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Commentary

Malignant mesothelioma in females: the institutional failure by WHO and IARC to protect public health

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Malignant mesothelioma (MM) is a highly aggressive and difficult-to-diagnose tumor that is almost always caused by asbestos or other asbestiform fibers. Chapter 2 in the Fourth (2015) and Fifth (2021) Editions of the WHO/IARC Classification of Tumours is devoted to the classification and pathologic diagnosis of MM. The authors of these Chapters state that most of the cases of MM in females do not show asbestos as the cause when, in fact, the epidemiologic literature shows that the risk of MM in females exposed to asbestos approaches that in males.

While it is correct that the overall incidence of MM in females is lower than in males, the view that MM in females is not caused by asbestos is unsupported. This view results from an inadequate occupational history, the failure to recognize the importance of environmental exposures, and the misrepresentation of published literature by the selection of limited literature and biased bibliographies, often by authors with financial conflicting interests.

In this article, we present an example of the institutional failure (1) to protect the public health by permitting the publication of inaccurate statements about the adverse health effects of exposure to asbestos among females, and (2) to make suggested corrections that more accurately reflect reality.

Responsibility for correcting the misinformation lies, in our assessment, both with the authors of the erroneous statements and with the editors and publisher of the books that contain these statements. At issue is nothing less than scientific accuracy, the fate of at-risk females for whom early diagnosis could result in improved health outcome, a missed opportunity to promote primary and secondary prevention, and the social injustice of the loss of compensation for females so affected. We describe the steps that we took to correct the inaccuracies, and to expose the dereliction of duty among responsible parties based, at least in part, on what we believe to be undisclosed conflicting interests. Our efforts failed.

INTRODUCTION[1]

Malignant mesothelioma (MM) is a highly aggressive tumor caused almost exclusively by asbestos or other asbestiform fibers. There is no cure. Life expectancy is short following diagnosis.[1] It is a predominantly preventable disease.

Epidemiologic studies have shown that the dose-response relationship between asbestos exposure and MM is linear, without evidence of a threshold.[2-6] Mesothelioma risk increases with a power function of time since first exposure (TSFE).[7] However, recent studies also showed a decline in the risk increase after TSFE longer than 40 years.[8,9] Loomis et al., in their study of chrysotile-exposed workers, suggest a linear relationship between TSFE and MM mor-

1 This example relates to Chapters 2 of the two WHO (World Health Organization)/IARC (International Agency for Research on Cancer) Blue Books:
• WHO/IARC book WHO Classification of tumours of the lung, pleura, thymus, and heart., WHO Classification of Tumours, 4th Edition 2015. Authors of Chapter 2, Tumours of the pleura, are: F. Galateau-Salle, A Churg, V. Roggli, L.R. Chirieac, R. Attanoos, A. Borczuk, P. Cagle, S. Dacic, S. Hammar, A.N. Husain, K. lnai, M. Ladanyi, A.M. Marchevsky, D. Naidich, N.G. Ordonez, D.C. Rice, M.T. Sheaff, W.D. Travis, J. van Meerbeeck. Epidemiology section see p. 156 (Travis, Brambilla et al. eds. 2015),
• WHO/IARC book Thoracic Tumours., WHO Classification of Tumours, 5th Edition 2021. Authors of Chapter 2, Tumours of the pleura and pericardium, are: J. K. C. Chan, F. Gallateau-Salle, A.G. Nicholson, W.D. Travis, M.S. Tsao. Epidemiology section see p.194 (Chan, Gallateau-Salle et al, eds. 2021)

tality, and a less-than-linear relationship with cumulative dose.[10] Since the first studies, it has been observed that, while the risk increases with increasing cumulative exposure,[10] MM also occurs following low-level exposures for short periods of time,[11-15] consistent with the absence of a threshold effect. If there is a so-called background incidence of MM, either from unrecognized ambient asbestos or "spontaneous cancer," it is likely as low as 0.2 – 0.5 cases/million person-years,[16] and overall about 1 case/million person-years.[17]

Critical to a timely and informed diagnosis of MM by physicians and other healthcare providers is maintaining an index of suspicion and taking a comprehensive occupational and environmental exposure history. For males with a history of work at jobs historically associated with asbestos exposure, MM can be readily suspected. For females who often lack an occupational history suggestive of asbestos exposure, the same is not true. For females, asbestos exposure is more likely to be environmental, or para-occupational, or associated with the use of asbestos-contaminated products, such as talcum powder, and thus go unrecognized.[18] Diagnosis is delayed and the possibility of effective mitigation is all but lost.[19-22]

The *WHO Classification of Tumours* website (https://publications.iarc.fr/Book-And-Report-Series/Who-Classification-Of-Tumours/Thoracic-Tumours-2021) states about the Blue Book series: "*These authoritative and concise reference books provide indispensable international standards for anyone involved in the care of patients with cancer or in cancer research, underpinning individual patient treatment as well as research into all aspects of cancer causation, prevention, therapy, and education.*" Yet the Fourth and Fifth Editions of the Blue Book series, in the Chapters noted above, contain inaccurate statements that directly relate to causation, affect prevention and education, and may well delay diagnosis and treatment. Specifically impacted is MM in females. Included on the website as being among those "*Who should read this book?*" are oncologists, pulmonary physicians, thoracic radiologists, cancer researchers, epidemiologists, and cancer registrars.

Our concern has been, and continues to be, with the inaccurate statements contained in Chapter 2 in each of the Fourth and Fifth Editions entitled *Tumours of the pleura,* and *Tumours of the pleura and pericardium*, respectively.[23, 24] The authors of these Chapters misstate the proportion of MMs attributable to asbestos in females: *"only about 20%"* in North America and France and *"< 50%"* in western Europe and Australia (Fourth Edition); and *"only 20-40%"* in the USA and France (Fifth Edition).

Our finding that these statements are inaccurate is based upon a review of the relevant literature recently published as a Commentary[25] (Tables I A, B), and additional scientific findings. This review shows that the risk of MM in females exposed to asbestos corresponds to that in males when both occupational and environmental asbestos exposures are taken into account.

Epidemiologic studies with a focus on asbestos exposure and MM in females have yielded consistent results about MM risk increasing after occupational and non-occupational exposures. These include occupational cohort studies,[28-34] cohorts with domestic and environmental exposures,[35,36] and general population-based case-control studies.[37-40] Similar data were reported from the British HSE data base.[41]

Most recently, a study from the United States showed that the annual number of reported mesothelioma deaths among women increased significantly, from 489 in 1999, to 614 in 2020.[42] The largest number of deaths in 2020 was associated with the healthcare and social assistance industry (89; 15.7%) and homemaker occupations (129; 22.8%); while "missing" industries/occupations included the following: mining, utilities, wholesale trade, and management of companies and enterprises (27.0%). Although the age-adjusted death rate per 1 million women declined significantly over this period, from 4.83 in 1999 to 4.15 in 2020, the absolute number of reported MM deaths among females increased because of the ageing of the population and the age-cohort effect.[43] The occurrence of cases in association with work at occupations and in industries for which asbestos exposure is not usually suspected, and the absence of cases in others, illustrates the dilemma: the failure to find asbestos-related MM in females when asbestos-related MM is not suspected in the first place.

We brought the above findings on mesothelioma and asbestos exposures in females to the attention of the authors of each Chapter 2, as well as to the editors of the Fourth and Fifth Editions of the *WHO Classification of Tumours*. A correction in the form of a corrigendum was requested. We received an inadequate response that we deem scientifically incorrect and perpetuating the original misrepresentation. The editors and authors rejected our request and failed to provide any scientific explanation. We appealed this decision to IARC, the publisher of the Blue Book series.

That the incidence of MM in females is misrepresented in the first place is attributable to the following: (1) inadequate occupational history-taking in females, (2) failure to recognize the importance of environmental exposures in females, and (3) selection of limited and biased bibliographies by conflicted authors. The bibliographies chosen for the Chapters in question provide a case in point. We describe our unsuccessful steps to correct the literature in the next section.

THE EPIDEMIOLOGY SECTIONS IN EACH CHAPTER 2: INACCURACIES

The Fourth Edition of *WHO Classification of Tumours* is entitled "WHO Classification of Tumours of the Lung, Pleura, Thymus and Heart" and the Fifth Edition is entitled "Thoracic Tumours." The second Chapter in each is respectively entitled "Tumours of the Pleura" and "Tumours of the Pleura and Pericardium." Each contains inaccurate statements about the proportion of MMs attributable to asbestos

TABLE IA: EPIDEMIOLOGIC STUDIES OF MALIGNANT MESOTHELIOMA IN FEMALES[1]

FIRST AUTHOR /YEAR/COUNTRY	STUDY TYPE	OUTCOME	NO. CASES (FEMALE/ MALE)	RISK ESTIMATE [95% CI]
Ferrante D /2007/Italy	Cohort/ Asbestos in Females[2]	SIR	11/NA	25.19 [12.57-45.07]
Berry G /2000/UK	Occupational Cohort	MM Mortality Rate/ 100,000 Person-Years		
		Severe exposure ≤2yr	16/20	Females- 156/Males- 111
		Severe exposure >2yr	8/25	Females- 172/Males- 282
Magnani C /2008/Italy	Occupational Cohort	SMR	39/96	Females- 62.08/Males- 32.04 p<0.01/p<0.01
Luberto F /2019/Italy	Occupational Cohort	SMR	89/305	Females- 48.09/Males- 22.35 p<0.01/p<0.01
Rushton L /2012/Great Britain	Population-Based Analysis	AF % Occupation Domestic/ Environmental	Not Available	Females- 82.5/Males- 97.0
Panou V[26] /2019/Denmark	Population-Based Analysis	Asbestos exposure/ Distribution by category	87/NA	Occupational 9%; domestic 10%; environmental 22%; domestic/ environmental 34%; none identified 25%
Lacourt A /2014/France	Population-Based Case-Control	OR	75/362	8.0 [2.9-21.8]/13.0 [6.2-27.5]

[1] See Baur, Frank, et al, 2021 (Reference number 25).

[2] A cohort of wives of asbestos workers having only domestic exposure.

TABLE IB. ANALYSIS BY GENDER OF ASBESTOS EXPOSURE IN MALIGNANT MESOTHELIOMA REGISTRIES

FIRST AUTHOR /YEAR/COUNTRY	REGISTRY	OUTCOME	NO. CASES (FEMALE/ MALE)	RATIO
Marinaccio A, Corfiati M, et al /2018/Italy	ReNaM	Total incident MM	6,087/15,311	0.40
Marinaccio A, Binazzi, A et al[27] /2018/Italy		Asbestos exposure attribution*		
		Occupational: Pleural	1,321/9,525	0.14
		Non-occupational: Pleural	1,151/492	2.34

Abbreviations: CI, confidence interval; SIR, standardized incidence ratio; NA, not applicable; MM, malignant mesothelioma; SMR, standardized mortality ratio; AF, attributable fraction; OR, odds ratio; ReNaM, Registro Nazionale dei Mesoteliomi.

*Based on cases with completed asbestos exposure assessment.

exposures in females, asserting that most of the cases are not caused by asbestos.[2]

2 The Fourth Edition states: "*In North America and France, up to 80-90% of mesotheliomas in men are related to asbestos exposure, but only about 20% of cases in women (862, 2447). In Western Europe and Australia, a higher proportion of cases in women are asbestos-induced, but the attributable asbestos fraction is < 50% (312)*". The Fifth Edition states: *"There is also variation in population attributable fractions by sex: In the USA and France, 80-90% of mesotheliomas in males are caused by asbestos, but only 20-40% in females (1120, 1577, 83, respectively)."*

FRUITLESS EFFORTS TO HAVE WHO/IARC PUBLISH A CORRIGENDUM - CHRONOLOGY OF OUR EFFORTS

After recognizing the continuing and uncorrected inaccuracies in the epidemiology section of above-noted two Chapters, on September 3, 2021, we sent a letter to the responsible IARC Editorial Board Chair, Dr. Ian A. Cree, as well as to the editors of the book (Drs. Chan J. K. C., Gallateau-Salle F., Nicholson A.G., Travis W.D., and Tsao M.S.). We referred to our literature-based publication[25] and drew their attention to the aforementioned error relating to asbestos-caused MM incidence in females, and to their omission of domestic and residential exposures as significant causes of malignant mesothelioma, more relevant for females than males. We asked for a corrigendum and consideration of these concerns in any future publications.

Dr. Cree responded on September 20, 2021, with his decision to issue a corrigendum that was to include only the three words shown in bold below. The corrigendum, according to Cree, would avoid any doubt and would be added to the subscription website the next time it is updated: '*There is also variation in population attributable fractions by sex: in the USA and France, 80–90% of mesotheliomas in men are caused by* ***occupational exposure to*** *asbestos, but only 20–40% in women.*[44-46]

In our rebuttal of September 22, 2021, we requested that Dr. Cree and the authors of Chapter 2 reconsider our proposed inclusion of environmental asbestos exposures as a cause of MM in females.

Ignoring this request, Dr. Cree wrote on September 23, 2021: "*I think you may misunderstand the nature of the WHO Classification of Tumours, which is a taxonomy that underpins diagnosis. As such, it classifies tumours on the basis of shared characteristics and describes those characteristics. We try to base our classification on the best evidence, so independent systematic reviews such as the IARC Monographs and high-quality studies are preferred, rather than opinion, wherever possible.... Thank you again for bringing the ambiguity of this sentence in the Thoracic Tumours volume to our attention: this is being fixed and the matter is now closed.*"

In our letter of September 24, 2021, sent to Dr. Cree as well as to the authors of Chapter 2 (Drs. Chan J. K. C., Gallateau-Salle F., Nicholson A.G., Travis W.D., Tsao M.S.) we responded as follows: "*While we appreciate that you have considered the need for a corrigendum, we are of the view that your proposed solution misses the point and would cause more harm than good. Instead, we ask you to reconsider what effect your proposed corrigendum would have. As we see it, your proposed corrigendum omits the importance of causative environmental asbestos exposures, especially among females. It thus would leave the reader with the mistaken notion that females are less vulnerable to the adverse effects of asbestos than males. Accordingly, we propose for your consideration the following two sentences as a needed corrigendum, one that would more accurately reflect the currently known science: "The literature-based findings presented in the 2021 publication by Baur, Frank, Soskolne, Oliver, and Magnani show that females are as vulnerable to malignant mesothelioma as males, and therefore equally at risk from asbestos exposure. Because a considerable proportion of this highly malignant tumour in females is due to environmental exposures, in addition to occupational exposures, environmental exposure histories must be taken into consideration in assessing causality and attribution."*[25]

We received no further response, either from Dr. Cree, or from the authors and editors, and we have not found the promised corrigendum. Consequently, on January 31, 2022, we sent a letter to the IARC director, Dr. Weiderpass, with all of the correspondence included above and asked her to put her support behind the much-needed correction in this influential WHO publication.

Dr. Weiderpass declined, stating in her response of February 9, 2022, that Dr. Cree had consulted with colleagues and felt that it was necessary only to ensure that the information quoted referred to "*occupational exposure*" and had added these words to the text, which "*has yet to be updated online.*" Dr. Weiderpass added that the IARC Monographs 100C[47] clearly covered causative environmental asbestos exposures (see its Chapter 2.3.4 *Environmental exposures* on page 241[3]). She further stated: "*It is not in the remit or scope of the WHO Classification of Tumours to review the etiology of any tumour in great detail, so non-occupational exposure to asbestos is not covered in this volume, and I am aware that the topic remains controversial.*"

No corrigendum has been published to date despite the promise to include the words "**occupational exposure to**" in the upcoming online version of the WHO/IARC Blue Book. While Dr. Weiderpass claims that exposures beyond the occupational setting do not fall into the scope of their assessments, it is important to note that IARC Monograph 100C includes a discussion of environmental asbestos exposures as causes of MM (see mentioned misleading text in the WHO/IARC Blue Books as given in footnote 2 above).

DISCUSSION

In 2002, IARC, the cancer arm of the WHO, was criticized for failing to implement the disclosure rules used in the selection of experts for working groups writing IARC mono-

3 Copy from Monographs 100C: *2.3.4 Environmental exposures An excess of mesothelioma has been observed in several studies of communities with environ mental exposure to asbestos. A large excess of mesothelioma was reported in a study of people living in villages in Turkey exposed to erionite used to whitewash their homes (Baris et al., 1987) among people living near crocidolite mining regions in South Africa and Western Australia (Wagner & Pooley, 1986), among people residing in areas of tremolite contamination in Cyprus (McConnochie et al., 1987) and New Caledonia (Luce et al., 2000), and with non-occupational exposures in Europe (Magnani et al., 2000), Italy (Magnani et al., 2001), and California (Pan et al., 2005). Mesothelioma has also been reported to occur among household members of families of asbestos workers (Anderson et al., 1976; Ferrante et al., 2007).*

graphs on carcinogens.[48] The asbestos industry influence at IARC has continued to be a point of criticism of IARC research involvement.[49] This criticism, in part, led to the WHO updating its *Declaration of Interests for WHO Experts* policy on 25/09/2014 (see: WHO Declaration of Interests for Experts).

The clarified policy states that WHO experts serving in an advisory role must disclose any circumstances that could represent a potential conflict-of-interest (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence).

The extent to which Chapter 2 in each of the Fourth and Fifth Editions of the WHO Blue Book series misrepresent the truth is cast into stark relief by the scientific literature on MM risk by gender; see Tables I A, B.

The published data indicate a persistent and significant public health problem among females resulting from asbestos exposures and related MM. The rationale for the conscious publication of a statement that denies the existence and scope of this problem by the WHO is not provided in the Blue Books, nor by that organization. Our example draws attention to what we see as one reason: the ongoing process of corporate influence on what research scientists engage in and publish.[50] This unholy alliance adversely affects public health and undermines scientific integrity, especially when those scientists are not screened out as advisors and contributors to the work of scientific advisory boards and international agencies.[50-52]

Incomprehensibly, the 5th Edition of this WHO/IARC Blue Book series perpetuates the aforementioned error in the 4th Edition in its Etiology section of Chapter 2.[53,54] A recent review by Attanoos, Churg, Galateau-Salle, Gibbs and Roggli[55] contains misinformation very similar to that found in these Chapters, stating: "*In North America few mesotheliomas in women at any site are attributable to asbestos exposure, but in Europe the proportion is higher and varies considerably by locale,* and *"currently the epidemiology evidence correlating time trends, incidence in both sexes, and asbestos exposure suggest that a much smaller fraction of tumors in men are related to asbestos, and very few tumors in women".*[55]

We are aware of related statements repeating this misinformation by Drs. Chirieac and Marchesky, authors of Chapter 2 in the 4th Edition, in defense expert reports and depositions/testimonies in litigation: *In the Superior Court of the State of California in and for the County of Alameda, no. RG08404667*; and in the *Superior Court of the State of Delaware in and for New Castle County, no. 05C-06-216*).

These authors have questioned the well-established fact of MM causation by chrysotile asbestos[10,56-60] and defended the invalid safe-use theory of asbestos, providing further support for an underlying bias that undermines the importance and scope of the link between MM and asbestos exposures. Of note, one co-author, Roggli, is well-known for his restrictive asbestosis definition criteria and his use of analytical and statistical methods tailored to support his legal opinions on MM causation.[61-64]

In several US court reports, a basis for conflict-of-interest (COI) on Roggli's part has been demonstrated. A recent example stems from litigation in the *Circuit Court of the 11th Judicial Circuit Court in and for Miami-Dade County, Florida, Case No.08 –69204 CA 42*, where, at deposition or under cross-examination, he disclosed that he, among others, was paid for consulting with HONEYWELL INTERNATIONAL INC. a defendant in thousands of US personal injury cases arising from asbestos in Bendix brakes.[4] More details of his corresponding payment by defendants and their organizations in asbestos-related litigation are known from the Deposition of Victor L. Roggli of the United States District Court for the Western District of Kentucky at Owensboro Division, civil action no. 4:18-CV-168-JHM, February 26, 2020. The problem we have with Roggli in the context of this article is not that he testified as a defense expert and was paid for it, but that he either failed to disclose that he received such monies in his disclosure to WHO, or that WHO chose to discount this influence in the said two Chapters.

CONCLUSIONS

We have made several fruitless attempts to correct the record regarding the occurrence of MM in females. In publishing this example, we continue to argue for a suitable and complete corrigendum to the section in question in the 5th Edition of the WHO Blue Book, and for the avoidance of such erroneous and misleading epidemiologic data in future editions.

In sum, misrepresentation of the incidence of MM in females is attributable to:

- inadequate occupational history-taking in females,
- failure to recognize the importance of environmental exposures in females, and
- selection of limited and biased bibliographies by conflicted authors.

We see a moral imperative for greater care in vetting COI disclosures in all future work by the WHO/IARC, and for appropriate prior editing of Blue Book editions. Further, epidemiology sections which are stated to be relevant for readers, especially those related to etiology, should be written by independent experts experienced in this field, rather than solely by pathologists.

This example of institutional failure is consistent with our collective professional experience. Conflicting interests that fuel attempts to obfuscate the health hazards of asbestos are legion and play out in courts of law, in scientific publishing houses, in educational institutions, in government regulatory agencies, and in the public arena. Asbestos products and asbestos-containing products such as talc and vermiculite are targets of these attempts. The victims are

4 While these cited court documents are not in the public domain, they can be made available by the senior author on request.

patients with MM, in this case females and their families, as well as the public whose health is jeopardized because of delays in preventive action.

Identifying, managing and, ideally, eliminating, corporate influence on scientists and scientific policy are urgently needed. Many well-documented assaults by corporate entities on the integrity of research have been exposed; such assaults must be protected against and avoided in the future.[50-52,65-68]

IARC's goal to avoid influence is commendable. Yet, proper assessment of gender-based risk was missing from the two Chapters published under its auspices and identified in the Blue Books that provide the basis for this article.

To avoid such misrepresentation and misinformation in the future, we recommend institutional policy and mechanisms to exclude any scientist having an inadequately disclosed or an undisclosed COI(s). This recommendation is particularly true for IARC, an influential and far-reaching organization whose credibility must remain unassailable.

In summary, we present an example of institutional failure to appropriately edit and remove from educational texts reference materials that misrepresent the occurrence of asbestos-related MM in females. The target audience for the WHO Blue Book makes this omission more egregious. The bibliographies of both Chapters 2 are inconsistent with the published scientific literature, suggesting deliberate misrepresentation and raising the question of undisclosed COI as a factor. The consequences in this case are dire for the females at risk, for their families, and for the public at large.

Protecting the health of the public, preventing disease, and promoting well-being in a social justice context must be the unambiguous goal of education and research in occupational and environmental health. Even our most august of institutions, IARC, should be open to correction. A corrigendum is called for. Implementation of improved and rigorous screening for COI is required.

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