2nd Annual Summit on
STEM CELL RESEARCH, CELL & GENE THERAPY &
CELL THERAPY, TISSUE SCIENCE AND REGENERATIVE MEDICINE &
12th International Conference & Exhibition on
TISSUE PRESERVATION, LIFE CARE AND BIOBANKING
November 09-10, 2018 | Atlanta, USA

# Stem cell industry: Regulatory developments, FDA inspection and enforcement, legal issues for providers

**Matthew M Fischer**
Florida Healthcare Law Firm, USA

There are no off the shelf solutions when it comes to starting a new business or adding a new component to a practice. Between navigating regulations, receiving training, and marketing the service, there's a lot to address in a short time. Trying to do it all yourself? You may be a highly trained clinician, but given healthcare's ever-changing regulatory environment, it is highly encouraged for providers to seek experienced counsel first. To get started, here is a short summary of what to expect. The first issue is always protection when starting a business or adding a new service. Take the case of an orthopedic physician that wants to add stem cell treatments (e.g. PRP) to his or her practice. The initial inclination is usually to create a new entity separate from the medical practice. What the physician is unaware of is that this may create exposure to state self-referral laws. Typically, under these types of laws, the intent is not a requirement. Therefore, is it important to determine if your state has this type of law and if so, how to structure the new venture before moving forward? The FDA has the authority to regulate stem cell products. Most products are regulated by the FDA as an HCT/P while others are not. Many direct-to-consumer providers are unsure about what this means and need to know what they are able to do and say. Thus, it is imperative to be up to date on the issues and know what boundaries have been set by the FDA. With the rise of stem cell science and treatments, many state boards have warned physicians that they could face potential disciplinary action for failing to meet the prevailing professional standard of care or for performing an experimental procedure without first obtaining full, informed consent. Many physicians would like to have a mid-level practitioner (i.e. NP or PA) assist or provide injections. Once again, state regulations need to be reviewed to determine who can provide treatments and what level of supervision is required.

## Biography

Matthew Fischer is a Former Government Attorney with a passion for the emerging stem cell industry. Prior to joining the firm, he served as a Senior Attorney Advisor in the US Department of Health and Human Services, Office of Medicare Hearings and Appeals. He advised Federal Administrative Law Judges (ALJs) on reimbursement appeals, including Medicare contractor overpayment audits (i.e., RAC, ZPIC, and PSC), statistical sampling extrapolation issues, Medicare Part D exceptions, and secondary payer appeals. His current practice is concentrated in healthcare with a strong focus on stem cell regulatory development and enforcement.

matt@floridahealthcarelawfirm.com

**Notes:**