

**MASAC RECOMMENDATION ON FUNDING OF THE OFFICE OF
CELLULAR AND GENE THERAPIES**

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation on June 7, 2003, and adopted by the NHF Board of Directors on October 19, 2003.

Whereas the Office of Cellular and Gene Therapies (OCGT) of the FDA is responsible for regulatory oversight of therapies which may cure bleeding disorders;

Whereas the OCGT, a part of the Center for Biologics Evaluation and Review (CBER), has undergone significant reorganization as projects and resources have been shifted to the Center for Drug Evaluation and Review (CDER);

Whereas sufficient expertise and human resources are essential to safely move emerging technologies to potentially cure bleeding disorders into human clinical testing;

Therefore, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation recommends that sufficient resources be allotted to OCGT to allow for

1. A collaborative relationship to accelerate the development of innovative clinical studies, and
2. Rapid review of translational research from academic institutions and industry.

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