December 10, 2012

Dear Sir or Madam,

We recently learned that a systematic review protocol on HPV vaccine is currently being developed within the framework of the Cochrane Collaboration (http://summaries.cochrane.org/CD009069/prophylactic-vaccination-against-human-papillomaviruses-to-prevent-cervical-cancer-and-its-precursors).

We consider an independent evaluation of this vaccine an important and useful undertaking and will be pleased to see one done. However, we have some concerns about the current plans.

As the Cochrane Collaboration states in its Policy Manual (http://www.cochrane.org/policy-manual/2111-general-principle), "The performance of the review must be free of any real or perceived bias." This principle does not appear to be taken into account for this review: people responsible for the proposed assessment have conflicts of interest that may seriously compromise their work. For example, some have been supported by the pharmaceutical companies that produce HPV vaccines; have already worked as investigators in company-sponsored clinical trials of the vaccines; have already published their conclusions about the effectiveness and safety of vaccines in publications; work for the Authorities that have recommended vaccination, believing that the efficacy and safety of the HPV vaccines are demonstrated and acquired; or have otherwise conveyed support for the vaccines and vaccination programs either through continuing education activities or publications.

Based on these findings, it is clear that the majority of authors responsible for conducting the proposed Cochrane review on the HPV vaccine have serious risks of bias.

More specifically, the panel of reviewers includes two investigators involved in phase III trials on the quadrivalent vaccine (Joakim Dillner and Marc Steben) who have already reported conflicts of interest with manufacturers of vaccines. Another panel member is on the Advisory / Expert Board of GlaxoSmithKline Biologicals and Gen-Probe, and has also reported receiving travel grant honoraria from GlaxoSmithKline Biologicals and Sanofi Pasteur MSD (Andreas Kaufmann).

At least nine of the fourteen potential reviewers (Marc Arby, E. Paraskevaidis, P. Beutels, You-Lin Qiao, Fang-Hui Zhao, Achim Schneider, Andreas Kaufmann, Marc Steben, Joakim Dillner) have signed or co-authored scientific publications concluding that the vaccine was efficacious and safe, or wrote as if these endpoints were established.

Finally, one of the authors works for the CDC (Centers for Disease Control and Prevention), which recommends the HPV vaccine, thereby considering it safe and effective. Moreover, the CDC has used safety arguments to get approval to extend its use (Lauri E. Markowitz).

Attached is a detailed summary of our research on these conflicts of interest.

In other words, there is a high risk of bias, which may influence the selection, analysis and weighting of the data, with much of the data actually coming from the previous work some of the authors have done for the manufacturers and regulatory authorities. Thus, the studies that may be reviewed may already reflect bias in the methodological quality of the design of phase III clinical trials (efficacy and safety), placebos chosen for comparison and their definitions, statistical quality of data provided to regulators, unpublished data, conclusions drawn by the health authorities and professional medical societies from subgroups analyses and ecological studies, etc..

The Cochrane Collaboration is according to its mission statement independent and free from pharmaceutical interests. The reputation and credibility of the Cochrane Collection is at risk when its basic principles are compromised. We think this is the case here and we urge you to immediately reject these authors and allow others without conflicts of interest to do the rigorous evaluation of the HPV vaccine evaluation we all would welcome.

Please do not hesitate to contact us if you have any questions or seek further information.

Sincerely,

Catherine Riva
Journaliste indépendante
Rümikerstrasse 112
CH-8409 Wintetrhur

Dr Jean-Pierre Spinosa
Gynécologue-obstétricien
Rue des Terreaux 2
CH – 1003 Lausanne

Abby Lippman
PhD, Professor Emerita
Department of Epidemiology, Biostatistics. and Occupational Health
McGill University
Montréal, Québec

Neil Arya
BASc MD CCFP FCFP D. Litt
Adjunct Professor Environmental Studies University of Waterloo
Assistant Clinical Professor Family Medicine McMaster University
Director Global Health Office Western University

Pierre Biron
Professeur honoraire
Faculté de médecine
Université de Montréal
Canada

Geneviève Rail
Ph.D. Concordia University and CIHR recipient of a research grant on HPV vaccination (2012-2015)

Lyba Spring
Sexual Health Education and Consulting Services
414 Rushton Rd.
Toronto, Ontario
M6C 2Y3

Anne Taillefer B.SC., M.A.
Sociologue de la santé
Université du Québec à Montréal

Fernand Turcotte, MD. MPH. FRCPC
Professeur émérite de santé publique,
Université Laval
Québec, Canada