HOUSE BILL NO. 375

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SIXTH LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE GUTTENBERG

Introduced: 2/23/10
Referred: Health and Social Services, Finance

A BILL

FOR AN ACT ENTITLED

"An Act establishing a statewide registry for clinical trials of drugs and biological products; and relating to approval of drug studies."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 17.20 is amended by adding new sections to read:

Sec. 17.20.122. Clinical trials. (a) A person may not conduct clinical trials on a prescription drug or biological product in the state without first registering with the department under AS 17.20.125 and receiving the approval of an institutional review board recognized by the commissioner.

(b) The commissioner may only recognize an institutional review board that has complied with national and state standards established for conducting clinical trials for prescription drugs and biological products and that provides information necessary for publication in the clinical trials registry established under AS 17.20.125.

Sec. 17.20.125. Clinical trials registry. (a) A clinical trials registry for prescription drugs and biological products is created in the department to serve as a

comprehensive repository of information regarding all clinical trials conducted in the state, including information about the results of clinical trials, regardless of outcome, for access by the public.

(b) The commissioner shall establish and maintain the registry established under (a) of this section based on standards established by regulation and information available from the National Institutes of Health, United States Department of Health and Human Services, and from all other credible sources.

(c) The registry must include

(1) the name of the drug manufacturer or clinical trial sponsor;

(2) a summary of the purpose of the clinical trial;

(3) the beginning and ending dates of the clinical trial;

(4) information pertaining to the results of the clinical trial, including potential and actual adverse side effects of the drug or biological product associated with the trial; and

(5) any other information determined by the commissioner to be relevant and nonconfidential.

(d) A person or entity required to or authorized by the commissioner to report, receive, or disclose information related to the clinical trials registry is immune from liability for reporting, receiving, or disclosing the information.

*** Sec. 2.** AS 17.20.130 is amended to read:

Sec. 17.20.130. Exemptions. AS 17.20.110 does not apply to a drug

(1) **that has been approved for clinical trial by an institutional review board, is listed on the clinical trials registry under AS 17.20.125, and is** intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs if the drug is plainly labeled "for investigational use only"; or

(2) regulated under 42 U.S.C. 262.

*** Sec. 3.** AS 17.20.135 is amended by adding new paragraphs to read:

(3) "clinical trial" means a clinical investigation as defined by the United States Food and Drug Administration that involves an experiment to test the safety or efficacy of a prescription drug or biological product with one or more human

subjects and is intended to be submitted to, or held for inspection by, the United States Food and Drug Administration as part of an application for a research or marketing permit;

(4) "institutional review board" means an independent body made up of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs or biological products by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and materials to be used in obtaining and documenting informed consent of the trial subjects.

*** Sec. 4.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. This Act applies to clinical trials of prescription drugs and biological products that begin in the state on or after the effective date of this Act.