FDA Commissioner Warns of Stem Cell Crackdown at Annual Food and Drug Law Institute Conference

Last week FDA Commissioner Scott Gottlieb warned of upcoming crackdowns on stem cell therapies. During a speech at an enforcement-oriented conference, Gottlieb decried the lack of compliance by the medical stem cell industry and assured that “many of them will be hearing from us.”

At the same conference Melissa Mendoza, deputy director of the FDA’s Office of Compliance and Biologics Quality, added her voice to the same theme criticizing stem cell promoters for “aggressively promoting stem cell products for a wide range of serious and often life-threatening diseases” with little basis for their claims. Gottlieb’s speech and Mendoza’s comments effectively end a two-decade long era where FDA took a lax view of stem cell enforcement, hoping to encourage experimentation of what it saw as an enormously promising potential for advancement of healthcare therapies. During this era, legitimate, university-based research eventually gave way to opportunism without scientific rigor, with many companies trumpeting the “benefits” of unproven stem cell therapies all over the internet. The agency now sees more risk to Americans from lax regulation than benefit from unregulated activities that might produce therapeutic breakthroughs.

Since only a handful of stem cell treatments currently available are FDA approved for a narrow set of conditions, both manufacturers and health care providers are at risk in marketing or using stem cell treatments. Failure to comply with FDA rules can result in a wide range of enforcement, including criminal penalties. Adding to the complexity facing manufacturers and providers are the various levels of FDA approval, which is not necessarily required in certain instances. Behavior that is very similar might be a crime in one instance, and just the practice of medicine in another. Regular therapeutic stem cell use usually requires approval of the therapy as an FDA-regulated biologic. But other therapies constituting “the practice of medicine” are un-regulated by the FDA altogether, and other lower-risk treatments may meet the requirements for an exception to pre-market approval of human cells, tissues, and cellular tissue-based products (“HCT/Ps”), and are permitted to be sold and used without obtaining a biologics license. Additionally, stem cells may be distributed and used (but not commercially marketed) as part of a clinical investigation under an Investigational New Drug application.

Nelson Hardiman lawyers are experts in the regulation of stem cells and FDA rules.

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