HB 1072 -- INVESTIGATIONAL DRUG TRIALS

SPONSOR: Neely

This bill allows a manufacturer or prescribing physician to market an investigational drug, biological product, or device outside of a label-expansion, placebo-controlled trial to eligible patients. Upon informed consent from the eligible patient the manufacturer or prescribing physician must make the product available or provide the eligible patient with the contact information of a physician who will prescribe the investigational drug, biological product, or device to the eligible patient. Any manufacturer that violates this provision will be fined $100 per patient.

The bill creates the Investigational Drug Fund consisting of moneys collected from fines and any punitive damages awarded or settlements reached as a result of lawsuits filed by the Attorney General for the off-label marketing of investigational drugs, biological products, or devices. The fund must be used to cover the costs of eligible patients whose health care coverage does not cover off-label use of the investigational drug, biological product, or device.