



INNATE HEALTHCARE INSTITUTE STEM CELL TREATMENTS

Stem cells are a fairly new phenomenon in the medical field. Multiple studies and clinical trials have shown this unique biologic to have great benefits in several different aspects of healing. But many are still confused about the legality of using stem cells. There are some types of stem cells that are not legal to use, and there are some ways to use them that are outside legal parameters. However, Innate Healthcare Institute's protocols and treatments are compliant with all applicable laws and regulations. We have provided a legal summary below so you can understand and be comfortable with the Institute's standard of care.

Federal Law

You should first know that no federal law does or ever did ban stem cell research or use in the United States. Many people ask if the treatments we provide are approved by the FDA or some other agency. First, it is important to understand that the FDA has absolutely no jurisdiction over physicians and clinics. This includes how to practice, treat, or use drugs, devices, or biologics. This activity is governed by state law and is largely left to the independent medical judgment of the practitioner. The FDA actually admits openly that it does not *"regulate a physician's or nurse's practice [and] does not tell providers what to do when running their business or what they can or cannot tell their patients."*¹

The FDA does have some authority over the stem cell industry and regulates it in three ways. First, it regulates stem cell production by laboratories or other manufacturers. These must comply with a rigorous set of safety protocols and manufacturing practices. Second, it regulates *claims* that manufacturers and physicians make about the use of stem cells, including treatments, cures, efficacy, etc. For example, the federal government does not want medical practices advertising to the public that stem cells are a guaranteed cure for any particular condition.

The third way the FDA regulates the use of stem cells is by classifying them as drugs. If stem cells are taken from a human subject and manipulated or altered in a particular way, the FDA considers this new stem cell creation to be a drug. When this happens, the FDA has authority to regulate these substances, as well as the medical practices using them in procedures.

However, Innate Healthcare Institute does not alter stem cells in this way. It is not creating new "drugs," but is simply taking stem cells from a donated umbilical cord, which would otherwise be

¹ <https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices>



considered a waste product and disposed, and preparing them in a way that is absolutely compliant with pertinent laws and regulations and using them according to its experience, expertise, and independent medical judgment. Federal case law has positively established that the FDA has no jurisdiction when stem cells are not manipulated or altered.²

The Institute also does not make any public claims or advertise that its stem cell treatments will cure a particular condition. It looks at treatments on a case-by-case basis and determines if a stem cell protocol may be effective for a particular patient.

State Law

Arizona permits naturopathic physicians to diagnose and treat disease with a wide range of procedures and natural medicines. This includes administering stem cells for therapeutic use. Innate Healthcare Institute uses stem cells manufactured in its own lab as well as in a nationally-recognized academic facility and not manipulated in any meaningful way before use on a patient. Beyond this, almost no state regulation of stem cells exists. The only real way the state regulates stem cell use is through the Board of Medicine to ensure they are used according to the proper standard of care, as with any other procedure.

Effectiveness

Innate Healthcare Institute has clinical proof of beneficial patient outcomes from its stem cell protocols. This includes those with different types of conditions and needs. The Institute can supply written testimonials from these patients. It has been engaged for some time in extensive primary and secondary research to know how best to use stem cells and achieve the greatest possible outcomes. It is committed to continuing its practice based on the highest levels of knowledge, professionalism, and standard of care.

The Institute is also fully committed to staying compliant with all laws, regulations, and guidelines that govern the use of stem cells. It has retained a national law firm that specializes in healthcare and FDA law to guide it through the legal processes and provide the most up-to-date counsel. In this way, you can be sure that Innate Healthcare Institute will always serve its patients within all legal and medical parameters.

² *United States v. U.S. Stem Cell Clinic, LLC (2021)*