.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To require the Secretary of Health and Human Services to treat certain tests for tuberculosis as breakthrough devices eligible for expedited development and priority review, to require certain establishments that perform donor screening or testing to screen or test for active and latent tuberculosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MOOLENAAR introduced the following bill; which was referred to the Committee on _____

A BILL

To require the Secretary of Health and Human Services to treat certain tests for tuberculosis as breakthrough devices eligible for expedited development and priority review, to require certain establishments that perform donor screening or testing to screen or test for active and latent tuberculosis, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Effective Screening and Testing for Tuberculosis Act''.

SEC. 2. TREATMENT OF CERTAIN TESTS FOR TUBERCULOSIS AS BREAKTHROUGH DEVICES.

The Secretary of Health and Human Services shall treat a device as a breakthrough device eligible for expedited development and priority review under section 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3) if it is a new and innovative donor screening test with heightened sensitivity to effectively screen human cell, tissue, and cellular and tissue-based product donors for evidence of active or latent tuberculosis infection.

SEC. 3. REQUIRING CERTAIN ESTABLISHMENTS THAT PERFORM DONOR SCREENING OR TESTING TO SCREEN OR TEST FOR ACTIVE AND LATENT TUBERCULOSIS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate regulations revising part 1271 of title 21, Code of Federal Regulations, including sections 1271.75 and 1271.85, and any other applicable regulations, to require—

(1) an establishment that performs donor screening to screen for active and latent tuberculosis; and

(2) an establishment that performs donor testing to test for active and latent tuberculosis.

(b) REGULATIONS.—The Secretary of Health and Human Services shall—

(1) not later than 1 year after the date of enactment of this Act, propose the regulations required by subsection (a);

(2) not later than 3 months after the close of the comment period for such proposed regulations, promulgate such regulations as final; and

(3) not later than 6 months after the date such regulations are promulgated as final, begin implementation of such regulations.

(c) DEFINITIONS.—In this section, the terms ''establishment that performs donor screening'' and ''establishment that performs donor testing'' have the meanings given to such terms under part 1271 of title 21, Code of Federal Regulations.

SEC. 4. GUIDANCE ON CURRENT GOOD TISSUE PRACTICE AND ADDITIONAL REQUIREMENTS FOR MANUFACTURERS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS.

Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services,

acting through the Commissioner of Food and Drugs, and in coordination with the Director of the Centers for Disease Control and Prevention, shall—

(1) review the guidance titled ''Guidance for Industry—Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' (December 2011); and

(2) issue an updated version of such guidance.

SEC. 5. COMPLIANCE WITH CUTGO.

No additional funds are authorized to be appropriated to carry out this Act, and this Act shall be carried out using amounts otherwise available for such purpose.