Cell, Tissue, and Gene Therapies

You create new products at the speed of innovation. And regulators race to keep pace. Commercial success and compliance can sometimes seem at odds.

The lawyers at Hogan Lovells uncover opportunity and mitigate risk for clients regarding cell, tissue, and gene therapies. From responding to U.S., EU, and Asian regulators, to marketing regenerative medicine, new stem cell, and advanced therapy developments. Many of us have served as regulators, and maintain relationships with FDA, EMA, and other agencies. So we are primed for shifts in the regulatory landscape.

We also advise on commercial issues including tech transfer, reimbursement, licensing, and more.

With Hogan Lovells, you can prepare for future success.

Representative experience

We have advised human tissue companies on how to transition a product from 361 HCT/P status to licensure as a biologic under section 351 of the Public Health Service Act.

We have assisted leading pharmaceutical companies in determining the appropriate classification of their tissue products in the EU.

We have advised gene therapy companies on genotyping programs.

We obtained Healthcare Common Procedure Coding System
(HCPCS) codes for cellular therapies.

Assisted a client developing a gene therapy product for an orphan condition convince FDA to relinquish burdensome clinical trial endpoint requirements.

Counseled a gene therapy company and a company developing a drug to treat genetic obesity on genotyping programs and subject recruiting and patient identifying programs.

Counseled U.S. biotech companies seeking EU marketing authorization for advanced medicinal therapies, including issues involving clinical trials and patient identification.

**Latest thinking and events**

**Blog Post**
FDA aims to foster gene therapy developments with six new draft guidance documents

**Blog Post**
FDA shows that it means business in stopping stem cell clinics that put patients at risk

**Blog Post**
The Crackdown Continues: FDA Takes Action Against Company And Its Autologous Stem Cell Product, Alleging Significant Safety Concerns

**Blog Post**
FDA Clarifies and Expands Eligibility for RMAT Designation for Gene Therapies

**Blog Post**
FDA Issues New Guidance Documents on Regenerative Medicine but Delays Enforcement

**Blog Post**
Continuing Coverage of FDA’s Crackdown on Stem Cell Clinics: Florida Clinic Cited for Unapproved Marketing and Inadequate Sterility Assurance