Consumers Union Model Clinical Trials Bill, October 2005

Article _____. Related to information required for prescription drugs on the state's preferred drug list.

(a) Short title. This article may be referred to as the "Patient Safety and Drug Review Transparency Act."

(b) Purpose. The purpose of this Act is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, researchers, and the state. Making information about drug trials and their results available on a national, publicly-accessible database will assure that the State, in its role as purchaser of prescription drugs and administrator of prescription drug programs can assure those drugs are safe. It will improve safety of all citizens of this state by assuring they have complete safety information about the prescription drugs they take.

(c) Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

i. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

ii. "Manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer

iii. "Labeler" means an entity or person that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

(d) Disclosure of clinical trials of prescription drugs. A manufacturer or labeler of prescription drugs dispensed in this State shall post, with regard to those prescription drugs, on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October 15, 2002:

i. The name of the entity that conducted or is conducting the clinical trial;

ii. A summary of the purpose of the clinical trial;

iii. The dates during which the trial has taken place; and

iv. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug.

In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department of health.

(e) Fees. Beginning January 1, 2007, each manufacturer of prescription drugs that are provided to the state's residents through the state's Medicaid program under section _____ shall pay a fee of $1,000 per calendar year to the department. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection (d) and other relevant sites, assessing whether and the extent to which the state's residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection (f). Revenues received under this subsection shall be used for this purpose.

(f) Public education initiative. The department of health shall undertake a public education initiative to inform residents of the state about clinical trials and drug safety information.

(g) Penalties. A violation of this section is a violation of the state's Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

(h) Rulemaking. The department of health may adopt rules to implement this section.