S.A.N.E. VAX, INC.
Safe Affordable Necessary Effective

Dear Editors In Chief:

The article entitled "*Potential impact of a nine-valent vaccine in human papillomavirus related cervical disease*" [1] lists Silvia de Sanjosé as its corresponding author. This same author wrote a companion Editorial entitled "*HPV Prevention Series*" [2] in the *Journal*.

Since a scientific report published in conjunction with an Editorial traditionally represents an opinion endorsed by the Editorial Board of a peer-reviewed medical journal which in turn carries considerable weight in influencing health care policy making in various countries, we feel obligated to comment on this article. [1] Both the Editorial [2] and the subsequent article [1] list Dr. Sanjosé as the corresponding author who was financially supported by the vaccine manufacturer as disclosed; the article was also co-authored by an employee of the vaccine manufacturer and several consultants paid by the vaccine manufacturer. The publications are quite obviously promoting a new HPV vaccine.

The conclusion of the article states, *"If the nine-valent vaccine achieves the same degree of efficacy as has been shown for HPV 16 and 18, and vaccination programs are effectively implemented, almost 90% of ICC cases worldwide could be prevented"* [1] is blatantly misleading. The fact is that there is no evidence that HPV vaccination has prevented a single case of invasive cervical cancer.

The endpoint used in the HPV vaccine clinical trials was CIN2/CIN3 lesions. [3] The lesions are often self-reversing and in most cases never progress to invasive cervical cancer.[4, 5] In contrast, invasive cervical cancer has been reported in at least two young women shortly after receiving a full course of HPV vaccination, and at least one of them was a subject enrolled in an HPV vaccine clinical trial project.[6]

A more appropriate conclusion of the article [1] would have been "If the nine-valent vaccine achieves the same degree of efficacy as the current HPV vaccines in use, it may or may not prevent any ICC cases".

The authors' estimation of the relative contribution to invasive cervical cancer (ICC) and precancerous cervical lesions of the nine HPV types was based on using "*PCR with SPF-10 broad-spectrum primers followed by DNA enzyme immunoassay and genotyping with a reverse hybridization line probe assay.*"

A recent WHO survey has shown that 9 of the 12 (9/12) laboratories using the SPF-10 test were found to be "not proficient" in detecting the HPV types. [7] Therefore, the data presented in the article [1] are analytically unreliable, based on a "not proficient" testing method with an uncomfortably high 75% error rate.

In developed countries cervical cancer death is rare, occurring among women at a rate of 1.4-1.7 per 100,000 in countries like the USA, New Zealand and Australia [8] at an average age after 54,[9] and can be further reduced by better care through improved cervical screening, which is less invasive, cost effective and has no serious adverse outcomes. The current proposed policy of mass vaccination of young women age 9-12 at the cost of ~$40-100 million per 100,000 women, to prevent 1 or 2 cervical cancer deaths, is therefore not supported by either risk/benefit, or cost effectiveness analyses.

Numerous factors other than vaccination in a woman's life may be more important in determining the risk of developing invasive cervical cancer. [5]

Promoting an HPV vaccine at a very young age to possibly prevent cervical cancer death 45 years down the road must wait until more research is conducted to prove that the benefit of the HPV vaccine in

cervical cancer prevention in fact outweighs its risk which is substantial to the young girls who are being vaccinated. [10]

Sincerely,
Norma Erickson, President
SaneVax Inc.

The SaneVax mission is to promote only Safe, Affordable, Necessary and Effective vaccines and vaccination practices.

References

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[9] Lee NC: **Testimony before the House Committee on Commerce, Subcommittee on Health and Environment.** http://www.hhs.gov/asl/testify/t990316b.html

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