

MEDIA MENTION

# Mary Sylvia Discusses Recent Appeals Court Ruling on Stem Cells

*BioWorld Today*

February 18, 2014

Mary Sylvia, a partner in Wiley Rein's Intellectual Property Practice, was quoted in a February 7 *BioWorld Today* article about a recent U.S. Court of Appeals for the District of Columbia Circuit ruling on a stem cell product.

In a February 4 ruling, the court found that Regenexx-C, a stem cell product, is subject to labeling and regulation by the U.S. Food and Drug Administration (FDA). In concurring with arguments made by the government, the court found that culturing mesenchymal stem cells (MSCs) changes the stem cells' biological characteristics enough to exceed the FDA's "minimal manipulation" threshold, thereby subjecting it to regulation, according to the article. The ruling upholds an FDA injunction filed against Regenexx-C's manufacturer, Regenerative Sciences, in 2010.

"Even in autologous uses, removing cells and culturing them entails the addition of many externals ... that deserves oversight," Ms. Sylvia told *BioWorld Today*.

## Related Professionals

Mary Sylvia  
Partner  
202.719.4178  
[msylvia@wiley.law](mailto:msylvia@wiley.law)

## Practice Areas

Intellectual Property  
Patent