Stefania Boccia and Carlo La Vecchia, Editors-in-Chief Founding, Executive and Consulting Editors Epidemiology, Biostatistics and Public Health

August 11, 2015

Dear Dr. Boccia and Dr. La Vecchia,

Thank you for your message of July 23, 2015 in response to our complaint regarding the failure to disclose conflicting interests in the article *Critical reappraisal of Balangero chrysotile and mesothelioma risk* by Edward B. Ilgren et al, published by Epidemiology, Biostatistics and Public Health (EBPH).¹ We are glad that you have asked Dr. Ilgren and his co-authors to provide a conflict of interest statement. We request that EBPH also publish a conflict of interest statement for Professors Pira, Romano, Piolatto, La Vecchia, and Negri since Dr. Ilgren and his co-authors express "extreme thanks" to them for their provision of data for the article and discussion of same on various occasions over the past five years. We request that you publish these disclosure statements as a Correction in the EBPH.

We are glad to know that EBPH and the Italian Society of Medical Statistics and Clinical Epidemiology (SISMEC) are examining the adoption and implementation of a clear policy requiring Conflict of Interest Statements. We hope that this will be done through a transparent, participatory process and be accompanied by discussion and education sessions on this important ethical issue.

We request the EBPH to publish the rebuttal letter regarding the Ilgren Balangero article, submitted a few weeks ago by Prof. Corrado Magnani et al, and Dr. Ilgren's response without further delay. We believe that the Ilgren et al. article is seriously flawed on both the scientific and ethical level and that the longer it remains on the EBPH website without correction of the inaccurate information it contains and without proper COI disclosure, the greater the harm that is being done to EBPH's reputation and credibility, as well as harm to public health protection relating to asbestos.

We wish to raise additional concerns regarding another article by Ilgren et al. that EBPH has published as an Original Article, entitled *Further Studies of Bolivian Crocidolite – Part IV: Fibre Width, Fibre Drift and their relation to Mesothelioma Induction: Preliminary Findings.*²

As its title indicates, this article is part of a series of articles produced by Ilgren and RJ Lee Group (an industrial forensics consulting company in the USA), whose Director and Senior Consulting Scientist are co-authors of the article. Earlier articles by Ilgren et al. on Bolivian crocidolite asbestos are cited in the EBPH article. In these articles, the authors state that exposure to high levels of crocidolite asbestos (500-1000 f/ml) did not cause an elevated incidence of asbestos disease or mesothelioma amongst Bolivian workers and residents. These results "further indicate that current models may overestimate the risk of asbestos disease and mesothelioma," conclude the authors, noting that: "These findings are significant to both public

health and public policy." ³ RJ Lee Group argue that, on the basis of these studies, current asbestos risk models and regulations are outdated and should be re-evaluated: "The scientific and legal impact of these studies is that the results indicate that current models may overestimate asbestos risk." ^{4,5}

The conclusion put forward by Ilgren et al. that current models may overestimate the risk of asbestos disease and mesothelioma is, we trust you agree, a serious matter. We assume that whoever EBPH selected as peer reviewers of the Ilgren crocidolite article examined with extreme care and vigilance the articles cited by Ilgren regarding the authors' prior studies and Parts I, II and III of their studies of Bolivian crocidolite asbestos.

We wish to raise the following concerns:

1) Article by Ilgren et al. published in the journal Environment and Pollution

In 2014, Ilgren and his co-authors published an article regarding their studies of Bolivian crocidolite asbestos entitled *Environmental 'Low Dose' Mesotheliomas and Their Relationship to Domestic Exposures-Preliminary Report* in the journal Environment and Pollution.⁶ This journal is published by Mr. Wenwu Zhao, who has given himself the names "Canadian Center of Science and Education", "Macrothink Institute", "SciEdu Publishing" and "Redfame Publishing". Mr. Zhao's companies have been identified as disreputable, predatory publishers.^{7,8} Mr. Zhao's background and interests hardly inspire confidence.⁹ Mr. Zhao has published articles in his journals that deny evolution, that deny climate change, that list scientists as authors of articles that they did not, in fact, write.^{10,11}

We note that the person identified as the editor-in-chief of Mr. Zhao's journal, Environment and Pollution, at the time the Ilgren article was published, David Tsetse, stated, when contacted, that he had never done any work for the journal.¹²

2) Citation of articles published in the journal Annals of Respiratory Medicine

In their 2014 article in Environment and Pollution, Ilgren et al cite the articles below as having been published or being in press in the journal Annals of Respiratory Medicine.

- Igren, E., Van Orden, D., Lee, R., Kamiya, Y., & Hoskins, J. (2012). Further Studies of Bolivian Crocidolite —Part IV: Fibre Width, Fibre Drift and their relation to Mesothelioma Induction. Ann Resp. Med (in press).
- Van Orden, D., Lee, R., Zock, A., Sanchez, M., Kamiya, Y., & Ilgren, E. (2012). *Evaluation of Airborne Crocidolite Fibers at an Asbestos-Cement Plant: Part 2 The Size Distribution of Airborne Bolivian Crocidolite Fibers*. Ann Resp Med, Case Study, July 26, 2012.

- Van Orden, D., Lee, R., Zock, A., Sanchez, M., Kamiya, Y., & Ilgren, E. (2012). Evaluation
 of Airborne Crocidolite Fibers at an Asbestos-Cement Plant. Ann Resp Med, Case Report,
 July 26, 2012.
- Ilgren, E., Ramirez, R., Claros, E., Fernandez, P., Guardia, R., Dalenz, J., ... Hoskins, J. (2012a). Fiber Width as a Determinant of Mesothelioma Induction and Threshold Bolivian Crocidolite: Epidemiological Evidence from Bolivia Mesothelioma Demography and Exposure Pathways. Ann Resp Med. (in press).

We note that the first of the above articles, Further Studies of Bolivian Crocidolite –Part IV: Fibre Width, Fibre Drift and their relation to Mesothelioma Induction, which is cited as having been published in 2012 and also as being in press with Ann Resp Med in 2014, has the same title as the article EBPH has published as an Original Article in 2015 and, apparently, is the same article.

The publisher of the journal, Annals of Respiratory Medicine, is San Lucas Medical Inc. It is supposedly an open access journal which is available on the internet. However, neither the journal nor the publisher appear to exist. The journal is not listed in the Directory of Open Access Journals. There appears to be no website for the journal and no record providing information about the journal or its editors or publisher or body of published articles.

The website for the journal, Annals of Respiratory Medicine, is for sale at http://ww3.slm-respiratory.com with the following message: "The owner of slm-respiratory.com is offering it for sale for an asking price of 377 USD!" The website for the publisher, San Lucas Medical Inc., brings up an advertisement in Japanese selling cures for baldness http://sanlucasmedical.com/.

We note that in 2015, RJ Lee posted two of the Annals of Respiratory Medicine articles by Ilgren and its consultants on its company website. The articles state that they were published on a certain date, but the citations given in the articles indicate that in 2015 the article still had not been published. The citations in the articles state "www.slm-respiratory.com" - AoRM 2012; 000:(000)".

We also note that in the article, *The* Size *Distribution of Airborne Bolivian Crocidolite Fibers*, the journal spells "publication date" incorrectly, stating "Submission Date: 18 April 2012; Acceptance Date: 30 April 2012; Publicatixon Date: 26 July 2012". It seems to us improbable that a reputable journal would be unable to spell "Publication Date" correctly.

3) Article published in Epidemiology, Biostatistics and Public Health

In their 2015 article, Further Studies of Bolivian Crocidolite – Part IV: Fibre Width, Fibre Drift and their relation to Mesothelioma Induction: Preliminary Findings, published by EBPH, Ilgren et al. again cite a number of articles published by the journal, Annals of Respiratory Medicine:

- Igren E, Van Orden D, Lee R, Kamiya Y, Hoskins J. Further evidence for Fiber Width as a
 Determinant of Mesothelioma Induction and Threshold Anthophyllite, Bolivian
 Crocidolite and Cape Crocidolite. Ann Resp Med. 2012; (On Line First)
- Ilgren E, Ramirez R, Claros E, et al., Fiber Width as a Determinant of Mesothelioma Induction and Threshold

 – Bolivian Crocidolite: Epidemiological Evidence from Bolivia – Mesothelioma Demography and Exposure Pathways. Ann Resp Med. 2012; (On Line First).
- Van Orden DR, Lee RJ, Sanchez MS, Zock MD, Ilgren EB, Kamiya Y. *Evaluation of Airborne Crocidolite Fibers at an Asbestos-Cement Plant*; Ann. Resp. Med. 2012 (On line first).

In their article, Further Studies of Bolivian Crocidolite – Part IV: Fibre Width, Fibre Drift and their relation to Mesothelioma Induction: Preliminary Findings, in addition to concluding that there was an absence of a significant mesothelioma excess among persons exposed to Bolivian crocidolite asbestos, Ilgren et al. also put forward conclusions regarding mesothelioma demography in the Italian City of Casale Monferrato (which the authors, in error, call Casale Monteferrato throughout their article). In their conclusions, they state that their "preliminary findings undermine claims such as those made at Casale that crocidolite fibre can drift up to 15 km and remain airborne in quantities sufficient to contribute significantly to mesothelioma induction."

This is a significant conclusion. Prof. Corrado Magnani requested that Ilgren et al. provide a copy of a report on this matter which would substantiate the conclusion they put forward in their article in EBPH. Ilgren et al., however, provided no documentation to substantiate their conclusion. Instead, they sent only some (five) GOOGLE maps, with no written report and no comments.⁷

The above editorial flaws, such as the fact that Ilgren's articles are based on unreliable bibliographic references, that evidence for conclusions advanced by Ilgren et al. is lacking or extremely flimsy, and that there is the serious suspicion that at least one of the Ilgren articles may be a double publication, are, in our opinion, extremely serious and troubling matters. We therefore ask EBPH to evaluate the possibility of retracting Ilgren's articles. We also ask that EBPH and SISMEC initiate an independent investigation to evaluate whether Ilgren's articles comply with the scientific standards and the editorial policies of EBPH and whether there is any evidence of editorial fraud by Ilgren and colleagues.

Summary of requested actions

We request that EBPH and SISMEC carry out the following actions:

- Publish Corrections in EBPH that provide Conflict of Interest statements for all the authors of the three asbestos articles by Ilgren et al. and for Professors Pira, Romano, Piolatto, La Vecchia, and Negri.
- Initiate a transparent, participatory process for the adoption and implementation of clear ethical policies by EBPH and SISMEC, which include implementation of Conflict of Interest disclosure requirements.
- Publish the letter rebutting *Critical reappraisal of Balangero chrysotile and mesothelioma risk* without further delay.
- Seriously evaluate the possibility of retracting Ilgren's articles.
- Carry out a thorough evaluation of the scientific and ethical quality of the peer review process used by the EBPH reviewers to assess Ilgren's articles.
- Initiate an investigation to evaluate whether Ilgren's articles comply with the scientific standards and editorial policies of EBPH and whether there is any evidence of editorial fraud by Ilgren and colleagues.

We thank you and look forward to receiving your response.

Sincerely,

Francesco Forastiere, Dipartimento Epidemiologia Regione Lazio, Rome

Roberta Pirastu, Sapienza Rome University

Pietro Comba, Istituto Superiore di Sanità, Rome

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Colin L. Soskolne, Professor Emeritus, University of Alberta, Edmonton, AB, Canada; Adjunct Professor [July 1, 2013 - June 30, 2016], Faculty of Health, University of Canberra, Australia; Chair, International Joint Policy Committee of the Societies of Epidemiology (IJPC-SE); Fellow, Collegium Ramazzini, Italy

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Lygia T. Budnik, University of Hamburg, European Society for Environmental and Occupational Medicine, Berlin, Germany

*Kathleen Ruff, senior human rights adviser, Rideau Institute, Ottawa, Canada; founding director, human rights website, RightOnCanada.ca

Notes:

Titles and affiliations are given for identification purposes only.
*Please send responses to Kathleen Ruff, kruff@bulkley.net

Conflict of Interest Statement:

Roberta Pirastu, Maria Angela Vigotti, Guadalupe Madrid, Cuauhtémoc Pérez, Fernand Turcotte, Morris Greenberg, Lennart Hardell, T. Joshi, Rolf Petersen, Sanjay Chaturvedi, Annie Thébaud-Mony, Vilma Santanta, Mohamed Jeebhay, Lygia Budnik and Kathleen Ruff have no conflict of interest to declare. Elisabetta Chellini and Pietro Comba have served as a consultant for the Prosecutor in some criminal trials concerning asbestos and other environmental carcinogens. Francesco Forastiere has served as an expert witness for the Court in a trial for asbestos related mesotheliomas and has served as expert for the Judge in trials involving environmental contamination and occupational exposures. Prof Woitowitz has testified on behalf of plaintiffs in asbestos litigation cases in German Social Courts lawsuits. Xaver Baur has testified in occupational diseases litigation on behalf of plaintiffs and provides independent expert opinions for social courts or statutory insurances. Richard Lemen and Arthur Frank have been involved in asbestos litigation as expert witnesses on behalf of plaintiffs and serve as Co-Science Advisors to the Asbestos Disease Awareness Organization. Colin Soskolne has served as an expert witness between 2011 and 2013 on asbestos cases for plaintiff attorneys; all fees were donated to the University of Alberta.

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Italian Society of Medical Statistics and Clinical Epidemiology

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