

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO SENATE BILL NO. 681

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Green” and substitute “, Green, Britt, Conway, Gladden, Grosfeld, Hollinger, Pinsky, and Stone”; in line 2, strike “Trials” and substitute “Trials-”; in lines 2 and 16, in each instance, after “Bank” insert “Information and Publication of Results”; in line 3, strike “certain clinical trial to be listed in” and substitute “certain sponsor to submit to”; in line 4, after “Services” insert “certain information regarding a certain clinical trial”; in lines 4 and 5, strike “a certain” and substitute “the”; in line 5, after “may” insert “permit any person to”; in the same line, after “trial;” insert “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;”; strike beginning with “prohibiting” in line 5 down through “affecting” in line 6 and substitute “providing that this Act may not be construed to affect”; in line 7, after “requirements;” insert “providing that this Act may not be construed to prevent certain disclosures, submissions, or decisions to publish certain research;”; in the same line, after “the” insert “Office of the”; in lines 7 and 8, strike “, under certain circumstances;”; strike beginning with “and” in line 9 down through “Bank” in line 11 and substitute “in violation of this Act”; in line 11, after “terms;” insert “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;”; in line 12, strike “listing of”; and in the same line, strike “in the Clinical Trials Data Bank”.

AMENDMENT NO. 2

On page 1, in line 22, after “BANK” insert “INFORMATION AND PUBLICATION OF RESULTS”.

On pages 1 and 2, strike beginning with the colon in line 26 on page 1 down through “(2)” in line 3 on page 2.

(Over)

On page 2, in line 3, strike “FOR” and substitute “TO TEST THE EFFECTIVENESS OF”; in line 8, strike “SECTION” and substitute “§”; in line 9, after “THE” insert “FEDERAL”; after line 9, insert:

“(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.”;

in line 10, strike “(D)” and substitute “(H)”; and strike beginning with “NAME” in line 10 down through “TRIAL” in line 11 and substitute “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”.

AMENDMENT NO. 3

On page 2, in line 13, after “TO” insert “:

(1)”;

in line 14, after "TITLE" insert "; 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";

and strike in their entirety lines 16 and 17 and substitute:

"(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.

(Over)

(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.”.

AMENDMENT NO. 4

On page 2, after line 18, insert:

“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.”;

in line 19, before the first “THE” insert “(B)”; in lines 19 and 20, strike “: (1)”; strike beginning with the semicolon in line 21 down through “BANK” in line 24; strike in their entirety lines 25

through 30, inclusive; and in line 31, after “That” insert “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’.