



Stem Cell Therapies

Opportunities for Assuring the
Quality and Safety of
Unregulated Clinical Offerings
Workshop

18 November 2013
The National Academies
Washington DC

“unregulated” products

- **“Unapproved”?** But what of those not approved but nonetheless in a regulated research environment, such as in trials pursuant to an IND from FDA in the US?
- **“Unproven”?** But what of those, like some off-label uses of drugs, that have been proven to be safe and effective, at least to the satisfaction of the professional community, even if never submitted to a governmental agency?
- **“Pre-Approved”?** But what of those that don't need approval or for which 'regulation' might be in the form of professional licensure, professional norms and certifications, medical malpractice threats and professional discipline?

A background image showing a microscopic view of several cells. The cells have large, prominent nuclei stained in shades of blue and pink, with a lighter, granular cytoplasm. The cells are overlapping, creating a sense of depth and biological complexity.

Stem cells hold tremendous potential to advance health and medicine.

The evidence to support the medical use of stem cells is still limited, however. Few are proven to be safe and effective.

But consumer demand for treatments using stem cells has risen, fueled by direct-to-consumer advertising of stem cell-based treatments.

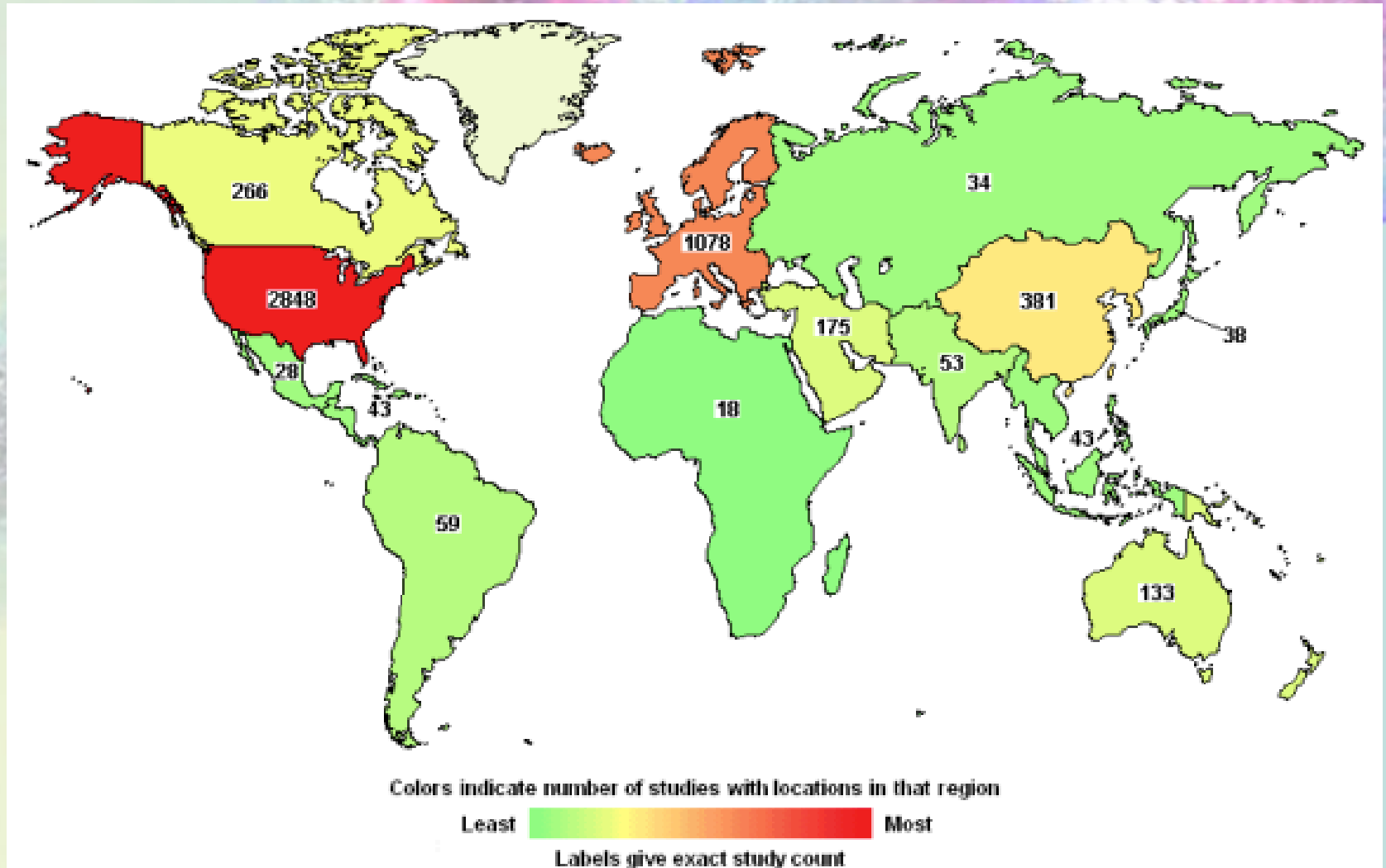
Clinics have been established throughout the world, both in newly industrialized nations such as China, India, and Mexico, as well as developed countries such as the United States and within Europe.

Their “treatments” have generally not received stringent regulatory oversight and have not been tested through rigorous trials.

Stem Cell Clinical Trials Map

Dr. Paul Knoepfler

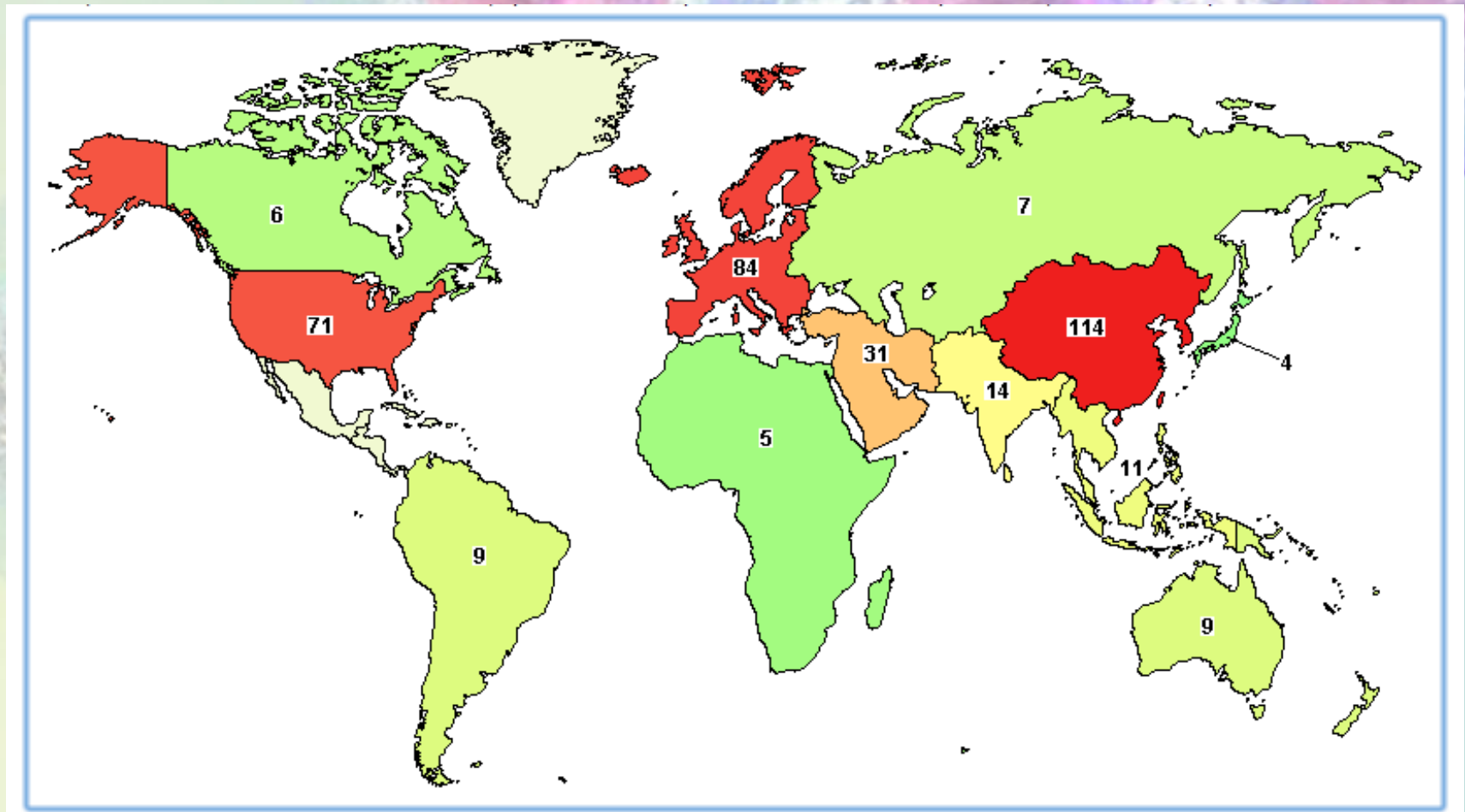
UC Davis School of Medicine (2013)



Mesenchymal Stem Cell Clinical Trials Map

Dr. Paul Knoepfler

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Serum, ingredients including human adult stem cells

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Within Minutes, Lines Appear Minimized: Smaller, Less Significant.

Stimulant III Perfecting Stem Cell Serum - Sunday Riley
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ReLuma Stem Cell Skin Illuminating Anti-Aging Serum (1.1oz)

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Availability: In stock

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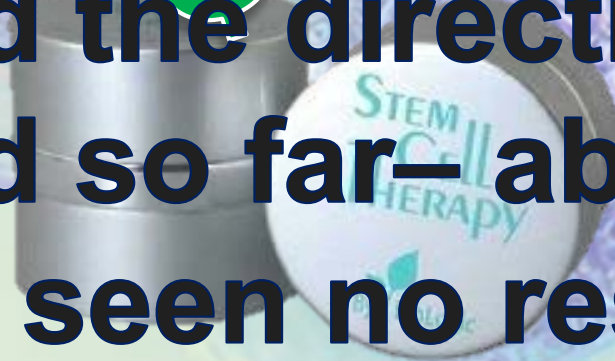
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letter and so far—abt a month
now – I've seen no results at all"**





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LASER SPINE INSTITUTE[®]



Mark Flood, D.O.
Chief of Surgical Innovation

RegenaDISCSM procedure explained by Mark Flood, D.O.

Listen to orthopedic spine surgeon, Mark Flood, D.O., explain how a RegenaDISCSM procedure is performed.

RegenaDISCSM

RegenaDISCSM provides stem cell tissue transplantation into a painful and/or degenerative lumbar disc of the spine after low-level laser spinal decompression for pain relief.



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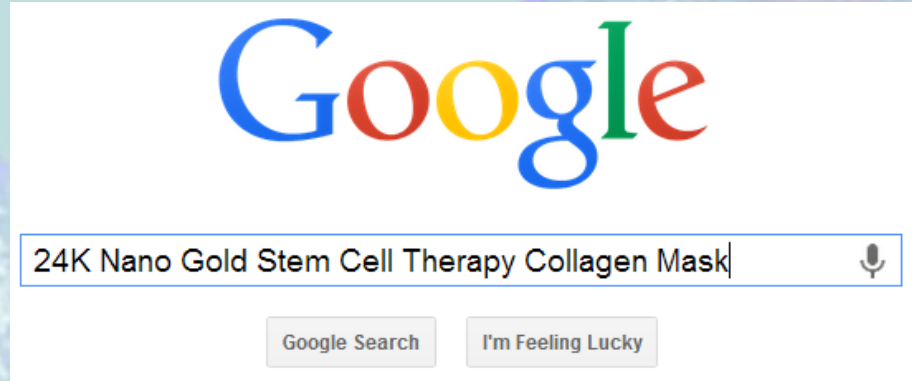
24K Nano Gold Stem Cell Therapy Collagen Mask



Available at [amazon.com](https://www.amazon.com)



Active Ingredients: 24K Gold Nano Powder, Y-PGA, Phyto-Collagen, Multi Peptide Complex, TGF, Tartaric Acid, Hyaluronic Acid, Glycerin, Rose Essential Oil, Grape Seed Oil, Hydrolyzed Soy Protein, Seaweed, Cucumber, Chamomile extract, Pearl Powder, Lavender, Glucosamine, Vitamins A E B5 and etc



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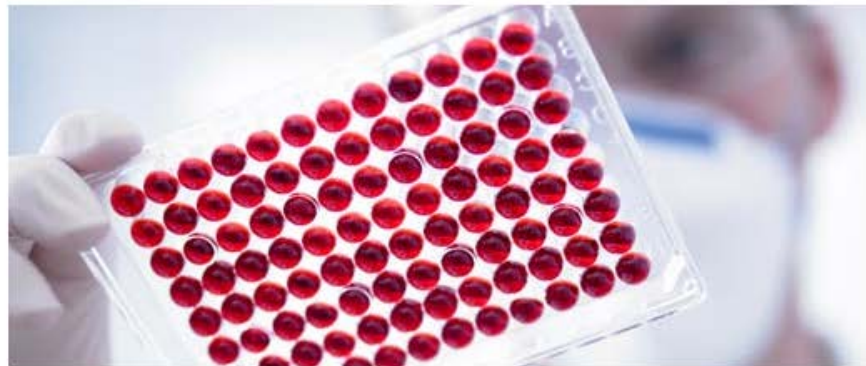
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Meet Heather

In addition to current, FDA-regulated clinical trials, the same types of stem cells that are found in cord blood and cord tissue are being used in early-stage research. Although researchers can't say what these studies will yield, newborn stem cells are demonstrating a growing range of potential uses across a variety of therapeutic areas.

Related Links:

- » [Center for Regenerative Medicine](#)
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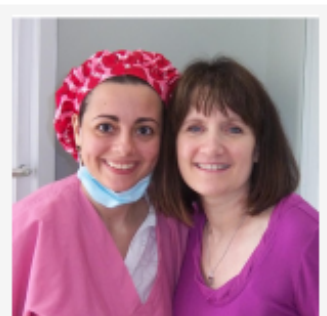


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- [Professor Arnold Caplan discusses mesenchymal stem cell therapy for multiple sclerosis](#)
- [Spinal cord injury patient demonstrates progress after treatment at Stem Cell Institute Panama](#)
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STEM CELL REJUVENATION CENTER PHOENIX, ARIZONA - USA



Located in beautiful Phoenix, Arizona, we are the original Stem Cell Rejuvenation Center. We have been performing stem cell therapies for over 10 years and all of our procedures are done on site at our clinic here in Phoenix. It is our top priority to provide you a safe, clean, sterile and friendly environment. Our Treatment Center is located just 8 minutes from the Phoenix Sky Harbor International Airport and many hotels provide shuttle service to and from our clinic making it ideal for out-of-town visitors. We provide stem cell therapy for a variety of conditions by using our revolutionary technology and treatments to isolate and reinfuse stem cells from a patient's own adipose stroma or fat (also called the Stromal Vascular Fraction (SVF)). We combine the best of technology, nature, and medicine to help improve the quality of our patients' lives. Stem cell therapy is offered to those who are qualified candidates and whom desire treatment.

We are a Stem Cell Therapy and Treatment Center, founded in the U.S.A., and performing all therapies within the United States. Neither our patients nor the stem cells that we harvest are transported outside the United States. We use less than minimally manipulated technology to provide Autologous Stem Cell and PRP therapies originally initiated during the 1990's.

To see if you are a candidate, please fill-out [this form](#) and provide as much detail as possible.



Our Integrative staff and Physicians use a variety of modalities including Anti-aging and Eclectic medicine. These approaches are used to treat many injuries and conditions. Below are some links to a journal database maintained by the NIH that relate to current research on stem cells and particular conditions.....

Please note that although we have supplied links to the research journals above on the use of stem cells for specific conditions, we are not saying that any of these studies would relate to your particular condition, nor that it would even be an effective treatment. Our Autologous Stem Cell Therapy is not an FDA approved treatment for any condition. We provide stem cell therapy (less than manipulated) as a service and as a practice of medicine only. Please see the bottom of the [FAQ page](#) for more information. These journal articles are for educational purposes only and are not intended to be used to sell or promote our therapy.

This Workshop

- **Will take a critical look at the current environment**
- **Speakers will examine the stem cell treatments that are being offered, the potential benefits and risks to individual health, the evidence base needed to substantiate the clinical application of stem cell technologies, and legal hurdles for establishing standards and criteria to govern stem cell trials and treatments.**
- **Potential avenues to enhancing assurances of quality of stem cell therapies will also be examined.**

Moderators

- **Ralph J. Cicerone, President, National Academy of Sciences**
- **Ellen Feigal, Senior Vice President, Research and Development, California Institute for Regenerative Medicine**
- **Irving Weissman, Virginia & D.K. Ludwig Professor for Clinical Investigation in Cancer Research, Stanford University School of Medicine**
- **Amy Comstock Rick, Chief Executive Officer, Parkinson's Action Network**
- **Harvey V. Fineberg, President, Institute of Medicine**