

118TH CONGRESS
1ST SESSION

H. R. 6705

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

DECEMBER 11, 2023

Mr. MOOLENAAR (for himself, Mrs. DINGELL, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Effective Screening
5 and Testing for Tuberculosis Act”.

1 **SEC. 2. TREATMENT OF CERTAIN TESTS FOR TUBER-**
2 **CULOSIS AS BREAKTHROUGH DEVICES.**

3 The Secretary of Health and Human Services shall
4 treat a device as a breakthrough device eligible for expe-
5 dited development and priority review under section 515B
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 360e–3) if it is a new and innovative donor screening test
8 with heightened sensitivity to effectively screen human
9 cell, tissue, and cellular and tissue-based product donors
10 for evidence of active or latent tuberculosis infection.

11 **SEC. 3. REQUIRING CERTAIN ESTABLISHMENTS THAT PER-**
12 **FORM DONOR SCREENING OR TESTING TO**
13 **SCREEN OR TEST FOR ACTIVE AND LATENT**
14 **TUBERCULOSIS.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services, acting through the Commissioner of
17 Food and Drugs, shall promulgate regulations revising
18 part 1271 of title 21, Code of Federal Regulations, includ-
19 ing sections 1271.75 and 1271.85, and any other applica-
20 ble regulations, to require—

21 (1) an establishment that performs donor
22 screening to screen for active and latent tuber-
23 culosis; and

24 (2) an establishment that performs donor test-
25 ing to test for active and latent tuberculosis.

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

3 (1) not later than 1 year after the date of en-
4 actment of this Act, propose the regulations required
5 by subsection (a);

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

9 (3) not later than 6 months after the date such
10 regulations are promulgated as final, begin imple-
11 mentation of such regulations.

12 (c) DEFINITIONS.—In this section, the terms “estab-
13 lishment that performs donor screening” and “establis-
14 hment that performs donor testing” have the meanings
15 given to such terms under part 1271 of title 21, Code of
16 Federal Regulations.

17 **SEC. 4. GUIDANCE ON CURRENT GOOD TISSUE PRACTICE**
18 **AND ADDITIONAL REQUIREMENTS FOR MAN-**
19 **UFACTURERS OF HUMAN CELLS, TISSUES,**
20 **AND CELLULAR AND TISSUE-BASED PROD-**
21 **UCTS.**

22 Not later than 6 months after the date of enactment
23 of this Act, the Secretary of Health and Human Services,
24 acting through the Commissioner of Food and Drugs, and

1 in coordination with the Director of the Centers for Dis-
2 ease Control and Prevention, shall—

3 (1) review the guidance titled “Guidance for In-
4 dustry—Current Good Tissue Practice (CGTP) and
5 Additional Requirements for Manufacturers of
6 Human Cells, Tissues, and Cellular and Tissue-
7 Based Products (HCT/Ps)” (December 2011); and

8 (2) issue an updated version of such guidance.

9 **SEC. 5. COMPLIANCE WITH CUTGO.**

10 No additional funds are authorized to be appro-
11 priated to carry out this Act, and this Act shall be carried
12 out using amounts otherwise available for such purpose.

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