SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Federal and Drug Administration ("FDA") and Lehigh Valley Technologies, Inc. ("LVT") (collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. LVT is a pharmaceutical company engaged in the development and commercialization of certain human drug products that is located in Allentown, Pennsylvania.

B. Pharma-Med is a company located in Bethlehem, Pennsylvania.

C. Pharma Research Software Solution, LLC ("PRSS") is an information technology company located in North Holland, Pennsylvania.

D. FDA regulates the approval of new drugs. A company seeking such approval must submit and receive FDA approval of a new drug application ("NDA") before the drug may be marketed or sold in the United States. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing.

E. Congress created the Prescription Drug User Fee Act ("PDUFA") in 1992 that authorizes and requires FDA to collect a "prescription drug user fee" or "application fee" from companies that submit an NDA. PDUFA gives the FDA a revenue source to fund the new drug approval process.