J3 5lr1495
CF 5lr0401

By: **Senators Brochin and Green**
Introduced and read first time: February 4, 2005
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Health - Clinical Trials Data Bank

FOR the purpose of requiring a certain clinical trial to be listed in the Clinical Trials Data Bank of the U.S. Department of Health and Human Services before a certain sponsor may enroll participants in the clinical trial; prohibiting certain requirements pertaining to the Clinical Trials Data Bank from affecting certain existing statutory requirements; authorizing the Attorney General, under certain circumstances, to seek certain relief to prevent the conduct of a clinical trial and to petition a court to impose a certain fine; establishing certain criminal penalties for conducting a clinical trial without listing the clinical trial on the Clinical Trials Data Bank; defining certain terms; and generally relating to listing of clinical trials in the Clinical Trials Data Bank.

BY adding to
Article - Health - General
Section 13-2101 through 13-2105 to be under the new subtitle "Subtitle 21. Clinical Trials Data Bank"
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

SUBTITLE 21. CLINICAL TRIALS DATA BANK.

13-2101.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "CLINICAL TRIAL" MEANS:

(1) A RESEARCH STUDY IN HUMAN VOLUNTEERS TO ANSWER SPECIFIC HEALTH QUESTIONS; AND

(2) A CLINICAL TRIAL FOR DRUGS, INCLUDING BIOLOGICAL DRUG PRODUCTS, TO TREAT SERIOUS OR LIFE-THREATENING DISEASES AND CONDITIONS CONDUCTED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION'S INVESTIGATIONAL NEW DRUG REGULATIONS (21 CFR PART 312).

(C) "DATA BANK" MEANS THE CLINICAL TRIALS DATA BANK IN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ESTABLISHED UNDER SECTION 113 OF THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997.

(D) "SPONSOR" MEANS THE NAME OF THE SPONSORING ORGANIZATION THAT TAKES RESPONSIBILITY FOR AND INITIATES A CLINICAL TRIAL.

13-2102.

NOTHING IN THIS SUBTITLE MAY BE CONSTRUED TO AFFECT THE REQUIREMENTS UNDER SUBTITLE 20 OF THIS TITLE.

13-2103.

BEFORE A SPONSOR MAY ENROLL PARTICIPANTS IN A CLINICAL TRIAL IN THE STATE, THE CLINICAL TRIAL SHALL BE LISTED IN THE DATA BANK.

13-2104.

THE OFFICE OF THE ATTORNEY GENERAL MAY:

(1) SEEK APPROPRIATE INJUNCTIVE OR OTHER RELIEF TO PREVENT THE CONDUCT OF A CLINICAL TRIAL IN VIOLATION OF THIS SUBTITLE; AND

(2) PETITION A COURT, IN A CRIMINAL ACTION DESCRIBED UNDER § 13-2105 OF THIS SUBTITLE, TO IMPOSE A FINE NOT TO EXCEED $1,000 FOR EACH DAY THAT A CLINICAL TRIAL PROCEEDS WITHOUT BEING LISTED IN THE DATA BANK.

13-2105.

(A) A PERSON MAY NOT CONDUCT A CLINICAL TRIAL IN VIOLATION OF THIS SUBTITLE.

(B) A PERSON WHO VIOLATES THIS SECTION IS GUILTY OF A MISDEMEANOR AND ON CONVICTION IS SUBJECT TO A FINE NOT TO EXCEED $1,000 FOR EACH DAY THAT A CLINICAL TRIAL PROCEEDS WITHOUT BEING LISTED IN THE DATA BANK.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2005.