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Stem cells to the market place

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Abstract

Stem Cells intended for use in humans are regulated under the U.S. Food and Drug Administration's regulations governing human cells, tissues, cellular and tissue based products (HCT/Ps). Depending upon such use and their functional impact within the body however, they may also be subject to FDA's drug, biologic or medical devices rules. This presentation will provide an overview of FDA's legal authority and regulation governing stem cells products, the criteria that the FDA uses to determine a product's regulatory status, and offer strategies for mitigating the potential risks associated with the marketing and selling a stem cell product in the U.S. Relying on recent FDA warning letters and court cases, the presenter will identify specific regulatory risks relevant to cellular products and therapies; and discuss methods for controlling such risks.

Biography

Karl M Nobert is a Food and Drug Regulatory Attorney with Squire Sanders (U.S.) LLP in Washington, DC. His legal practice focuses on the U.S. Food and Drug Administration's regulation of prescription and over-the-counter drug products, biologics including cellular and tissue products; medical devices and veterinary products. He has considerable experience working with clients on the design and adoption of FDA regulatory strategies covering the manufacturing, marketing and sale of both human and veterinary regenerative products. He frequently writes and presents on these topics