

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL NO. 54

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, 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; 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 “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; 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”; in line 12, strike “listing of” and substitute “the submission of information regarding”; and in the same line, strike “in” and substitute “to”.

AMENDMENT NO. 2

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.

AMENDMENT NO. 3

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) “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.”;

(Over)

in line 10, strike “(D)” and substitute “(E)”; 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”; and strike beginning with “BEFORE” in line 16 down through “BANK” in line 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.

(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:

“(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; and strike in their entirety lines 26 through 30, inclusive, and substitute:

“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.”.