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)