Workshop on Biologic Therapeutics for Very Rare Plasma Protein Disorders

- NIH Campus, Lister Hill Auditorium, June 13, 14, 2005.
- Focus: examine current and future pathways in the US and elsewhere for licensing plasma derivatives and recombinant analogues for very small patient populations, e.g., deficiencies of fibrinogen, FV, XI, etc.
- Topics include but are not limited to: challenges faced by industry; clinical trial design modifications; increasing clinical trial populations; balancing risks vs. benefits; potential of international harmonization of license requirements
- Organizing committee: FDA, CDC, NHLBI, EMEA, PPTA