PRESS RELEASE

IDFPR Warns Consumers About Unproven Stem Cell Therapy

CHICAGO, Illinois – May 31, 2019 – The Illinois Department of Financial and Professional Regulation (IDFPR) is warning consumers about unproven stem cell therapy treatments and those administered by providers who may not be licensed to so. This follows warnings provided by both the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

The department is currently investigating several consumer complaints related to this practice. In particular, the department urges consumers to avoid stem cell therapy treatments administered by chiropractors or others who are not licensed to provide such therapy absent collaboration with a medical doctor, doctor of osteopathy or other authorized health care provider.

“Stem cell therapy is largely an unproven and potentially dangerous treatment,” said Dr. Brian Zachariah, IDFPR’s Chief Medical Coordinator. “Our department will take all available action to protect consumers and ensure providers obey the law, but we urge consumers to proceed with caution. Check that the provider is properly licensed and trained to administer the treatments and be aware of the risks associated with stem cell therapy.”

IDFPR advises consumers who are considering stem cell therapy of the following:

- **Before undergoing stem cell treatment, be sure of the credentials of the provider offering this therapy**. Per the State’s Medical Practice Act, stem cell injections can only be ordered and administered by physicians licensed to practice medicine in all its branches (MDs and DOs). The Illinois Medical Practice Act does permit an Advanced Practice Registered Nurse or Physician Assistant to administer injectables under certain circumstances.
- **Ask about the products to be used for the proposed treatment**. The only stem cell-based products that are FDA-approved consist of blood-forming stem cells derived from cord blood and these are approved for only limited use to treat disorders of the body’s blood production (hematopoietic) system. There are certain exceptions to the FDA’s guidance for blood removed from the patient’s body. The FDA does not prohibit this procedure.
- **Ask what the proposed treatment is supposed to do.** Even properly licensed providers must not make unsupported claims regarding the efficacy of stem cells or any other treatment. Stem cells are only known to be effective in a very limited number of diseases. While providers may market their treatments as useful for a variety of

conditions such as joint pain or neurological problems, they should not claim efficacy for the treatment of any particular disease other than hematopoietic disorders.

- **Be sure you understand the risks and benefits of the proposed treatment.** While state law allows so-called “off label” use of approved products for the treatment of other health conditions, patients should be aware that any such use of stem cells is unproven and should be thoroughly apprised of the risks and benefits of the proposed treatment before consenting to it. If the planned treatment is part of an FDA- approved clinical trial, you should be informed of this and formally consent to participating in the study.

All medical treatments have potential risks and benefits, but unapproved and unproven stem cell therapies can be particularly unsafe. The CDC has investigated an outbreak of bacterial infections in patients who received one form of stem cell therapy and the FDA found that the company processing this product was not adequately screening cord blood donors. Some patients have gone blind or had the growth of new tumors after stem cell treatments. Failure of the cells to work as expected is a common complaint among stem cell treatment recipients. Statutorily, IDFPR cannot take adverse action against a licensee based solely on the use of a medical procedure performed within the standard of care that fails to provide ideal results. However, medical providers cannot make claims for their products that are untrue and lack scientific support.

If a patient or member of the public believes a provider is not properly licensed to administer stem cell treatments, that the licensee’s action has caused harm, that it was not performed with the requisite standard of care or that the claims for the product are untrue, he or she may file a complaint with IDFPR.

Further information regarding stem cell treatments from the CDC and the FDA may be found at the following links:

https://www.cdc.gov/hai/outbreaks/stem-cell-products.html

https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies