 DOI: 10.1111/risa.13312

Potential Airborne Asbestos Exposure and Risk Associated with the Historical Use of Cosmetic Talcum Powder Products

Amanda M. Burns,[1] Christy A. Barlow,[2] Amber M. Banducci,[3] Kenneth M. Unice,[4] and Jennifer Sahmel[3,*]

Over time, concerns have been raised regarding the potential for human exposure and risk from asbestos in cosmetic-talc–containing consumer products. In 1985, the U.S. Food and Drug Administration (FDA) conducted a risk assessment evaluating the potential inhalation asbestos exposure associated with the cosmetic talc consumer use scenario of powdering an infant during diapering, and found that risks were below levels associated with background asbestos exposures and risk. However, given the scope and age of the FDA's assessment, it was unknown whether the agency's conclusions remained relevant to current risk assessment practices, talc application scenarios, and exposure data. This analysis updates the previous FDA assessment by incorporating the current published exposure literature associated with consumer use of talcum powder and using the current U.S. Environmental Protection Agency's (EPA) nonoccupational asbestos risk assessment approach to estimate potential cumulative asbestos exposure and risk for four use scenarios: (1) infant exposure during diapering; (2) adult exposure from infant diapering; (3) adult exposure from face powdering; and (4) adult exposure from body powdering. The estimated range of cumulative asbestos exposure potential for all scenarios (assuming an asbestos content of 0.1%) ranged from 0.0000021 to 0.0096 f/cc-yr and resulted in risk estimates that were within or below EPA's acceptable target risk levels. Consistent with the original FDA findings, exposure and corresponding health risk in this range were orders of magnitude below upper-bound estimates of cumulative asbestos exposure and risk at ambient levels, which have not been associated with increased incidence of asbestos-related disease.

KEY WORDS: Cosmetic talc; exposure reconstruction; infant and adult scenarios; talcum powder

1. INTRODUCTION

Talc is a hydrated sheet silicate mineral composed of magnesium, silica (SiO_2: silicone and oxygen), and water. Since large bodies of pure talc are rare, the commercial term "talc" refers to "various rocks composed of magnesium silicates in which talc may be dominant, abundant, minor, or entirely absent" (Grexa & Parmentier, 1979, p. 29; International Agency for Research on Cancer, 2010). Talc is used commercially for a variety of purposes, including as an antisticking or anticaking agent, or as a lubricant, thickener, pigment, absorbent, carrier, or filler (International Agency for Research on Cancer, 2010). There are two general grades of commercial talcs: industrial and cosmetic. These grades are classification standards that refer to the purity of the commercial talc product. Cosmetic talc mainly consists of relatively pure platiform talc, whereas industrial talc may be platiform or fibrous and may contain other minerals (American Conference of Governmental

[1]Cardno ChemRisk, Brooklyn, NY, USA.
[2]GZA GeoEnvironmental, Inc., Boulder, CO, USA.
[3]Insight Risk, LLC, Boulder, CO, USA.
[4]Cardno ChemRisk, Pittsburgh, PA, USA.
[*]Address correspondence to Jennifer Sahmel, Insight Risk, LLC, Boulder, CO, USA; tel: (720) 287-3441; jennifer.sahmel@insightrisk.com.

Industrial Hygienists, 2010; International Agency for Research on Cancer, 2010). Platiform or platy refers to a mineral shape consisting of overlying plates with one short and two longer dimensions, while fibrous is used to generally describe the morphology of a mineral occurring in long, thin particles (Campbell, Blake, Brown, Cather, & Sjoberg, 1977).

Talc is formed under geological conditions that give rise to a unique mineral composition and characteristic crystal shape, or habit, that varies depending on the geographical location of the talc deposit (Campbell et al., 1977; Van Gosen, Lowers, Sutley, & Gent, 2004). It has been reported that the most common minerals occurring with talc include chlorite, magnesite, dolomite, anthophyllite, serpentine, quartz, and tremolite (International Agency for Research on Cancer, 2010). Within a single talc deposit, amphiboles, if present, can occur in a range of habits from blocky, prismatic, and acicular (all considered nonasbestiform) to asbestiform (Van Gosen et al., 2004). Asbestiform and nonasbestiform particles exhibit distinct mineralogical characteristics that allow them to be distinguished from one another (Campbell et al., 1977; National Institute for Occupational Safety and Health, 2011; Strohmeier et al., 2010; Wylie & Verkouteren, 2000; Wylie, Virta, & Russek, 1985). Asbestiform describes "the unusual crystallization morphology that these minerals display when formed as aggregates of thin, hair-like fibres," whereas nonasbestiform describes minerals that form random, multidirectional growth patterns (Gunter, Belluso, & Mottana, 2007; Strohmeier et al., 2010, p. 802). Asbestiform fibers have a high length-to-width ratio (aspect ratio), high tensile strength, and flexibility (Addison & McConnell, 2008; U.S. Environmental Protection Agency, 1993). Further, the U.S. Environmental Protection Agency (EPA) explained that the asbestiform habit is generally recognized by fiber aspect ratios of 20:1 to 100:1 or higher for fibers greater than 5 μm in length and usually less than 0.5 μm in diameter (U.S. Environmental Protection Agency, 1993).

Many regulatory and public health agencies and organizations, as well as scientific bodies, agree that the biological activity of asbestiform and nonasbestiform structures is markedly different, the latter being "less bioreactive and cytotoxic" (Addison & McConnell, 2008, p. S200; Agency for Toxic Substances and Disease Registry, 2001b; American Thoracic Society, 1990; Consumer Product Safety Commission, 1988; Gamble & Gibbs, 2008; Mossman, 2008; Occupational Safety and Health Administration, 1992; Vu, 1993). The mechanical forces present during mining and milling techniques used to process raw minerals can create cleavage fragments from nonasbestiform structures. This is particularly relevant during the processing of raw talc containing nonasbestiform tremolite (Hamer, Rolle, & Schelz, 1976; International Agency for Research on Cancer, 2010; Pang, Schonfeld, & Nazar, 1987). Campbell et al. reported that "a few elongated particles" generated from the crushing of nonasbestiform tremolite may resemble fibers similar to those derived from an asbestiform mineral sample (Campbell et al., 1977, p. 39). Further, the Agency for Toxic Substances and Disease Registry (ATSDR) noted that "sometimes it can be difficult to distinguish an isolated non-asbestiform cleavage fragment from an isolated asbestos fiber" (Agency for Toxic Substances and Disease Registry, 2001a, p. 8). Even though such elongated particles are derived from a nonasbestiform source and would be classified as cleavage fragments, they would be counted with asbestiform fibers if they fall under the dimensional definition of a fiber using the phase contrast microscopy (PCM) analytical method alone (Agency for Toxic Substances and Disease Registry, 2001b; Virta, 2001). Several federal agencies define a fiber as a particle with a length of 5 μm or longer and an aspect ratio of 3:1 or greater (National Institute for Occupational Safety and Health, 2011; Occupational Safety and Health Administration, 1994). However, such criteria do not apply in the determination of whether a mineral sample, such as tremolite, is asbestiform.

Concerns were raised in the late 1960s and early 1970s that cosmetic talc products sourced from some mineralogical formations subject to specific geological conditions could contain asbestos. Asbestos encompasses a group of six chemically and physically diverse types of asbestiform mineral fibers that are characterized according to morphology as serpentine (chrysotile) or amphibole (crocidolite, amosite, tremolite, anthophyllite, and actinolite). Some early studies conducted during this same period of time attempted to characterize the asbestos content of consumer talcum powder samples (Cralley, Key, Groth, Lainhart, & Ligo, 1968; Lewin, 1972; Rohl & Langer, 1974; Rohl et al., 1976; Snider, Pfeiffer, & Mancuso, 1972). However, it became apparent to the Food and Drug Administration (FDA), and other regulatory bodies, that many of the analytical methods applied in these studies were not performed or interpreted correctly or consistently. In many cases, the available analytical approaches used were unable to

distinguish between asbestiform and nonasbestiform minerals (Swanson, 1986). The limited reliability of the reported results was subsequently recognized, in some cases by the original authors themselves, resulting in scientific and regulatory efforts to increase the sophistication and reliability of bulk asbestos analysis in talc (Addison & Langer, 2000; Caneer, 1973; International Agency for Research on Cancer, 2010; Krause, 1977; Rohl & Langer, 1979; Swanson, 1986). Amid these concerns and in an effort to properly characterize asbestos content in cosmetic talcum powders, the FDA conducted a series of bulk sample analyses of cosmetic talcum powders throughout the 1970s, and as recently as 2010, to assess potential health risks to consumers. Nearly all FDA bulk cosmetic talc sample testing results indicated that no asbestos was present in the products evaluated. For example, in the results from surveys conducted in 1975 (73 products), 1977 (46 samples of an unreported number of products), and 2009 and 2010 (34 products), no asbestos was reported, with the possible exception of three samples (Eiermann, 1976a, 1976b; Kennedy, 1979; U.S. Food and Drug Administration, 2018). For these three samples, the results were reported to be at or below the acceptable limit of 0.1% asbestos in cosmetic talc proposed by the FDA in 1973, and may have included nonasbestiform mineral particles, based on the sampling method (Brown, 1985a; Kennedy, 1979; U.S. Food and Drug Administration, 1973).

In 1985, in response to a citizen's petition, the FDA's Quantitative Risk Assessment (QRA) Committee conducted an analysis of the potential for cancer risk from consumer exposure to asbestos during the use of cosmetic talc. This risk assessment was based on what the FDA considered to be an upper-bound or worst-case scenario of applying talcum powder to an infant during multiple daily diaper changes over an estimated two-year period. Based on 1977 FDA cosmetic talc testing and "other recent samples," the committee estimated that cosmetic talc could have contained, as an upper bound, as much as 0.1% asbestos (Brown, 1985a, p. 1). Previously, the FDA found, based on its analysis of cosmetic talcum powders in 1977, that the "cosmetic grades of talc are usually free of asbestiform particles," and when present, "the level was only 0.1 percent or less" (Kennedy, 1979, p. 3). Following a detailed analysis using four comparative asbestos risk assessment approaches, the FDA concluded, in 1985, that over a two-year period of infant diapering, the "added human risk of lung cancer and mesothelioma from possible asbestos in talc is less than 10^{-8} lifetime risk and quite possibly orders of magnitude less" (Brown, 1985a, p. 1, 1985b). The FDA further stated that, while the adult performing the diapering could also receive an exposure during each event, "their added lifetime risk from talc should be relatively smaller than the infant's since their mouths and noses are considerably further from" any airborne talc dust (Brown, 1985a, p. 5). The FDA also compared the estimated cumulative exposure from use of cosmetic talcum powder to cumulative ambient or background asbestos exposures and concluded that "the risk from a worst-case estimate of exposure to asbestos from cosmetic talc would be less than the risk from environmental background levels of exposure to asbestos (non-occupational exposure) over a lifetime" (Swanson, 1986, p. 2). The FDA has continued to receive petitions to place a cancer warning label on cosmetic talcum powder products despite the analysis and conclusions presented in its risk assessment; petitions have been denied as recently as 2014 (Musser, 2014).

The FDA risk assessment made use of state-of-the-art risk assessment knowledge and talc dust exposure measurements at the time; however, a significant amount of research and data have been collected since the 1985 assessment. It was of interest to determine if the original conclusions of the assessment are still relevant and applicable, given the quantity of new data that address a far broader range of cosmetic talc use scenarios compared to the original FDA assessment. Additionally, the methods used in the 1985 assessment may no longer represent the regulatory position with respect to nonoccupational risk assessment. For example, the EPA has published and subsequently updated a formal regulatory approach to asbestos risk assessment since that time, and additional benchmarks and data with respect to risk characterization relevant to understanding nonoccupational exposures have been published. Further, it was also of interest to evaluate whether the infant diapering scenario was in fact a worst-case talc exposure scenario. The purpose of this assessment was, therefore, to address concerns over the possible presence of asbestos in talc-containing consumer products by comparing the original FDA risk assessment approach with a contemporary risk-based U.S. regulatory approach. This assessment provides an evaluation of the applicability of the FDA assessment using current regulatory methods and data. It also addresses important data gaps by expanding on the original risk assessment and characterizing the

potential exposures and risks associated with typical use scenarios not originally characterized in the FDA risk assessment. This updated analysis focused on measured PCM airborne fiber concentration data from all identified uses of cosmetic talc in the literature, as well as total and respirable dust air concentration data, in order to evaluate potential exposure and risk to users of cosmetic talcum powder products using a consistent metric of fibers per cubic centimeter (f/cc). This method allowed for an upper-bound characterization across all studies for the airborne fiber concentration associated with the application of cosmetic talc. Human health risks were also evaluated using a comparative benchmark approach for cumulative exposures associated with the cosmetic talc application scenarios of interest compared to background and regulatory levels. To our knowledge, this is the first analysis to date in which a comprehensive risk assessment was performed that evaluated the potential for asbestos exposure and human health risk for four infant and adult cosmetic talc use scenarios using the EPA's current nonoccupational asbestos regulatory risk assessment methods and other important relevant benchmarks, including the best available current data on general population background airborne fiber concentrations and cumulative lifetime asbestos exposures and risk, consistent with FDA's original analysis.

2. METHODS AND MATERIALS

2.1. Literature Search

A detailed literature review was conducted to identify studies that provided measured airborne concentration and/or health risk data associated with the use of cosmetic talcum powders. Our search included both peer-reviewed literature and reports published for governmental organizations, as well as other available unpublished studies. All studies that provided task-based personal airborne concentration measurement data associated with the use of cosmetic talcum powder products were included in our analysis.

2.2. Exposure Assessment

An exposure assessment was conducted to evaluate the potential for cumulative lifetime asbestos exposure associated with the consumer talc use scenarios that have been described in the literature (Sahmel et al., 2014, 2016; Sahmel, Devlin, Paustenbach, Hollins, & Gaffney, 2010). Cumulative exposure to asbestos, expressed as fibers per cubic centimeter-years (f/cc-yr), was calculated using the following equation:

$$\mathrm{CEC_{ENV}} = C \times E_T \times E_F \times E_D \times C_F, \qquad (1)$$

where $\mathrm{CEC_{ENV}}$ is cumulative asbestos exposure over time on an environmental basis (f/cc-yr); C is task-based personal airborne fiber concentration (f/cc); E_T is the exposure time (minutes/use); E_F is the exposure frequency (number of uses/year); E_D is the exposure duration (years); and C_F is the conversion factor for the number of total minutes in a year (year/minutes).

Expressing cumulative exposure as an environmental year (i.e., 24 hours a day, seven days a week) allows for a direct comparison to ambient exposures to asbestos to the general population in the United States. However, such a metric is not directly comparable to the cumulative asbestos exposures presented in occupational studies. For the purposes of this assessment, the results were presented in environmental years rather than occupational years; an occupational year typically includes approximately 2,080 working hours per year rather than 8,760 total hours per environmental year. These environmental cumulative exposure values will therefore be lower than if converted to an equivalent occupational cumulative exposure value.

2.2.1. Exposure Duration and Frequency (E_T, E_F, E_D)

Duration and frequency were compiled from the studies identified in the literature review. Study-reported sample duration was used to estimate exposure time (E_T).

It has been noted in the literature that a duration of two years is approximately the time after which an infant would begin to transition out of diapers (Schmitt, 2004). Consistent with the literature and the 1985 FDA risk assessment, an exposure duration (E_D) of two years was selected for the infant powdering scenarios in this analysis. Based on a survey conducted of 76 mothers applying talcum powder to their infants and the average frequency for use of baby powder on an infant reported in the EPA's *Exposure Factors Handbook*, a frequency (E_F) of five applications per day was used for the exposure

calculations in this assessment (Hildick-Smith, 1976; U.S. Environmental Protection Agency, 2011).

This assessment also characterized typical personal adult cosmetic talc exposures potentially experienced during daily use over a 70-year lifetime; 70 years is a standard assumption for a lifetime used in EPA risk assessments (U.S. Environmental Protection Agency, 2011). Consistent with the average frequency reported in the EPA's *Exposure Factors Handbook* and Zazenski et al. (1995), a frequency (E_F) of one adult cosmetic talc application per day, seven days a week, was identified for the adult application scenarios (U.S. Environmental Protection Agency, 2011; Zazenski et al., 1995).

2.2.2. Airborne Talc Concentration (C)

Both airborne dust and fiber concentrations were assessed from published studies and publicly available reports. This analysis focused solely on quantitative personal or breathing zone airborne concentration measurement data specifically collected during the use or application of cosmetic talcum powder. In addition to reported airborne fiber concentration data, all available total and respirable dust data published in the peer-reviewed literature were evaluated as surrogate data in support of the exposure assessment. A summary of the reported airborne dust and fiber concentration measurements associated with the consumer application of cosmetic talcum powder is presented in Table I.

All total and respirable airborne dust concentration data reported in the relevant studies were converted to an estimated airborne fiber concentration to allow for comparisons across all available consumer talc use measurement studies. Conversion methods and calculations were carefully reviewed and compared with the published literature and are described in detail in Section 4.2. For the airborne fiber concentrations, an upper-bound estimate of 0.1% asbestos in cosmetic talc was applied. This is also the same value that was used in the 1985 FDA's risk assessment, in which they indicated that the estimated upper-bound percentage of asbestos in the bulk talc is proportional to the percentage of asbestos fibers in the measured air concentration. Cumulative asbestos exposure estimates were then calculated for each identified consumer talc use scenario using measured and estimated airborne fiber concentration data and the asbestos content factor of 0.1% (Taylor, 1984).

2.2.3. Comparison to Daily Occupational Talc Exposure Levels (C_{8hr})

The talcum powder airborne dust concentration measurements reported in the literature were also used to estimate daily eight-hour time weighted averages (TWAs) in order to compare calculated consumer exposure potential to the established U.S. Department of Labor's, Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for talc dust of 20 million particles per cubic foot (mppcf) or approximately 3 milligram per cubic meter (mg/m^3) (National Institute for Occupational Safety and Health, 1988). Similar analyses have been performed by others for the purposes of benchmark comparisons (Zazenski et al., 1995).

The eight-hour TWA was calculated as follows:

$$C_{8\text{hr}} = \frac{\sum_i^n C_i t_i}{480 \text{ minutes}}, \quad (2)$$

where $C_{8\text{hr}}$ is the eight-hour TWA concentration (f/cc), C_i is the concentration during the ith use (f/cc), t_i is the time duration of the ith use (minutes), and n is the number of discrete uses.

2.3. Regulatory Risk Characterization

Asbestos inhalation risks were estimated using the current standard EPA nonoccupational regulatory asbestos risk equation for inhalation carcinogens (U.S. Environmental Protection Agency, 2008):

$$\text{Risk} = \text{EPC} \times \text{TWF} \times \text{IUR}, \quad (3)$$

where EPC is the exposure point concentration (f/cc), TWF is the time weighting factor (unitless), and IUR is the inhalation unit risk $(f/cc)^{-1}$.

TWF is the fraction of the year during which exposure from a particular activity can occur. It was calculated as follows:

$$\text{TWF} = \frac{E_{T\,(TWF)} \times E_{F\,(TWF)}}{(24 \text{ hr/day}) \times (365 \text{ day/year})}, \quad (4)$$

where $E_{T\ (TWF)}$ is the exposure time (hours exposed/day) and $E_{F\ (TWF)}$ is the exposure frequency (days/year).

IUR represents the unit risk associated with age at first exposure and exposure duration for a given exposure scenario. The asbestos IUR does not distinguish between the asbestos fiber types (U.S. Environmental Protection Agency, 2008).

The theoretical risks calculated using the current EPA regulatory risk model assumptions provide a value that can be compared against appropriate

Table I. Summary of the Representative Dust and Fiber Exposure Measurement Data Associated with the Infant and Adult Application of Cosmetic Talcum Powder

Application Description	Powdering Time	Sample Duration	Sample Size	Measured Airborne Dust Concentration		Measured Airborne Fiber Concentration	Converted Dust to Fiber Concentration (f/cc)[a]	Reference
				mppcf	mg/m^3	PCM (f/cc)		
Scenario 1: Infant exposure—diapering								
Application of powder in "normal way," container with sprinkler closure	15–60 sec	5 min	32	–	0.21	–	2.4	Aylott et al., 1979
Application around diaper area followed by spreading the powder[b]	15 sec	2 min	7	–	–	2.4	–	Dement et al., 1972
Application around diaper area followed by spreading the powder[b]	5 sec	3 min	6	–	–	0.53	–	Dement et al., 1972
Application around diaper area followed by spreading the powder[b]	15 sec	3 min	7	–	–	1.6	–	Dement et al., 1972
Application of powder around arm pit area	30 sec	5 min	10	–	0.02207	–	0.25	Moon et al., 2011
Application of powder around diaper area, twist-top container	0.52 ± 0.17 min	0.52 ± 0.17 min	48	–	0.19	–	2.2	Russell et al., 1979
Scenario 2: Adult exposure—diapering								
Application around diaper area followed by spreading the powder[b]	15 sec	2 min	7	–	–	2.7	–	Dement et al., 1972
Application around diaper area followed by spreading the powder[b]	5 sec	3 min	6	–	–	0.85	–	Dement et al., 1972
Application around diaper area followed by spreading the powder[b]	15 sec	3 min	7	–	–	1.2	–	Dement et al., 1972
Simulated application of powder, product dusting into shallow tray[c]	10 sec	1.25 min	–	0.14	–	–	0.24	Hildick-Smith, 1976
Application of powder around arm pit area	30 sec	5 min	10	–	0.00527	–	0.060	Moon et al., 2011
Scenario 3: Adult exposure—face powdering								
Application of loose face powder, puff applicator	10–26 sec	5 min	16	–	0.48	–	5.5	Aylott et al., 1979

(*Continued*)

Table I (Continued)

Application Description	Powdering Time	Sample Duration	Sample Size	Measured Airborne Dust Concentration		Measured Airborne Fiber Concentration	Converted Dust to Fiber Concentration (f/cc)[a]	Reference
				mppcf	mg/m^3	PCM (f/cc)		
Scenario 4: Adult exposure—body powdering								
Application of powder in a typical fashion[b,d]	13–47 sec	6 min	20	–	1.46	0.23	17	Anderson et al., 2017
Application of powder in "normal way," container with sprinkler closure	15–80 sec	5 min	32	–	1.13	–	13	Aylott et al., 1979
Application to upper body, shaker container	55 sec	5 min	1	–	–	4.8	–	Gordon et al., 2014
Application to upper body, puff applicator	57 sec	4 min	2	–	–	20	–	Gordon et al., 2014
Application to upper body, puff applicator	57 sec	3.3 min	1	–	–	60	–	Gordon et al., 2014
Application of powder in a "normal manner," twist-top container	1.23 ± 0.55 min	1.23 ± 0.55 min	44	–	2.03	–	23	Russell et al., 1979

[a]Measured airborne dust concentration data converted to fiber using the following conversion ratios: 1 mppcf: 0.15 mg/m^3 and 1.72 f/cc: 1 mppcf; f/cc, fibers per cubic centimeter; mppcf, million particles per cubic foot (Dement & Zumwalde, 1979; National Institute for Occupational Safety and Health, 1988).
[b]Arithmetic mean of measured airborne concentration data calculated from reported data.
[c]Data were reported to the author via personal communication; it was reported that the dust concentrations for the simulated mother and infant were similar. Time weighted average was calculated for 10 seconds dusting time (0.243 mppcf) and 65 seconds settling time (0.124 mppcf) using the following equation $[(c1 \times t1) + (c2 \times t2) / (t1 + t2)]$.
[d]Sample duration per event was approximately six minutes.

environmental target risk levels, such as 1×10^{-4}, 1×10^{-5}, or 1×10^{-6}. These theoretical risk estimates correspond to population-based risk equivalents of approximately 1 in 10,000, 1 in 100,000, or 1 in 1 million, respectively (U.S. Environmental Protection Agency, 2008).

3. RESULTS

3.1. Literature Search

The initial literature search returned 590 results. In total, seven of these studies contained measured airborne concentration data associated with the consumer use of cosmetic talcum powder products (Anderson, Sheehan, Kalmes, & Griffin, 2017; Aylott, Byrne, Middleton, & Roberts, 1979; Dement, Shuler, & Zumwalde, 1972; Gordon, Fitzgerald, & Millette, 2014; Hildick-Smith, 1976; Moon et al., 2011; Russell, Merz, Sherman, & Sivertson, 1979). Of the studies identified, four studies presented measured airborne dust concentration data and two presented measured airborne fiber concentration data. One study presented both dust concentration and airborne fiber concentration data (Table I).

Based on the literature review, four exposure scenarios were identified: (1) infant exposure during diapering, (2) adult exposure from infant diapering, (3) adult exposure from face powdering, and (4) adult exposure from body powdering.

3.2. Respirable and Total Dust to Airborne Fiber Concentration Conversion Analysis

Where respirable dust data were expressed in terms of mg/m^3, a conversion to units of mppcf was performed. It was reported by NIOSH that the current OSHA PEL for talc dust of 20 mppcf is approximately equivalent to 3 mg/m^3 (National Institute for Occupational Safety and Health, 1988). In addition, Equation (5) has been described in the literature as a method for converting airborne talc dust concentrations between mppcf and mg/m^3 (International Agency for Research on Cancer, 2010; Oestenstad, Honda, Delzell, & Brill, 2002):

$$\ln\left(\mathrm{mg/m^3}\right) = \ln(\mathrm{mppcf}) \times 0.62 - 1.20. \qquad (5)$$

For low airborne dust concentrations associated with the use of cosmetic talc products, the use of the conversion factor reported by NIOSH was shown to be more conservative (i.e., resulted in a higher conversion value). Therefore, the NIOSH conversion factor expressed as 1 mppcf to 0.15 mg/m^3 rather than Equation (5) was used to perform the conversion so as not to underestimate the asbestos exposure potential.

Next, a conversion to units of f/cc was required for total dust data (both measured and converted) expressed in mppcf. In 1979, Dement and Zumwalde (1979) published a study presenting concurrent airborne dust (mppcf) and fiber (f/cc) exposures for talc miners and millers working at a mining region located in New York State. Based on these data, a talc-specific mppcf to fiber conversion factor was calculated; only the miller data were utilized as it is more likely that the exposures experienced by end-users of the finished product would be more comparable to the material handled by millers. The reported average TWA for millers in mppcf was 2.9 and the average TWA for millers in f/cc was 5.0; this equated to a ratio of approximately 1.72 f/cc to 1 mppcf for talc. A published conversion factor for asbestos of 6 to 1 for the relative ratio of f/cc to mppcf noted by OSHA and EPA in their asbestos risk assessments was also considered (Lynch & Ayer, 1968; Occupational Safety and Health Administration, 1983; U.S. Environmental Protection Agency, 1986a). Additionally, the ATSDR has stated that when a more accurate value is not available for conversion, a conversion ratio of 3 to 1 for the relative ratio of f/cc to mppcf can be used (Agency for Toxic Substances and Disease Registry, 2001b; Lane et al., 1968). The 6 to 1 and the 3 to 1 ratios may overestimate the potential for airborne fiber concentrations associated with talc use specifically, given that the side-by-side measured data from the talc-specific Dement and Zumwalde study provided a conversion factor of 1.72 to 1 for f/cc to mppcf. As such, the application of the 6 to 1 ratio serves as an upper-bound means of converting between mppcf and f/cc for talc exposure data in the analysis, while the application of the 1.72 to 1 ratio may be more consistent with talc-specific exposure potential when fibers are present in talc.

Subsequent to the conversion analysis, an analysis was performed whereby all the data were compared using the same exposure metric. The measured airborne dust concentration data reported in units of mg/m^3 and mppcf were converted to f/cc using both the 1.72 to 1 and 6 to 1 (f/cc: mppcf) conversion factors and plotted against the measured PCM data reported in the literature to ensure the validity of the conversion factors and to identify any potential outliers. The data converted to units of f/cc using the

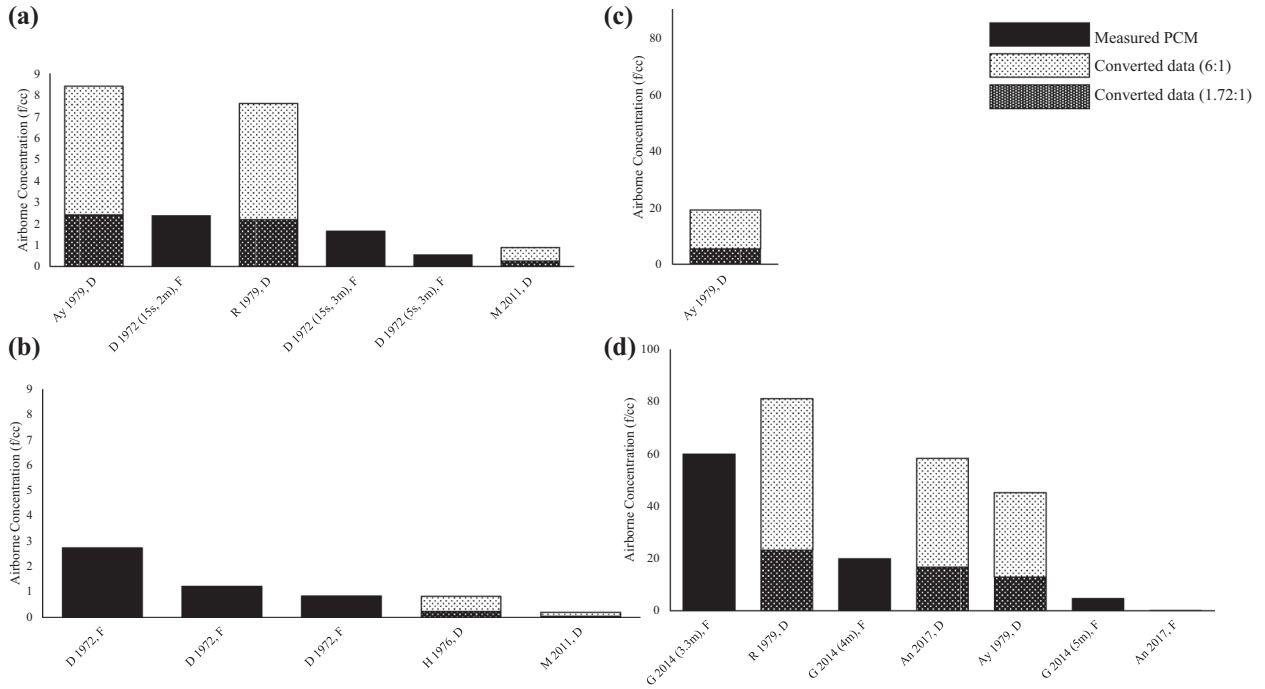

Fig. 1. Comparison of reported PCM and converted airborne dust data to f/cc infant powder scenarios 1 (a) and 2 (b) and for adult powder scenarios 3 (c) and 4 (d).
Note: D, dust data; F, fiber data; D 1972, Dement et al. (1972); Ay 1979, Aylott et al. (1979); R 1979, Russell et al. (1979); H 1976, Hildick-Smith (1976); M 2011, Moon et al. (2011); G 2014, Gordon et al. (2014); An 2017, Anderson et al. (2017).

1.72 to 1 conversion factor were well within the range of measured PCM airborne fiber data (Fig. 1). Further, the results of this analysis demonstrated that the use of the 6 to 1 ratio skewed the estimated airborne fiber concentration data above the highest measured fiber data for the adult and infant use scenarios. Therefore, the 1.72 to 1 conversion factor, which was specific to talc, appeared to be most appropriate for the scenarios evaluated in this study, and was used for the purposes of our risk analysis. The respirable dust conversions, along with all identified measured cosmetic talc exposure data, are reported in Table I.

3.3. Exposure Assessment

3.3.1. Scenario 1: Infant Powdering—Infant Exposure

Aylott et al. (1979), Russell et al. (1979), and Moon et al. (2011) reported respirable talc particle exposures to an infant generated from the application of cosmetic talcum powder during diapering activities. Sample durations ranged from 0.35 to 5 minutes with powdering times from 15 to 60 seconds. The estimated cumulative exposures based on an environmental year using data from studies reporting talc dust airborne concentrations and the previously reported duration and frequency of use parameters ranged from 0.000009 to 0.00008 f/cc-yr (8.8×10^{-6} to 8.4×10^{-5} f/cc-yr; Table II). Dement et al. (1972) was the only study that presented measured airborne fiber concentrations associated with use of cosmetic talc for the infant powdering scenario. Sample durations ranged from 2 to 3 minutes with powdering times from 5 to 15 seconds. The cumulative exposure for an environmental year ranged from 0.00001 to 0.00003 f/cc-yr (1.1×10^{-5} to 3.4×10^{-5} f/cc-yr; Table II).

3.3.2. Scenario 2: Infant Powdering—Adult Exposure

Hildick-Smith (1976) and Moon et al. (2011) reported respirable talc particle exposure to an adult produced during the powdering of an infant while diapering. Sample durations were 1.25 minutes and 5 minutes with respective powdering times of 10 seconds and 30 seconds. The estimated cumulative exposures based on an environmental year using data from Hildick-Smith (1976)

Table II. Infant and Adult Cumulative Exposure Estimates Associated with Four Consumer Application Scenarios

Application Description	Exposure Time (E_T) (Min/Use)[a]	Exposure Frequency (E_F) (Uses/Year)[b,c]	Exposure Duration (E_D) (Years)	Airborne Concentration (f/cc)[d]	Cumulative Exposure (f/cc-yr)[e]	Reference
Scenario 1: Infant exposure—diapering						
Application of powder in "normal way," container with sprinkler closure	5	1,825	2	*0.0024*	8.4E-05	Aylott et al., 1979
Application around diaper area followed by spreading the powder	2	1,825	2	0.0024	3.3E-05	Dement et al., 1972
Application around diaper area followed by spreading the powder	3	1,825	2	0.00053	1.1E-05	Dement et al., 1972
Application around diaper area followed by spreading the powder	3	1,825	2	0.0016	3.4E-05	Dement et al., 1972
Application of powder around arm pit area	5	1,825	2	*0.00025*	8.8E-06	Moon et al., 2011
Application of powder around diaper area, twist-top container	0.69	1,825	2	*0.0022*	1.0E-05	Russell et al., 1979
Scenario 2: Adult exposure—diapering						
Application around diaper area followed by spreading the powder	2	1,825	2	0.0027	3.8E-05	Dement et al., 1972
Application around diaper area followed by spreading the powder	3	1,825	2	0.00085	1.8E-05	Dement et al., 1972
Application around diaper area followed by spreading the powder	3	1,825	2	0.0012	2.6E-05	Dement et al., 1972
Simulated application of powder, product dusting into shallow tray	1.25	1,825	2	*0.00024*	2.1E-06	Hildick-Smith, 1976
Application of powder around arm pit area	5	1,825	2	*0.000060*	2.1E-06	Moon et al., 2011
Scenario 3: Adult exposure—face powdering						
Application of loose face powder, puff applicator	5	365	70	*0.0055*	1.3E-03	Aylott et al., 1979
Scenario 4: Adult exposure—body powdering						
Application of powder in a typical fashion[f]	6	365	70	0.00023	6.6E-05	Anderson et al., 2017
Application of powder in "normal way," container with sprinkler closure	5	365	70	*0.013*	3.1E-03	Aylott et al., 1979
Application to upper body, shaker container[f]	5	365	70	0.0048	1.2E-03	Gordon et al., 2014
Application to upper body, puff applicator[f]	4	365	70	0.020	3.9E-03	Gordon et al., 2014
Application to upper body, puff applicator[f]	3.3	365	70	0.060	9.6E-03	Gordon et al., 2014
Application of powder in a "normal manner," twist-top container	1.78	365	70	*0.023*	2.0E-03	Russell et al., 1979

[a]When available, the sample duration reported for each application scenario was used for exposure time (E_T). Anderson et al. (2017) reported that each simulation lasted 48 minutes, including eight applications each lasting 6 minutes; therefore, 6 minutes was used as the E_T for this study. Russell et al. (1979) did not report a sample duration; therefore, the maximum reported powdering time was used.

[b]Daily exposure frequency of five uses per day, based on diapering frequency data presented in Hildick-Smith (1976) and EPA's *Exposure Factors Handbook* (2011).

[c]Daily exposure frequency of one use per day, based on adult use presented in Zazenski et al. (1995) and EPA's *Exposure Factors Handbook* (2011).

[d]Fiber concentrations in italics were converted from dust concentrations to fiber concentrations using the 1.72:1 fiber to dust conversion factor and the application of the 0.1% asbestos factor to the airborne fiber concentration, based on the FDA 1985 approach.

[e]Cumulative asbestos exposure over time on an environmental basis (f/cc-Year) = $C_{(f/cc)} \times E_T \times E_F \times E_D \times C_F$; where C_F: (Year/Min), or 1.9E-06 (1 year / [365 days/year] × [24 hours/day] × [60 minutes/hour]).

[f]Reported PCM (f/cc) concentrations used for analysis.

and Moon et al. (2011), along with the previously identified usage parameters, were both 0.000002 f/cc-yr (2.1×10^{-6} f/cc-yr; Table II). In comparison, the measured airborne fiber concentrations reported by Dement et al. (1972) represent the upper bound of estimated exposures for this scenario, where the cumulative exposure for an environmental year ranged from 0.00002 to 0.00004 f/cc-yr (1.8×10^{-5} to 3.8×10^{-5} f/cc-yr; Table II). Sample durations ranged from 2 to 3 minutes with powdering times from 5 to 15 seconds. Similar to Scenario 1, all study results were within a consistent range of an order of magnitude.

3.3.3. Scenario 3: Adult Face Powdering

Aylott et al. (1979) was the only study identified that presented measured airborne talc concentrations during the consumer application of cosmetic facial talcum powder. Powdering times ranged from 10 to 26 seconds with a sample duration of 5 minutes. The authors reported respirable talc particle concentrations of 0.48 mg/m^3. Calculated cumulative exposure for lifetime daily use on an environmental year basis was 0.001 f/cc-yr (1.3×10^{-3} f/cc-yr; Table II).

3.3.4. Scenario 4: Adult Body Powdering

Aylott et al. (1979) and Russell et al. (1979) reported respirable talc particle concentrations during consumer application of body powder. Sample durations ranged from 0.68 to 5 minutes with powdering times from 15 to 107 seconds. The estimated cumulative exposures for daily lifetime talc application to the body based on an environmental year using data from studies reporting talc dust airborne concentrations were 0.002 f/cc-yr (2.0×10^{-3} f/cc-yr) and 0.003 f/cc-yr (3.1×10^{-3} f/cc-yr), respectively.

Both Gordon et al. (2014) and Anderson et al. (2017) analyzed airborne fiber concentrations associated with the consumer use of cosmetic talcum powder using the NIOSH 7400 (PCM) and 7402 (PCM equivalent, PCME) methods. Sample durations used in Gordon et al. (2014) ranged from 3.3 to 5 minutes with powdering times of 55 or 57 seconds. Anderson et al. (2017) collected eight sequential powdering events over the course of 48 minutes, at approximately 6-minute intervals per application event; powdering times ranged from 13 to 47 seconds. There was substantial disagreement between these two studies using the NIOSH 7402 method. It is important to note that detection of measurable fibers via TEM analysis does not necessarily positively identify the presence of asbestiform mineral fibers. For example, as the NIOSH 7402 method explains, the presence of minerals chemically similar to asbestos (e.g., pyroxenes, massive amphiboles, and talc fibers) "may warrant the use of more powerful diffraction pattern analysis before positive identification can be made" because "high concentrations of background dust," such as talc, can "interfere with fiber identification" (National Institute for Occupational Safety and Health, 1994, p. 1, 5). Therefore, in an effort to eliminate any potential issues over the limitations of the analytical methods used to identify asbestos fibers, only the PCM data presented in Gordon et al. (2014) and Anderson et al. (2017) were used to calculate a hypothetical cumulative exposure concentration. These values were also then directly comparable to the Dement PCM data and the converted dust measurements. The cumulative asbestos exposure estimates for daily lifetime talc use calculated using PCM data from the Gordon et al. (2014) study ranged from 0.001 to 0.01 f/cc-yr (1.2×10^{-3} to 9.6×10^{-3} f/cc-yr). These estimates represent talc application using a shaker method and puff applicator method, respectively. The cumulative asbestos exposure estimate calculated using PCM data from Anderson et al. (2017) was 0.00007 f/cc-yr (6.6×10^{-5} f/cc-yr).

3.4. Risk Characterization

3.4.1. Regulatory Risk Assessment

The noncontinuous or less-than-lifetime IUR (for lung cancer and mesothelioma combined) was used to characterize risk from all scenarios evaluated in this analysis due to the intermittent or episodic nature of typical use scenarios involving cosmetic talcum powder products. The exposure duration selected for infant and adult exposure during infant powdering scenarios (Scenarios 1 and 2) was two years with an age at start of exposure of 0 years for the infant and 18 years for the adult, resulting in IURs of 0.020 and 0.010, respectively. A less-than-lifetime IUR of 0.22 f/cc^{-1} was calculated for the adult use over a 70-year lifetime (with an age at start of exposure of 0 years; Scenarios 3 and 4) (U.S. Environmental Protection Agency, 2008). The cancer risk estimates calculated for the two infant diapering scenarios (Scenarios 1 and 2: infant and adult exposure over the course of two

years for one infant) resulted in 10^{-8} to 10^{-6} added theoretical risk. The cancer risk estimates calculated for the consumer application of facial talcum powder (Scenario 3: adult exposure over the course of 70 years) resulted in less than 10^{-5} added theoretical risk. Similarly, the cancer risk estimates calculated for consumer application of body powder (Scenario 4: adult exposure over the course of 70 years) resulted in less than 10^{-4} added theoretical risk.

3.4.2. Benchmark Analysis to Lifetime Cumulative Ambient Exposures and Risk

Estimated cumulative asbestos exposures for typical consumer use of talcum powder were compared with the estimated cumulative lifetime exposures associated with exposure to background levels of asbestos in ambient air for reference (Table III). This comparison is consistent with the FDA's risk assessment, in which it also compared its results to background asbestos exposures.

For the purpose of benchmark comparison for human health risk assessment, it is important to consider the level of ambient or background exposure to which persons may actually be exposed based on human activity patterns. The U.K. Committee on Carcinogenicity states that ambient conditions are "the normal conditions surrounding a person," which includes both indoor and outdoor air (Committee on Carcinogenicity, 2013, p. 3). According to the EPA's 2011 *Exposure Factors Handbook*, an individual spends on average 20 hours indoors (range = 19–24 hours) per day and four hours outdoors (range = 0–5 hours) per day (U.S. Environmental Protection Agency, 2011). A number of peer-reviewed and government studies have reported measurements of airborne fiber and asbestos-specific fiber concentrations found in both the indoor and outdoor ambient air in the United States.

Measurements of asbestos-specific ambient fiber concentrations of at least 5 μm in length or longer are the most relevant to human health risk assessment. Abelmann et al. (2015) conducted a review and assessment of outdoor ambient airborne asbestos concentrations in the absence of known asbestos emission sources from the 1960s to the 2000s, and reported a fiber concentration range from nondetectable to 0.050 f/cc; this analysis included PCM measurements, which do not distinguish asbestos fibers from other fibers. Additionally, they reported an asbestos-specific concentration ranging from nondetectable to 0.0047 f/cc (not including mass-based data) (Abelmann et al., 2015). Nolan and Langer (2001) and Lee and Van Orden (2008) collectively reported measured asbestos-specific airborne concentration measurements for fibers at least 5 μm in length or longer in the outdoor ambient air to be in the range of nondetectable to 0.0047 f/cc (Lee & Van Orden, 2008; Nolan & Langer, 2001). For indoor ambient concentrations of asbestos fibers at least 5 μm in length or longer with no disturbance of known asbestos-containing materials, Nolan and Langer (2001) and Lee and Van Orden (2008) reported measurements ranging from nondetectable to 0.0057 f/cc (Lee & Van Orden, 2008; Nolan & Langer, 2001). The ATSDR stated in its 2001 *Toxicological Profile for Asbestos* that the estimated range of indoor ambient concentrations for asbestos is 0.00003–0.006 f/cc (Agency for Toxic Substances and Disease Registry, 2001b). It has also been noted that historical ambient concentrations may have been higher (Abelmann et al., 2015; Agency for Toxic Substances and Disease Registry, 2001b). Studies have reported measurable concentrations of both chrysotile and amphibole fibers in air, with chrysotile fibers more commonly detected. The fiber types reported include chrysotile, tremolite, actinolite, amosite, and anthophyllite (Baxter, Ziskind, & Shokes, 1983a, 1983b; Cal/EPA Air Resources Board, 2015; Lee & Van Orden, 2008; Lee, Van Orden, Corn, & Crump, 1992). For the purposes of this analysis, a lower- and upper-bound cumulative ambient asbestos exposure potential for the United States was calculated using the range of measured asbestos-specific airborne concentrations for both indoor and outdoor ambient exposures and the number of hours per day, on average, that a person spends indoors and outdoors (Agency for Toxic Substances and Disease Registry, 2001b; Lee & Van Orden, 2008; Nolan & Langer, 2001; U.S. Environmental Protection Agency, 2011). The lifetime ambient cumulative exposure using this approach ranged from approximately 0.002 to 0.4 f/cc-year over a 70-year lifetime (8,760 hours per year). This range is consistent with the range of cumulative lifetime indoor ambient asbestos exposures reported by the U.S. ATSDR (Agency for Toxic Substances and Disease Registry, 2001b).

The cumulative exposure estimates presented in Table II for all available studies demonstrate that cumulative exposures to asbestos associated with consumer use of cosmetic talc on an infant over

Table III. Summary of Calculated Cumulative Exposures for Each Scenario with Comparison to Benchmarks

Scenario	Age Range of Exposure	Cumulative Exposure (f/cc-yr)
Scenario 1: Infant talc exposure—diapering: average	0–2	0.00003
Scenario 2: Adult talc exposure—diapering: average	18–20	0.00002
Scenario 3: Adult talc exposure—face powdering: average	0–70	0.001
Scenario 4: Adult talc exposure—body powdering: average	0–70	0.003
Predicted scenario using current ACGIH TLV for talc[a]	0–70	0.007
Predicted scenario using current OSHA PEL for talc[a]	0–70	0.01
Ambient air (indoor + outdoor)—lower bound[b]	0–70	0.002
Ambient air (indoor + outdoor)—upper bound[b]	0–70	0.4
Current OSHA PEL for asbestos: occupational exposure[c]	18–63	1.1

[a]For the predicted scenario, the 0.1% asbestos factor from FDA was applied to exposure at the OSHA PEL for talc (20 mppcf) as well as the ACGIH TLV for talc (2 mg/m^3) after conversion to f/cc. An exposure duration of six minutes and daily exposure frequency of one use per day was used.

[b]Cumulative ambient exposure calculated over period of 70 years using the following equation: cumulative ambient asbestos exposure = ([indoor airborne concentration (f/cc) × 20 hours/day + outdoor airborne concentration (f/cc) × 4 hours/day] / 24 [hours/day]) × 70 years. Indoor ambient airborne concentration ranged from 0.00003 f/cc to 0.006 f/cc; outdoor ambient airborne concentration ranged from 0.00003 f/cc to 0.0047 f/cc (Agency for Toxic Substances and Disease Registry, 2001b; Lee & Van Orden, 2008; Nolan & Langer, 2001).

[c]Cumulative occupational exposure to asbestos at the OSHA PEL was expressed on an environmental year basis as 0.1 f/cc × ([2,080 hours/year] / [8,760 hour/year]) × 45 years, or 1.1 f/cc-year.

a two-year period and on an adult over a 70-year lifetime fall well within or below the range of lifetime cumulative ambient asbestos exposures reported for the general U.S. population (Table III). Further, the average theoretical risk estimates calculated for lifetime asbestos-related cancer risk for all scenarios evaluated were within or below the comparable estimates for ambient asbestos exposure.

3.4.3. Comparison to the OSHA PEL for Talc

Zazenski et al. (1995) calculated eight-hour TWAs for the airborne talc dust concentration data reported in Russell et al. (1979) and Aylott et al. (1979). We conducted a similar analysis in order to make a comparison between nonoccupational airborne dust concentrations associated with the four scenarios of talcum powder application and the current OSHA PEL for talc. The maximum eight-hour TWA from all scenarios was 0.12 mppcf (Table IV). The calculated eight-hour TWAs reported in Table IV were up to several orders of magnitude below regulatory and recommended occupational limits for talc. In addition, the calculated eight-hour talc dust TWAs presented here are orders of magnitude below the dust exposures experienced by talc miners and millers (Boundy, Gold, Martin, Burgess, & Dement, 1979; Coggiola et al., 2003; Gamble, Greife, & Hancock, 1982; Rubino, Scansetti, Piolatto, & Romano, 1976). These results further demonstrate that the intensity of exposure as well as the frequency and duration of exposure associated with consumer application are much lower than occupational exposures experienced by miners and millers of talc.

4. DISCUSSION

In this study, we presented a comprehensive risk assessment that evaluated the potential for asbestos exposure and human health risk using the updated EPA nonoccupational regulatory approach associated with the use of consumer talcum powder products. The analysis also expanded on the regulatory exposure and risk assessment for consumer use of cosmetic talcum powder conducted by the FDA in 1985. All relevant publicly available measured exposure data were considered in order to provide a contemporary comparison to the original risk assessment. In addition to the assessment of exposure and risk during the powdering of an infant over a period of two years, as originally evaluated by the FDA, the current analysis also assessed exposure potential associated with three additional cosmetic talc use scenarios.

4.1. Cumulative Exposure Assessment

The results of this assessment provide cumulative asbestos exposure potential estimates for both the infant and adult powdering scenarios. The upper-bound estimated cumulative exposure for a

Table IV. Infant and Adult Eight-Hour TWA Estimates Associated with Four Consumer Application Scenarios

Application Description	Airborne Dust Concentration (mppcf)[a]	Eight-Hour TWA (mppcf)[b]	Reference
Scenario 1: Infant exposure—diapering			
Application of powder in "normal way," container with sprinkler closure	1.4	0.073	Aylott et al., 1979
Application of powder around arm pit area	0.15	0.0077	Moon et al., 2011
Application of powder around diaper area, 14 oz. twist-top canister	1.3	0.0091	Russell et al., 1979
Scenario 2: Adult exposure—diapering			
Application of powder ranging from diaper area to full infant body	0.14	0.0018	Hildick-Smith, 1976
Application of powder around arm pit area	0.035	0.0018	Moon et al., 2011
Scenario 3: Adult exposure—face powdering			
Application of loose face powder, puff applicator	3.2	0.033	Aylott et al., 1979
Scenario 4: Adult exposure—body powdering			
Application of powder in a typical fashion	9.7	0.12	Anderson et al., 2017
Application of powder in "normal way," container with sprinkler closure	7.5	0.078	Aylott et al., 1979
Application of powder in a "normal manner," twist-top container	14	0.050	Russell et al., 1979
Current OSHA PEL for talc	-	20	National Institute for Occupational Safety and Health, 1988

[a]Airborne dust data are presented in Table I, only studies that reported total or respirable dust were considered in this analysis. Dust concentrations in mg/m^3 were converted to mppcf using a conversion factor of 1 mppcf: 0.15 mg/m^3 (National Institute for Occupational Safety and Health, 1988).

[b]Eight-hour time weighted average (TWA) was calculated using the following equation: eight-hour TWA = concentration (mppcf) × exposure duration/day (minutes) / 480 minutes/day. Where exposure duration per day is calculated using the following equation: talc use duration × frequency of use/day; duration and frequency parameters are provided in Table II.

two-year period was 0.00008 f/cc-yr (8.4×10^{-5} f/cc-yr) for the infant's exposure while being powdered and 0.00004 f/cc-yr (3.8×10^{-5} f/cc-yr) for an adult's exposure while powdering an infant. It should be noted that these upper-bound estimates, which were calculated based on the studies of Aylott et al. (1979) and Dement et al. (1972), may not be indicative of actual exposures, particularly once more clear specifications with regard to the measurement of asbestiform fibers in talc were established (Cosmetic, Toiletry, and Fragrance Association, 1990). The upper-bound estimated lifetime cumulative exposure potential for adult use of both face and body powder were 0.001 f/cc-yr (1.3×10^{-3} f/cc-yr) and 0.01 f/cc-yr (9.6×10^{-3} f/cc-yr), respectively.

4.1.1. Effect of Measured Versus Estimated Fiber Concentrations on Cosmetic Talc Cumulative Exposure Potential

In this assessment, the PCM metric was used as a standard for comparison across all studies with measured data. Consistent with the FDA, we applied a 0.1% factor to the airborne fiber concentration data (both measured and estimated using the 1.72 f/cc to 1 mppcf conversion factor) in order to estimate potential cumulative asbestos exposures associated with the historic use of certain talcum powder products. There is uncertainty with the use of any adjustment factor. However, as outlined in the 2017 National Academies of Science report "Using 21st Century Science to Improve Risk-Related Evaluations," the strength of agreement between exposure studies is an important consideration when selecting appropriate exposure data (National Academy of Sciences, 2017, p. 29). This report notes that "confidence in any exposure assessment is increased when there is concordance, consistency, or agreement between multiple methods of exposure assessment" (National Academy of Sciences, 2017, p. 30). Specifically, it is noted that there is a higher level of confidence in the results of an exposure assessment when there is a convergence of predicted, measured, and surrogate data (National Academy of

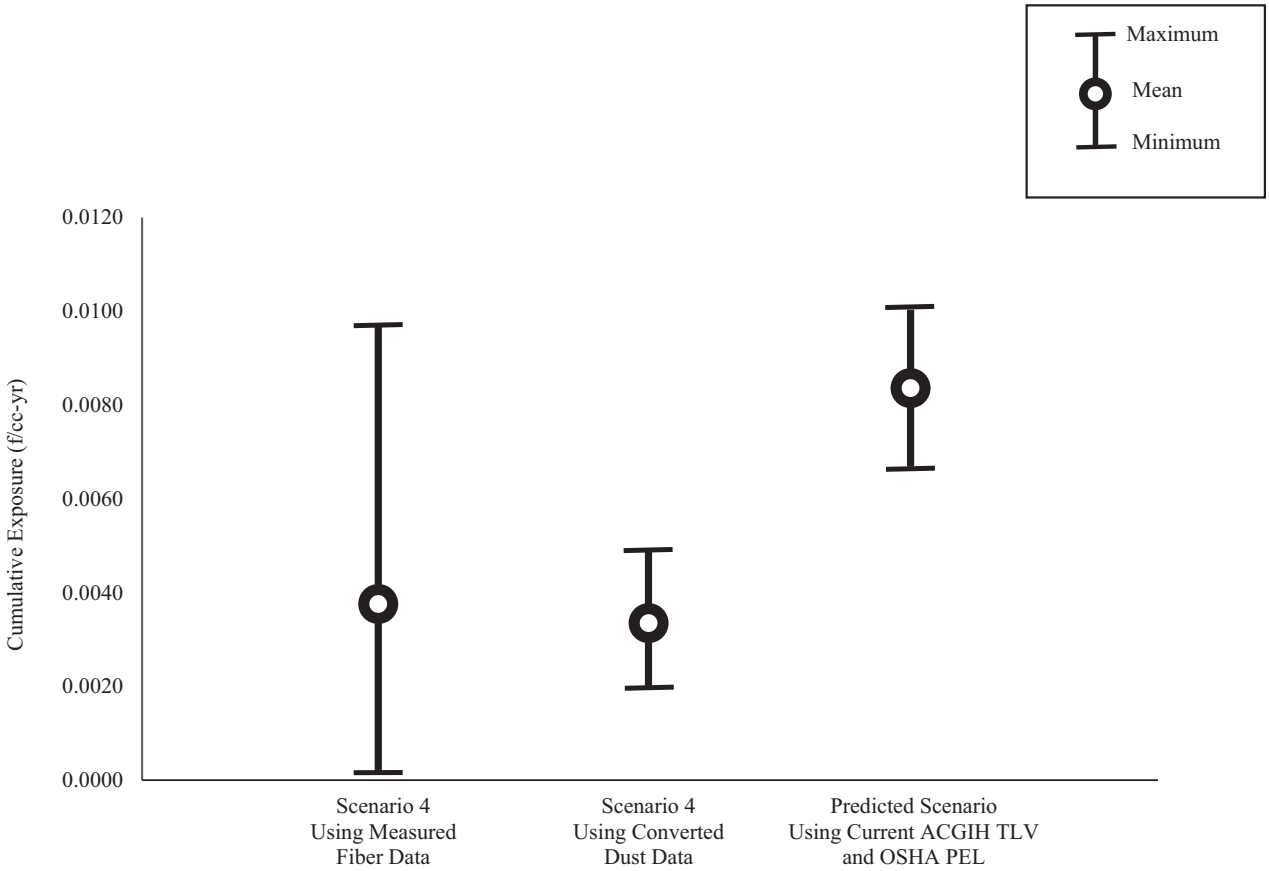

Fig. 2. Comparison of estimated cumulative exposure using measured fiber exposure data (reported PCM data) from Scenario 4, converted dust exposure data from Scenario 4 (using the 1.72 f/cc to 1 mppcf conversion factor), and predicted exposure using the OSHA PEL limiting model with the OSHA PEL and ACGIH TLV for talc.

Sciences, 2017). For comparison in the current analysis, cumulative exposure estimates for the adult body powder use scenario (Scenario 4) were calculated as previously described using measured fiber exposure data (reported PCM data), converted dust exposure data (using the 1.72 f/cc to 1 mppcf conversion factor), and predicted exposure data. The predicted exposure data were calculated using the OSHA PEL limiting model with the OSHA PEL and ACGIH TLV for talc as benchmarks (Table III, Fig. 2) (U.S. Environmental Protection Agency, 2013). For this purpose, the limiting model was used to bound the upper plausible limit for airborne talc dust in the scenarios evaluated (U.S. Environmental Protection Agency, 1988). This model assumes that exposure levels are likely to be limited by established occupational exposure limits. For the predicted scenario, the 0.1% asbestos factor was applied to airborne exposure at the OSHA PEL for talc (20 mppcf; approximately 3 mg/m^3) as well as the ACGIH TLV for talc (2 mg/m^3). An exposure duration (E_T) of 6 minutes (maximum exposure time used in this analysis) was used, resulting in a maximum predicted cumulative exposure concentration of 0.01 f/cc-yr (1.0×10^{-2} f/cc-yr) and 0.007 f/cc-yr (6.7×10^{-3} f/cc-yr), respectively. The convergence between the presented cumulative exposure assessment calculations in this analysis utilizing identified measured fiber data, converted dust data, and a predicted upper-bound exposure scenario is shown in Fig. 2. It should be noted that if we had used either the PCME values reported in the literature (instead of PCM values) or the 6 f/cc to 1 mppcf instead of the 1.72 f/cc to 1 mppcf conversion factor, the average theoretical cancer risk would still have been below the maximum calculated risk associated with lifetime ambient asbestos exposures to the general U.S. population (Anderson et al., 2017; Gordon et al., 2014).

4.1.2. Effect of Particle and Fiber Settling on Cosmetic Talc Cumulative Exposure Potential

A critical consideration of cosmetic talc exposure potential is the likelihood of fibers present in talc to be removed from the air or agglomerate, reducing the possibility that individual, measurable fibers can be found in the air and therefore be available for inhalation. For this reason, it is necessary to incorporate a factor to account for the relationship between fibers and other particles in air (i.e., 1.72 f/cc to 1 mppcf or 6 f/cc to 1 mppcf), as noted in our analysis, and as used by U.S. regulatory agencies (Occupational Safety and Health Administration, 1983; U.S. Environmental Protection Agency, 1986a). The interspersion of any asbestiform fibers in an airborne cloud, particularly of much larger and heavier talc particles, is likely to have a substantial effect on the rate of removal of the asbestos fibers from the air. Consistent with the effects associated with these differences in physical characteristics, according to the airborne talc measurement data specifically, Dement et al. (1972) noted that fiber levels were highest in the first 30 seconds of the talc application activity "and dropped off sharply during the rest of the diaper change" (p. 5). Hildick-Smith (1976) also reported a substantial reduction in the airborne concentration from talc dust after application. During a 10-second talc application event, the total median airborne dust concentration was 0.243 mppcf; the median airborne concentration decreased to 0.124 mppcf after a 65-second dust-settling period. Similarly, in performing an initial risk assessment analysis for the FDA, Taylor (1984) also recognized the substantial reduction in exposure potential associated with fiber settling after short time periods during the use of talc and incorporated this reduction into her risk assessment recommendations to the FDA. In our analysis, the exposure time (E_T), when reported, was set equal to the sampling time with the exception of one study, where multiple uses occurred within an extended sampling period (Anderson et al., 2017). Further, with the exception of Russell et al. (1979), in which only powdering time was reported, the sampling times accounted for a post-application period (end of powder application to end of sample collection), which ranged from 65 to 347 seconds across the studies (Anderson et al., 2017; Aylott et al., 1979; Dement et al., 1972; Gordon et al., 2014; Hildick-Smith, 1976; Moon et al., 2011; Russell et al., 1979). This range was longer than the 30-second fiber settling period examined and reported by Dement et al. (1972) and the 65-second dust-settling period examined and reported by Hildick-Smith (1976).

A number of physical forces may affect the settling time or removal time for fibers in air, including the settling velocity, impaction on other bodies in the air, centrifugation, agglomeration/coagulation, Brownian motion, and diffusion (Drinker & Hatch, 1954; Hinds, 1999a; Reist, 1984). Cosmetic talc particles often range in size from less than 37 μm (face powders) to less than 74 μm (body powders) in diameter compared with asbestos fibers, which are often less than 10 μm in length and less than 1 μm in width (Zazenski et al., 1995). The regulatory definition of an asbestos fiber sets the maximum diameter at 3 μm (Occupational Safety and Health Administration, 1986). Large particles, such as cosmetic talc, can act as a collection medium for small particles such as asbestiform fibers (Hinds, 1999b). This is due, in part, to agglomeration between the particles. As a number of researchers have shown, van der Waals, electrostatic, and surface tension interactions present on the particulate surface of dissimilar-sized and nonspherical particles may result in substantial particle-to-particle agglomeration, thereby increasing effective mass, diameter, and settling velocity (Corn & Stein, 1966; Esmen, 1996; Hinds, 1999b; Reist, 1984; Zazenski et al., 1995).

Sufficiently high relative humidity levels may also affect airborne particle or fiber concentrations. In their 1979 study of airborne talc, Aylott et al. (1979) noted that "at a high relative humidity (>90%) a noticeably smaller quantity of respirable dust … was collected" (p. 184). Other researchers have also found that relative humidity levels above an ambient level in air can result in the increasing adhesion of dust to surfaces or to each other (Corn & Stein, 1965; Walton, 2008; Zimon & Corn, 1969). Elevated humidity levels during talc application, such as may be experienced in a small bathroom after showering, could, therefore, substantially reduce the available respirable dust particles in the air.

According to the available evidence, the basic morphological (i.e., platy vs. fibrous) and physical (i.e., dimension) differences between talc and asbestos fibers would likely impact the amount of surface contact between a fiber and a surface, which could, in turn, affect the adhesive attraction and rate of removal from air. The adhesion forces may also increase with higher than ambient relative humidity levels. All these factors should be considered when

estimating the potential for airborne exposure to fibers potentially found in cosmetic talc.

4.1.3. Airborne Fiber Concentrations and the Association with Bulk Concentrations

As discussed above, particle physics indicate that the raw number of fibers in a bulk material with large particle sizes, such as talc, are very unlikely to each be discreetly measurable in the air. Consistent with the FDA, we applied a 0.1% asbestos factor to measured airborne dust and fiber concentrations to estimate cumulative asbestos exposure potential associated with the historic use of certain talcum powder products (Brown, 1985a). Measured data reported in the literature for asbestos are consistent with the use of the conversion factors noted in this analysis to determine the estimated proportional airborne fiber concentrations associated with a known asbestos concentration in a bulk material. For example, Addison, Davies, Robertson, and Willey (1988) measured the corresponding airborne particulate and fiber concentrations when soils containing 0.001%, 0.01%, 0.1%, and 1% asbestos were made airborne. The results of this analysis showed a general trend of increasing airborne asbestos concentrations with increasing bulk content of asbestos, that is, a higher bulk asbestos content in the soil resulted in higher airborne fiber concentrations. It should be noted that this study was conducted in a glovebox, which is not representative of actual human exposures, and may overestimate airborne fiber concentrations. Despite the limited comparability of this study to the cosmetic use of talc, the normalized ratio of f/cc to mg/m^3 values considered in our analysis was consistent with the measured data collected by Addison et al. (1988) for soils containing 0.1% asbestos, demonstrating further evidence supporting the approach that we used.

4.2. Risk Characterization

There are several published approaches for evaluating the risk of disease associated with asbestos, including the OSHA risk assessment model, the EPA model, the Hodgson and Darnton model, and the Berman and Crump model (Berman & Crump, 2003, 2008a, 2008b; Hodgson & Darnton, 2000; Occupational Safety and Health Administration, 1983; U.S. Environmental Protection Agency, 1986a, 1988, 2008). While these models apply different methods to estimate asbestos-related cancer risk, all rely on historical epidemiologic literature of various heavily asbestos-exposed cohorts in occupational scenarios, which can lead to inherent challenges and uncertainties when attempting to extrapolate down in order to estimate low-dose cancer risks. The use of the linear low-dose extrapolation model approach for carcinogen risk assessment by the EPA follows a "long-standing science policy position" that such a model is unlikely to underestimate the risk associated with exposure to carcinogens when the mechanism of action is unknown, such as for asbestos (U.S. Environmental Protection Agency, 2005, pp. 1–19). The mesothelioma potency factors derived in these regulatory risk assessment models were based on cohorts exposed to cumulative asbestos doses of 52–500 f/cc-yr or more of mixed or amphibole fibers. Further, the EPA has acknowledged that linear extrapolation models do not necessarily give a realistic prediction of risk and that the "true value of the risk is unknown, and may be as low as zero" (U.S. Environmental Protection Agency, 1986b, p. 13; 2005). Despite the use of factors designed to overestimate rather than underestimate the theoretical risk, particularly at cumulative exposure levels consistent with background population exposures to asbestos, the EPA's regulatory asbestos risk assessment approach was used in this study as an updated comparison to the original 1985 FDA cosmetic talc risk assessment approach. A benefit of this model for the purposes of this assessment is that it follows the current U.S regulatory approach for nonoccupational asbestos risk assessment. The use of the EPA's updated linear no-threshold model for asbestos risk assessment also provided a relatively simple method by which to compare the various regulatory theoretical risk estimates associated with consumer use of cosmetic talcum powder to each other as well as to other benchmarks. One of the factors used in the EPA model is the asbestos IUR, which is based on epidemiological studies that included occupational exposure to chrysotile, amosite, or mixed composition of amosite, chrysotile, and/or crocidolite (U.S. Environmental Protection Agency, 1988). More recent analyses support that the IUR originally identified by the EPA is inclusive of both chrysotile and amphibole fiber types (U.S. Environmental Protection Agency, 2014).

4.2.1. Comparison to the 1985 FDA Risk Assessment

In its 1985 risk assessment, the FDA performed a comparative human health risk assessment using four different methods to calculate the added

lifetime cancer risk associated with theoretical upper-bound quantities of asbestos in talc of up to 0.1% (Brown, 1985a, 1985b). The committee assumed 43.8 minutes/week of talc application for 52 weeks per year, and estimated that for this scenario, babies would inhale no more than 6.5×10^3 asbestiform fibers per year (4.95 talc fibers/cc $\times$ 1000 cc/1 $\times$ 0.58 l/min breathing rate $\times$ 43.8 minutes per week powdering $\times$ 52 weeks/year $\times$ 0.1% asbestos in talc). The FDA noted that all four risk assessment methods it considered returned consistent results, and therefore it recommended using the simplest method, or Method 1, for consumer asbestos in talc risk calculations (Brown, 1985b). However, ultimately Method 4, which was based on a nonincidental analysis and first-stage effect in a generalized multistage process, was the most consistent with the current EPA asbestos risk assessment methodology. The EPA regulatory asbestos risk assessment approach, when initially published in 1986, was described as an absolute risk model in which "the incidence is independent of the age at first exposure and increases according to a power of time from onset of exposure" (U.S. Environmental Protection Agency, 1986a, p. 82). According to the FDA's risk assessment, the measure of mesothelioma risk per year (K_m) value calculated using its model was 1.5×10^{-8}, compared with a mean K_m value of 1×10^{-8} reported by the EPA, demonstrating a level of consistency between the two model approaches (U.S. Environmental Protection Agency, 1986b, 2008). The risk values calculated by the FDA for the two-year infant scenario were between 0.5×10^{-8} and 1.5×10^{-8}, depending upon which risk assessment method was selected. Overall, the FDA noted that all four methods reported extremely consistent results, and concluded that the risk for this scenario "was less than 10^{-8} lifetime risk and quite possibly orders of magnitude less" (Brown, 1985a, p. 1). Consistent with the FDA analysis, the approach used in this analysis demonstrated that the risk values for both the infant and the adult exposures during diapering activities (assuming a 0.1% airborne asbestos content factor) were less than 10^{-6} using the current EPA regulatory asbestos risk assessment methodology. Additionally, we found that risk values for the adult face and body powdering scenarios ranged from 10^{-6} to less than 10^{-4}, demonstrating that estimated adult exposures over a 70-year lifetime likely result in a greater theoretical risk compared to the infant diapering scenarios. Ultimately, however, from a practical standpoint, it is important to note that all scenarios evaluated resulted in a theoretical risk that was within or below the range of EPA's target risk levels. According to EPA guidance, it is "common practice" to use a target risk level of 10^{-4} for scenarios involving short-term, intermittent exposures (U.S. Environmental Protection Agency, 2008, p. 28). Similarly, NIOSH uses a target risk level of 10^{-4} for occupational risk assessment purposes (National Institute for Occupational Safety and Health, 2016).

4.2.2. Lifetime Cumulative Ambient Exposures and Risk

The comparison of estimated cumulative asbestos exposures for typical consumer use of cosmetic talcum powder and estimated cumulative lifetime exposures associated with ambient air (Table III) was consistent with the FDA's assessment in which it also compared its results to lifetime ambient asbestos exposures. The same conclusion can be drawn from our analysis, that consumer use of cosmetic talcum powder products results in a cumulative exposure to asbestos that is within or below the range of cumulative ambient asbestos exposures in the United States.

Collectively, published epidemiology studies have indicated that exposures to ambient asbestos concentrations of any fiber type are not associated with a significantly increased incidence of asbestos-related disease (Antman, Schiff, & Pass, 1997; McDonald, 1985; McDonald & McDonald, 1994; Moolgavkar, Meza, & Turim, 2009; Moore, Parker, & Wiggins, 2008; Price & Ware, 2004, 2005; Teta, Mink, Lau, Sceurman, & Foster, 2008). For example, Price and Ware (2004) reported that, despite a likely increase in women's environmental asbestos exposures since the 1930s with the increasing use of asbestos in the United States, "the mesothelioma risk for women has not increased" (p. 111). Further, the authors stated that "environmental exposure levels, although increasing, have not triggered a risk response in women. Therefore, those exposure levels must have been below a threshold for mesothelioma" (Price & Ware, 2004, p. 111). Similarly, Glynn et al. (2018) found that there was no increase in incidence rates of pleural mesothelioma among females in urban versus rural areas in the United States between 1973 and 2012, despite measured differences of up to 10-fold or more in ambient airborne asbestos concentrations between these different geographical areas (Glynn,

Keeton, Gaffney, & Sahmel, 2018). According to the authors, these results suggested that ambient exposures to asbestos over a wide range of background concentrations have not significantly affected the incidence of pleural mesothelioma in the United States over the past 40 years, and that each incremental fiber exposure cannot be assumed to contribute to disease risk at similarly low concentrations. Further, the consistency of background mesothelioma rates over time despite substantial fluctuations in the rate of cosmetic talc use over time do not support any association between cosmetic talc use specifically and mesothelioma rates (National Cancer Institute, 2018; U.S. Geological Survey, 2016). OSHA has also stated that, based on widely varying background levels of asbestos and the technological feasibility of measuring levels below 0.1 f/cc in the workplace, "the Agency cannot make the general statement that any exposure above ambient background levels presents a significant risk" (Jeffress, 1999, p. 2). Moreover, the EPA stated that the "extrapolation of risks of asbestos cancers from occupational circumstances can be made, although numerical estimates in a specific exposure circumstance have a large (approximately tenfold) uncertainty" and acknowledged that, "because of this uncertainty, calculations of unit risk values for asbestos at the low concentrations measured in the environment must be viewed with caution" when using the EPA asbestos risk assessment model (U.S. Environmental Protection Agency, 1986a, p. 2).

5. CONCLUSIONS

This assessment characterized the potential for asbestos exposure that may have occurred during the use of cosmetic talc products under the worst-case assumptions determined by the FDA regarding the potential asbestos content in cosmetic talc. In this analysis, we expanded on the original FDA risk assessment and evaluated the potential cumulative asbestos exposure and risk for four consumer talc use scenarios: (1) infant exposure during diapering, (2) adult exposure from infant diapering, (3) adult exposure from face powdering, and (4) adult exposure from body powdering. Our assessment focused on the careful selection of exposure factors based on the available published data to characterize potential cumulative asbestos exposures associated with typical consumer use scenarios of historical talcum powder products using the FDA's estimate of 0.1% airborne asbestos content. The estimated range of cumulative asbestos exposure potential for all scenarios ranged from 0.0000021 to 0.0096 f/cc-yr (2.1×10^{-6} to 9.6×10^{-3} f/cc-yr), which was well below the upper bound of measured cumulative ambient asbestos exposures in the United States and that corresponded to a calculated asbestos-related cancer risk that was within or below the EPA's target risk level using its linear no-threshold regulatory model for asbestos risk assessment.

Several important data gaps were addressed in this analysis, including (1) a synthesis of historical dust and fiber exposure data as well as duration and frequency of use parameters for cosmetic talc, (2) the analysis of airborne dust-to-fiber conversion factors when applied to talc, (3) the evaluation of three additional talc use scenarios for which measured data were available and that previously had not been evaluated in terms of cumulative exposure or risk potential, (4) an updated regulatory risk assessment for the use of cosmetic talc using current nonoccupational regulatory approaches, and (5) an expanded analysis and comparison to available exposure benchmarks for risk characterization purposes, including the best available data on ambient asbestos exposures to the U.S. population and equivalent cumulative exposures at regulatory asbestos exposure levels. In this analysis, we found that the risk values for the adult body powdering scenarios yielded greater theoretical risks than the infant exposures; however, all scenarios were below the EPA's target risk level for short-term intermittent exposures. Our analysis also confirmed the original finding of the FDA that the risks associated with cosmetic talc use were below the corresponding cumulative upper-bound lifetime risk of background asbestos exposures to the general population. The results also indicate that using the FDA's upper-bound assumption of asbestos content (i.e., 0.1%) in cosmetic talc products, many typical consumer use scenarios are unlikely to pose a cumulative asbestos exposure risk using conservative regulatory approaches to risk assessment.

ACKNOWLEDGMENTS

The authors of this article are employees of consulting firms that provide scientific advice to entities including governments, corporations, law firms, and various scientific/professional organizations. At the time of acceptance and publication, Barlow was employed by GZA GeoEnvironmental, Inc.; Sahmel and Banducci were employed by Insight Risk, LLC; and Burns and Unice were employed

by Cardno ChemRisk. This article was prepared and written exclusively by the authors. No outside entities provided input to the study or reviewed it prior to publication. No outside financial support was provided to any of the authors or their employers for preparing the article. Three of the authors (Burns, Barlow, and Sahmel) have served as experts in talc- and/or asbestos-related litigation. It is likely that this work will be relied upon in occupational health and exposure assessment research and litigation.

REFERENCES

Abelmann, A., Glynn, M. E., Pierce, J. S., Scott, P. K., Serrano, S., & Paustenbach, D. J. (2015). Historical ambient airborne asbestos concentrations in the United States: An analysis of published and unpublished literature (1960s–2000s). *Inhalation Toxicology*, *27*(14), 754–766.

Addison, J., Davies, L. S. T., Robertson, A., & Willey, R. J. (1988). *The release of dispersed asbestos fibres from soils.* Research Report TM/88/14. Edinburgh: Institute of Occupational Medicine.

Addison, J., & Langer, A. M. (2000). *Draft comments on the NTP draft report on carcinogens background document for talc asbestiform and non-asbestiform*. Yorkshire: John Addison Consultancy.

Addison, J., & McConnell, E. E. (2008). A review of carcinogenicity studies of asbestos and non-asbestos tremolite and other amphiboles. *Regulatory Toxicology and Pharmacology*, *52*(1 Suppl), S187–S199.

Agency for Toxic Substances and Disease Registry. (2001a). *Chemical-specific health consultation: Tremolite asbestos and other related types of asbestos*. September 22, 2005. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Agency for Toxic Substances and Disease Registry. (2001b). *Toxicological profile for asbestos.* September 2001. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

American Conference of Governmental Industrial Hygienists. (2010). Talc: TLV-TWA, 2 mg/m3, respirable particulate matter (containing no asbestos and <1% crystalline silica). In *TLV(R) chemical substances*, 7th ed. documentation. Cincinnati, OH: Author.

American Thoracic Society. (1990). Health effects of tremolite. *American Review of Respiratory Disease*, *142*(6 Pt 1), 1453–1458. (This official statement of the American Thoracic Society was adopted by the ATS Board of Directors, June 1990.)

Anderson, E. L., Sheehan, P. J., Kalmes, R. M., & Griffin, J. R. (2017). Assessment of health risk from historical use of cosmetic talcum powder. *Risk Analysis*, *37*(5), 918–929.

Antman, K. H., Schiff, P. B., & Pass, H. I. (1997). Benign and malignant mesothelioma. In V. T. DeVita, S. S. Hellman, & S. A. Rosenberg (Eds.), *Cancer: Principles & practice of oncology* (5th ed., Vol. *2*, pp. 1853–1878). Philadelphia, PA: Lippincott-Raven Publishers.

Aylott, R. I., Byrne, G. A., Middleton, J. D., & Roberts, M. E. (1979). Normal use levels of respirable cosmetic talc: Preliminary study. *International Journal of Cosmetic Science*, *1*(3), 177–186.

Baxter, D., Ziskind, R., & Shokes, R. (1983a). *Final report: Ambient asbestos concentrations in California, field number and mass concentration summaries, volume II*, Sacramento, CA: California Air Resources Board.

Baxter, D., Ziskind, R., & Shokes, R. (1983b). *Final report: Ambient asbestos concentrations in California, volume I*, Sacramento, CA: California Air Resources Board.

Berman, D. W., & Crump, K. S. (2003). *Final draft: Technical support document for a protocol to assess asbestos-related risk (EPA# 9345.4-06)*. Washington, DC: U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response.

Berman, D. W., & Crump, K. S. (2008a). A meta-analysis of asbestos-related cancer risk that addresses fiber size and mineral type. *Critical Reviews in Toxicology*, *38*(Suppl 1), 49–73.

Berman, D. W., & Crump, K. S. (2008b). Update of potency factors for asbestos-related lung cancer and mesothelioma. *Critical Reviews in Toxicology*, *38*(Suppl 1), 1–47.

Boundy, M. G., Gold, K., Martin, K. Jr., Burgess, W. A., & Dement, J. A. (1979). Occupational exposures to non-asbestiform talc in Vermont. In R. Lemen & J. M. Dement (Eds.), *Dusts and disease* (pp. 356–378). Park Forest South, IL: Pathotox Publisher.

Brown, R. (1985a). *Memo from quantitative risk assessment committee to W. Gary Flamm, Ph.D. (Director, Office of Toxicological Sciences—Food and Drug Administration), RE: Asbestos in talc*, June 6, 1985.

Brown, R. (1985b). *Memo from Robert Brown to QRAC (Quantitative Risk Assessment Committee), RE: Four methods for quantitating mesothelioma risk based on Selikoff et al. insulation workers asbestos study*. Technical support for QRAC's asbestos risk assessment, May 21, 1985.

Cal/EPA Air Resources Board. (2015, May 20). *Asbestos air monitoring: Oakridge High School, El Dorado Hills*. Retrieved from https://www.arb.ca.gov/toxics/asbestos/orhs.htm.

Campbell, W. J., Blake, R. L., Brown, L. L., Cather, E. E., & Sjoberg, J. J. (1977). *Selected silicate minerals and their asbestiform varieties: Mineralogical definitions and identification-characterization* (Information Circular 8751). Washington, DC: U.S. Department of the Interior, U.S. Bureau of Mines Report of Investigations.

Caneer, W. T. (1973). *Memo from W. T. Caneer (Colorado School of Mines Research Institute) to W. H. Ashton, RE: Meeting with Bowling Green State University Geological Staff*, June 8, 1973.

Coggiola, M., Bosio, D., Pira, E., Piolatto, P. G., La Vecchia, C., Negri, E., … Bacaloni, A. (2003). An update of a mortality study of talc miners and millers in Italy. *American Journal of Industrial Medicine*, *44*(1), 63–69.

Committee on Carcinogenicity. (2013). *Statement of the relative vulnerability of children to asbestos compared to adults* (CC/13/S1). United Kingdom: Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment, Public Health England.

Consumer Product Safety Commission. (1988). *Briefing package of the CPSC Office of the Secretary on a petition to ban play sand with non-asbestiform tremolite*. Washington, DC: U.S. Consumer Product Safety Commission.

Corn, M., & Stein, F. (1965). Re-entrainment of particles from a plane surface. *American Industrial Hygiene Association Journal*, *26*, 325–336.

Corn, M., & Stein, F. (1966). Mechanism of dust redispersion. In B. R. Fish (Ed.), *Surface contamination* (pp. 45–54). Gatlinburg, TN: Pergamon Press.

Cosmetic, Toiletry, and Fragrance Association. (1990). Talc. In J. M. Nikitakis, G. N. McEwen, & A. G. Wich (Eds.), *CTFA Compendium of cosmetic ingredient composition. Volume 1: Specifications*. Washington, D.C.: Author.

Cralley, L. J., Key, M. M., Groth, D. H., Lainhart, W. S., & Ligo, R. M. (1968). Fibrous and mineral content of cosmetic talcum products. *American Industrial Hygiene Association Journal*, *29*(4), 350–354.

Dement, J. M., Shuler, P. J., & Zumwalde, R. D. (1972). *Preliminary report: Fiber exposure during use of baby powders*. Cincinnati, OH: Environmental Investigations Branch, Division of Field Studies and Clinical Investigations, National Institute for Occupational Safety and Health.

Dement, J. M., & Zumwalde, R. D. (1979). Occupational exposures to talcs containing asbestiform minerals. In R. Lemen & J. M. Dement (Eds.), *Dusts and disease* (pp. 287–305). Park Forest South, IL: Pathotox Publishers, Inc.

Drinker, P., & Hatch, T. (1954). *Industrial dust, hygienic significance, measurement, and control* (2nd ed.). New York, NY: McGraw-Hill.

Eiermann, H. J. (1976a). *Internal memo from Heinz J. Eiermann (U.S. FDA—Director, Division of Cosmetics Technology) to Robert M. Schaffner (U.S. FDA—Associate Director for Technology), RE: Asbestos in talc*, March 18, 1976.

Eiermann, H. J. (1976b). *Memorandum of telephone conversation between John D. Klein (Reporter, Channel 7 News) and Heinz J. Eiermann, (Director, Division of Cosmetics Technology—Food and Drug Administration), RE: Asbestos in talc*, March 8, 1976.

Esmen, N. A. (1996). Adhesion and aerodynamic resuspension of fibrous particles. *Journal of Environmental Engineering*, *122*(5), 379–383.

Gamble, J. F., & Gibbs, G. W. (2008). An evaluation of the risks of lung cancer and mesothelioma from exposure to amphibole cleavage fragments. *Regulatory Toxicology and Pharmacology*, *52*(1 Suppl), S154–S186.

Gamble, J. F., Greife, A., & Hancock, J. (1982). An epidemiological-industrial hygiene study of talc workers. *Annals of Occupational Hygiene*, *26*(8), 841–859.

Glynn, M. E., Keeton, K. A., Gaffney, S. H., & Sahmel, J. (2018). Ambient asbestos fiber concentrations and long-term trends in pleural mesothelioma incidence between urban and rural areas in the United States (1973–2012). *Risk Analysis*, *38*(3), 454–471.

Gordon, R. E., Fitzgerald, S., & Millette, J. (2014). Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women. *International Journal of Occupational and Environmental Health*, *20*(4), 318–332.

Grexa, R. W., & Parmentier, C. J. (1979). Cosmetic talc properties and specifications. *Cosmetics & Toiletries*, *94*, 29–33.

Gunter, M. E., Belluso, E., & Mottana, A. (2007). Amphiboles: Environmental and health concerns. *Reviews in Mineralogy & Geochemistry*, *67*, 453–516.

Hamer, D. H., Rolle, F. R., & Schelz, J. P. (1976). Characterization of talc and associated minerals. *American Industrial Hygiene Association Journal*, *37*(5), 296–304.

Hildick-Smith, G. Y. (1976). The biology of talc. *British Journal of Industrial Medicine*, *33*(4), 217–229.

Hinds, W. C. (1999a). *Aerosol technology: Properties, behavior, and measurement of airborne particles* (2nd ed.). New York: Wiley.

Hinds, W. C. (1999b). Coagulation. In W. C. Hinds (Ed.), *Aerosol technology: Properties, behavior, and measurement of airborne particles* (2nd ed., pp. 260–277). New York: Wiley.

Hodgson, J. T., & Darnton, A. (2000). The quantitative risks of mesothelioma and lung cancer in relation to asbestos exposure. *Annals of Occupational Hygiene*, *44*(8), 565–601.

International Agency for Research on Cancer. (2010). Talc. In IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (Ed.), *IARC monographs on the evaluation of carcinogenic risks to humans. Volume 93, carbon black, titanium dioxide, and talc* (pp. 277–413). Lyon: International Agency for Research on Cancer, World Health Organization.

Jeffress, C. N. (1999, July 23). *Letter from C.N. Jeffress (Assistant Secretary, OSHA) to W.L. Dyson, RE: Clarification of OSHA's risk assessment and approach for setting the asbestos PEL.[1910.1001(c); 1926.1101(c)]*. Retrieved from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22770.

Kennedy, D. (1979). *Memo from Donald Kennedy (Commission of Food and Drugs) to Sidney M. Wolfe, M.D, and Mr. Benjamin Gordon (Public Citizen), RE: Letter from Sidney M. Wolfe and Mr. Benjamin Gordon Dated August 4, 1978, Discussing talc carcinogenesis (with attachments)*, January 11, 1979.

Krause, J. B. (1977). Mineralogical characterization of cosmetic talc products. *Journal of Toxicology and Environmental Health*, *2*(5), 1223–1226.

Lane, R. E., Barnes, J. M., Hickish, D. E., Jones, J. G., Roach, S. A., King, E. & Committee on Hygiene Standards of the British Occupational Hygiene Society. (1968). Hygiene standards for chrysotile asbestos dust. *Annals of Occupational Hygiene*, *11*(2), 47–69.

Lee, R. J., & Van Orden, D. R. (2008). Airborne asbestos in buildings. *Regulatory Toxicology and Pharmacology*, *50*(2), 218–225.

Lee, R. J., Van Orden, D. R., Corn, M., & Crump, K. S. (1992). Exposure to airborne asbestos in buildings. *Regulatory Toxicology and Pharmacology*, *16*(1), 93–107.

Lewin, S. Z. (1972). *Memo from Seymour Z. Lewin (Professor of Chemistry, New York University) to Dr. Alfred Weissler (Acting Director, Division of Colors and Cosmetics Technology, Office of Product Technology, Food and Drug Administration), RE: Lewin's final analytical results on the mineral compositions of 102 examples of standard, commercial products containing talc (with attachment)*, August 3, 1972.

Lynch, J. R., & Ayer, H. E. (1968). Measurement of asbestos exposure. *Journal of Occupational Medicine*, *10*(1), 21–24.

McDonald, J. C. (1985). Health implications of environmental exposure to asbestos. *Environmental Health Perspectives*, *62*, 319–328.

McDonald, J. C., & McDonald, A. (1994). Mesothelioma: Is there a background? In M. Jaurand & J. Bignon (Eds.), *The mesothelial cell and mesothelioma* (pp. 37–45). New York: Marcel Decker.

Moolgavkar, S. H., Meza, R., & Turim, J. (2009). Pleural and peritoneal mesotheliomas in SEER: Age effects and temporal trends, 1973–2005. *Cancer Causes and Control*, *20*(6), 935–944.

Moon, M. C., Park, J. D., Choi, B. S., Park, S. Y., Kim, D. W., Chung, Y. H., … Yu, I. J. (2011). Risk assessment of baby powder exposure through inhalation. *Toxicological Research*, *27*(3), 137–141.

Moore, A. J., Parker, R. J., & Wiggins, J. (2008). Malignant mesothelioma. *Orphanet Journal of Rare Diseases*, *3*, 34–38.

Mossman, B. T. (2008). Assessment of the pathogenic potential of asbestiform vs. nonasbestiform particulates (cleavage fragments) in in vitro (cell or organ culture) models and bioassays. *Regulatory Toxicology and Pharmacology*, *52*(1 Suppl), S200–S203.

Musser, S. (2014). *Letter from S.M. Musser (Deputy Director for Scientific Operations, Center for Food Safety and Applied Nutrition) to S.S. Epstein (Cancer Prevention Coalition), RE: Docket Nos. 94P-0420 and FDA-2008-P0309-0001/CP, April 1, 2014*. College Park, MD: U.S. Food and Drug Administration.

National Academy of Sciences, Engineering, and Medicine. (2017). *Using 21st century science to improve risk-related evaluations*. Washington, DC: National Academies Press.

National Cancer Institute. (2018. April). *SEER*Stat Database: Incidence - SEER 9 Regs Research Data, Nov 2017 Sub (1973-2015) <Katrina/Rita Population Adjustment>- Linked To County Attributes - Total U.S., 1969–2016 Counties, based on the November 2017 submission. Nov 17 Sub ed.* Retrieved from https://seer.cancer.gov.

National Institute for Occupational Safety and Health. (1988). *Talc. 1988 OSHA PEL project documentation*. Retrieved from http://www.cdc.gov/niosh/pel88/14807-96.html.

National Institute for Occupational Safety and Health. (1994). *NIOSH method 7402: Asbestos by transmission electron microscopy (TEM). NIOSH manual of analytical methods* (DHHS Publication No. 94–113). Washington, DC: Author.

National Institute for Occupational Safety and Health. (2011). *Current intelligence bulletin 62. Asbestos fibers and other elongate mineral particles: State of the science and roadmap for research (DHHS (NIOSH) Publication No. 2011–159)*. Cincinnati, OH: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

National Institute for Occupational Safety and Health. (2016). *Current intelligence bulletin: 68. NIOSH chemical carcinogen policy. December 2016 (DHHS (NIOSH) Publication No. 2017–100)*. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

Nolan, R. P., & Langer, A. M. (2001). Concentration and type of asbestos fibers in air inside buildings. In R. P. Nolan, A. M. Langer, M. Ross, F. J. Wicks, & R. F. Martin (Eds.), *The health effects of chrysotile asbestos: Contribution of science to risk-management decisions. The Canadian Mineralogist Special Publication* (Vol. *5*, pp. 39–51). Ottawa, Canada: Mineralogical Association of Canada.

Occupational Safety and Health Administration. (1983). *Occupational Safety and Health Administration's quantitative risk assessment for asbestos related cancers*. Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration.

Occupational Safety and Health Administration. (1986). 29 CFR Parts 1910 and 1926: Occupational exposure to asbestos, tremolite, anthophyllite, and actinolite; Final Rules, June 20, 1986. *Federal Register*, *51*(119), 22612–22790.

Occupational Safety and Health Administration. (1992). 29 CFR Parts 1910 and 1926: Occupational exposure to asbestos, tremolite, anthophyllite and actinolite; Final Rule, June 8, 1992. *Federal Register*, *57*(110), 24310–24331.

Occupational Safety and Health Administration. (1994). 29 CFR Parts 1910, 1915, and 1926. RIN: 1218-AB25. Occupational exposure to asbestos; Final Rule, August 10, 1994. *Federal Register*, *59*(153), 40964–41162.

Oestenstad, K., Honda, Y., Delzell, E., & Brill, I. (2002). Assessment of historical exposures to talc at a mining and milling facility. *Annals of Occupational Hygiene*, *46*(7), 587–596.

Pang, T. W. S., Schonfeld, F. A., & Nazar, M. A. (1987). The determination of tremolite asbestos in talc powder samples. *Annals of Occupational Hygiene*, *31*(2), 219–225.

Price, B., & Ware, A. (2004). Mesothelioma trends in the United States: An update based on Surveillance, Epidemiology, and End Results Program data for 1973 through 2003. *American Journal of Epidemiology*, *159*(2), 107–112.

Price, B., & Ware, A. (2005). Mesothelioma: Risk apportionment among asbestos exposure sources. *Risk Analysis*, *25*(4), 937–943.

Reist, P. C. (1984). *Introduction to aerosol science*. New York: MacMillan.

Rohl, A. N., & Langer, A. M. (1974). Identification and quantitation of asbestos in talc. *Environmental Health Perspectives*, *9*, 95–109.

Rohl, A. N., & Langer, A. M. (1979). Fibrous mineral content of consumer talc-containing products. In R. Lemen & J. M. Dement (Eds.), *Dusts and disease* (pp. 393–403). Park Forest South, IL: Pathotox Publishers.

Rohl, A. N., Langer, A. M., Selikoff, I. J., Tordini, A., Klimentidis, R., Bowes, D. R., & Skinner, D. L. (1976). Consumer talcums and powders: Mineral and chemical characterization. *Journal of Toxicology and Environmental Health*, *2*(2), 255–284.

Rubino, G. F., Scansetti, G., Piolatto, G., & Romano, C. A. (1976). Mortality study of talc miners and millers. *Journal of Occupational Medicine*, *18*, 186–193.

Russell, R. S., Merz, R. D., Sherman, W. T., & Sivertson, J. N. (1979). The determination of respirable particles in talcum powder. *Food and Cosmetics Toxicology*, *17*(2), 117–122.

Sahmel, J., Barlow, C. A., Gaffney, S., Avens, H. J., Madl, A. K., Henshaw, J., … Paustenbach, D. J. (2016). Airborne asbestos take-home exposures during handling of chrysotile-contaminated clothing following simulated full shift workplace exposures. *Journal of Exposure Science and Environmental Epidemiology*, *26*, 48–62.

Sahmel, J., Barlow, C. A., Simmons, B., Gaffney, S. H., Avens, H. J., Madl, A. K., … Paustenbach, D. J. (2014). Evaluation of take-home exposure and risk associated with the handling of clothing contaminated with chrysotile asbestos. *Risk Analysis*, *34*(8), 1448–1468.

Sahmel, J., Devlin, K., Paustenbach, D., Hollins, D., & Gaffney, S. (2010). The role of exposure reconstruction in occupational human health risk assessment: Current methods and a recommended framework. *Critical Reviews in Toxicology*, *40*(9), 799–843.

Schmitt, B. D. (2004). Toilet training your child: The basics. *Contemporary Pediatrics*, *21*(3), 120–122.

Snider, D. W., Pfeiffer, D. E., & Mancuso, J. J. (1972). Asbestos form impurities in commercial talcum powders. *Compass of Sigma Gamma Epsilon*, *49*, 65–67.

Strohmeier, B. R., Huntington, J. C., Bunker, K. L., Sanchez, M. S., Allison, K., & Lee, R. J. (2010). What is asbestos and why is it important? Challenges of defining and characterizing asbestos. *International Geology Review*, *52*(7), 801–872.

Swanson, J. W. (1986). *Memo from J.W. Swanson (Acting Associate Commissioner for Regulatory Affairs—U.S. Food and Drug Administration) to Mr. Phillippe Douillet, RE: Docket Number 1982P-404, denying a November 8, 1983, petition requesting that cosmetic talc be labeled with an asbestos warning statement (includes enclosures/talc documents)*, July 11, 1986.

Taylor, L. (1984). *FDA memo from Linda Taylor. Request for CAC evaluation of the hazard of asbestos contamination of cosmetic talc*, November 15, 1984.

Teta, M. J., Mink, P. J., Lau, E., Sceurman, B. K., & Foster, E. D. (2008). US mesothelioma patterns 1973–2002: Indicators of change and insights into background rates. *European Journal of Cancer Prevention*, *17*(6), 525–534.

U.S. Environmental Protection Agency. (1986a). *Airborne asbestos health assessment update (EPA/600/8-84/003F)*. Washington, DC: U.S. Environmental Protection Agency, Office of Health and Environmental Assessment.

U.S. Environmental Protection Agency. (1986b). *Guidelines for carcinogen risk assessment (EPA/630/R-00/004)*. Washington, DC: Risk Assessment Forum, U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency. (1988). *Asbestos (CASRN 1332-21-4), carcinogenicity assessment for lifetime exposure*. Washington, DC: Author.

U.S. Environmental Protection Agency. (1993). *Test method: Method for the determination of asbestos in bulk building materials (EPA/600/R-93/116)*. Research Triangle Park, NC: Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency. (2005). *Guidelines for carcinogen risk assessment (EPA/630/P-03/001F)*. Washington, DC: Risk Assessment Forum, U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency. (2008). *Framework for investigating asbestos-contaminated superfund sites (OSWER Directive 9200.0-68)*. Washington, DC: U.S. Environmental Protection Agency, Office of Solid Waste and

Emergency Response, Technical Review Workgroup, Asbestos Committee.

U.S. Environmental Protection Agency. (2011). *Exposure factors handbook, 2011 edition (EPA/600/R-090/052F)*. Washington, DC: National Center for Environmental Assessment, Office of Research and Development.

U.S. Environmental Protection Agency. (2013). *ChemSTEER user guide: Chemical screening tool for exposures and environmental releases*. Washington, DC: Author.

U.S. Environmental Protection Agency. (2014). *Toxicological review of Libby amphibole asbestos: In support of summary on the integrated risk information system (IRIS). December 2014 (EPA/635/R-11/002F)*. Washington, DC: Integrated Risk Information System, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency.

U.S. Food and Drug Administration. (1973). 21 CFR Parts 121, 128, 133. Asbestos particles in food and drugs. Notice of proposed rulemaking, September 28, 1973. *Federal Register*, *38*(188), 27076–27081.

U.S. Food and Drug Administration. (2018, August 21). *Talc*. Retrieved from http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm.

U.S. Geological Survey. (2016, December 19). *Bureau of Mines minerals yearbook (1932s–1993)*. U.S. Geological Survey, U.S. Department of the Interior. Retrieved from https://minerals.usgs.gov/minerals/pubs/usbmmyb.html.

Van Gosen, B. S., Lowers, H. A., Sutley, S. J., & Gent, C. A. (2004). *Using the geologic setting of talc deposits as an indicator of amphibole asbestos content* (Vol. 45n). Berlin: Springer.

Virta, R. L. (2001). *Some facts about asbestos*, Reston, VA: U.S. Geological Survey.

Vu, V. T. (1993). Regulatory approaches to reduce human health risks associated with exposures to mineral fibers. In G. D. Guthrie Jr. & B. T. Mossman (Eds.), *Health effects of mineral dusts. Volume 28: Reviews in mineralogy* (pp. 545–554). Washington, DC: Mineralogical Society of America.

Walton, O. R. (2008). Review of adhesion fundamentals for micron-scale particles. *KONA Powder and Particle Journal*, *26*, 129–141.

Wylie, A. G., & Verkouteren, J. R. (2000). Amphibole asbestos from Libby, Montana: Aspects of nomenclature. *American Mineralogist*, *85*(10), 1540–1542.

Wylie, A. G., Virta, R. L., & Russek, E. (1985). Characterizing and discriminating airborne amphibole cleavage fragments and amosite fibers: Implications for the NIOSH method. *American Industrial Hygiene Association Journal*, *46*(4), 197–201.

Zazenski, R., Ashton, W. H., Briggs, D., Chudkowski, M., Kelse, J. W., MacEachern, L., … Gettings, S. D. (1995). Talc: Occurrence, characterization, and consumer applications. *Regulatory Toxicology and Pharmacology*, *21*(2), 218–229.

Zimon, A. D., & Corn, M. (1969). *Adhesion of dust and powder*. New York: Plenum Press.