



Banning asbestos in talcum powder: Time for action in India

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ABSTRACT

Long-term use of asbestos-contaminated talcum powder has been reported to be the main causative agent for carcinogenesis in many research studies. In recent developments Johnson & Johnson has lost multimillion-dollar lawsuits for being associated with the development of mesothelioma and ovarian cancer by its talc-based baby powder. In May 2020, the company announced, the end of the sale of its baby powder in the USA and Canada and in August 2022, announced the global discontinuation by 2023. However, in India vast proportions of people are using talc-based baby powder and the products are readily available in the market. The purpose of this communication is to create awareness and draw attention of authorities for effective regulation, including prohibition of sale and retraction of the contaminated talc-based products from the Indian market at the earliest.

1. Background

In the late 1800s, companies began manufacturing and selling talcum powder to ease and prevent skin irritations such as diaper rash and chafing. Talc, the main component of talcum powder, is mined as a stacked form from the underground deposits either by opencast or mining method. To meet the industry demands the talc stacked are processed through hammer mills or pulverisers to crash and ground and graded as Grade A, B, C or D talc according to the whiteness percentage [1]. By many names, the pulverized talc is used in pharmaceutical and cosmetic industries, including “foot powder” and “medicated powder”. Anthophyllite, actinolite, grunerite, chrysotile, tremolite and riebeckite are the six minerals commercially termed as asbestos that occurs in the asbestiform habit [2]. However, these six chemicals occur more commonly in a nonasbestiform habit and may also be found in the underground talc deposits as a potential contaminant of talc when mined due to the mining practices [3,4,5,6]. The geological and industrial communities have observed intimate relationships between talc and asbestos formation since late 19th century [7,8,9,10,11,12]. Although there were challenges in differentiating asbestiform fibers from their non-asbestiform counterparts in the methodologies employed during the 1960s and 1970s [12,13,14], some of these techniques are still in use today [15,16]. Therefore, the presence or absence of asbestos in talc cannot be accepted unquestionably. Understanding the distinction between the two is crucial for assessing potential health risks. Some studies

have indicated that non-asbestiform fibers pose no health risks [17,18]. However, since evidence of asbestiform materials in talc deposits often coincides with asbestos fibers, it is challenging to determine the role non-asbestos asbestiform might play in the population under study [19].

Asbestos causes harm by lodging in the lung tissue leading to diseases such as asbestosis, lung cancer and mesothelioma. Talc containing asbestos has the potential to cause cancer if inhaled. However, talc that does not have asbestos can lead to talcosis, a form of pulmonary dust disease [20,21,3]. Akhtar et al. 2014 reported that nonotalc has the potential to induce oxidative stress, cytotoxicity and apoptosis in human lung epithelial cells despite of collected from two different geographical regions such as American origin and Indian origin [22].

Inhaled asbestos fibers have been reported to exhibit local tumorigenic properties and fibrogenic effects in humans [23,24,25]. Long-term use of asbestos-contaminated talcum powder has been reported leading to cancer in many research studies [26,27]. A causal association between all forms of asbestos exposure and cancer of the lung, larynx, ovaries, pleural mesothelioma and peritoneal mesothelioma has been established by the International Agency for Research on Cancer (IARC) [28]. The non-malignant diseases that are associated with asbestos include asbestos warts, asbestosis, pleural plaques, pleural effusion and diffuse pleural fibrosis [28]. Other diseases that are caused due to the exposure of asbestos include oropharyngeal, renal and gastrointestinal cancers [28,29]. However, in some of the epidemiological studies there are disparities in results reported between case-control and cohort

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studies. The case-control studies reported positive associations whereas the cohort studies reported null may be due to systematic errors, bias and confounding [30]. However, recent evidences revealed cosmetic talc is not and was never free from asbestos [31]. Moreover, based on the interpretations of various company and court documents, one group of investigators (who are mostly plaintiffs' experts) opine that the talc industries have been playing a crucial role in delaying and eventually hindering the federal regulations of cosmetic talc since 1970s till date [32].

Going back to 1960s, many published scientific literatures have suggested a possible association between the incidence of ovarian cancer and genital area use of powder containing talc with asbestos [33,34,35,36]. Nevertheless, some studies support an opposing perspective [37,38,39,40]. While certain studies have explored the link between talc exposure and ovarian cancer [30,41], there has been insufficient research on the tissue specific effects on the female genital system. In particular, the molecular and genetic processes associated with exposure to a cosmetic ingredient and the initial stages of cancer development have not been thoroughly investigated. Moreover, the U.S. FDA has ongoing research in this area titled "non-clinical mechanistic studies in addressing ovarian cancer risk from talc use in cosmetics (Special funding)" [42].

More than a decade ago, the International Agency for Research on Cancer (IARC), World Health Organization (WHO), in its monograph 100C, concluded that there is sufficient evidence of asbestos being carcinogenic in humans and to cause ovarian cancer. This assessment of asbestos being carcinogenic was based on 11 cohort studies in 13 populations; 3 studies with environmental exposure; 10 studies with occupational asbestos exposure and one case-control study [23]. In IARC Monograph 2010 the working group decided to expand the name of the Group I carcinogens from "talc containing asbestiform fibers" to "talc containing asbestos or other asbestiform fibers" which "should be understood to mean any mineral, including talc, when it grows in the asbestiform habit" [21]. IARC also pointed out the occurrence of mesothelioma among individuals living in the asbestos factory and crocidolite mine neighbourhoods and in persons living with asbestos workers. Extensive epidemiological research on asbestos has been conducted and numerous epidemiological investigations have well established the association between asbestos exposure, mesothelioma and lung cancer [28]. In specific mines, IARC (2010) reported the absence of detectable asbestos. However, the same report noted other mines with measurable asbestos levels [21]. Additionally, most research studies focused on talc mines in the western regions of the world, leaving a data gap regarding talc deposits in the east. The question persists: are there comparable instances of contamination or asbestos comineralization in cosmetic talc products in India and Southeast Asia, potentially leading to personal injuries related to personal hygiene, in the presence of commercial talc deposits existing in the region [9,14,43,44,45,46]?

According to the International Agency for Research on Cancer (IARC), the U.S. Department of Health and Human Services (HHS), the U.S. Environmental Protection Agency (EPA) asbestos has been classified as a known carcinogen [47,48,49,50]. There are 125 million people worldwide reported by the World Health Organization (WHO) to be occupationally exposed to asbestos and half of the occupational cancer deaths are caused due to asbestos. Besides, several thousand deaths are annually reported globally due to household exposure of asbestos [51]. Moreover, there is a lack of adequate data on individual exposed to potential asbestos contaminants in personal care products making asbestos-induced burden of disease unavailable. This contributes significantly in underreporting of traditional diseases such as mesothelioma [52]. In the western part of the world, there are capabilities available for surveillance of diseases caused by asbestos exposure [53], however, there are lack in surveillance exercises in many developing nations throughout southeast Asia [54]. Besides, majority of these countries in southeast Asia, continue to permit commercial asbestos use despite of its ill health effects [55,56]. All these collective situations

augment the public health challenges. The link between occupational asbestos exposure and the development of bronchogenic carcinoma and malignant mesothelioma is well established [57]. Despite this, the precise mechanism by which asbestos induces cancer remain unknown. Studies suggest that the type and size of asbestos fibers are crucial factors in the carcinogenicity, a mechanism similar to cancer induction seen with plastic film exposure [57]. Numerous researchers have conducted thorough risk-benefit analyses [58,59]. One study highlighted that specific agents post significantly higher risks in industrial settings compared to societal contexts, citing asbestos as an illustrative example [58]; while other has pointed out the potential fallacy in determining many benefit-risk related to industrial and occupational hazards [59]. This latter group emphasized the importance of eliminating hazardous agents from the environment, replacing them with safer alternatives, which is crucial for society's well-being. Exposure to asbestos, both individually and in cases of asbestosis, is thought to impact both cell-mediated immunity and humoral immunity. Studies have indicated decreased levels of dihydrorhodamine (DHR) and fewer T cells, along with diminished T cell proliferative responses in individuals with asbestosis [60,61].

Nevertheless, disparities exist between findings from animal studies and observations in humans. In animals, mesothelioma is induced by chrysotile fibers, whereas in humans, amphibole fibers are linked to mesothelioma development [62]. The length of the fibers is closely linked to the associated health risks [63]. Fibers measuring 2 μm , 5 μm and > 10 μm are reported to be connected with the development of asbestosis, mesothelioma and lung cancer, respectively. Additionally, the diameter of the fibers also plays a significant role. For instance, fibers with a diameter less than 0.5 μm are associated with mesothelioma development due to their ability to migrate from the deposition site to other organs through the lymphatic system [64]. However, the safety threshold of asbestos has not been established by the World Health Organization or any other organization till date. In December 2022, the Modernization of Cosmetics Regulation Act (MoCRA) was signed in the U.S. expanding the authority of U.S. Food and Drug Administration (FDA) in regulating cosmetics. The U.S. FDA is authorized to issue regulations for standard testing methods for detecting asbestos in talc products and the proposed rule is due by December 29, 2023 [65].

In 1894, with the introduction of Johnson & Johnson's Baby Powder, the world got the most famous brand in the category of pulverized talc. In the last 1960s, scientists first reported on "fibrous talc" probably about asbestos in cosmetic talc products [66,67]. However, one of the study groups reconsidered their initial discovery of asbestos fibers in talc, deeming it as a likely occurrence based on the established geological characteristics of the talc deposits [67]. Fibrous talc is referred to any talc that contains any form of fibers including asbestos [7]. Nevertheless, according to a certain team of researchers, minerals appearing as elongated, slender particles are classified as fibrous in mineralogical terminology. These researchers also propose that labelling talc products as fibrous does not necessary indicate the presence or absence of other minerals, such as amphibole asbestos. Industrial talc might contain fibrous or platy talc minerals and could also contain measurable amounts of non-talc minerals [68]. In 1971, The New York Post reported presence of asbestos in paint and talcum powder found by Mt. Sinai Researchers and after repeated inquiries the brand names were revealed as Landers and Johnson & Johnson on 16th June 1972 [69,70]. Dr. Seymour Lewin, another researcher from New York University, reported presence of chrysotile and/or tremolite asbestos in 43 out of 102 talc product samples commercially available in 1972 [71]. 5% asbestos by weight was reported by Dr. Lewin in Johnson & Johnson's shower to Shower, Baby Powder and Medicated Powder and since then baby powder and talcum powders other brands have tested positive for asbestos [72,73,74]. In the early 1976, while examining samples of 19 American talcum powder products asbestos was found by researchers at Mount Sinai Hospital, USA in 10 out of 19 samples with 2% to 20% asbestos content [8]. The 1976 study found ZBT baby powder with baby

oil with highest asbestos content followed by Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc ranging between 8 and 20% asbestos fibers. Bauer & Black Baby Talc was found with 15% asbestos content which was no longer in market at that time. Whereas, Yardley Invisible Talc, Faberge Brut Talc, Yardley Black Label Baby Powder, English Leather After Shave Talc and Mennen Shave Talc was found with less than 5% asbestos content. However, Avon Bird of Paradise Beauty Dust, Ammen's Medicated powder, Two Johnson & Johnson's Baby Powder, Johnson & Johnson's Medicated powder, Yardley After Shave Powder, Mennen Bath Talc and Yardley Original Body Powder found uncontaminated by the researchers [75]. In the year 2019, chrysotile asbestos was detected by FDA in Johnson & Johnson Baby Powder. However, this lot of asbestos-containing Johnson & Johnson Baby Powder was passed both the Transmission electron microscopy (TEM) and CTFA J4-1 method [76]. Besides, FDA tested official samples of cosmetic products containing talc for asbestiform fibers by AMA Analytical Services, Inc. (AMA) and released the summary of results in 2022 [77]. Even though the summary report indicated negative results for all 50 samples tested using PLM and TEM, it's important to note that Johnson & Johnson baby powder was not among the samples studied [78]. Another study reported 10 series ovarian cancer cases in women in the United States of America who exclusively used a variety of cosmetic talc products of Johnson & Johnson such as Johnson & Johnson Shower to Shower (STS), Johnson & Johnson's Baby Powder and Johnson & Johnson's Shower to Shower Shimmer [79] with 8 out of 10 affected women found asbestos in their tissue samples [76]. Even in 2018, asbestos was found in Johnson & Johnson's Baby Powder, in an investigation, conducted by Reuters which exposed the asbestos contamination tracing it from earlier decades [80]. However, Johnson & Johnson in their various press releases indicated about their repeated negative findings on the presence of asbestos in their products with the same lots tested positive and pointed the possible cause of either sample contamination or analytical error by authorities including FDA [81,82,83]. Upon thorough reviewing the cited documents, the authors opine that unlike other talc companies Johnson & Johnson also continued to provide industry influenced scientific support to FDA by organizing workshops and meetings etc. [84].

Johnson & Johnson has been held accountable by the courts for asbestos-associated cancers such as mesothelioma of lung and ovarian cancer, which were alleged to have been caused by its products and approximately \$4 billion have been paid so far to cover the lawsuits against the company in USA and Canada [80]. In the ovaries of women with this form of cancer, medical biopsies have shown embedded talc particles and most of them claimed daily use of baby powder. Several litigations were filled against the manufacturers of talcum powder and J&J was one of the biggest names among them [85]. Like many other companies J&J has always denied publicly the fact that their talcum powder cause cancer. However, in 2017 unsealed documents revealed that executives of J&J company were well aware of the asbestos liabilities as early as the 1970s [80]. After long-term use of the talc baby powder, thousands of women who developed ovarian cancer, blamed J&J for their negligence and failure to warn consumers of the possible consequences of their products. With this wake of several litigations and huge public outcry, the company decided to discontinue about 100 products permanently including J&J baby powder in the North American Market (i.e., Canada and U.S.A) stating there is a decline in demand. However, the sale of its products continues in other markets including India [86]. In May 2020, the company announced, the end of the sale of its baby powder in the USA and Canada and in August 2022, and announced the global discontinuation by 2023. However, they would continue to make baby powder based on corn starch versions in USA and Canada.

In the low- and middle-income countries like India, due to the tropical climate of the country talcum powder is used by most of the population to fight against odor and perspiration. India shares the largest market for Johnson & Johnson's Baby Powder portfolio which is

about 60 to 70% [87]. Johnson & Johnson has indicated that the talc-based baby powder will be discontinued in India but the retail sale will continue until the manufacturing stops. They are being questioned by experts for not recalling the product off the market in India.

2. Recommendations

Many Indian dermatologists stated that for both babies and adults it is not advisable to use talc-based products, as it does more harm than good to the skin [88,86]. The danger lies in inhaling the powder and if inhaled it can lead to respiratory distress and gut disorders. Using talc-based products in the genital area also may lead to the development of ovarian cancer [30]. Moreover, the manufacturing license of the Johnson & Johnson's Baby Powder has been cancelled by one of the Indian States (Maharashtra) in September 2022 after it found that the pH value was not within the mandated limit set by the Maharashtra FDA [89]. The company was notified to cancel their license for both manufacturing and sale of the talc-based baby powder in the state.

As Johnson and Johnson's Baby powder is still available at retail shelves and e-commerce platforms in India, the Central Drugs Standard Control Organization (CDSCO) of India and the state drug regulatory bodies should take prompt action in this case and ease the retraction of the contaminated products from the Indian markets at the earliest. Further, directions should be issued by concerned ministries e.g., Ministry of Electronics Information and Technology (MeitY) and departments for prohibiting online sale, advertising and distribution of the contaminated products. The Indian Medical Association and related professional bodies should mandate doctors not to prescribe, recommend or endorse the use of talc-based powders and suggest alternatives such as corn starch, arrowroot starch, etc. The Indian Institute of Toxicology Research (IITR), Lucknow reported in their annual report 2005-2206 about the presence of asbestos fibre in five brands of talcum powder being sold in Indian market [90]. The first study on asbestos in commercial Indian talc was reported in 2019 highlighting the presence of tremolite asbestos in Indian talc products. As per the study results, 7 out of 13 tested products reported to be contained with tremolite asbestos with no information on the talc source used by the manufacturers [3]. Due to the hot and tropical climate, throughout India and Southeast Asia, large quantity of body talc products is used. If these talc products contain asbestos, they pose a huge public health risk for asbestos related diseases, especially cancers due to asbestos exposure. More research should focus on talc-based products and its cancer risks on Indian and Southeast Asian population. In 1976, The Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 method was implemented by the cosmetic industries to voluntarily test asbestos in talc raw materials [91]. A similar method is being used by the talc suppliers to certify "Absence of Asbestos" in talc to meet the United States Pharmacopeia's (USP) requirement [92]. Till date, both the methods utilize Infrared (IR) spectroscopy or X-ray diffraction (XRD) followed by the use of polarized light microscopy (PLM) provided that the sample comes positive for serpentine or amphibole minerals in talc by XRD or IR. Despite of the log-recognized shortcomings in sensitivity and specificity, the CTF J4-1 and USP methods remained standard testing protocol [15,16]. Moreover, reports on testing of cosmetic products indicated that the shortcomings in sensitivity of light microscopy (PLM) may not detect the finely-sized particles of asbestos and other minerals even though they are present in talc [93,94]. For example, the U.S. FDA during its long-term study could only detect the presence of asbestos in nine out of 52 cosmetic products using transmission electron microscopy (TEM) and two out of those nine products showed presence of asbestos highlighting the shortcomings of optical microscopy methods. These differences attributes to lack of uniformity in testing with misleading reporting on asbestos presence [15]. Besides, most modern laboratories with asbestos testing expertise, do not solely rely on PLM instead they routinely perform testing using electronic microscopy. Moreover, the 1976 CTFA J4-1 specification was reported to be defective as it

permitted the carcinogens presence such as fibrous talc and chrysotile and could only detect amphiboles at the level over 0.5% [95,96]. In IS 1462(1985): SPECIFICATION FOR TALC FOR COSMETIC INDUSTRY, the Indian standard for talc in cosmetics is given which contains the prescribed requirements and methods of talc sampling and testing used in cosmetic industry [86]. In India, the Central Drug Standard Control Organization (CDSCO) is the responsible organization for regulating talc powders and talc-containing cosmetics. In 2018, J&J was ordered to stop manufacturing of its baby powder by CDSCO until it is proven free from asbestos. However, the company advertised their baby powder to be of standard quality and asbestos free after getting a clean chit from a government laboratory in Chandigarh [86]. Although, India follows appropriate monitoring methods for asbestos detection in talc ensuring suitability as a raw material to be used as a cosmetic ingredient [15], the possibilities of asbestos contamination, lack of high-quality and rigorous testing by manufacturers, poor surveillance and monitoring by the regulatory authorities cannot be unforeseen. Moreover, it is needless to mention that the measurement of asbestos in any product needs high-quality and rigorous testing protocol making it extremely challenging for a developing nation like India [97]. More states and regulatory bodies should come forward in testing talc-based products and based on the test outcomes take appropriate regulatory actions and as may be appropriate, prohibit their manufacturing and sale within their jurisdictions. Policy makers, physicians and regulatory bodies should become skilful at identifying industry influences over such issues that may cause harm to environmental and human health.

Authors' contributions

SS Conceptualized the topic. SS, SRP performed literature search and wrote the paper contents. PKS and AY reviewed and edited the paper.

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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