FDA Extends Enforcement Discretion Policy for Certain Regenerative Medicine Products

On July 20, 2020 the Food and Drug Administration (FDA) announced it is extending the enforcement discretion policy for certain human cell, tissue, and cellular and tissue-based products (HCT/Ps). In recognition of the challenges posed by the COVID-19 public health emergency, the FDA will provide manufacturers and potential sponsors of HCT/Ps another six months to determine if they need to submit an Investigational New Drug (IND) or marketing application and to prepare and submit such an application, if appropriate. Accordingly, the FDA also announced that it would extend its Tissue Reference Group Rapid Inquiry Program ("TRIP"), which provides non-binding assessments regarding how a specific HCT/P product is regulated, until March 21, 2021.

In its November 2017 guidance, the FDA outlined its regenerative medicine policy framework, and outlined its intent to exercise enforcement discretion until November 2020 in order to allow manufacturers time to determine what requirements apply and take the required steps in terms of agency approval, if any. This enforcement discretion will now be exercised through May 2021.

While this is good news, we note that Peter Marks, M.D., Ph.D., Director of FDA's Center for Biologics Evaluation and Research, was quick to point out that the policy of enforcement discretion **only pertains to certain HCT/Ps that do not raise significant safety concerns or reported safety concerns**, and that the FDA will continue to take action against manufacturers and health care providers who are offering regenerative medicine products that have the potential to put patients at significant risk.

As a result, we expect the FDA to continue its enforcement efforts against the marketing and use of unapproved products that are viewed as unsafe, for example most stem cell products. In the Journal of the American Medical Association article published in June 2020, FDA Commissioner Stephen Hahn and CBER Director Peter Marks noted that an "increasing number of adverse events" following the use of unapproved regenerative medicine therapies is necessary cause for the FDA to act to prevent harm. They further admonished the companies involved in selling such products as doing so under the "erroneous assertion that they are exempt" from FDA regulations.

For this reason, we recommend that HCT/P manufacturers take advantage of the additional time to gain clarity on FDA's regulation of their product and not to ignore FDA's previous statements and enforcement activity in deciding whether to use or market an unapproved product during the extended enforcement discretion period.

Nelson Hardiman lawyers are expert in the regulation of regenerative medicine products and FDA rules.

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