Dr Christopher Wild
Director, International Agency for Research on Cancer
World Health Organization

December 13, 2012

Dear Dr Wild:

We wish to bring to your urgent attention the following serious concerns, which were discussed by Arthur Frank, Barry Castleman, Kurt Straif and Ivan Ivanov in Delhi last week.

1) Concerns that inaccurate data, minimizing health risk posed by chrysotile asbestos, is put forward in an IARC paper, *Estimating The Asbestos-Related Lung Cancer Burden From Mesothelioma Mortality* by V McCormack, J Peto, G Byrnes, K Straif and P Boffetta.

We are concerned that the paper, *Estimating the asbestos-related lung cancer burden from mesothelioma mortality*, puts forward outdated and inaccurate information that understates the risk to health posed by chrysotile asbestos. Attached is the Power Point presentation of the paper, given by Valerie McCormack and Joachim Schuz on behalf of IARC at the Kiev conference, November 21-22, 2012, *Chrysotile asbestos: assessment and risk management.* The Kiev presentation likewise puts forward out-of-date and misleading information that incorrectly minimizes the risk to health posed by chrysotile asbestos. Below are examples that illustrate our concern.

1a) Ratio of mesothelioma risks regarding chrysotile, amosite and crocidolite asbestos is inaccurate

McCormack & Schuz, in presenting evidence from the published paper, *Estimating the asbestos-related lung cancer burden from mesothelioma mortality*, at the Kiev conference, put forward a table (Slide 6) showing that chrysotile asbestos causes 1 case of mesothelioma for every 100 caused by amosite and 500 caused by crocidolite

(Hodgson and Darnton, 2000). Both in the paper and in the Power Point presentation, they ignore the 2009 revision of this ratio, one which the original authors, Hodgson and Darnton, had reduced by a factor of 10 (i.e., by one order of magnitude) to be 1:10:50.

In addition they only cite this one estimate, the highest, and ignore the range of estimates made by other researchers, including those of Nicholson et al., 1982 and many others. Also, they fail to discuss the major difficulties in obtaining accurate risk analysis of asbestos-related diseases, see EPA risk-analysis conclusions and paper by Silverstein, Welch, Lemen, 2009

The McCormack et al. paper states: *Reference lists of retrieved articles and previous relevant reviews were also checked for omissions (Hodgson and Darnton, 2000; Boffetta,*

2007). Yet the significant, published correction of this pertinent ratio by Hodgson and Darnton was excluded.

Below is a section from the Position Statement on Asbestos of the Joint Policy Committee of Societies of Epidemiology (JPC-SE), which addresses this issue:

Position Statement on Asbestos, Joint Policy Committee of the Societies of Epidemiology (JPC-SE), July 2012, page 12 http://www.jpc-se.org/documents/03.JPC-SE-Position_Statement_on_Asbestos-June_4_2012-Full_Statement_and_Appendix_A.pdf

The main controversies today are about relative potency of the different types of asbestos and not about causality. There has been a continuing debate in the literature about the mesotheliogenic potency of chrysotile asbestos relative to other forms of asbestos (Hodgson and Darnton, 2000). The Hodgson and Darnton (2000) article was a quantitative risk assessment (QRA) performed for regulatory purposes. QRA on the relative potency of the different forms of asbestos fibre types has been rejected on the grounds of inadequate data (Kane letter to EPA, 2008). However, Hodgson and Darnton (2000) estimated that, on a fibre-for-fibre basis, the risk ratio from crocidolite to amosite to chrysotile was '500:100:1' for mesothelioma.

After the Carolina cohort update by Loomis et al. (2009), Hodgson and Darnton modified their estimates, increasing the mesothelioma potency of chrysotile in their QRA model by a factor of 10; by increasing the potency of chrysotile by one order of magnitude, their relative potency ratio is now reduced from '500:100:1' to '50:10:1' (Hodgson and Darnton, 2009). This change reveals the instabilities of regulatory exercises in QRA on the relative potency estimates of the various forms of asbestos.

1b) Inaccurate and incomplete information: mesothelioma cases related to chrysotile asbestos

The paper omits data contained in the 2012 IARC Monograph on Asbestos. The 2012 Monograph cites the most recent update by Mirabelli et al. in 2008 on the Italian chrysotile mining cohort. The Mirabelli study found a total of 27 cases of mesothelioma associated with the site, including not only miners, but also relatively low-dose "white collar" and environmental cases stemming from the mine. IARC 2012 stated that the mine was "pure" chrysotile exposure without any amphiboles of any type. McCormack et al's paper excludes this information and, instead, cites an out-of-date study - the 1990 Italian Mining cohort study by Piolatto et al., which reported only 2 mesothelioma cases in miners. The McCormack et al paper and the Kiev Power Point presentation use incomplete information on this cohort that minimizes chrysotile asbestos risk. It is disturbing that the McCormack et al paper omits IARC's most current 2012 Monograph on Asbestos and stops at the earlier IARC (1987) *Overall evaluations of carcinogenicity: an updating of IARC Monographs.*

1c) Inaccurate and incomplete information: lung cancer cases related to chrysotile asbestos

In slide 7 of their presentation to the Kiev conference, McCormack and Schuz put forward the 2000 Hodgson & Darnton finding that states that the ratio range for lung cancer risk per fibre with regard to chrysotile, amosite and crocidolite asbestos is between 1:10:10 and 1:50:50.

However, they excluded studies that question this finding, such as *A Meta-Analysis of Asbestos and Lung Cancer: Is Better Quality Exposure Assessment Associated with Steeper Slopes of the Exposure-Response Relationships?* by Virissa Lenters, Roel Vermeulen, Sies Dogger, Leslie Stayner, Lützen Portengen, Alex Burdorf, Dick Heederik. This meta-analysis included only studies that met quality control standards regarding exposure. The authors concluded: *Asbestos-lung cancer risk relationships are highly heterogeneous, and factors describing the exposure assessment strategy seem to account for part of the disparity between studies' lung cancer potency factors. Combining only higher quality studies yields higher meta-estimates of lung cancer risk per unit of exposure in comparison with a meta-estimate based on all available studies. Given these results, it is difficult to distinguish differences in potency between chrysotile and amphiboles for lung cancer, because too many studies have major limitations in the exposure assessment component. When analysis is restricted to only studies with few quality limitations of the exposure assessment component, the epidemiological evidence base is too sparse to draw deductions about potency differences per fiber type. Only further research will satisfactorily clarify the controversial issue of fiber-specific potencies, and is furthermore warranted considering the politically sensitive nature of this question and the widespread public health impact of historic and current asbestos use. These results highlight how imperative it is that careful attention be paid to the quality of the exposure assessment component of epidemiological studies on occupational and environmental risk factors. These results cast doubt on assertions that the epidemiological evidence for lung cancer strongly supports a difference in potency for different asbestos fiber types.* [Emphasis added.]

1d) Inaccurate and incomplete information: reliance on conclusions of Quebec studies, financed by the asbestos industry, that chrysotile asbestos is "virtually innocuous"

The McCormack et al paper states that figures showing mesotheliomas related to chrysotile asbestos exposure may be erroneously over-reported and warns that: *Mesothelioma ratio in chrysotile cohorts may be dominated by two large errors. First, the lung cancer excess depends critically on the rates on which the SMR is based. Second, it seems likely that many of the mesotheliomas in such (chrysotile) cohorts are actually due to amphibole exposure (...). Furthermore, many mesotheliomas occurring in asbestos that is predominantly chrysotile may actually be due to other asbestos types. McDonald et al (1997) argued that the mesotheliomas among chrysotile miners and millers in Quebec were caused either by amphibole exposure elsewhere, or by the tremolite that contaminated most Canadian chrysotile.*

The McCormack et al paper omits the fact that McDonald's 1997 conclusions that chrysotile asbestos is "virtually harmless", when workers are exposed to levels up to 45 f/cc for 20 years, has not been supported by any independent research. ("Thus it is concluded from the point of view of mortality that exposure in this industry to less than 300 MPPCF.years has been essentially innocuous". *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Development from 1904 and Mortality to 1992,* Liddell, McDonald & McDonald.)

The McCormack et al. paper omits to mention the criticisms that have been expressed regarding the Quebec research, largely funded by the Quebec Asbestos Mining Association. This research was excluded from the Lenters et al study, referred to above, as it did not meet the quality of the exposure assessment standard. Criticisms expressed in the Position Statement on Asbestos of the JPC-SE (page 12) include:

The Canadian asbestos industry is largely responsible for creating and advancing the idea that chrysotile asbestos is safer than asbestos of other fibre types (McCulloch and Tweedale, 2008). Egilman and colleagues (2003) previously evaluated published and unpublished studies carried out by researchers at McGill University and funded by the Quebec Asbestos Mining Association (QAMA). These QAMA-funded researchers had claimed that Quebec-mined chrysotile was essentially harmless and that the contamination of chrysotile with oils, tremolite or crocidolite was the source of occupational health risk. Careful review of these claims revealed unsound selection, sampling, and analytical techniques, with the rejection of their contention that chrysotile was "essentially innocuous". Nevertheless, these refuted QAMA-funded studies have been used to promote the marketing and sale of asbestos, with a substantial effect on policy and occupational health litigation (Egilman et al., 2003; Bohme et al., 2005).

The idea that Canadian chrysotile cannot cause mesothelioma or does so only because of contamination is not consistent with the finding that UICC Chrysotile B (Canadian chrysotile) from 8 working Canadian mines was shown to be tremolite free and has caused all forms of asbestos disease when studied by scientists, including mesotheliomas. It caused as many in animals as crocidolite when studied by Wagner (Frank, AL, Dodson, RF, and Williams MG, *Carcinogenic implications of the lack of tremolite in UICC reference chrysotile,* Am J Industrial Med 34:314-317, 1998).

1e) Concerns about recommendations put forward in the McCormack et al paper, that align with the agenda of the asbestos industry

After putting forward incomplete and out-of-date information that minimizes harm caused by chrysotile asbestos, the paper concludes with the following recommendation: *There is thus an urgent need for limiting exposure through strict regulation of asbestos use, and encouragement of smoking cessation to reduce mortality among formerly exposed workers*.

It is also disturbing that the paper does not put forward the recommendation of the World Health Organization to end all use of asbestos. Instead, the recommendation seems to call only for "strict regulation" of the use of asbestos. Furthermore, the recommendation for smoking cessation is only applied to "formerly exposed workers" and omits "currently exposed workers", as if no problem exists regarding "currently exposed workers".

The asbestos industry claims that their research shows a 99.8% success rate in "safe, controlled use" of chrysotile asbestos in Russia, Kazakhstan, India, Indonesia, etc., and that there is therefore no need for any concern about "currently exposed workers" (*Safety in the Use of Chrysotile - Requirements and Achievements*, Chrysotile Institute, Montreal, Quebec, page 20 & 21) http://www.chrysotile.com/en/sc_publi/). This claim by the asbestos industry is not based in fact and has no credibility.

1f) IARC disregarded a request, specifically made to IARC, to put forward updated, accurate scientific information at the Kiev conference

Dr Stanley H. Weiss, Chair of the Joint Policy Committee of the Societies of Epidemiology (JPC-SE), wrote to Dr Joachim Schüz, Head of IARC's Section of Environment & Radiation, on November 17, 2012 and directed his attention to the July 2012 Position Statement on Asbestos of the JPC-SE (correspondence attached). This Position Statement puts forward the most up-to-date, accurate scientific information regarding health risks of asbestos. The Position Statement also documents the ways in which the asbestos industry, like the tobacco industry, has sought to subvert public health policy by denying the overwhelming scientific evidence that all forms of asbestos cause harm to health and that all use of asbestos should end.

Dr Weiss expressed concern that the conference appeared "to have been stacked" and urged that, if IARC chose to attend the conference, that IARC ensure that the up-to-date, accurate information, contained in the Position Statement, be presented and that IARC issue a media release to expose scientific deficits in any contrary presentations. He provided a copy of the Position Statement to Dr Schüz and also gave him the link to the Position Statement in Russian on the JPC-SE website.

It is thus particularly disturbing that, in their presentation at the Kiev conference, Dr Schüz and Dr McCormack chose to ignore the accurate, updated information that was specifically brought to their attention and instead presented outdated, inaccurate information, that minimized harm caused by chrysotile asbestos. Furthermore, IARC has stayed silent in the face of the presentations at the Kiev conference, and the recommendation passed by the Kiev conference, which deny the clear scientific evidence of harm caused by chrysotile asbestos, oppose the recommendation of the WHO to end use of all forms of asbestos and, instead, advocate continued trade and use of chrysotile asbestos, without even minimal warnings of its hazards.

2) Concerns regarding IARC's participation in the Kiev conference

The evidence indicates that the Kiev conference was specifically organized with the aim of defeating the recommendation of the Rotterdam Convention's Chemical Review Committee (CRC), after thorough study of the evidence, to list chrysotile asbestos as a hazardous substance. At the 2011 Rotterdam Convention Conference of the Parties, countries opposed to the listing of chrysotile asbestos called for a scientific conference to look at all the "modern" data, which, they claim, shows that chrysotile asbestos is not a hazardous substance that should be put on the Convention's List. Countries that support the listing of chrysotile asbestos opposed this recommendation: *An international scientific conference on chrysotile asbestos to examine all scientific data prior to CRC8 was proposed. This was opposed by several parties, who noted that the CRC's recommendation is final* (Conference resume). Attached is the Announcement of the Kiev conference and the draft Resolution put forward at the conference, which opposes listing of chrysotile asbestos under the Convention.

Five of the presenters at the Kiev conference were scientists who testified before the Supreme Court of Brazil in August 2012, as witnesses on behalf of the Brazilian asbestos industry, supporting the industry's position that use of chrysotile asbestos should continue. These scientists argued against the recommendation of the WHO that use of chrysotile asbestos should end, and instead argued that chrysotile asbestos does not pose a threat to health, can be safely used, and should continue to be used.

Other presenters at the Kiev conference are well known for promoting the use of chrysotile asbestos in India, Thailand, Brazil and elsewhere.

At the end of the conference, the participants passed a resolution opposing the listing of chrysotile asbestos as a hazardous substance under the Rotterdam, claiming that there is "ongoing debate on chrysotile asbestos as a carcinogenic risk factor" and "insufficient evidence on safety of the proposed asbestos substitutes".

This was not a bona fide scientific conference, but a conference with a political agenda to defeat the recommendation of the Rotterdam Convention's CRC to list chrysotile asbestos as a hazardous substance. Respected, independent scientists and public health advocates from around the world asked the IARC not to participate in this sham conference. We are disappointed and disturbed that IARC ignored these appeals.

By its participation, IARC added a cloak of legitimacy to this conference whose purpose was to sabotage a U.N. Convention, which provides a minimal health protection and a basic human right in the form of prior informed consent and safe use guidelines to low and middle income countries, where asbestos is being exported today.

In our opinion, IARC's reputation is tarnished by its participation in this sham conference. IARC would not, we hope, participate in any conference organized to subvert the WHO Framework Convention on Tobacco Control and aimed at defeating the efforts of the WHO to end tobacco use. Likewise, IARC should, in our view, not have participated in the Kiev conference, designed to do the same with chrysotile asbestos.

IARC's participation is all the more disturbing in that IARC's own presentation minimized harm caused by chrysotile asbestos by presenting inaccurate, misleading information; created doubt by citing asbestos industry financed studies whose validity has been questioned by independent scientists; failed to cite WHO/IARC positions on chrysotile asbestos; and made recommendations that contradict the recommendations of the WHO and lend themselves to misuse by the asbestos industry.

3) Concerns that a senior scientist in an IARC research project regarding chrysotile asbestos-use in Russia is a leading defender of the Russian asbestos industry

The lead scientist in the following IARC study is Evgeny Kovalevskiy: *Historical cohort study of cancer mortality following exposure to chrysotile asbestos at the Uralasbest plant in Asbest, Russian Federation,* Evgeny Kovalevskiy (SRIOH), Hans Kromhout (IRAS); IARC: Sara Schonfeld, Valerie McCormack, Joachim Schüz
http://www.iarc.fr/en/staffdirectory/displaystaff.php?id=40294

Dr Kovalevskiy is a leading promoter of use of chrysotile asbestos. He testified before the Supreme Court of Brazil in August 2012, as witness on behalf of the Brazilian Chrysotile Institute. He testified that there is no evidence whatsoever to justify banning the use of chrysotile asbestos; that he opposes placing chrysotile asbestos on the Rotterdam Convention's List of Hazardous Substances; that, in the past, harm to health was caused by the use of amphibole asbestos and excessive, prolonged exposure levels to chrysotile asbestos, but that, today, chrysotile asbestos is causing no harm to health in Russia.

We consider that it is unacceptable that a scientist, who is a promoter of chrysotile asbestos use, should be a lead scientist on an IARC research project regarding chrysotile asbestos. As we have already pointed out, a few years ago, WHO Director General Margaret Chan withdrew the designation of a WHO collaborating centre from the Russian Academy of Medical Sciences' Institute of Occupational Health, with which Dr Kovalevskiy is associated, because of its promotion of continued use of chrysotile asbestos and conflicts of interest endangering WHO's credibility.

According to a BBC investigative report, the former director of the Institute of Occupational Health, Nikolai Izmerov, was the first president of the Russian Chrysotile Association, an industry lobby group.

A media release, *Thailand: Understanding 21st Century Science in Support of the Correct use of Chrysotile*, July 21, 2006, sent out by the Montreal Chrysotile Institute announced that new scientific research would be presented in Thailand that "clearly demonstrates that chrysotile, as used today, presents no measurable risk to human health (http://www.prnewswire.co.uk/news-releases/thailand-understanding-21st-century-science-in-support-of-the-correct-use-of-chrysotile-153388035.html).The release states: "Chrysotile is often confused with amphibole fibres creating a climate of fear around products which present no measurable risk to health."

The Chrysotile Institute's release announced that Professor John Bridle will say: "Chrysotile products present no measurable risk to health under any conditions used today." The release also celebrated that fact that Professor Bridle "has recently been awarded a prestigious honorary degree in 'Asbestos Sciences' by the Russian Institute of Occupational Health. His new professorship makes him the foremost authority on asbestos science in the world."

Mr Bridle has no known scientific qualifications whatsoever. He was found guilty and fined by a British court for falsely claiming a qualification relating to asbestos that he did not possess. A BBC investigative report documented that a number of qualifications related to asbestos that Mr. Bridle claimed to possess did not exist. The British regulatory agency, Ofcom, dismissed Mr. Bridle's complaint regarding the BBC report.

While having no known scientific qualifications, Mr. Bridle has for decades worked as a strong promoter of use of chrysotile asbestos. He worked for or owned companies selling asbestos-cement products for more than 30 years; recently, Bridle was the UK spokesperson for the Asbestos Cement Product Producers' Association, "a world wide association dedicated to supplying scientific information for the safe handling of Chrysotile". (*Sham Conference in Montreal,* Laurie Kazan-Allen, International Ban Asbestos Secretariat, May 18, 2006 http://www.ibasecretariat.org/search_item.php?l0=13+31+40&f=lka_sham_conf_montreal.php).

The decision by the Russian Academy of Medical Sciences' Institute of Occupational Health to award an honorary degree in Asbestos Sciences to a leading promoter of chrysotile asbestos use, who has no known scientific qualifications whatsoever, serves the interests of the Russian asbestos industry, but brings discredit and dishonour on the Russian Academy of Medical Sciences.

REQUEST

WHO Director General Margaret Chan made a correct and ethical decision in withdrawing WHO collaborating centre status from the Russian Academy of Medical Sciences' Institute of Occupational Health in order to protect the integrity of the WHO. We call on IARC to make a similar decision to withdraw its collaboration with the Russian Academy of Medical Sciences in order to protect the integrity of IARC.

As was requested in the letter sent to Director General Margaret Chan by numerous scientists and health defenders around the world on November 19, 2012, we would like to know how the above study is being funded and whether the IARC Ethics Committee has approved the involvement of IARC.

We understand that a scientific review committee has been set up for this research project. Further to this, we request complete disclosure about the composition of any scientific committee involved and of any ethics reviews done to date.

We request that you, as IARC director, confirm that IARC agrees with WHO and ILO that the use of all forms of asbestos, including chrysotile asbestos, should end and that international trade in chrysotile asbestos which does take place among countries that have not banned its use should be governed by strict adherence to the Prior Informed Consent requirements of the Rotterdam Convention.

We request that IARC discontinue any collaboration with the Russian promoters of asbestos or with institutes that have been cut off by WHO as collaborating centers. WHO should freshly examine this situation from the ethical standpoint before any further work on this collaboration is allowed to proceed at IARC.

We urgently await your response to these grave concerns regarding IARC's reputation and integrity.

Sincerely,

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ON BEHALF OF:

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DR JEAN ZIGBY, MD, Family Physician, Palliative Care Specialist; President, Canadian Association of Physicians for the Environment, Canada

NOTES:

*** Titles and affiliations are given for identification purposes only.**

*** Some of the signers have been involved in asbestos litigation.**

Copy to:
Margaret Chan, Director General, World Health Organization
Dr. Eduardo Seleiro, IARC Ethics Committee

Dr. Abha Saxena, WHO Research Ethics

ATTACHMENTS:

- Announcement of Kiev conference
- Correspondence between Stan Weiss and Joachim Schuz, Nov. 17, 2012
- Position Statement on Asbestos of the Joint Policy Committee of the Societies of Epidemiology; List of Endorsing Organisations; List of Individual Endorsers
- IARC Power Point Presentation to Kiev conference, Nov. 21-22, 2012
- Resolution passed at the Kiev conference, Nov. 21-22, 2012
- Press Release, The Chrysotile Institute