J3 5lr0401
CF 5lr1495

(PRE-FILED)

By: **Delegates Pendergrass, Goldwater, Hubbard, Madaleno, and Mandel**
Requested: August 12, 2004
Introduced and read first time: January 12, 2005
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 1, 2005

CHAPTER_____

AN ACT concerning

Health - Clinical Trials Data Bank

FOR the purpose of requiring a ~~certain clinical trial to be listed in~~ certain sponsor to submit to the Clinical Trials Data Bank of the U.S. Department of Health and Human Services certain information regarding a certain clinical trial before ~~a certain~~ the sponsor may permit any person to enroll participants in the clinical trial; providing for a certain exception; prohibiting a person from conducting a clinical trial in violation of this Act; ~~prohibiting certain requirements pertaining to the Clinical Trials Data Bank from affecting~~ providing that this Act may not be construed to affect certain existing statutory requirements; authorizing the Office of 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~~ in violation of this Act; requiring the Office of the Attorney General to report to the General Assembly, on or before a certain date and annually thereafter, on certain violations and certain actions of the Office; defining certain terms; and generally relating to ~~listing of~~ the submission of information regarding clinical trials ~~in~~ to 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~~ TO TEST THE EFFECTIVENESS OF 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 FEDERAL FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997.

(D) "SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION" MEANS A DISEASE OR CONDITION THAT HAS BEEN IDENTIFIED OR DESCRIBED AS SERIOUS OR LIFE-THREATENING IN THE PUBLISHED GUIDANCE OF THE U.S. FOOD AND DRUG ADMINISTRATION RELATING TO THE CLINICAL TRIALS DATA BANK.

~~(D)~~ (E) "SPONSOR" MEANS THE ~~NAME OF THE SPONSORING ORGANIZATION THAT TAKES RESPONSIBILITY FOR AND INITIATES A CLINICAL TRIAL~~ PERSON THAT HOLDS THE INVESTIGATIONAL NEW DRUG EXEMPTION UNDER WHICH A CLINICAL TRIAL WILL BE CONDUCTED IN ACCORDANCE WITH APPLICABLE REGULATIONS OF THE U.S. FOOD AND DRUG ADMINISTRATION.

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~~

(A) EXCEPT AS PROVIDED IN SUBSECTION (B) OF THIS SECTION, A SPONSOR MAY NOT PERMIT ANY PERSON TO ENROLL A PARTICIPANT IN A CLINICAL TRIAL IN THE STATE UNLESS, NOT LATER THAN 21 DAYS AFTER A CLINICAL TRIAL HAS BEEN OPENED TO ENROLLMENT, THE SPONSOR HAS SUBMITTED TO THE DATA BANK:

(1) A DESCRIPTION OF THE PURPOSE OF AN EXPERIMENTAL DRUG USED IN THE CLINICAL TRIAL;

(2) THE ELIGIBILITY CRITERIA FOR PARTICIPATION IN THE CLINICAL TRIAL;

(3) A DESCRIPTION OF THE LOCATION OF CLINICAL TRIAL SITES IN THE STATE; AND

(4) IDENTIFICATION OF A POINT OF CONTACT FOR INDIVIDUALS WHO WANT TO ENROLL IN THE CLINICAL TRIAL.

(B) IF A CLINICAL TRIAL IS EXEMPT FROM LISTING IN THE DATA BANK BECAUSE THE SPONSOR OF THE CLINICAL TRIAL HAS SUBMITTED A DETAILED CERTIFICATION TO THE SECRETARY OF HEALTH AND HUMAN SERVICES AS AUTHORIZED BY § 113 OF THE FEDERAL FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997, THE SPONSOR NEED NOT SUBMIT THE INFORMATION SPECIFIED IN SUBSECTION (A) OF THIS SECTION.

13-2104.

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

(B) 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.~~

ON OR BEFORE DECEMBER 31, 2006, AND ANNUALLY THEREAFTER, THE OFFICE OF THE ATTORNEY GENERAL SHALL REPORT, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, TO THE GENERAL ASSEMBLY ON THE NUMBER AND

TYPES OF VIOLATIONS OF THIS SUBTITLE THAT OCCURRED DURING THE PREVIOUS CALENDAR YEAR AND THE ACTIONS TAKEN BY THE OFFICE IN RESPONSE TO THE VIOLATIONS.

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