GENE THERAPY TIMELINE

1980 – Richard Mulligan, an M.I.T. researcher, shows that genetically engineered mouse-leukemia retroviruses were effective messengers for carrying human genes into mouse DNA.

1989 – Dr. French Anderson, Eli Gilboa and Dr. Michael Blaese win approval from an National Institutes of Health (NIH) advisory panel for a test that would transfer bacterial genes into immune cells of terminal cancer patients. The trial paves the way for dozens of gene-therapy efforts.

1990 - Dr. French Anderson and Michael Blaese perform the world’s first officially approved gene therapy by manipulating human genes. The patient is a 4 year-old girl named Ashanti DeSilva. She inherited a defective gene from both parents and suffered from ADA (adenosine deaminase) deficiency. The scientists introduce millions of Ashanthi’s own white blood cells into her bloodstream that were extracted from Ashanthi’s blood and genetically engineered to contain a corrected (“therapeutic”) copy of the adenosine deaminase gene. The scientists hope these cells will restore Ashanthi’s immune function by producing a normal version of the defective enzyme. The treatment appears to have been a success.

1999 - The sudden death of Jesse Gelsinger, a patient undergoing experimental treatment for a rare liver disorder at the University of Pennsylvania, raises scores of questions about various aspects of gene therapy. Penn officials say Gelsinger’s immune system had a severe inflammatory reaction that caused multiple organs in his body to fail.

1999- NIH discovers that researchers did not report 6 gene therapy patient deaths. Public backlash intensifies

2000 - Reporters uncover hundreds of unreported cases of “adverse effects” for gene therapy trail.

2001 - First germline gene transfer – 30 children born as a result of ooplasmic transfer. Ooplasmic transfer (also referred to as ooplasmic or cytoplasmic transplantation) is a fertility procedure used by women who cannot conceive because of defects in their ooplasm – their eggs’ cytoplasm. The procedure is performed by inserting healthy ooplasm from donor eggs into the eggs with defective ooplasm. By inserting healthy ooplasm from the donor eggs into the mother’s defective eggs, a small amount of mitochondrial DNA is transferred into the egg. This is considered germline gene transfer because the mitochondrial DNA of these children, and of their offspring, will always be from the donating mother.

2002 - Two children who were cured of “bubble baby syndrome” (X-SCID), were discovered to have developed a leukemia-type disease.

2003 - FDA temporarily halts gene therapy trials using retroviral vectors in blood stem cells. This is the first restriction of government regulation of gene therapy trails since they were allowed in 1989.