HB 1169 -- PRODUCT DISCLOSURES

SPONSOR: Jones

This bill specifies that any product that acts as, or exposed to processes that could result in the product potentially acting as, a gene therapy or that could possibly impact, alter, or introduce genetic material or a genetic change into the user of the product or certain other people must be conspicuously labeled with the words "Potential Gene Therapy Product", and reasonable steps must be taken to ensure a potential purchaser or user is made aware of the presence of this label. If a product is known to be a gene therapy product, the product must be conspicuously labeled with the words "Gene Therapy Product".

Upon the written request, any entity that produces, sells, or distributes a product with the capacity to infect an individual with a disease or to expose an individual to certain genetically modified material must provide all information related to the ways in which individuals who did not directly obtain or use such product may be exposed to the product or a component of the product. Any product manufacturer, government agency, or organization that has an interest in the production, sale, or distribution of such a product is also subject to the disclosure requirement and must provide all relevant reports, research, and knowledge upon request. Information requested must be provided as soon as reasonably practicable, but at least within 21 days, after receipt of the written request.

Any entity that makes a product available that could infect, transmit to, or be absorbed in any way that would act as a medical intervention, vaccine, drug, or genetic modification must obtain fully informed consent from all individuals who could be exposed to such product before exposure may occur. Fully informed consent requires, at a minimum, that an individual is made aware of all benefits and risks, including side effects, of the product, any adverse events of special interest, and any other reasonably possible impacts of the product.