



## 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

### Contacts

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### Practices

Pharmaceuticals and  
Biotechnology Regulatory

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### Industries

Life Sciences and Health  
Care

(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

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (1 - 5 June 2020)

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (25 - 29 May 2020)

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (18 - 22 May 2020)

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (11 - 15 May 2020)

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (4 - 8 May 2020)