



NEWS RELEASE

New USPSTF Draft Cervical Cancer Screening Recommendations Are a Step Back for Women's Health, Would Put Lives at Risk

9/14/2017

MARLBOROUGH, Mass., Sept. 14, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) is deeply concerned that the United States Preventive Services Task Force (USPSTF) did not include a grade for co-testing (also known as Pap+HPV Together) in draft cervical cancer screening recommendations released this week. These draft recommendations do not consider the wealth of data supporting the value of co-testing, and will put the lives of American women at risk if implemented.

"These draft recommendations represent a significant change from current practice and are a clear step back in protecting women from cervical cancer," said Steve MacMillan, Hologic's Chairman, President and Chief Executive Officer. "We are concerned that lives will be lost if women are denied access to co-testing if these draft recommendations are implemented."

Multiple large studies conducted in the United States demonstrate that screening with co-testing identifies more cervical pre-cancer and cancer than either test used alone.^{1,2,3,4,5,6} In fact, the largest retrospective study of cervical cancer screening strategies found that nearly one out of five cases of cervical cancer was missed with HPV alone screening.*²

Evidence cited in the USPSTF draft recommendations relied heavily on studies conducted outside the United States, including some that employed cytology methods no longer widely used in the United States, and HPV tests that are not FDA-approved for primary use. Further, the USPSTF cited findings from a modeling study that potentially unfairly skewed results in favor of HPV alone testing.

"We find it disturbing that the USPSTF did not place more weight on the results of important studies in American

women, but instead included European studies employing outdated technologies that have limited, if any, relevance to the U.S. healthcare landscape," said Edward Evantash, M.D., Hologic's Medical Director and Vice President, Medical Affairs. "Further, the limited information available on the design of the modeling study makes it difficult to interpret the results, but it seems to defy logic that these two valuable tests together did not perform as well as HPV alone testing."

The draft recommendations also grant a grade A to the Pap test at a three-year interval for women ages 21-65. Hologic believes strongly in the power of the Pap test and the valuable contribution it has made to women's health. Before introduction of the Pap test, cervical cancer was the leading cause of cancer related deaths for women in the U.S., but now ranks 14th in frequency.⁷ Studies demonstrate, however, that administering a Pap and HPV test at the same time is the ideal strategy for detecting cervical cancer and pre-cancer in women ages 30 and older.^{3,4,5} Large, U.S.-based studies also show that a co-testing interval of three years is optimal.^{8,9}

"We urge USPSTF to reinstate an A grade for co-testing and to add language within revised recommendations to allow screening interval flexibility for healthcare providers and their patients, as was recently recommended by the Health Resources and Services Administration (HRSA) in their Women's Preventive Health Services Guidelines,"¹⁰ said Dr. Evantash.

The preponderance of available data supports co-testing every three years as the optimal strategy for preventing cervical cancer. Along with the clinical community, professional societies and others, Hologic will submit formal comments to the USPSTF during the public comment period to ensure that final USPSTF recommendations place the health and well-being of women at the forefront.

More information about the value of co-testing is available at PapPlusHPV.com.

About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's diagnostic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein

to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

Hologic, Pap+HPV Together, and ThinPrep are trademarks and/or registered trademarks of Hologic, Inc. in the United States and/or other countries.

*A positive screening result may lead to further evaluation with cytology and/or colposcopy.

Investor Contact:

Michael Watts

+1 858.410.8588

michael.watts@hologic.com

Media Contact:

Jane Mazur

+1 508.263.8764 (direct)

+1 585.355.5978 (mobile)

jane.mazur@hologic.com

References

Zhou, H., Mody, R. R., Luna, E., Armylagos, D., Xu, J., Schwartz, M. R., Mody, D. R. and Ge, Y. (2016), Clinical performance of the Food and Drug Administration–Approved high-risk HPV test for the detection of high-grade cervicovaginal lesions. *Cancer Cytopathology*. doi: 10.1002/cncy.21687

Blatt, A. J., Kennedy, R., Luff, R. D., Austin, R. M. and Rabin, D. S. (2015), Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. *Cancer Cytopathology*, 123: 282–288. doi: 10.1002/cncy.21544 [Study included ThinPrep®, SurePath, Hybrid Capture 2 assay].

Katki HA, Kinney WK, Fetterman B, et al. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. *Lancet Oncol*. 2011;12(7):663-72. PMID: 21684207. [http://dx.doi.org/10.1016/S1470-2045\(11\)70145-0](http://dx.doi.org/10.1016/S1470-2045(11)70145-0).

Gage JC, Hunt WC, Schiffman M, et al. Similar risk patterns after cervical screening in two large U.S. populations. 2016;128(6):1248-57.

Gage JC, Schiffman M, Katki HA, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. *J Natl Cancer Inst*. 2014;106(8). PMID: 25038467.

<http://dx.doi.org/10.1093/jnci/dju153>. Accessed September 13, 2017.

Katki HA, Schiffman M, Castle PE, et al. Five-year risks of CIN 3+ and cervical cancer among women who test Pap-negative but are HPV-positive. *J Low Genit Tract Dis*. 2013;17(5 Suppl 1):S56-63.

NIH Fact Sheets Home. Cervical Cancer. <https://www.report.nih.gov/nihfactsheets/viewfactsheet.aspx?csid=76>. Accessed September 13, 2017.

Kinney W, Wright TC, Dinkelspiel HE, DeFrancesco M, Thomas Cox J, Huh W. Increased cervical cancer risk associated with screening at longer intervals. *Obstet Gynecol.* 2015;125:311–315.

Kulasingam SL, Havrilesky LJ, Ghebre R, Myers ER. Screening for cervical cancer: A modeling study for the US Preventive Services Task Force. *J Lower Genit Tract Dis.* 2013;17:193–202.

HRSA. Women's Preventive Services Guidelines. <https://www.hrsa.gov/womensguidelines/>. Accessed September 13, 2017.

SOURCE Hologic, Inc.