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Biosketch

Amy Rosenberg received her medical degree from Albert Einstein College of Medicine and is Board Certified in Internal Medicine. She was a post-doctoral fellow in Al Singer's Laboratory in the NCI before coming to CBER, FDA in 1988. She became Director of the Division of Therapeutic Proteins, CBER/CDER in 2000. Her division (now DBRR3 in the Office of Biotechnology Products, CDER) regulates diverse protein therapeutics, including monoclonal antibodies and fusion proteins, enzyme replacement therapies, hematologic and somatic cell growth factors, and immunomodulatory agents. She has been a driving force in risk evaluation and mitigation pertaining to the immunogenicity of therapeutic proteins (Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products) and in the elucidation and implementation of immune tolerance induction protocols in clinical settings. Most recently, she co-edited the AAPS/Springer Book "Biobetters: Protein Engineering to Approach the Curative".

Abstract: Mechanisms of immune tolerance

My presentation will cover the immunologic background for drug induced liver injury, specifically focusing on mechanisms of immune tolerance, both central and peripheral. I will also present information on the known mechanisms by which drug induced autoimmunity may abrogate such tolerance.