Inappropriate 2003 FDA (PMA) approval of expanded use of HPV test

- At the open session microbiology devices panel meeting, March 8, 2002, the device’s modified indications were presented “for use as a general population screening test in conjunction with the Papanicolaou (Pap) smear for women age 30 and older, as an aid to determining the absence of high-grade cervical disease or cancer.”

- In the approval letter for Digene Hybrid Capture HC2 High-Risk HPV DNA Test dated March 31, 2003 and signed by OIVD, the test was approved for: “1. To screen patients with ASCUS Pap smear results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.”

(Approved by Steven Gutman/Elizabeth Mansfield, over the objections of the FDA review scientists and the Panel members)