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By: **Senators Brochin ~~and Green~~, Green, Britt, Conway, Gladden, Grosfeld, Hollinger, Pinsky, and Stone**
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Assigned to: Finance
Reassigned: Education, Health, and Environmental Affairs, February 10, 2005

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 15, 2005

CHAPTER_____

AN ACT concerning

Health - Clinical ~~Trials~~ Trials - Data Bank Information and Publication of Results

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; authorizing an institutional review board to approve a certain clinical trial only if a certain investigator has made certain written statements; 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; providing that this Act may not be construed to prevent certain disclosures, submissions, or decisions to publish certain research; 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; defining certain terms; requiring the Office of the Attorney General to report to the General Assembly on or before a certain date on certain violations and certain actions of the Office; 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 Information and Publication of Results"
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 INFORMATION AND PUBLICATION OF RESULTS.

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) "INSTITUTIONAL REVIEW BOARD" HAS THE MEANING STATED IN § 13-2001(D) OF THIS TITLE.

(E) "PRINCIPAL INVESTIGATOR" MEANS AN INDIVIDUAL WHO:

(1) IS ACCOUNTABLE FOR THE CONDUCT OF A CLINICAL TRIAL; AND

(2) REQUESTS APPROVAL FROM AN INSTITUTIONAL REVIEW BOARD TO CONDUCT A CLINICAL TRIAL IN THE STATE.

(F) "RESULTS OF A CLINICAL TRIAL" MEANS OUTCOMES, AS DETERMINED BY THE PRINCIPAL INVESTIGATOR AND OTHERS INVOLVED IN THE CLINICAL TRIAL IN ACCORDANCE WITH CUSTOMARY SCIENTIFIC PRACTICE, WITH RESPECT TO THE HYPOTHESES AND GOALS IDENTIFIED AT THE INITIATION OF THE CLINICAL TRIAL.

(G) "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)~~ (H) "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:

(1) AFFECT THE REQUIREMENTS UNDER SUBTITLE 20 OF THIS TITLE; OR

(2) PREVENT:

(I) DISCLOSURE BY A SPONSOR OF INFORMATION ABOUT A CLINICAL TRIAL TO THE PUBLIC BY A METHOD IN ADDITION TO THE DATA BANK;

(II) SUBMISSION BY A SPONSOR OF INFORMATION ABOUT RESEARCH THAT IS NOT A CLINICAL TRIAL TO THE DATA BANK; OR

(III) ANY VOLUNTARY DECISION OR CONTRACTUAL OBLIGATION TO PUBLISH OR OTHERWISE PUBLICLY DISSEMINATE THE RESULTS OF RESEARCH THAT IS NOT A CLINICAL TRIAL.

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.

AN INSTITUTIONAL REVIEW BOARD MAY APPROVE A CLINICAL TRIAL ONLY IF THE PRINCIPAL INVESTIGATOR HAS STATED IN WRITING TO THE INSTITUTIONAL REVIEW BOARD THAT:

(1) THE PRINCIPAL INVESTIGATOR HAS BEEN INFORMED BY THE SPONSOR THAT THE SPONSOR INTENDS TO COMPLY WITH § 13-2103 OF THIS SUBTITLE; AND

(2) (I) EXCEPT AS PROVIDED IN ITEM (II) OF THIS PARAGRAPH, THE RESULTS OF THE CLINICAL TRIAL WILL BE SUBMITTED FOR PUBLICATION IN A PEER-REVIEWED JOURNAL; OR

(II) IF THE RESULTS OF THE CLINICAL TRIAL WILL NOT BE SUBMITTED OR ARE NOT ACCEPTED FOR PUBLICATION IN A PEER-REVIEWED JOURNAL, THE PRINCIPAL INVESTIGATOR WILL MAKE AVAILABLE TO THE PUBLIC AN EXPLANATION RELATED TO THE RESULTS OF THE CLINICAL TRIAL.

13-2105.

(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.~~

SECTION 2. AND BE IT FURTHER ENACTED, That on or before December 31, 2007, 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 Act that occurred during the previous calendar year and the actions taken by the Office in response to the violations.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2005.