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Via email <u>CSE@CouncilScienceEditors.org</u> (with attachments); and fax 303-422-8894 (without attachments)-total 3 pages.

Subject: New England Journal of Medicine editor suppresses dissent to protect special interests

Dear Sir:

Recently I submitted a manuscript (submission) [1] to the New England Journal of Medicine (*Journal*) to be considered for publication, in order to present dissenting evidence to balance the bias of a *Perspective* [2] published in the *Journal*. The latter *Perspective* promotes a one-sided blanket endorsement of a set of new guidelines for cervical-cancer screening issued by the American College of Obstetricians and Gynecologists [3], which incorrectly blames the use of Papanicolaou (Pap) tests in patients below 21 years of age as the cause for the recent upsurge of excessive unnecessary harmful colposcopic biopsies on women at great cost to society. My submission presented evidence published in the literature to show that these excessive unnecessary cervical biopsies were actually caused by the liquid-based cytology and the use of human papillomavirus assays as a triage of ambiguous "*cervical cytology results to determine the need for referral to colposcopy*" in all ages. The latter two new technologies have been promoted by the ACOG practice guidelines of 2003 [4], the New Guidelines of 2009 [3], and by the *Perspective* [2] published in the *Journal*.

The first letter dated 1/19/2010 from the *Journal's* editor stated "*After considering its focus, content, and interest, we made the editorial decision not to consider your submission further.*" [5].

I then explained to the editor that the "focus" of the submission is to put on record dissenting evidence to balance the *Journal*'s one-sided blanket endorsement of ACOG Practice Bulletin No. 109 for cervical cancer screening. The "content" is largely composed of direct *verbatim* quotations and data cited from third-party publications in peer-reviewed scientific journals. The "interest" is to search for a truthful etiology for the excessive number of unnecessary colposcopic biopsies. I believed that to convey the focus, content and interest of my submission to the readers

is consistent with the *Journal's* stated "mission to publish current, authoritative, and unbiased information about advances in medical research".[6]

Without challenging my explanation in science or in fact, the editor wrote in a letter dated 1/26/2010 "Due to the volume of submissions, we must decline over 92 percent of the manuscripts that we receive. Please consider this our final decision." [7]. The reasoning of rejection as stated in the two editorial letters [5, 7] lacks consistency, and is grossly disingenuous. Such practice is highly unusual among editors of natural science journals.

The atypical editorial practice in this incidence has raised the possibility that the Journal might be under pressure to protect certain groups with special interest in maintaining HPV assays as the triage of ambiguous Pap test results to colposcopic biopsies even when such triage leads to unnecessary cervical biopsies, while using "over use of Pap tests in young women" as the scapegoat for the current practice of excessive unnecessary cervical biopsies. About 6 years earlier, the Journal published a highly influential article in 2003 which stated "The commercially available Hybrid Capture II (Digene) high-risk HPV test includes all of the types we have classified as high-risk types except types 26, 53, 66, 73, and 82." without informing the readers that at least 3 of the authors of that article received consulting fees from or served on the advisory board of Digene Corporation [8]. The latter publication played a pivotal role in endorsing the 2003 ACOG guidelines to promote Digene HPV assays as the triage of ambiguous cytology results, which in turn augmented the recent upsurge of excessive unnecessary colposcopic biopsies in the United States. Since the New England Journal of Medicine is possibly the most prestigious medical journal in North America [9] and a leading member journal of the Council, I am requesting that the Council consider an enquiry into such atypical editorial practice of the Journal to maintain its historical reputation.

I am a full-time hospital-based pathologist receiving a fixed annual salary. I have recently formed a company (www.hifidna.com) specializing in transferring the Sanger DNA sequencing technology to clinical laboratories to increase the specificity of HPV detection and genotyping.

Thank you for reading this letter and the attached references.

Sincerely,

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References

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- 2. Sawaya GF. Cervical-Cancer Screening—New Guidelines and the Balance between Benefits and Harms. N Engl J Med 2009; 361:2503-5.
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- 5. Malina D. Tue 1/19/2010 1:10 PM. NEJM email corres.doc (attached file NEJM corres. doc).
- 6. Lee SH. January 25, 2010 NEJM Dr. Malina.doc (attached file NEJM Dr. Malina. doc).
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- Muñoz N, Bosch FX, de Sanjosé S, Herrero R, Castellsagué X, Shah KV, Snijders PJ, Meijer CJ; International Agency for Research on Cancer Multicenter Cervical Cancer Study Group. Epidemiologic classification of human papillomavirus types associated with cervical cancer. N Engl J Med. 2003 Feb 6;348(6):518-27.
- 9. Michele Landsberg, Toronto Star, Dec 21, 1997.