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(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To direct the Director of the National Institutes of Health to conduct a study and submit to Congress a report on the development of a standardized, noninvasive test for HPV in men, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mrs. MCIVER introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To direct the Director of the National Institutes of Health to conduct a study and submit to Congress a report on the development of a standardized, noninvasive test for HPV in men, 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 “Closing the HPV Test-  
5 ing Gap Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1           (1) Human papillomavirus (in this section re-  
2           ferred to as “HPV”) is the most common sexually  
3           transmitted infection in the United States, with a  
4           significant proportion of HPV-related cancers, par-  
5           ticularly oropharyngeal cancers, occurring among  
6           men.

7           (2) There is currently no HPV diagnostic test  
8           for men that is approved by the Food and Drug Ad-  
9           ministration, creating a critical gap in public health  
10          surveillance, prevention, and treatment.

11          (3) The National Academies of Sciences, Engi-  
12          neering, and Medicine, in its 2023 report titled “Na-  
13          tional Cancer Control Efforts Should Address the  
14          System, Not Its Individual Parts”, emphasized the  
15          importance of coordinated, system-wide strategies  
16          for cancer prevention.

17          (4) Expanding HPV detection efforts to include  
18          men would promote gender equity in cancer preven-  
19          tion and enhance national cancer control and public  
20          health outcomes.

21          (5) The absence of a standardized HPV diag-  
22          nostic test for men contributes to sustained trans-  
23          mission pathways and delayed detection that directly  
24          impact women’s health outcomes, including cervical

1 cancer incidence, thereby reinforcing inequities in  
2 cancer prevention.

3 **SEC. 3. NIH STUDY AND REPORT ON DEVELOPMENT OF**  
4 **STANDARDIZED, NONINVASIVE HPV TEST**  
5 **FOR MEN.**

6 (a) STUDY.—The Director of NIH shall, not later  
7 than 24 months after the date of the enactment of this  
8 Act, conduct a comprehensive study on the development  
9 of a standardized, noninvasive test for HPV in men.

10 (b) CONSULTATION; COORDINATION.—The Director  
11 of NIH shall conduct the study under subsection (a)—

12 (1) in consultation with the Director of the  
13 Centers for Disease Control and Prevention, the  
14 Commissioner of Food and Drugs, the Administrator  
15 of the Health Resources and Services Administra-  
16 tion, and the National Academy of Medicine;

17 (2) in consultation with scientific and clinical  
18 experts, public health agencies, and relevant re-  
19 search institutions; and

20 (3) in coordination with the President of the  
21 National Academy of Medicine.

22 (c) ELEMENTS.—In conducting the study under sub-  
23 section (a), the Director of NIH shall—

1           (1) assess the current state of development, sci-  
2           entific knowledge, and research gaps related to  
3           standardized, noninvasive tests for HPV in men;

4           (2) explore potential approaches and methodolo-  
5           gies for noninvasive HPV testing in men, including  
6           evaluation of multi-site testing (such as testing of  
7           oral, pharyngeal, anal, and penile and urine testing);

8           (3) provide considerations for future implemen-  
9           tation, including advancing research to improve un-  
10          derstanding of HPV-related cancer risk in men, po-  
11          tential pilot studies or population-level testing proto-  
12          cols, and identify areas where further research could  
13          inform public health strategies;

14          (4) assess the feasibility of conducting pilot and  
15          implementation studies related to such tests in men  
16          across diverse populations (including high-risk and  
17          underserved communities) and across multiple sites  
18          affected by HPV (including testing of oral, pharyn-  
19          geal, anal, and penile sites and urine testing);

20          (5) develop recommendations for interagency  
21          coordination to facilitate regulatory approval of such  
22          tests, community-based screening of HPV in men,  
23          and equitable access to such tests through the Food  
24          and Drug Administration and the Health Resources  
25          and Services Administration; and

1           (6) conduct such other pilot and feasibility  
2           studies as the Secretary determines appropriate to  
3           complete the study under subsection (a).

4           (d) INTERAGENCY WORKING GROUP.—The Director  
5           of the National Institutes of Health shall establish an  
6           interagency working group, which shall include represent-  
7           atives from the Food and Drug Administration, the Cen-  
8           ters for Disease Control and Prevention, the Health Re-  
9           sources and Services Administration, and the National  
10          Academy of Medicine, to ensure that throughout the pe-  
11          riod of the study under this section, the study is imple-  
12          mented by coordinating among scientific, regulatory, and  
13          community implementation pathways.

14          (e) REPORT.—Not later than 30 months after the  
15          date of enactment of this Act, the Director of NIH shall  
16          submit to Congress a report describing—

17               (1) the findings and conclusions of the Director  
18               based on the study;

19               (2) recommendations for developing and imple-  
20               menting a standardized, noninvasive test for HPV in  
21               men; and

22               (3) interagency strategies for integrating HPV  
23               testing into national cancer prevention and health  
24               equity initiatives.

25          (f) DEFINITIONS.—In this section:

1           (1) DIRECTOR OF NIH.—The term “Director of  
2           NIH” means the Director of the National Institutes  
3           of Health.

4           (2) HPV.—The term “HPV” means the human  
5           papillomavirus.

6           (3) STUDY.—The term “study” means the re-  
7           ferred to in subsection (a).

8           (g) FUNDING.—To carry out this section, the Direc-  
9           tor of NIH shall use funds appropriated or otherwise  
10          made available to the Director of NIH for each of fiscal  
11          years 2026 through 2030.