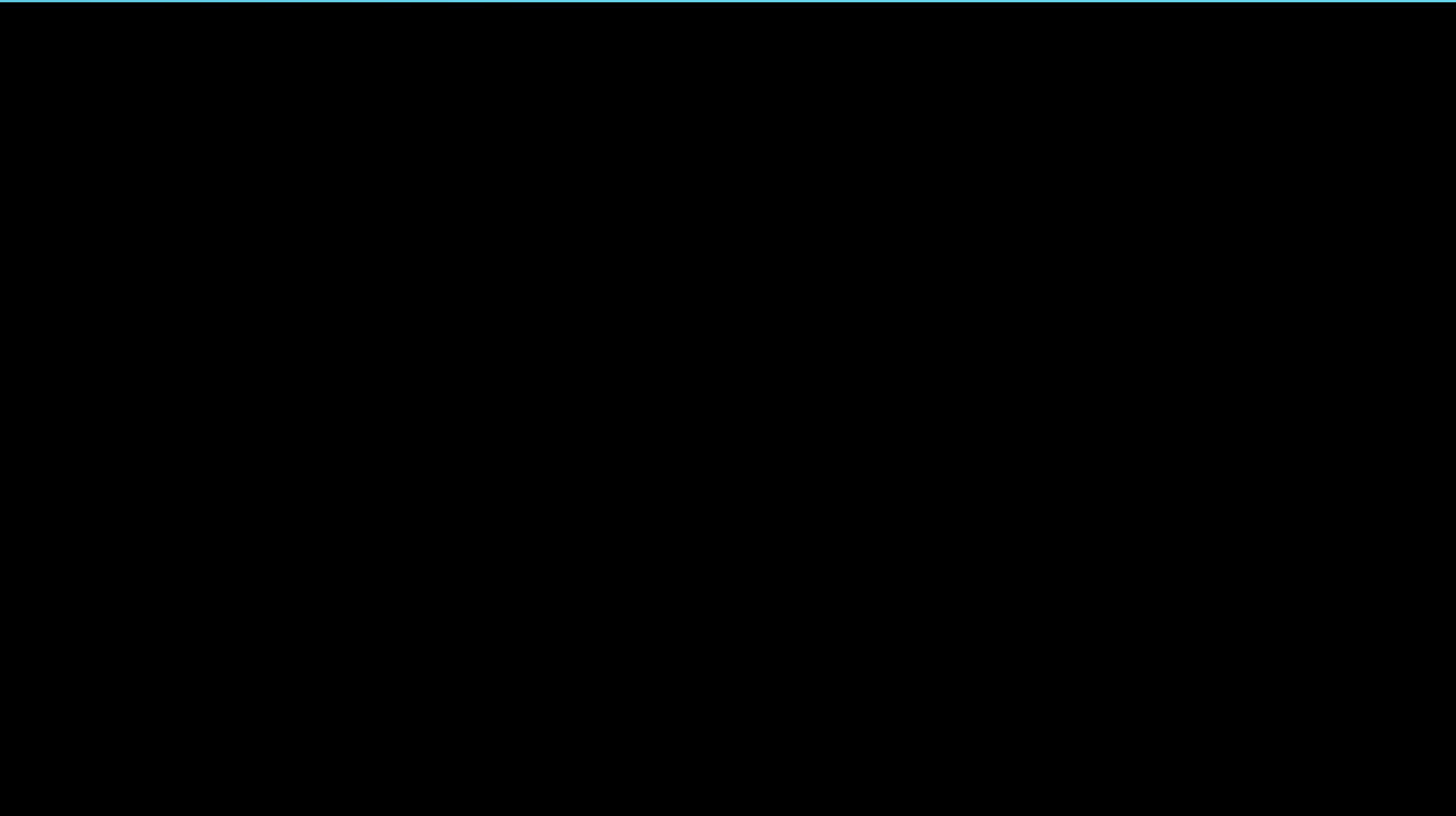
A.J. Farshchian, MD, Suny Kim, MD, David Nebbeling, DO, Joseph Purita, MD, William Song, MD, Leonid Macheret, MD

The American Academy of Stem Cell Physicians' (AASCP) Ethical Committee was formed with the purpose of overseeing and ensuring that medical experimentation and human research are carried out in an ethical manner in accordance with national and international law. While medical research advances so quickly the Ethical Committee of the AASCP notes that many medical and research bodies must adapt to the growing changes and maintain ethical composure. The Ethical Committee of the AASCP will gladly assist and guide those who find difficulty with finding ethical compliance. The American Academy of Stem Cell Physicians (AASCP) is an organization created to advance research and the development of therapeutics in regenerative medicine, including diagnosis, treatment, and prevention of disease related to or occurring within the human body. Secondly, the AAOSCP aims to serve as an educational resource for physicians, scientists, and the public in diseases that can be caused by physiological dysfunction that are amenable to medical treatment.



The consortium is dedicated to foster compliance within the industry.







American Academy of Stem Cell Physicians

Research Consortium

Committed to supporting research to validate regenerative therapies and dedicated to fostering a culture of compliance within the industry.

Biologics: 361 vs. 351

These HCT/P's are regulated solely as "361 products" when they meet all of the criteria in 21 CFR 1271.10(a):

- BONE (including DEMINERALIZED BONE
- LIGAMENTS
- TENDONS
- FASCIA
- CARTILAGE
- OCULAR TISSUES (CORNEAS & SCLERA)
- SKIN
- VASCULAR GRAFTS (VEINS & ARTERIES),
except preserved umbilical cord veins
- PERICARDIUM
- AMNIOTIC MEMBRANE (when used alone (-
without added cells-) for ocular repair)
- DURA MATER
- HEART VALVE ALLOGRAFTS
- HEMATOPOIETIC STEM CELLS DERIVED
FROM PERIPHERAL OR UMBILICAL CORD
BLOOD
- SEMEN
- OOCYTES
- EMBRYOS

HUMAN SOMATIC CELL THERAPY AND GENE THERAPY PRODUCTS Regulated under Section 351 of the PHS Act and/or the FD&C Act

This grouping includes products that FDA has determined do not meet all of the criteria in 21 CFR 1271.10(a) and are regulated as drugs and/or biological products.

- CULTURED CARTILAGE CELLS
- CULTURED NERVE CELLS
- LYMPHOCYTE IMMUNE THERAPY
- GENE THERAPY PRODUCTS
- HUMAN CLONING
- HUMAN CELLS USED IN THERAPY INVOLVING THE
TRANSFER OF GENETIC MATERIAL (cell nuclei,
oocyte nuclei, mitochondrial genetic material in
ooplasm, genetic material contained in a genetic
vector)
- UNRELATED ALLOGENEIC HEMATOPOIETIC STEM
CELLS
- UNRELATED DONOR LYMPHOCYTES FOR
INFUSION

An HCT/P is regulated solely under Sec. 361 of the PHSA if it meets all of the following criteria:

- **The HCT/P is minimally manipulated;**
- **The HCT/P is intended for homologous use only; The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage; and either:**

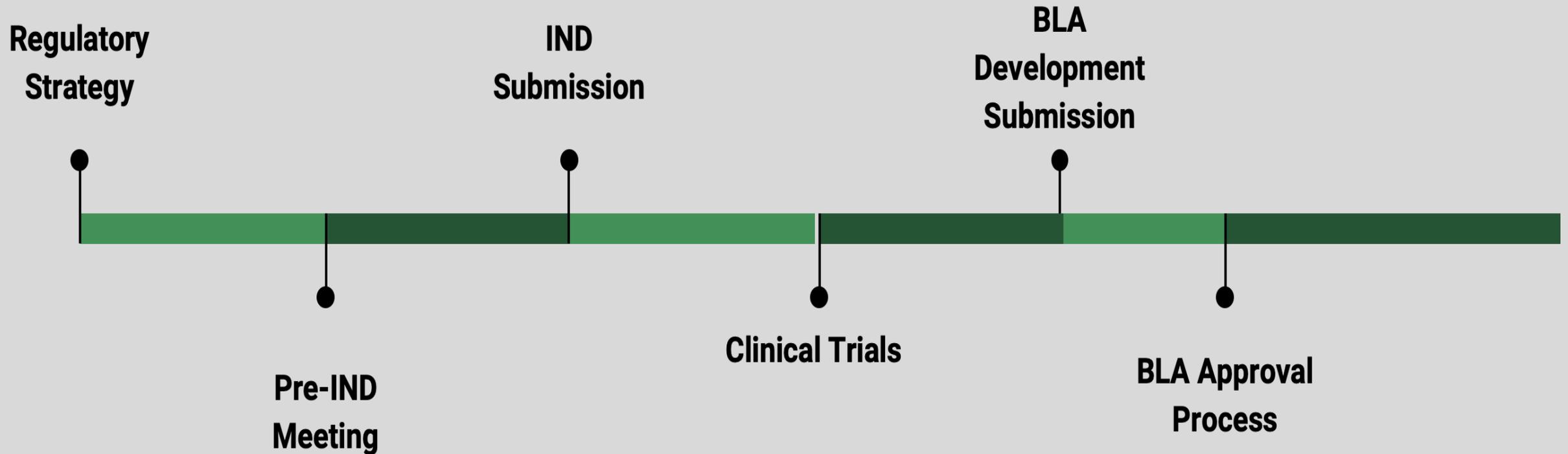
(i) the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or (ii) the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and (a) is for autologous use; (b) is for allogeneic use in a first-degree or second-degree blood relative; or (c) is for reproductive use.

Classification of the Biologic

Biologics that do not meet FDA's criteria for being regulated as an HTC/P under 361 are regulated by FDA under Sec 351 of the PHSA, which requires FDA approval of a Biologics License Application (BLA) for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.

Following initial laboratory and animal testing that show that investigational use in humans is reasonably safe, biological products (like other drugs), can be studied in clinical trials in humans under an investigational new drug application (IND) in accordance with the regulations at 21 CFR 312

Creating a Pathway to Compliance



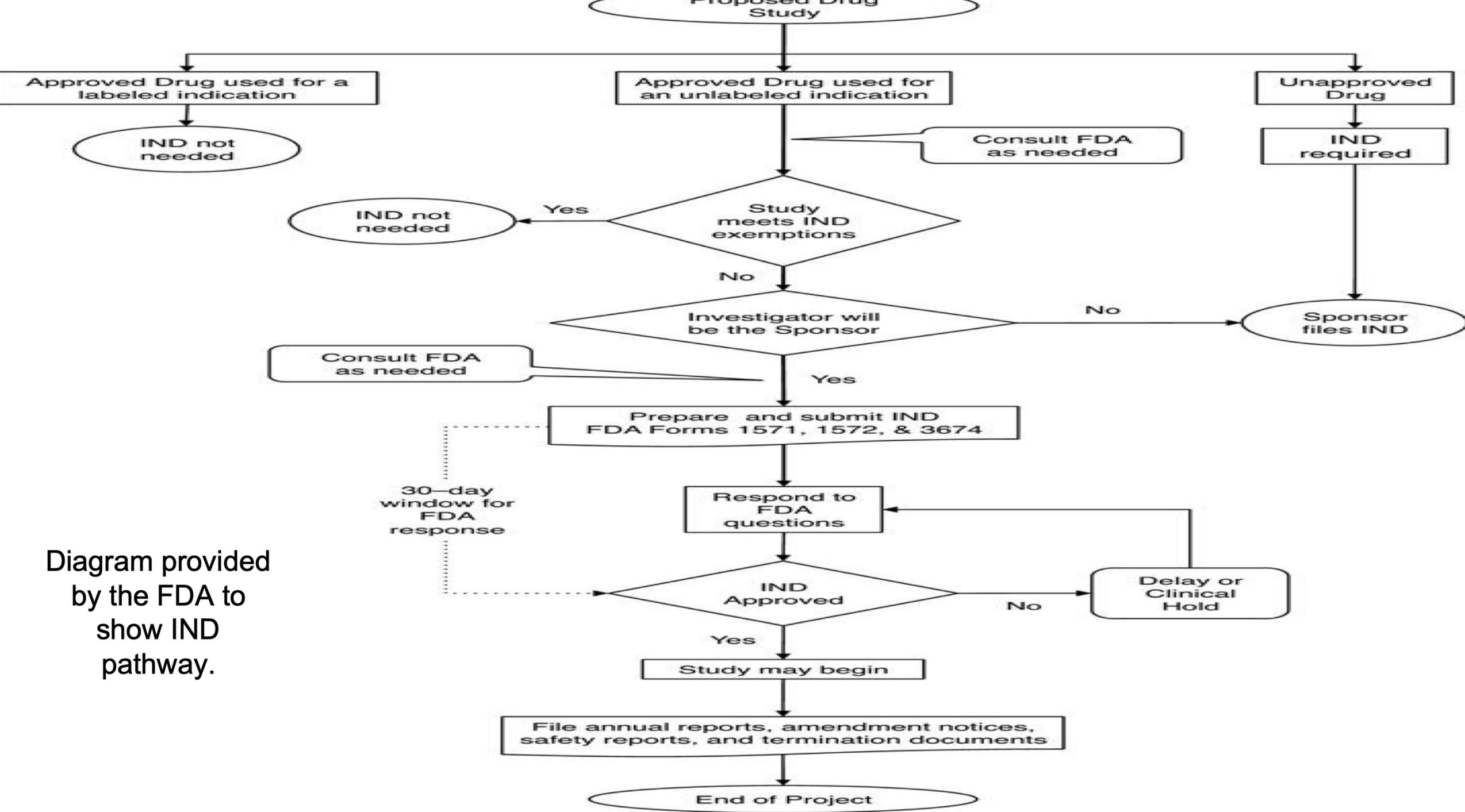
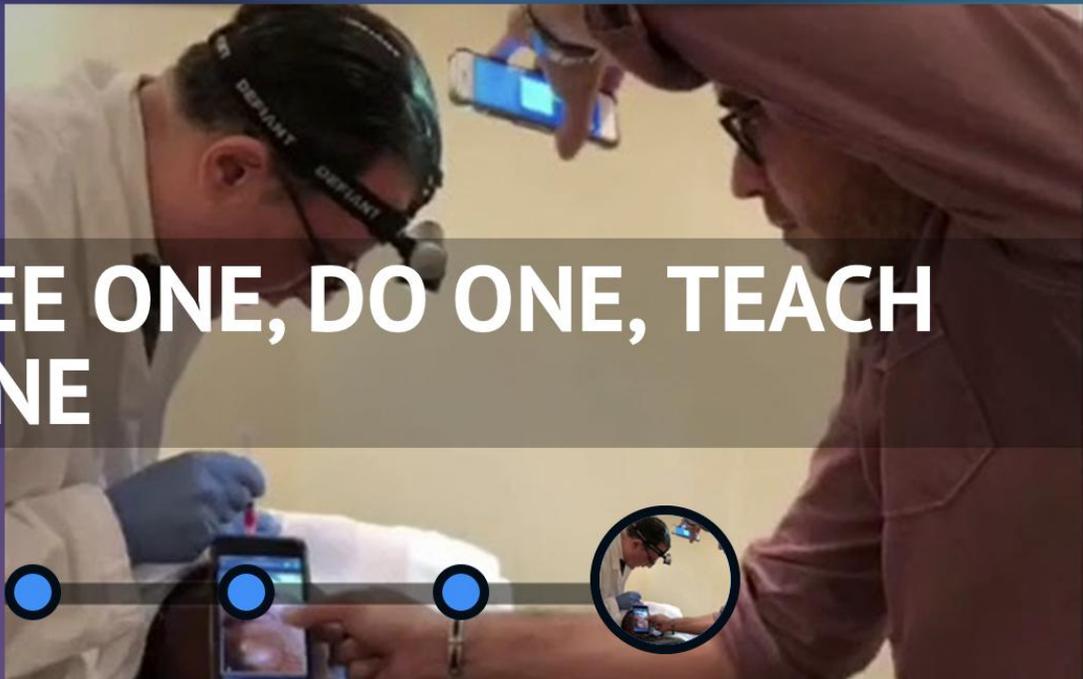


Diagram provided by the FDA to show IND pathway.



NEUROREGENESIS

A PEER REVIEWED PROTOCOL



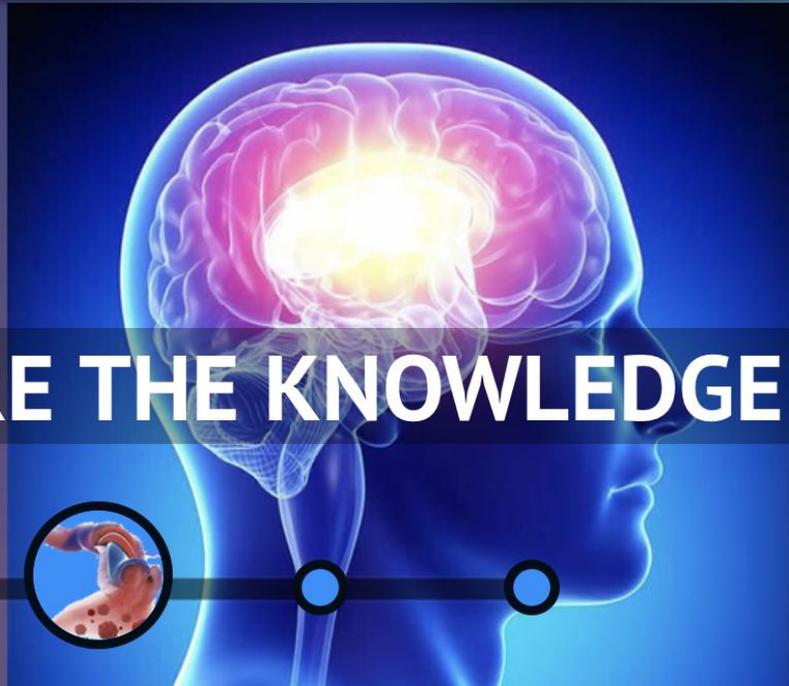
SEE ONE, DO ONE, TEACH ONE



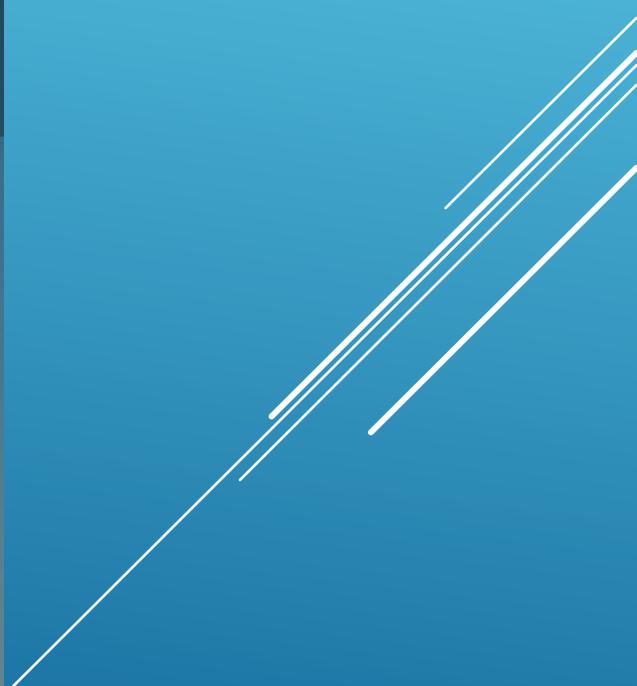


NEUROREGENESIS

A PEER REVIEWED PROTOCOL



SHARE THE KNOWLEDGE



Parasympathetic

- constricts pupils
- increases saliva production

- reduces the heart rate
- constricts bronchia

- stimulates the activity of the digestive organs
- stimulates the activity of the pancreas
- stimulates the gall bladder

- constricts urinary bladder
- stimulates erection of genitals of man and woman

Cerebrum (Brain)

cranial

cervical

thoracal

lumbal

sacral

spinal cord

sympathetic chain

Sympathetic

- dilates pupils
- inhibits saliva production

- dilates bronchia
- raises the heart rate

- inhibits the activity of the digestive organs
- inhibits the activity of the pancreas

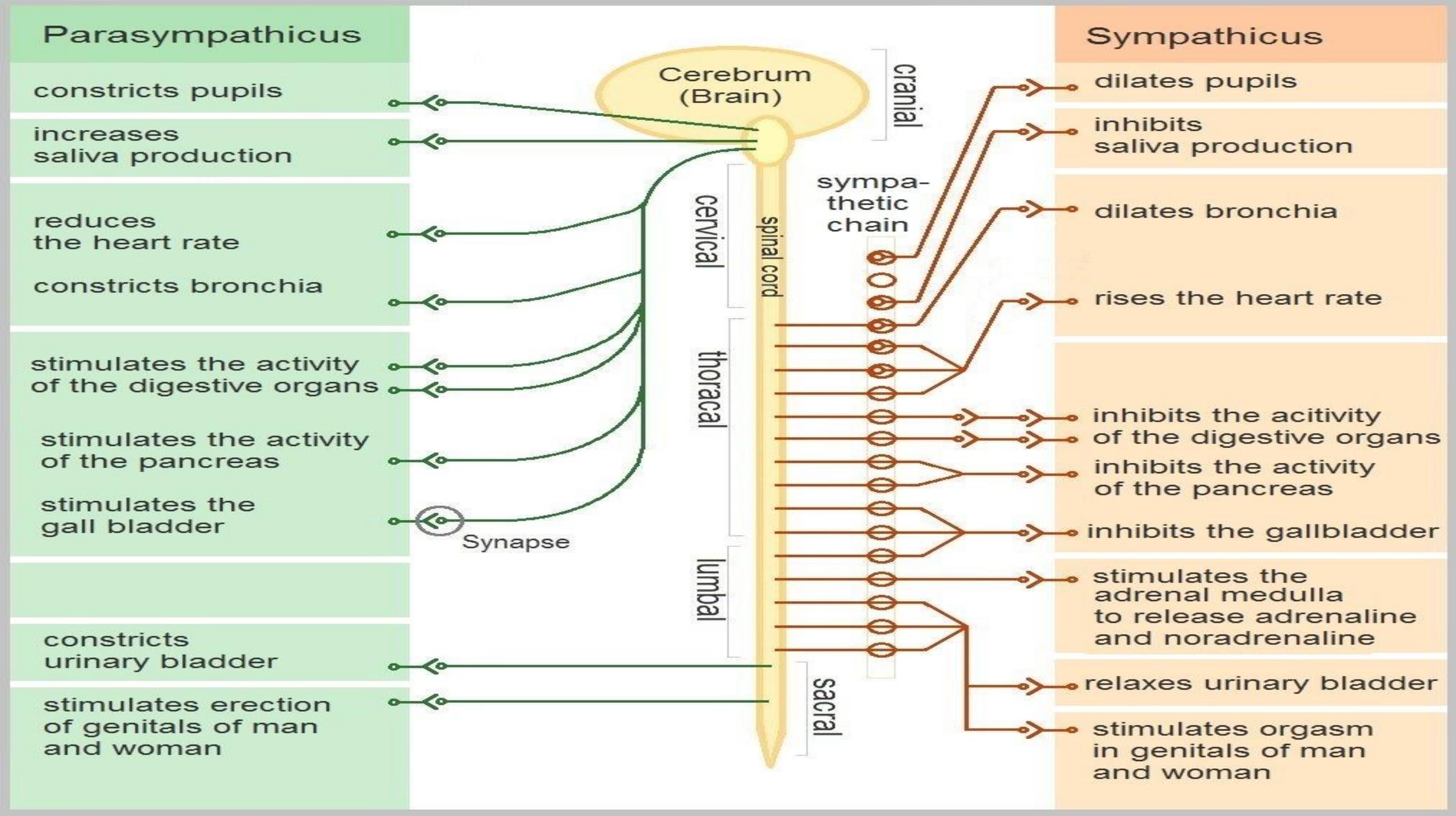
- inhibits the gallbladder

- stimulates the adrenal medulla to release adrenaline and noradrenaline

- relaxes urinary bladder

- stimulates orgasm in genitals of man and woman

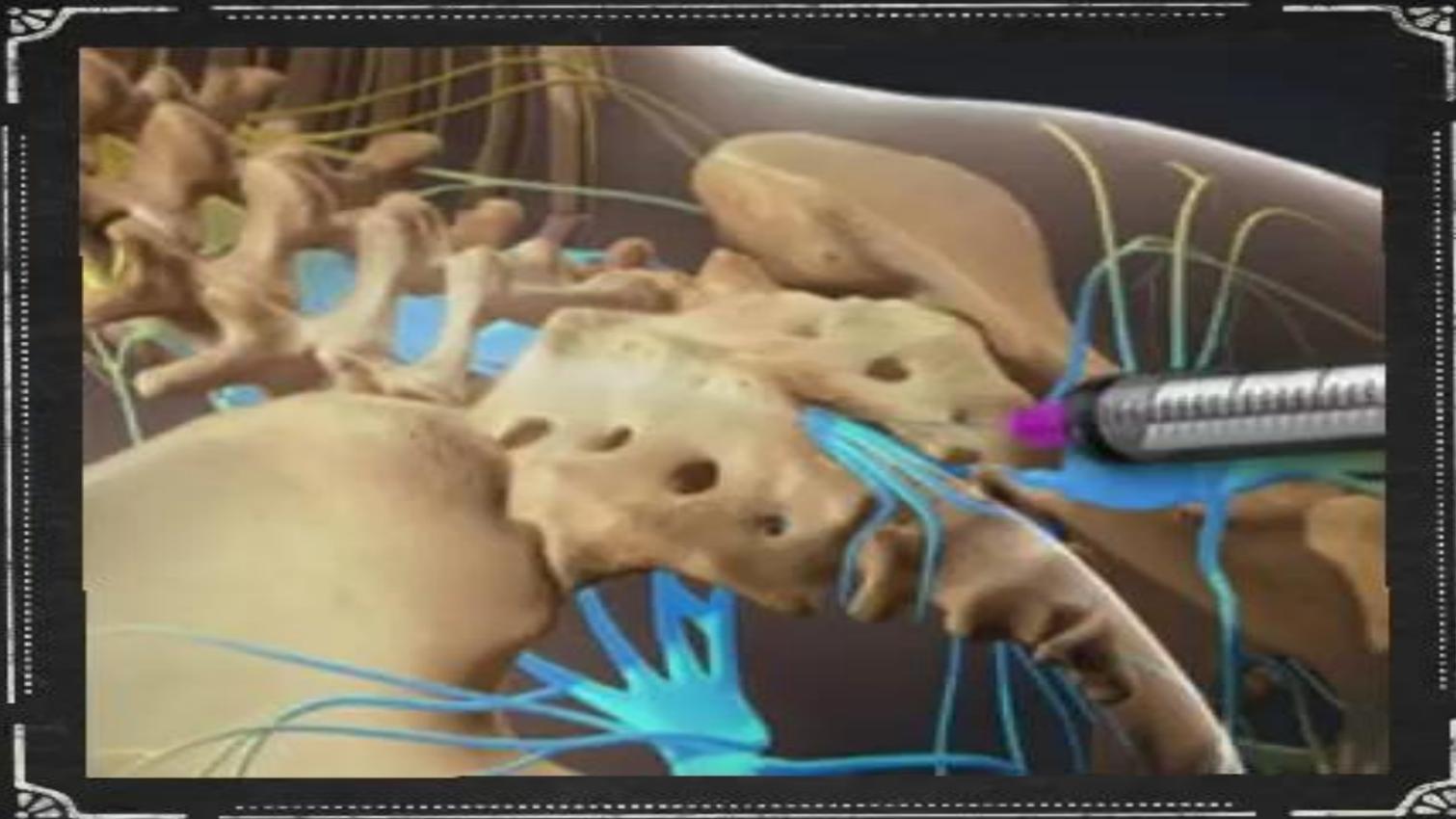
Synapse



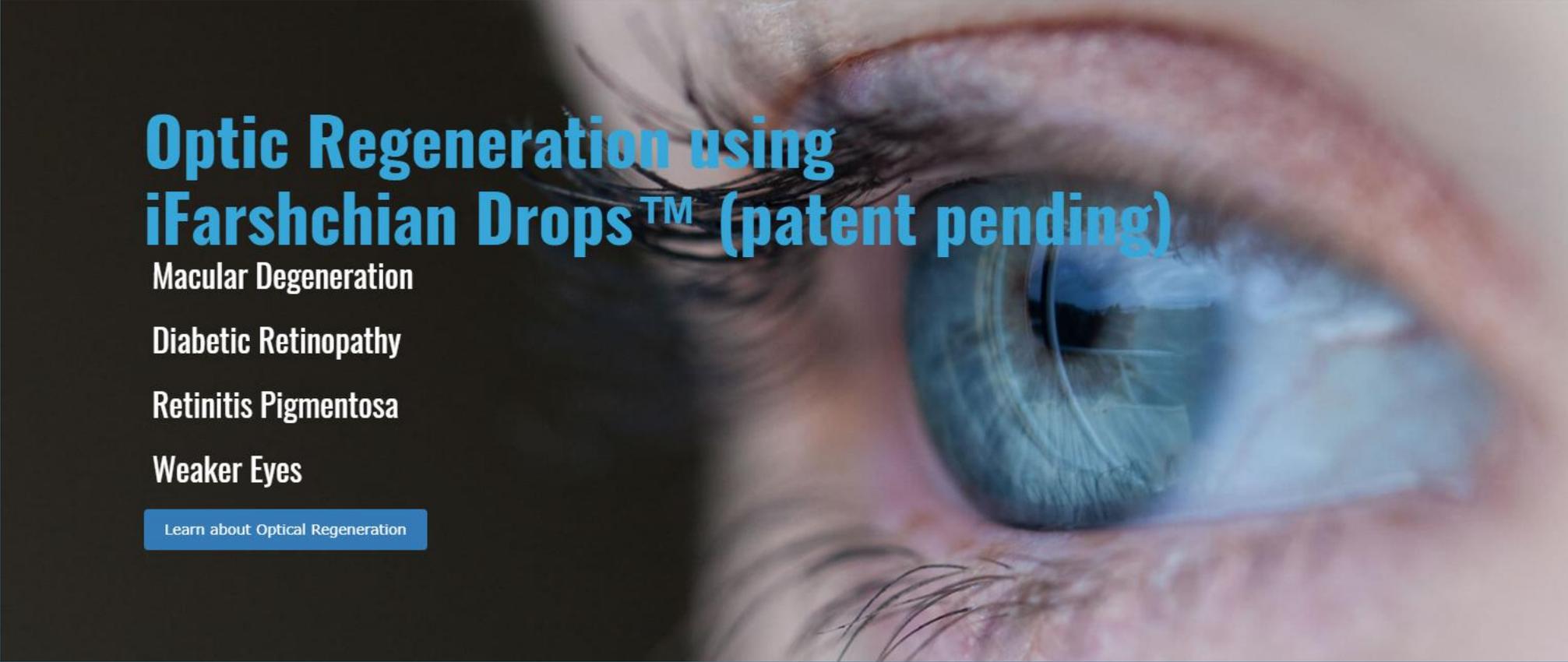
Common symptoms **include**:

- an inability to stay upright
- dizziness, **vertigo**, and fainting
- fast, slow, or irregular heartbeat
- chest pain
- low blood pressure
- problems with the gastrointestinal system
- nausea
- disturbances in the visual field
- weakness

- breathing difficulties
- mood swings
- anxiety
- fatigue and intolerance to exercise
- migraines
- tremors
- disrupted sleep pattern
- frequent urination
- Temperature Regulation Problems
- concentration and memory problems
- poor appetite
- overactive senses, especially when exposed to noise and light



CAUDAL THERAPY



Optic Regeneration using iFarshchian Drops™ (patent pending)

Macular Degeneration

Diabetic Retinopathy

Retinitis Pigmentosa

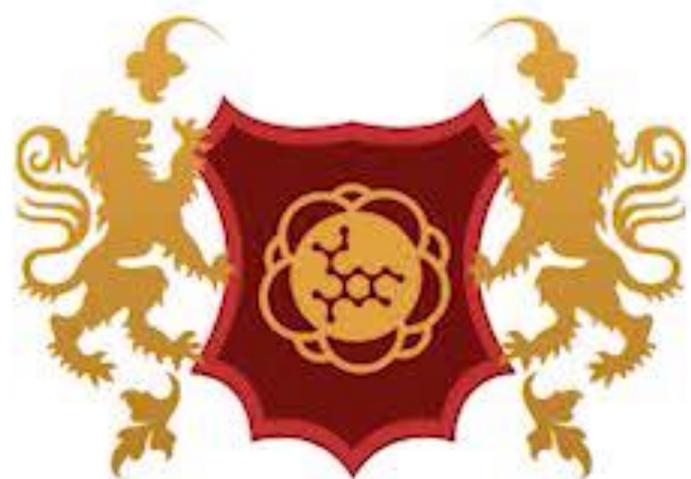
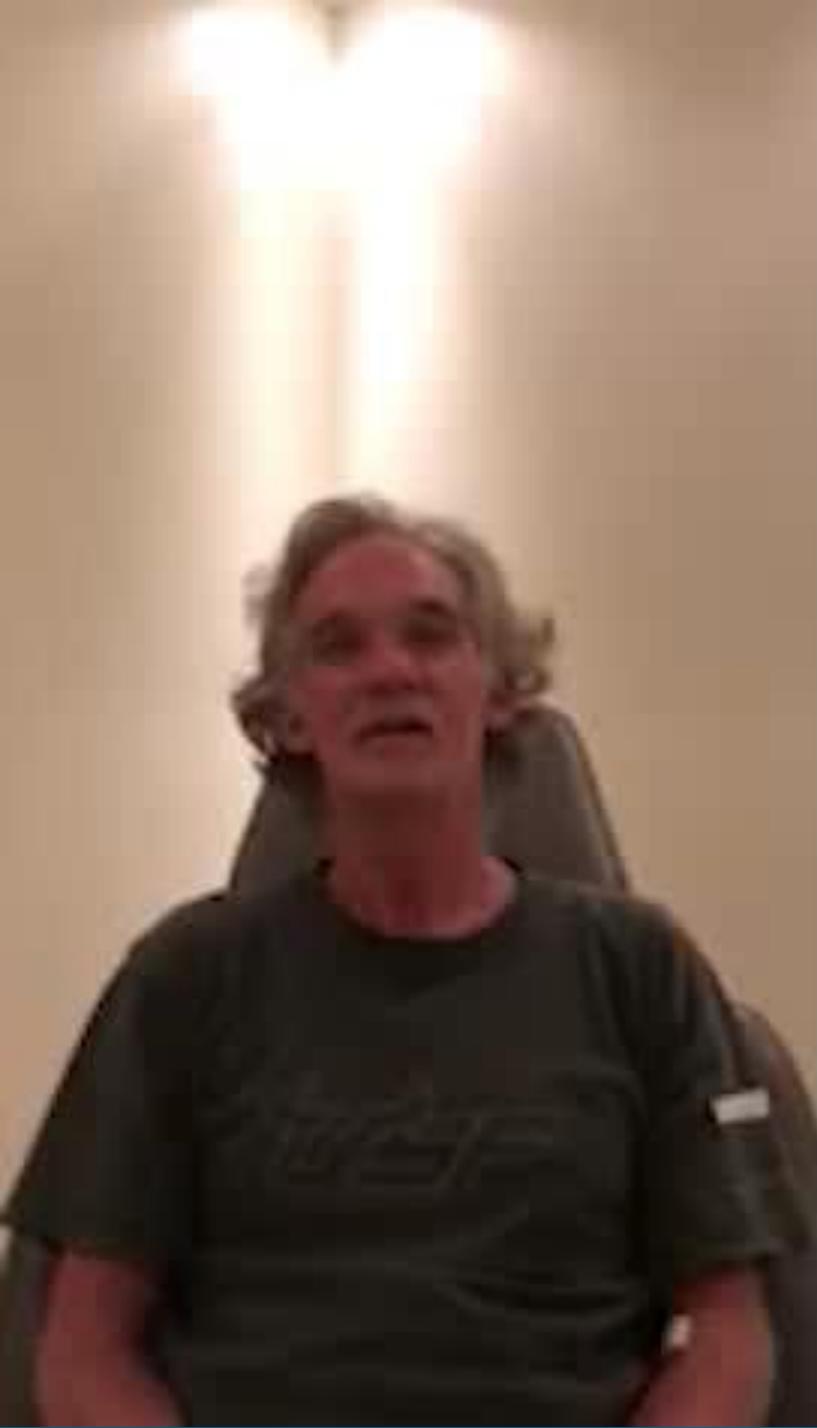
Weaker Eyes

[Learn about Optical Regeneration](#)

OPTIC REGENESIS



Symptoms include
decreased vision in low
light and tunnel vision



**THE CENTER FOR
REGENERATIVE MEDICINE**

Patient Testimonial



Heal the Earth through the Arts





NEUROREGENESIS

Nasal administration of stem cells: a promising novel route to treat neonatal ischemic brain damage.

van Velthoven CT, et al. *Pediatr Res.* 2010.

[Show full citation](#)

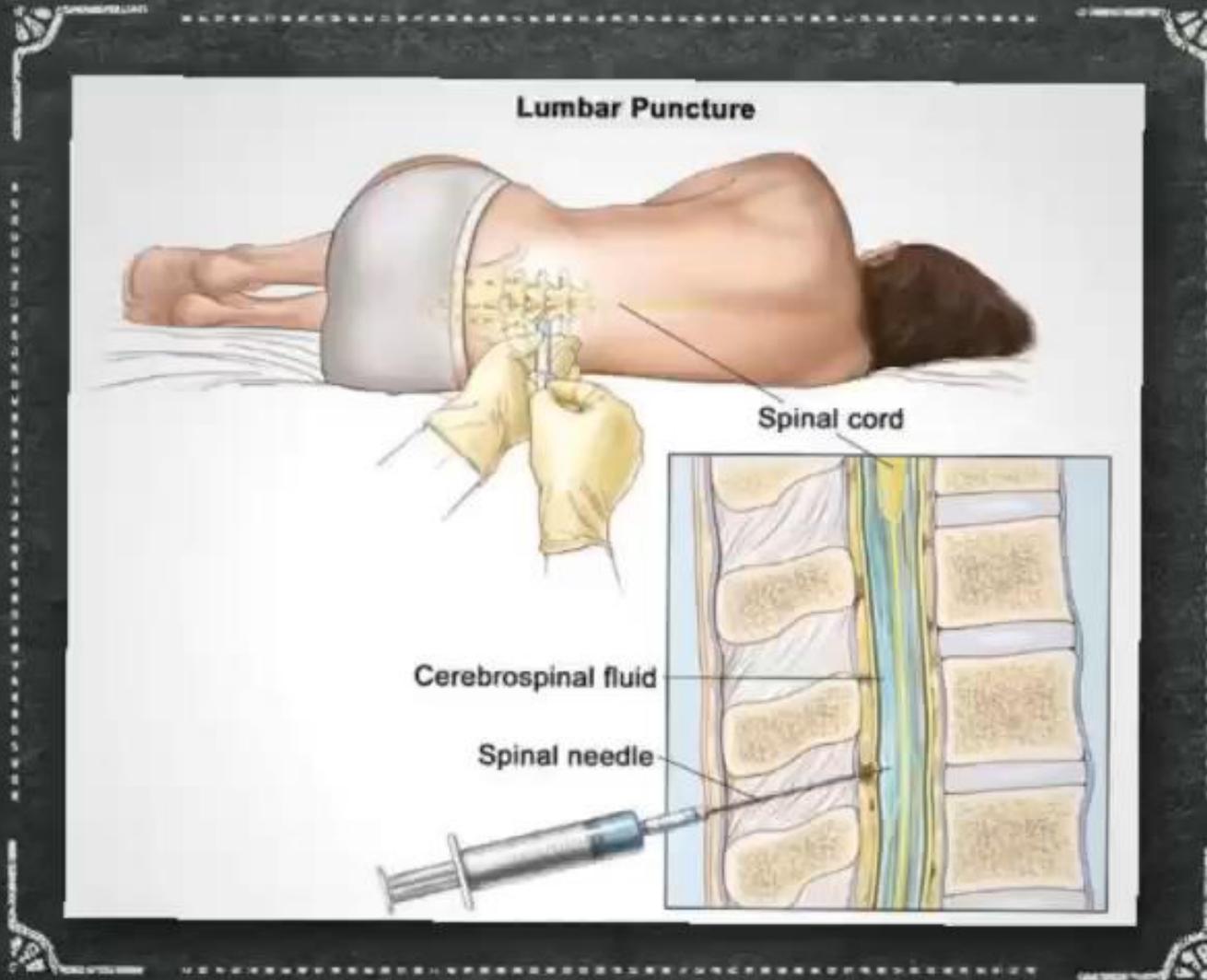
Abstract

Mesenchymal stem cell (MSC) transplantation is a promising therapy to regenerate the brain after an ischemic event. We investigated the possibility to use the nasal route as a noninvasive method to repair the neonatal damaged brain. Nine-day-old mice underwent cerebral hypoxia-ischemia (HI), and MSCs were transplanted intranasally 10 d after HI. At 28 d after HI, MSCs were still present in the affected hemisphere but had not differentiated into cerebral cell types. Intranasal MSC treatment significantly improved sensorimotor function in the cylinder rearing test at 21 and 28 d after HI. Furthermore, intranasal MSC treatment decreased gray and white matter area loss when determined 28 d after HI by 34



O utpatient

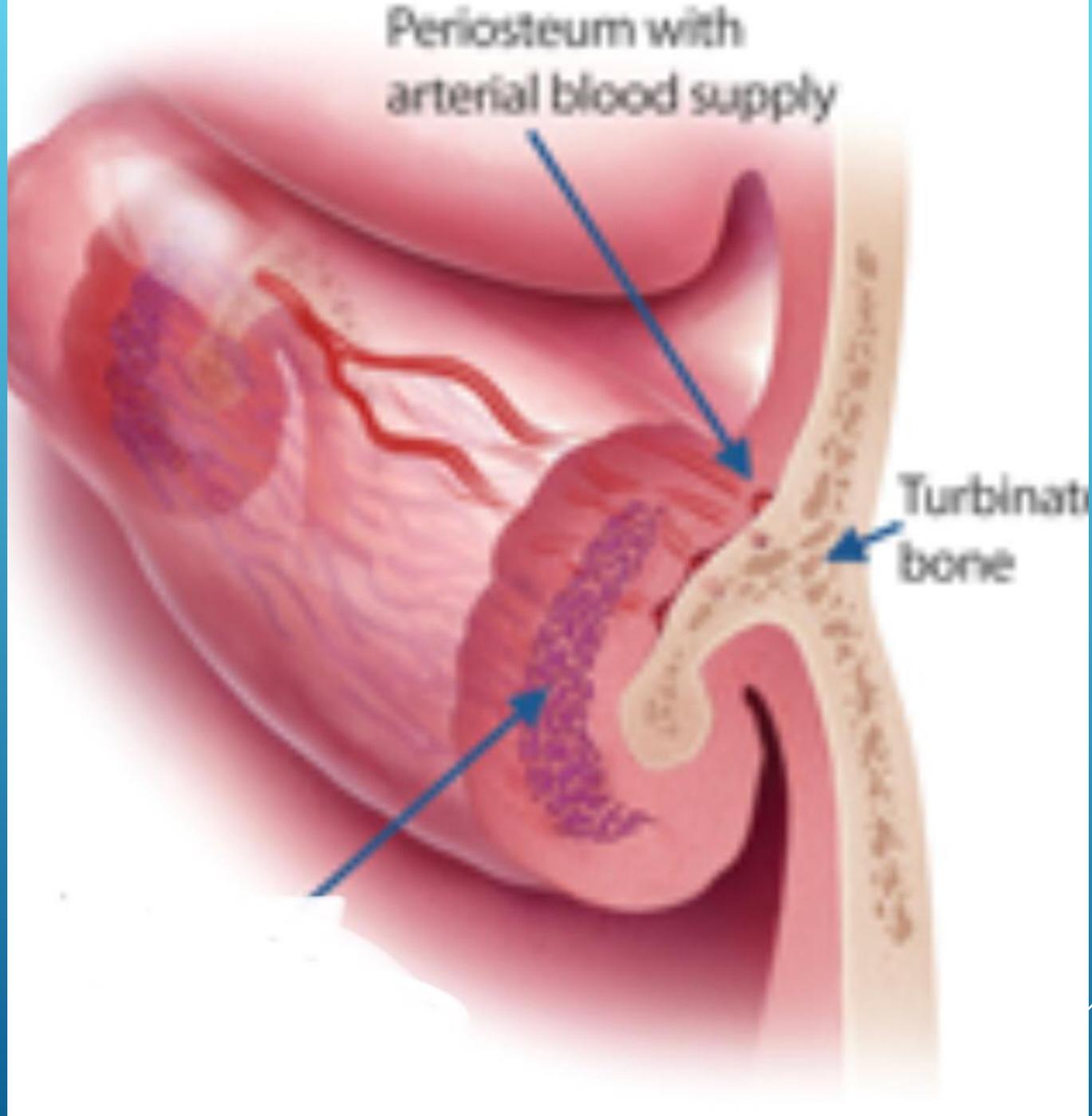
Outpatient
procedure

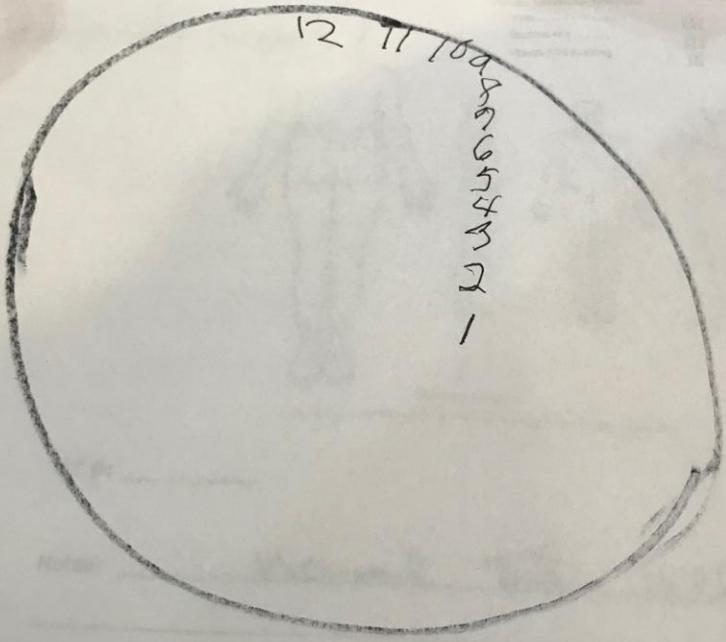


Other routes:







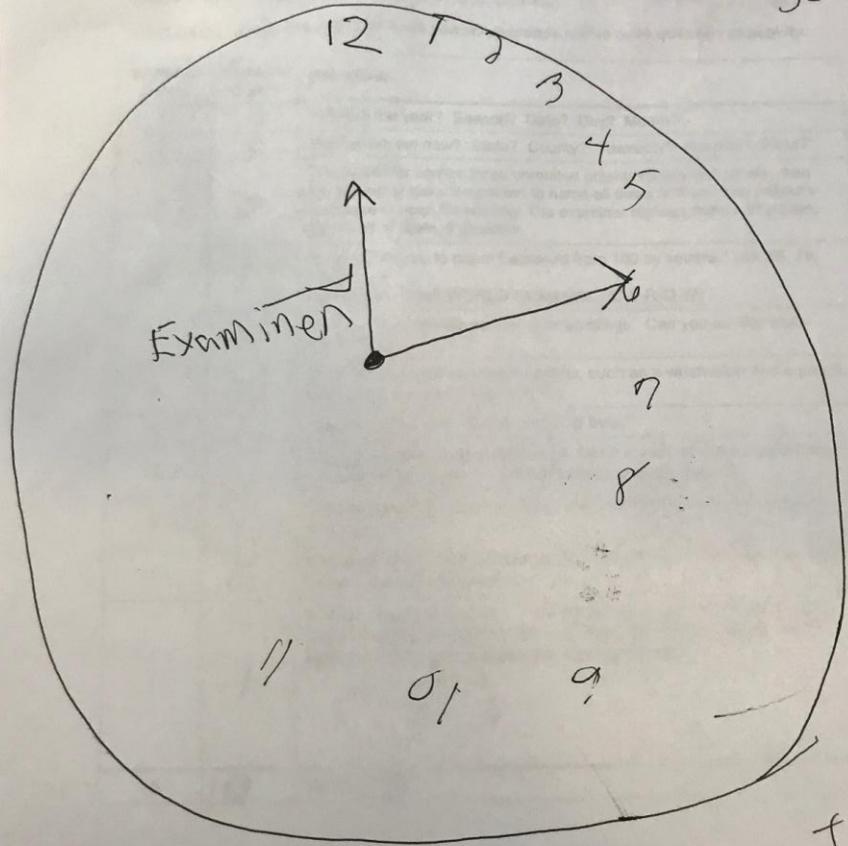


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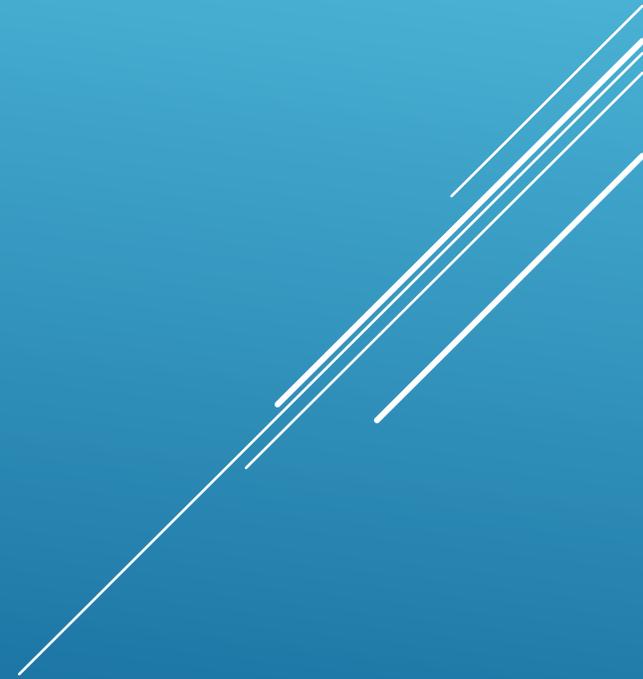
15 on 30

15-5-13

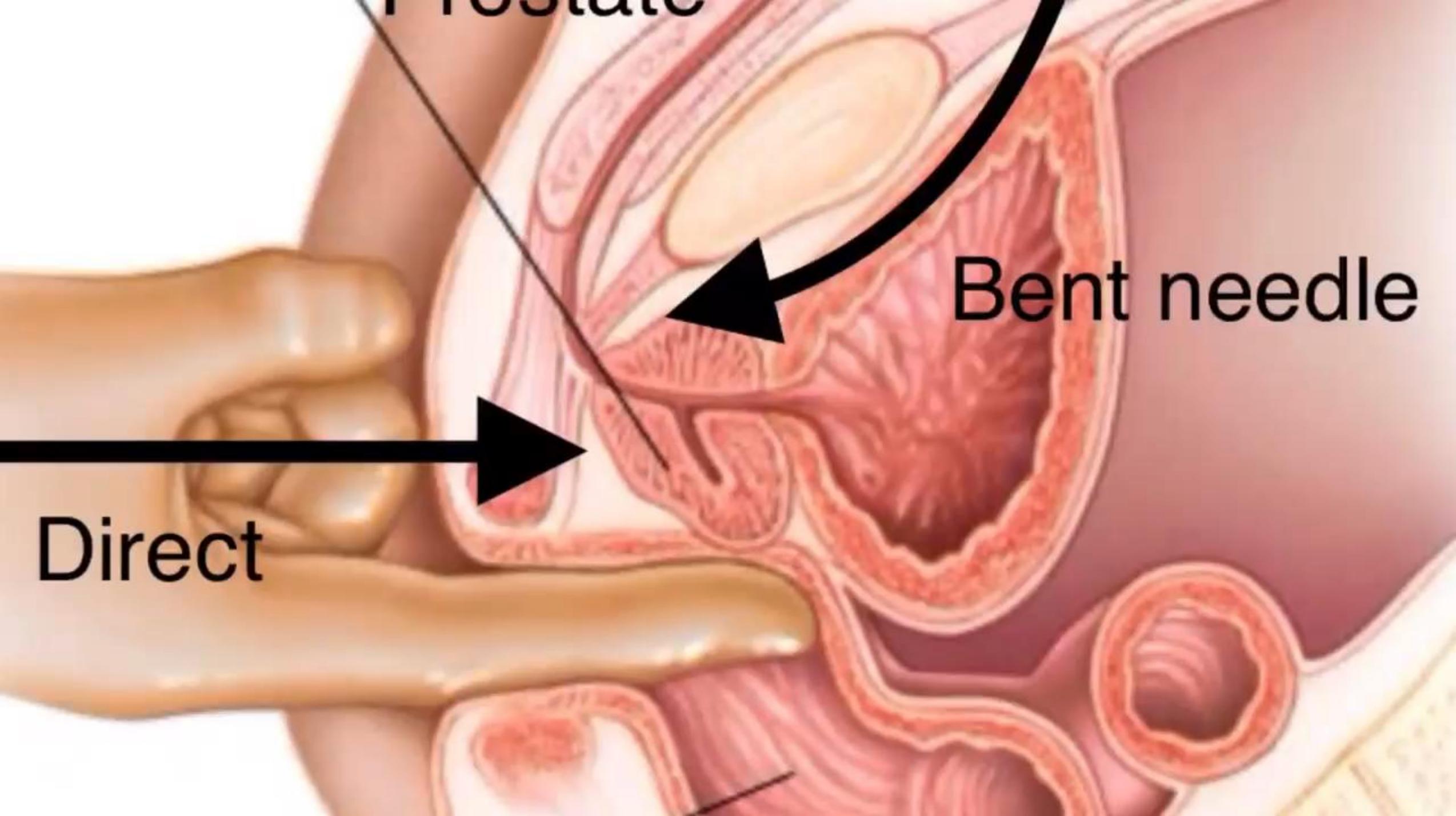
12
30



post:
12-29-17





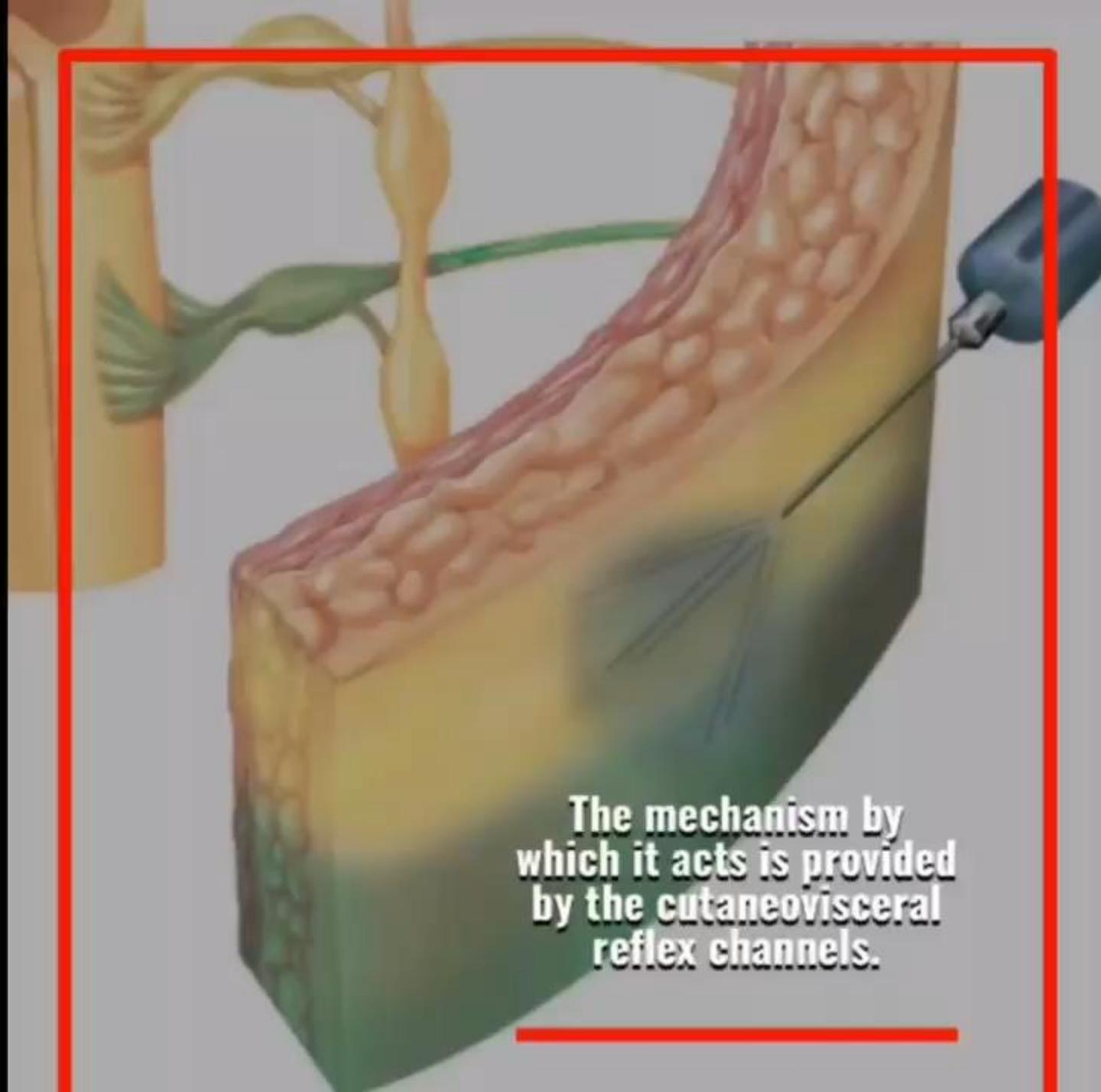


Ulna

Bent needle

Direct



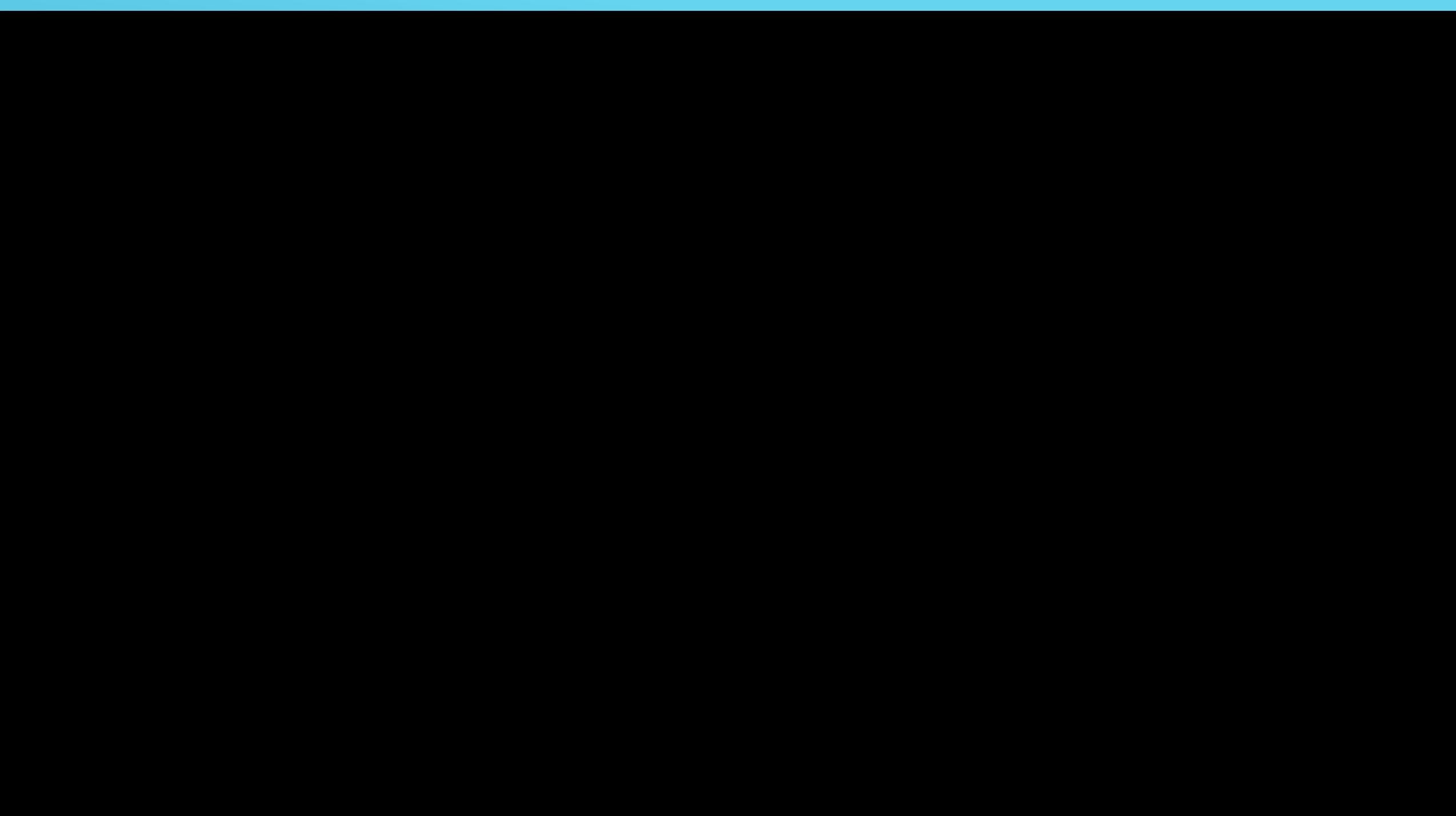


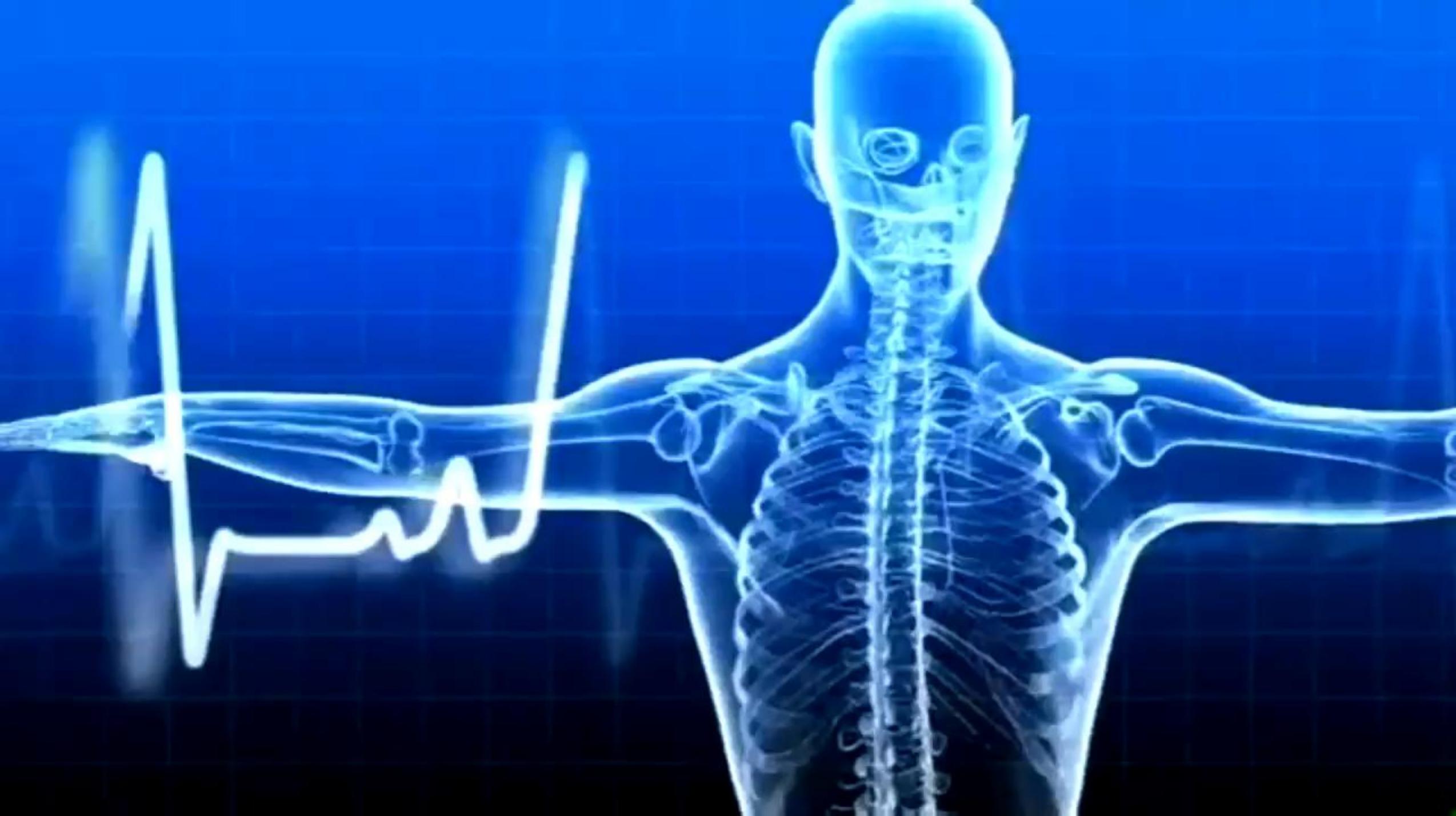
The mechanism by which it acts is provided by the cutaneovisceral reflex channels.

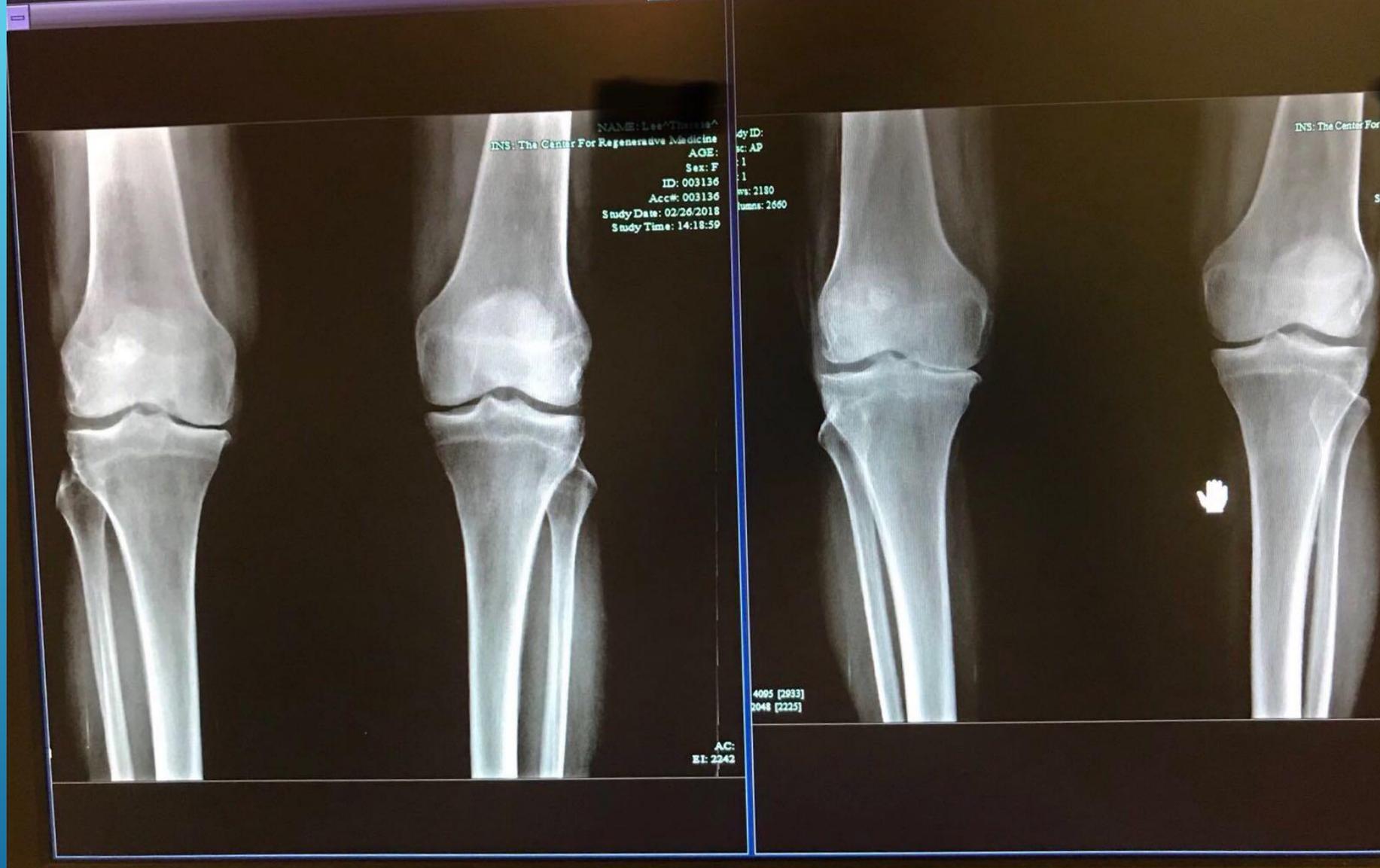


Hippocrates

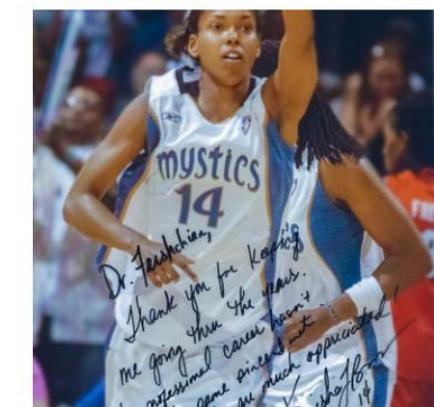
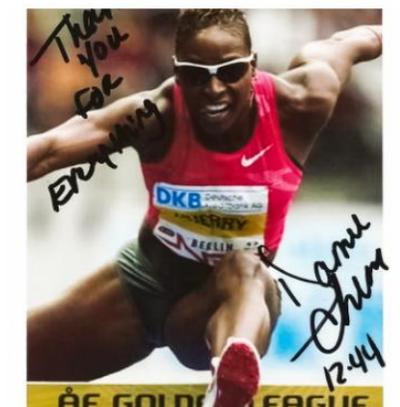
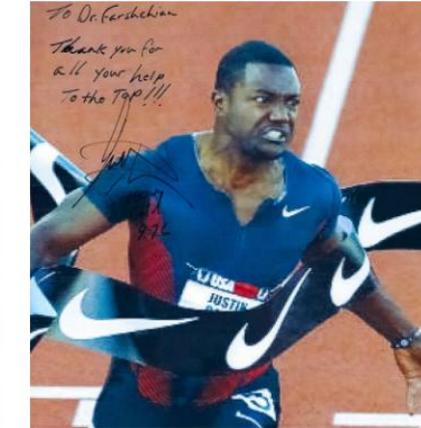
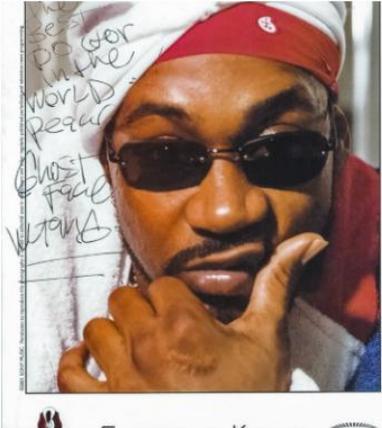
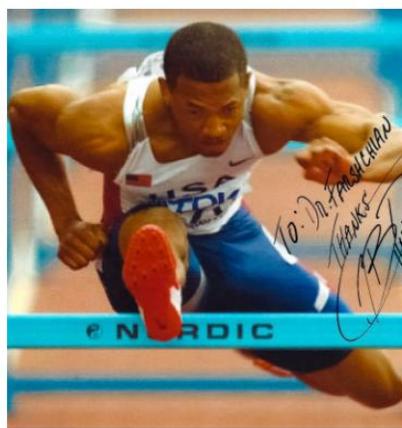
Genius of his time and
the father of
Regenerative Medicine







AFTER & BEFORE



HALL OF FAME...



READ SHIRLEY'S EXPERIENCE WITH STEM CELLS

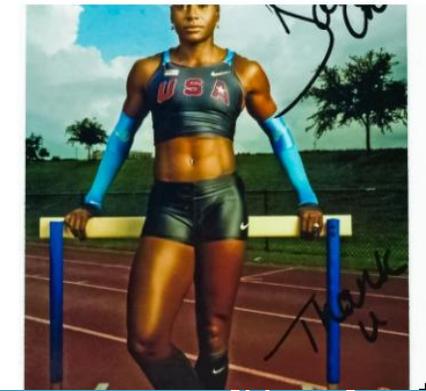
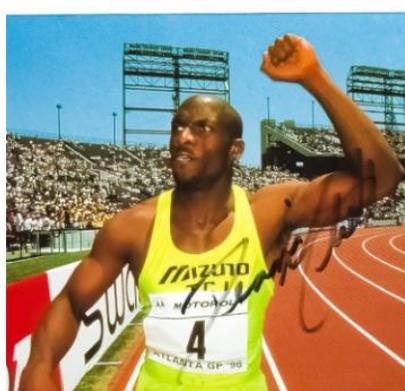
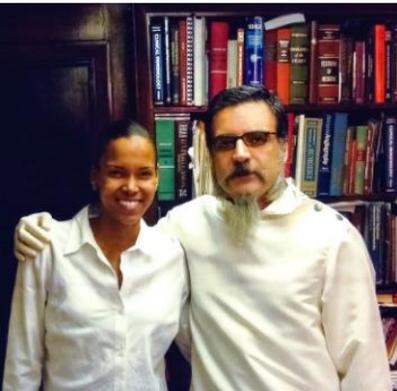
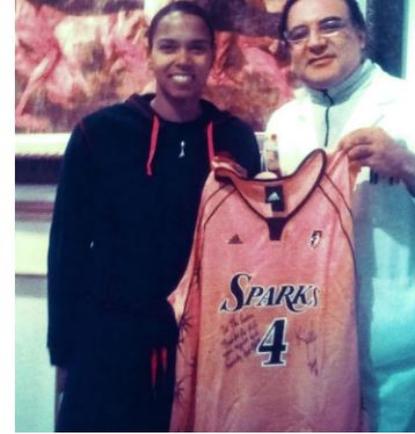
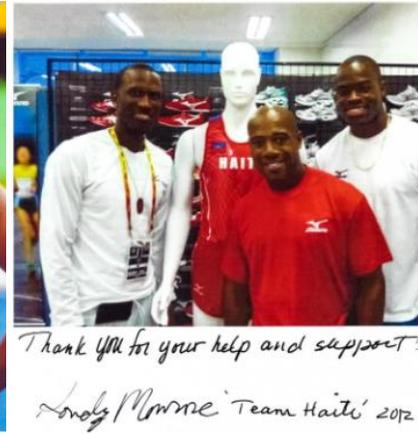
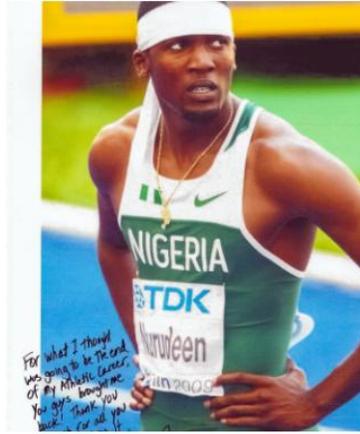
[Read More](#)

SHIRLEY MACLAINE TESTIMONIAL

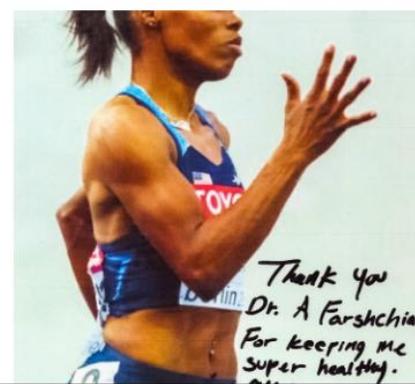
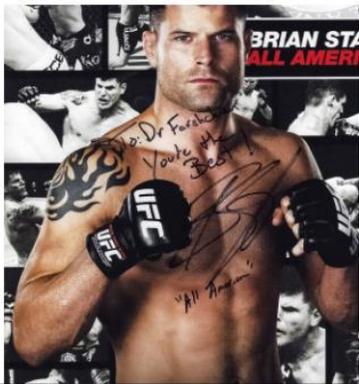
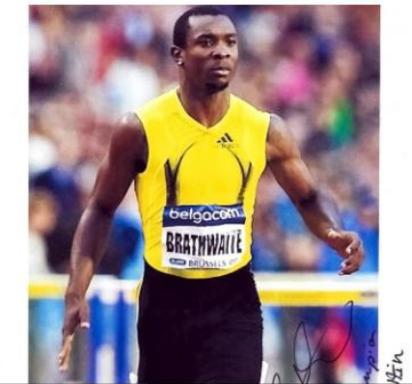
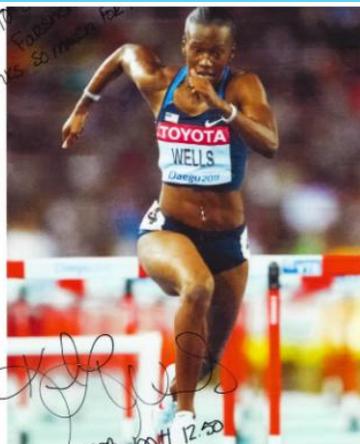
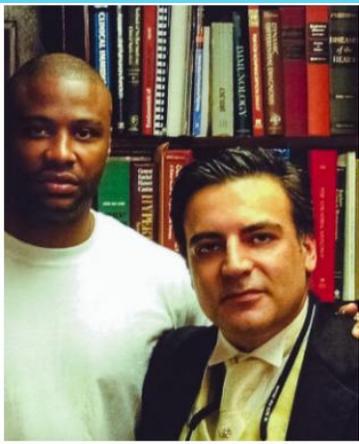
The following is an excerpt from Shirley MacLaine's new book "Above Line"

I waited for the stem cells to take effect. I did my boring ultra-scheduled water therapy every day, regulating my life and activity around the pain, which continued without any hint of letting up. Bathing suit, slippers. Warm water, driving and eating in the car, up at 8:27 with the dogs, lying down and writing. Bathing suit, slippers. Warm water . . . repeat and then repeat again. Then on the tenth day after the injections, I realized I was pain-free . My world changed. In fact, I didn't know what to do with myself. As the days passed, the pain didn't return. I didn't have to lie down four hours a day just to bear being alive. Then I noticed that I needed to seriously adjust to being peaceful and physically happy, not easy for an overachiever who wants to learn everything.





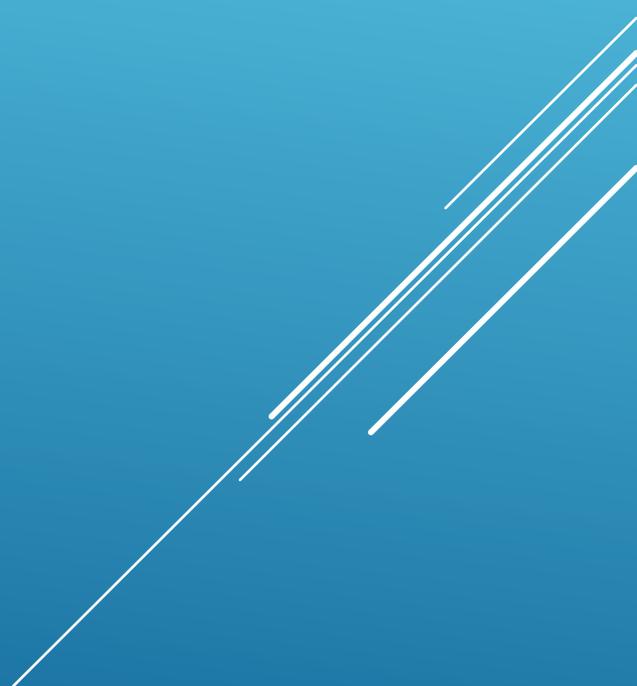
HALL OF FAME..



HALL OF FAME.



HALL OF FAME



Sources of Stem Cells



The embryos of
aborted fetuses



Umbilical cord
and cord blood of a
new born baby



Bone Marrow



Peripheral
Bloodstream



Adult Tissues



Amniotic Fluid

- Two main sources:
1. The patient (autologous).
 2. Pregnancy's byproducts (allograft).



The Center for
Regenerative Medicine

Platelet Rich Plasma



The Center for
Regenerative Medicine

MSC from
Bone
marrow.



Requirements

Clients

Su

018

DEA # _____

NPI # _____

THE CENTER FOR REGENERATIVE MEDICINE

ALIMORAD FARSHCHIAN, M.D.

FL Lic # ME77664

1001 N.E. 125TH STREET

MIAMI, FL 33161

305-866-8381

WWW.ARTHRITISUSA.NET



NAME

Joe SMITH

DOB

ADDRESS

DATE

Rx (PLEASE PRINT)

Drink 2 glasses
of water
q 3h

LABEL

REFILL

PRE

NR

TO INSURE PROPER DISPENSING, PRESCRIBER MUST WRITE 'MEDICALLY NECESSARY' ON THE PRESCRIPTION.

M.D.

11-17-11



TRI1111171000932851080591

UNIFORM BLUE BACKGROUND WITH WHITE Rx SYMBOL VISIBLE • VOID APPEARS WHEN COPIED • WATERMARK ON REVERSE SIDE

FULL DESCRIPTION OF SECURITY FEATURES ON REVERSE SIDE

DEA # _____

NPI # _____

THE CENTER FOR REGENERATIVE MEDICINE
ALIMORAD FARSHCHIAN, M.D.
FL Lic # ME77664
1001 N.E. 125TH STREET
MIAMI, FL 33161
305-866-8384
WWW.ARTHRITISUSA.NET



NAME

JOE SMITH

DOB

ADDRESS

DATE

R (PLEASE PRINT)

NO SUGAR
NO MEAT.
1 MEAL BID

triple

LABEL

REFILL

TIMES

PER

TO INSURE ACCURATE DISPENSING, PRESCRIBER MUST WRITE 'MEDICALLY NECESSARY'
ON THE PRESCRIPTION.

M.D.

11-17-11



TR1111171000932851080591

UNIFORM BLUE BACKGROUND WITH WHITE Rx SYMBOL VISIBLE • VOID APPEARS WHEN COPIED • WATERMARK ON REVERSE SIDE

DEA # _____

NPI # _____

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FL Lic # ME77664
1001 N.E. 125TH STREET
MIAMI, FL 33161
305-866-8384
WWW.ARTHRITISUSA.NET



NAME

Joe SMITH

DOB

ADDRESS

DATE

Rx (PLEASE PRINT)

*Sleep PR 8 hrs
- 10 hrs
plus*

AT

REFILL _____ TIMES PER _____ NR

TO INSURE BRAND NAME DISPENSING, PRESCRIBER MUST WRITE 'MEDICALLY NECESSARY' ON THE PRESCRIPTION. _____ M.D.

11-17-11

TRI1111171000932851080591

UNIFORM BLUE BACKGROUND WITH WHITE PH SYMBOL VISIBLE • VOID APPEARS WHEN COPIED • WATERMARK ON REVERSE SIDE

FULL DESCRIPTION OF SECURITY FEATURES ON REVERSE SIDE

DEA # _____

NPI # _____

THE CENTER FOR REGENERATIVE MEDICINE
ALIMORAD FARSHCHIAN, M.D.
FL Lic # ME77664
1001 N.E. 125TH STREET
MIAMI, FL 33161
305-866-8384
WWW.ARTHRITISUSA.NET



UNIFORM BLUE BACKGROUND WITH WHITE RX SYMBOL VISIBLE • VOID APPEARS WHEN COPIED • WATERMARK ON REVERSE SIDE

NAME **Joe Smith** DOB _____

ADDRESS _____ DATE _____

Rx (PLEASE PRINT)

Exercise 30 Mins



g-d

Triple



LAN

REFILL _____ TIMES _____ PRN _____ NR _____

M.D.
TO INSURE BRAND NAME DISPENSING, SUBSCRIBER MUST WRITE 'MEDICALLY NECESSARY'
ON THE PRESCRIPTION.

11-17-11



TRH111171000932851080591

FULL DESCRIPTION OF SEVERAL FEATURES ON REVERSE SIDE

DEA # _____

NPI # _____

THE CENTER FOR REGENERATIVE MEDICINE
ALIMORAD FARSHCHIAN, M.D.
FL Lic # ME77664
1001 N.E. 125TH STREET
MIAMI, FL 33161
305-866-8384
WWW.ARTHRITISUSA.NE



UNIFORM BLUE BACKGROUND WITH WHITE RX SYMBOL VISIBLE • VOID APPEARS WHEN COPIED • WATERMARK ON REVERSE SIDE

NAME

JOE SMITH

DOB

ADDRESS

DATE

Rx (PLEASE PRINT)

Sing for 15 Min
TID
Triple



FULL DESCRIPTION OF SECURITY FEATURES ON REVERSE SIDE

LABEL

REFILL

TIMES

INR

[Handwritten signature]

M.D.

TO INSURE BRAND NAME DISPENSING, PRESCRIBER MUST WRITE 'MEDICALLY NECESSARY' ON THE PRESCRIPTION.

11-17-11



TR11111171000932851080591