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**Cervical-Cancer Screening--New Guidelines and the Balance
between Benefits and Harms**

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**Cervical-Cancer Screening—New Guidelines and the Balance
between Benefits and Harms**

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Confidential: For Review

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6 Dr. Sawaya's blanket endorsement [1] of ACOG Practice Bulletin No.109 for cervical-cancer
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8 screening [2] needs to be challenged in fact and in science for the record.
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12 In fact, the Bulletin incorrectly blames the Pap cytology testing of young women below 21 years
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14 of age as the cause of the harm resulting from unnecessary colposcopic biopsies. Historically,
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16 after the introduction of the ASC-US Pap cytology classification in 1988, the number of referrals
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18 to colposcopic biopsy increased 3-fold [3]. The use of the liquid-based cytology system [4] and
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20 the hope to rely on HPV testing to improve the accuracy of borderline Pap test results by some
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22 pathologists [5] further augmented the number of ASC-US results. The aggressive marketing of
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24 the FDA-approved HPV DNA assay as a cancer test "*to screen patients with ASC-US Pap smear*
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26 *results to determine the need for referral to colposcopy* [6, 7]" has finally pushed the number of
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28 unnecessary colposcopic biopsies to the current alarming level. Inappropriate use of the Pap test
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30 results may harm the patients. However, to blame Pap testing among young women as the cause
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32 of the harm is not supported by factual evidence.
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41 In science, the Bulletin's statement that "*The utility of HPV DNA testing has been well*
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43 *demonstrated for primary triage of cervical cytology test results read as ASC-US*" is misleading.
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45 In this country, "*More than 95% of referrals to colposcopy for diagnostic workup are false*
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47 *positive and/or potentially excessive*", and "*Screening with combined cytologic and HPV testing,*
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49 *regardless of patient age, leads to the highest number of excessive colposcopic referrals*" [8]. To
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51 use a one-occasion positive high-risk HPV test which is associated with a positive predictive
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53 value of 6% to 19.6% [9-11], and a false-negative rate of 4.1% to 18.2% [12, 13] in the detection
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3 of CIN2/3 lesions for primary triage is bound to further lower the cancer-screening predictive
4 values of the imperfect ASC-US cytology results. The latter conclusion needs little scientific
5 research to validate because, mathematically, the product of two fractions is invariably smaller
6 than either of the two fractions. Any conclusions not compliant with this basic arithmetic rule
7 can only be derived from manipulation of data for product-marketing purposes.
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18 The Bulletin stated correctly that *“The HPV type and the persistence of an HPV infection are*
19 *perhaps the most important determination of progression”*, but gave no guidelines to the
20 practitioners on getting accurate HPV genotyping and on the methods used to evaluate persistent
21 HPV infection for their patients.
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30 The Bulletin recommended to not screen women below 21 years of age because there are only 1-
31 2 cases of cervical cancer per 1,000,000 females aged 15-19 years, namely about 15 to 30 new
32 cervical cancers each year among women aged 15-21 in the United States. Who would be legally
33 and morally responsible for making no effort to detect their cancer for these 15-30 women before
34 the tumor reaches life-threatening stages?
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44 *“Primary HPV DNA-based screening with cytology triage and repeat HPV DNA testing of*
45 *cytology-negative women appears to be the most feasible cervical screening strategy [14].”* To
46 implement such a futuristic approach requires more accurate new technologies to perform HPV
47 DNA screening and HPV genotyping, and the effective use of the residual cytopathology human
48 resources still available in this country. Until the leaders in our profession can put science ahead
49 of their business and personal agendas, there will be little hope to find a real solution to the
50 excessive number of unnecessary colposcopic biopsies.
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