DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products

Docket No. FDA-2023-N-4225

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would impose small costs on affected firms, relative to annual revenue, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The 2023 threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits, Costs, and Transfers

The proposed rule, if finalized, would require testing of talc-containing cosmetic products using standardized testing methods for detecting and identifying asbestos that may be present as a contaminant in talc. We summarize the benefits, costs, and transfers of the proposed rule in Table 1.

The benefits of the proposed rule include potential public health benefits from fewer asbestos exposures. To the extent the proposed rule would reduce exposures to asbestos, health benefits would include fewer illnesses, such as mesothelioma, lung cancer, larynx cancer, and ovarian cancer. We lack data to quantify these public health benefits, so we instead discuss them qualitatively. Benefits would also include cost savings to manufacturers of talc-containing cosmetics from fewer recalls each year. At a 7 percent discount rate, the present value of

monetized benefits over 10 years[1] would range from $0.00 million to $10.42 million, with a primary estimate of $0.48 million. At a 3 percent discount rate, the present value of monetized benefits over 10 years would range from $0.00 million to $12.25 million, with a primary estimate of $0.56 million. Annualized monetized benefits over 10 years would range from $0.00 million to $1.39 million at a 7 percent discount rate, with a primary estimate of $0.06 million, and from $0.00 million to $1.39 million at a 3 percent discount rate, with a primary estimate of $0.06 million.

The costs of the proposed rule include monetized costs to read and understand the rule, monetized asbestos testing costs, and monetized costs of subsequent testing conducted on new batches of talc when an initial sample of talc tests positive for asbestos. We expect that talc producers, talc suppliers, and manufacturers of talc-containing cosmetics would all read and understand the rule. Also, we assume that all manufacturers of talc-containing cosmetics would rely on certificates of analysis from talc suppliers to comply with asbestos testing requirements in the proposed rule. As a result, talc suppliers would incur costs to test lots or batches of talc for asbestos, and manufacturers of talc-containing cosmetics would incur costs to maintain qualified talc-suppliers. At a 7 percent discount rate, the present value of monetized costs over 10 years would range from $9.72 million to $50.97 million, with a primary estimate of $26.58 million. At a 3 percent discount rate, the present value of monetized costs over 10 years would range from $11.41 million to $59.85 million, with a primary estimate of $31.20 million. Annualized monetized costs over 10 years would range from $1.29 million to $6.78 million at a 7 percent discount rate, with a primary estimate of $3.54 million, and from $1.30 million to $6.81 million at a 3 percent discount rate, with a primary estimate of $3.55 million.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2023 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$0.06	$0.00	$1.39	2023	7%	10 years	
		$0.06	$0.00	$1.39	2023	3%	10 years	
	Annualized Quantified				2023	7%		
					2023	3%		
	Qualitative	Benefits from reduced consumer exposure to asbestos.						
Costs	Annualized Monetized ($m/year)	$3.54	$1.29	$6.78	2023	7%		
		$3.55	$1.30	$6.78	2023	3%		
	Annualized Quantified				2023	7%		
						3%		
	Qualitative							

[1] From the Office of Management and Budget's Circular A-4, the "ending point for your analysis should be far enough in the future to encompass, to the extent feasible, all the important benefits and costs likely to result from all regulatory alternatives being assessed." We estimate that this proposed rule would have one-time costs immediately following the publication of the rule, then recurring benefits and costs following the effective date of the proposed rule. We therefore choose a 10-year time horizon to encompass all important benefits and costs.

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Transfers	Federal Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local, or Tribal Government: None Small Business: Not significant Wages: None Growth: None							

II. Preliminary Economic Analysis of Impacts

A. Background

1. Talc in Cosmetic Products

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) requires that manufacturers comply with regulations that FDA will promulgate to require testing of talc-containing cosmetic products using standardized methods for detecting and identifying asbestos that may be present as a contaminant in talc.

The Federal Food Drug and Cosmetics Act (FD&C) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body… for cleansing, beautifying, promoting attractiveness, or altering the appearance."[2] This definition includes skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and components of cosmetic products, but excludes soap.

Talc is a naturally occurring mineral, mined from the earth, and composed of magnesium, silicon, oxygen, and hydrogen. Talc has many uses in cosmetics. For example, cosmetic manufacturers use talc as an ingredient to absorb moisture, to prevent caking, to make facial makeup opaque, or to improve the feel of a product. In Table 27 in the Appendix, we present the categories of cosmetic products that contain talc as an ingredient. Product categories include, among others, facial cosmetics, like face powders and blushers, and body powders, like baby powder.

2. Asbestos in Talc

"Asbestos" refers to a unique fibrous morphology that occurs when minerals crystallize. Particles of such minerals are hazardous when inhaled or ingested.

[2] FD&C Act Section 201(i)

Asbestos is a known human carcinogen (Ref. 1). The International Agency for Research on Cancer concluded in 2009 that there is sufficient evidence that exposure to asbestos, primarily through inhalation, causes mesothelioma and cancers of the lung, larynx, and ovaries (Ref. 2). They also concluded that there is limited evidence that exposure to asbestos causes cancers of the colorectum, pharynx, and stomach. These findings were not specific to cosmetic products use. However, a study by Gordon et al. (2014) found airborne asbestos in the vicinity of the user during simulated use of a talc-containing cosmetic product (Ref. 3).

Talc is mined as a naturally occurring hydrous magnesium silicate and may contain asbestos fibers from serpentine or amphibole minerals present in proximity to talc deposits. Furthermore, any asbestos present in talc ore can be difficult to remove during processing to manufacture talc for use in cosmetics. To avoid contamination, manufacturers may test cosmetic talc (that is, talc used as a cosmetic ingredient) or talc-containing cosmetic products.

The only published methods or standards for testing for asbestos in talc are the "Asbestiform Amphibole Minerals in Cosmetic Talc" (J4-1) method by the Cosmetic, Toiletry, and Fragrance Association (Ref. 4) and the "Absence of Asbestos" test method in the U.S. Pharmacopeia monograph for Talc (Ref. 5). These both rely on X-ray diffraction (XRD) or infrared (IR) spectroscopy followed by polarized light microscopy (PLM) if XRD or IR is positive for amphibole or serpentine minerals.

In 2021, the Interagency Working Group on Asbestos in Consumer Products (IWGACP) concluded that these methods are not specific or sensitive enough to detect the presence of asbestos (Ref. 6). Results from FDA testing of talc-containing cosmetic products by AMA Laboratories, on behalf of FDA, in 2019 support this conclusion.[3] AMA Laboratories tested talc-containing cosmetic products for asbestos using both PLM and Transmission Electron Microscopy (TEM). TEM revealed the presence of asbestos in nine products. Seven of these products had false negative findings when using PLM alone.

B. Need for Federal Regulatory Action

This proposed rule is a response to the statutory requirement in MoCRA that FDA establish standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics products. The testing methods proposed in this rule are consistent with the scientific opinions made by the subject matter experts in the IWGACP (Ref. 6).

A failure exists in the market for talc-containing cosmetic products arising from incomplete information about asbestos contamination. In the absence of suitable, standardized testing methods, manufacturers cannot accurately determine if their talc-containing cosmetic products are contaminated with asbestos. As a result, distribution of these products creates systemic health risks for consumers if asbestos is both undetected and present in the products. If adverse events occurred shortly after exposure, consumers would likely stop using the contaminated products and the market would adjust. However, exposure to asbestos may not immediately result in illness. For example, one study found that the latency period between asbestos exposure and malignant mesothelioma ranges from 13 to 70 years (Ref. 7). Such extended latency periods

[3] https://www.fda.gov/media/135911/download

make it difficult for consumers to know that they have been exposed to asbestos and to adjust their behavior accordingly.

C. Purpose of the Proposed Rule

The proposed rule, if finalized, would require testing of talc-containing cosmetic products using standardized testing methods for detecting and identifying asbestos that may be present as a contaminant in talc, which are:

1. PLM with dispersion staining to detect and identify asbestos based on optical crystallographic properties of particles and particle morphology; and
2. TEM/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED) to detect and identify asbestos based on elemental composition, crystal structure of particles, and particle morphology.

Under the proposed rule, if finalized, manufacturers would satisfy these testing requirements by:

1. Testing a representative sample of each batch or lot of the finished talc-containing cosmetic product;
2. Testing a representative sample of each batch or lot of the talc intended for use as a cosmetic ingredient; or
3. Relying on a certificate of analysis from the talc supplier for each batch or lot of talc intended for use as a cosmetic ingredient.

Manufacturers relying on a certificate of analysis to satisfy the testing requirement would also maintain qualified talc suppliers. Manufacturers would qualify the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through initial verification of the results of the supplier's tests for asbestos and subsequently annually thereafter test the talc intended for use as a cosmetic ingredient to verify the validity of the talc supplier's reported asbestos test results. Manufacturers would maintain detailed records of all asbestos testing for three years.

The proposed testing method would improve manufacturers' ability to detect the presence of asbestos in talc-containing cosmetic products and prevent such products from entering commerce. Thus, the proposed rule, if finalized, would help alleviate the market failure arising from incomplete information about asbestos contamination. As a result, the distribution of contaminated talc-containing cosmetic products would fall, reducing health risks to consumers.

D. Baseline Conditions

Due to uncertainty regarding current and expected firm behavior and incomplete data, we have made certain assumptions, including our baseline, to estimate the potential effects of the proposed rule. We base the assumptions underlying our analysis on our experience with industry through inspections and enforcement actions, public meetings, and public comments. We request comment and data on all of our assumptions about baseline industry practices. In this section we characterize the industry for talc-containing cosmetic products as well as the talc industry, and we provide baseline rates of contamination in talc-containing cosmetic products.

1. Characterizing the Market for Talc-Containing Cosmetic Products

To understand the size and scope of the market for talc-containing cosmetic products, we combine data from several sources. In this section, we describe the different sources we use to estimate the number of talc-containing products, the number of manufacturers of talc-containing products, and the sales of talc-containing products in the United States in 2022.

a. Estimated Share of Cosmetic Products that Contain Talc

To estimate the share of cosmetic products that contain talc, we use internal data from FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP, which FDA discontinued in March 2023 to develop a program for submission of the facility registrations and product listings mandated by MoCRA,[4] was a voluntary reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. Manufacturers, packers, and distributors may file ingredient composition statements, which include, among other information, the cosmetic product category or categories and the ingredients in the product. In Table 27 in the Appendix, we present the number of products filed in each product category, as well as the number of products in each product category with "talc" listed in their ingredient composition statement.

We then assume that the population ratio of talc-containing cosmetic products to all cosmetic products within a given product category equals the sample ratio for that product category in the VCRP. Though we believe the VCRP represents the best available data on ingredients in cosmetic products, this assumption has several limitations. First, the VCRP was voluntary and therefore does not present a complete picture of cosmetics in the United States. Second, we are unable to estimate trends in talc use in cosmetic products using historical VCRP. While anecdotal evidence suggests that the share of cosmetic products that contain talc has been declining over time due to, in part, high-profile product recalls and litigation related to asbestos in talc- we cannot estimate this trend given the available data. We request comment and data on the trends in talc use in cosmetic products.

b. Estimated Market for Talc-Containing Cosmetic Products at Multi-Outlet and Convenience Retailers

We rely on data from Information Resources Inc. (IRI) to estimate the number of cosmetic products, the number of cosmetic manufacturers, and the annual sales of cosmetic products at multi-outlet and convenience retailers in 2022.[5] IRI defines multi-outlet and convenience retailers as brick-and-mortar food, drug, mass-market (including Walmart), club (excluding Costco), dollar, military, and convenience stores. We discuss estimates related to online sales in the next section. We obtained data on dollar sales, unit sales, and manufacturer name from all products at the Universal Product Code (UPC) level for the product categories and sub-categories listed in Table 28 in the Appendix.

[4] https://www.fda.gov/food/cfsan-constituent-updates/fda-has-stopped-accepting-submissions-voluntary-cosmetic-registration-program-vcrp

[5] Food and Drug Administration custom research definitions based on Information Resources Inc. data (Calendar Year 2022 ending 01-01-23) Dollar Sales and Unit Sales, Total Multi-Outlet + Convenience.

The data from IRI does not distinguish between talc-containing cosmetic products and products that do not contain talc. To estimate the number of talc-containing cosmetics products, the number of manufacturers of talc-containing cosmetics products, and the annual sales of talc-containing cosmetics products at multi-outlet and convenience retailers, we match the product sub-categories in IRI to the product sub-categories in the VCRP. We then estimate the share of products that contain talc within each IRI product sub-category. We present these estimates in Table 28 in the Appendix.

We assign each UPC in the IRI data a probability of containing talc equal to the share of products that contain talc within that UPC's IRI product sub-category. Then, we perform a Monte Carlo simulation with 2,000 iterations, drawing in each iteration the subset of products that contain talc.[6] In each iteration, we calculate, for the drawn subset of talc-containing products,

- The annual sales in dollars,
- The annual sales in number of units sold,
- The number of unique manufacturers,
- The number of UPCs, and
- The number of private label UPCs, where a private label UPC has the manufacturer name "PRIVATE LABEL."

We present the mean, 5th percentile, and 95th percentile of these random variables over 2,000 iterations in Table 2. The estimates represent the market for talc-containing products at multi-outlet and convenience retailers in 2022.

Table 2. Overview of the Estimated Market for Talc-Containing Products at Multi-Outlet and Convenience Retailers in 2022

Variable	5th Percentile	Mean	95th Percentile
Annual Sales ($m)	$1,227.60	$1,350.64	$1,484.12
Annual Units Sold (m Units)	176.15	197.58	220.41
Number of Manufacturers	357	376	395
Number of UPCs	6,441	6,548	6,652
Number of Private Label UPCs	125	141	157

c. Estimated Market for Talc-Containing Cosmetic Products in Other Distribution Channels

As discussed previously, the IRI data does not cover all distribution channels for cosmetic products. Notably, the data does not include online sales and sales from specialty retailers. Therefore, we adjust our estimates in Table 2 to account for talc-containing products sold through other distribution channels.

According to a 2023 report from Euromonitor International (Ref. 8), offline grocery retailers, including convenience retailers, supermarkets, hypermarkets, discounters, warehouse clubs, and small local grocers, accounted for 29.10 percent of all sales in the Beauty and Personal Care

[6] Specifically, for each UPC in each iteration, we draw from a Bernoulli distribution an indicator variable that equals 1 if the UPC contains talc and 0 otherwise.

market in the United States in 2022. Offline general merchandise stores accounted for 8.30 percent of sales and offline pharmacies accounted for 10.20 percent of sales. In total, these three distribution channels, which correspond to the multi-outlet and convenience sample represented in IRI, accounted for 47.60 percent of all sales in 2022 (29.10 percent + 8.30 percent + 10.20 percent).

We therefore assume that the estimates in Table 2 represent 47.60 percent of the total market for talc-containing products. That is, IRI data excludes 52.40 percent (100 percent – 47.60 percent) of sales, including sales by specialty and online retailers. Given this assumption, we divide the values in Table 2 by 47.60 percent to estimate the size of the market for talc-containing products across all distribution channels. We present our adjusted estimates in Table 3.

Table 3. Overview of the Estimated Market for Talc-Containing Products Across All Distribution Channels in 2022

Variable	5th Percentile	Mean	95th Percentile
Annual Sales ($m)	$2,578.99	$2,837.49	$3,117.91
Annual Units Sold (m Units)	370.07	415.09	463.05
Number of Manufacturers	750	790	830
Number of UPCs	13,532	13,756	13,975
Number of Private Label UPCs	263	297	330

This approach has a few limitations. First, we apply a market share based on dollar sales to adjust unit sales, implying that average prices in multi-outlet and convenience distribution channels equal average prices in other distribution channels. However, luxury products with higher prices may account for a greater share of sales in other distribution channels, like specialty and department stores, than in multi-outlet and convenience distribution channels. To the extent that the average price in other distribution channels is higher than the average price in multi-outlet and convenience distribution channels, we overestimate the annual units sold across all distribution channels.

Second, we implicitly assume that UPCs sold at multi-outlet and convenience retailers are not sold in other distribution channels. That is, we do not account for any overlap in UPCs marketed across distribution channels. In the absence of better product listing data, we are unable to determine which products are exclusive to certain distribution channels. We expect that the true estimate of the number of talc-containing products on the market lies between the estimates in Table 2 and the estimates in Table 3. This implicit assumption also applies to our estimate of the number of manufacturers of talc-containing products on the market also shown in Table 2 and Table 3.

d. Private Label Products

To avoid identifying retailer-specific sales information, IRI masks information on private label, or "store brand," products. Specifically, they aggregate private label products with the same product characteristics under a single UPC and the manufacturer name "PRIVATE LABEL." As a result, relying on IRI data leads us to underestimate the number of private label UPCs and manufacturers.

Euromonitor (Ref. 8) estimates that sales of private label products accounted for 3.60 percent of total sales in the Beauty and Personal Care market in 2022. Applying this estimate, we assume that 3.60 percent of talc-containing products are private label. Using the information from Table 3, we estimate that, at the mean, there are 13,459 non-private label talc-containing products on the market (13,756 UPCs – 297 private label UPCs). Given the number of non-private label products on the market, we then expect that, at the mean, there are 503 private label talc-containing products on the market ((13,459 non-private label UPCs × 3.60 percent private label penetration) ÷ (1 – 3.60 percent private label penetration)). The total number of talc-containing products on the market then equals 13,961 (13,459 non-private label UPCs + 503 private label UPCs) at the mean. We summarize these calculations in Table 4.

Table 4. Estimated Number of Talc-Containing Products, Adjusted for Private Label Penetration

Row Number	Variable	5th Percentile	Mean	95th Percentile	Source
1	Number of UPCs (Unadjusted)	13,532	13,756	13,975	Table 3
2	Number of Private Label UPCs (Unadjusted)	263	297	330	Table 3
3	Number of Non-Private Label UPCs	13,269	13,459	13,645	Row 1 – Row 2
4	Private Label Penetration	3.60%	3.60%	3.60%	Ref. 8
5	Number of Private Label UPCs (Adjusted)	496	503	510	(Row 3 × Row 4) ÷ (1 – Row 4)
6	Number of UPCs (Adjusted)	13,764	13,961	14,155	Row 3 + Row 5

We then adjust the number of manufacturers of talc-containing products to account for the private label adjustment to our estimate of the number of talc-containing UPCs. Using information from Table 3, we estimate that the ratio of the unadjusted number of manufacturers to the unadjusted number of UPCs is 0.06 (790 manufacturers ÷ 13,756 UPCs). Applying this ratio to the adjusted number of UPCs from Table 4 yields an adjusted estimate of 801 manufacturers of talc-containing products (13,961 UPCs × 0.06 manufacturers per UPC). We summarize these calculations in Table 5.

Table 5. Estimated Number of Manufacturers of Talc-Containing Products, Adjusted for Private Label Penetration

Row Number	Variable	5th Percentile	Mean	95th Percentile	Source
1	Number of UPCs (Unadjusted)	13,532	13,756	13,975	Table 3
2	Number of Manufacturers (Unadjusted)	750	790	830	Table 3
3	Ratio of Manufacturers to UPCs	0.06	0.06	0.06	Row 2 ÷ Row 1
4	Number of UPCs (Adjusted)	13,764	13,961	14,155	Table 4
5	Number of Manufacturers (Adjusted)	763	801	841	Row 4 × Row 3

We request comment and data on the assumptions underlying our analysis of the market for talc-containing cosmetic products.

2. Characterizing the Talc Industry

The talc industry includes talc mining firms and talc distributors. According to the United States' Geological Survey, three firms mined talc in the United States in 2022 (Ref. 9). Little data exists on the international talc supply chain, and we are unable to estimate the number of firms operating mines outside the United States. Most imported talc comes from Pakistan, Canada, and China, in order of amount of imports (Ref. 9). Additionally, an Internet search suggests that there are approximately 30 talc distributors in the United States.[7] Some of these firms both mine and distribute talc. For the purposes of our analysis, we assume that the proposed rule would affect 30 talc mines and distributors, though this assumption likely underestimates the number of affected firms by excluding foreign talc mines. We request comment and data on the talc industry and supply chain.

3. Baseline Industry Testing Practices

For purposes of this analysis we assume, in the baseline, those manufacturers or suppliers that voluntarily test talc intended for use in cosmetics use the Cosmetic, Toiletry, and Fragrance Association's J4-1 method. Under the J4-1 method, manufacturers or suppliers first screen for asbestos using XRD. Then, if the sample is positive for amphibole minerals, they then test for asbestos using PLM.[8]

We are uncertain as to the extent of asbestos testing in the baseline. For example, we do not know whether manufacturers or suppliers test every batch or lot of talc for asbestos. We also do not know how frequently manufacturers or suppliers detect asbestos in XRD screening, leading them to testing for asbestos using PLM. We also do not know the extent to which manufacturers or suppliers have already adopted the testing methods described in this proposed rule.

For the purposes of our analysis, we assume that the baseline number of PLM and TEM tests conducted on each batch or lot of talc from a supplier is zero. We believe that this assumption captures the notions that (1) manufacturers or suppliers do not currently test every batch or lot of talc in the baseline and (2) manufacturers or suppliers only conduct PLM testing when a sample is positive for amphibole minerals under XRD screening. We welcome comment and data on current industry practice and our assumptions.

4. Estimated Baseline Rates of Contamination in Talc-Containing Cosmetics

Several sampling studies have tested talc-containing cosmetics for asbestos contamination using TEM. We summarize the results of these studies in Table 6. In 2019,[9] 2021,[10] and 2022,[11] AMA Laboratories tested talc-containing cosmetic products for asbestos using TEM on behalf of FDA. AMA Laboratories found no asbestos in any of the products tested in 2021 or in 2022. However, in 2019, 9 of the 52 products sampled tested positive for asbestos using TEM, for a rate of contamination of 17 percent. Notably, only 2 of these products tested positive for

[7] Available from https://www.go4worldbusiness.com/suppliers/united%20states/talc.html. Accessed February 27, 2024.
[8] Notably, XRD only detects amphibole minerals and not serpentine minerals.
[9] https://www.fda.gov/media/135911/download
[10] https://www.fda.gov/media/153415/download
[11] https://www.fda.gov/media/163572/download

asbestos using PLM. The overall rate of contamination in the three years of FDA studies was 6 percent.

Stoiber et al. (2020) tested 21 powder-based cosmetic products and found asbestos in 3 products using TEM (Ref. 10), for a rate of contamination of 14 percent. All 3 products that tested positive for asbestos were eye shadows and one of the products was an eye shadow from a toy make-up kit for children.

Finally, on February 4, 2020, FDA held a public meeting on testing methods for asbestos in talc and talc-containing cosmetic products. A public comment by Sean Fitzgerald of the Scientific Analytical Institute (SAI) stated that SAI had tested 600 talc-containing cosmetic products for asbestos using TEM and found asbestos in over 100 of them, for a rate of contamination of 17 percent.[12]

Table 6. Summary of Results of TEM Testing of Talc-Containing Cosmetic Products

Study	Year	Products Tested	Positive for Asbestos (TEM)	Rate of Contamination
FDA	2019	52	9	17%
FDA	2021	50	0	0%
FDA	2022	50	0	0%
Stoiber et al.	2020	21	3	14%
SAI	2015-2019	600	100	17%
Total	2015-2022	773	112	14%

Only the Stoiber et al. study is peer-reviewed. The FDA tests were published at FDA.gov and the SAI tests were presented to FDA in a public meeting. To our knowledge, the results in this table represent all published TEM testing results.

We present the information here for illustrative purposes. Though the data is not representative of the percent of products on the market contaminated with asbestos, it does demonstrate that the TEM method identified asbestos in 14 percent of products tested. While these studies suggest that the baseline rate of asbestos contamination in talc-containing cosmetics is nonzero, we do not have any information from representative sampling studies needed to estimate a population-level rate of contamination. The sampling for the FDA studies was investigational rather than representative. Investigators selected products based on product type, price range, popularity on social media and in advertisements, and intended audience (specifically, children and women of color). The sample size in the Stoiber et al. study was small, and the paper has limited information about the methods used to select products. Finally, the SAI comment at the FDA public meeting contained no information about sampling methods and we did not find these results published anywhere in the academic literature.

We assume that, in the baseline, manufacturers of talc-containing cosmetics have not yet adopted the methodology proposed in this rulemaking. We request comment on this assumption. To the extent that manufacturers of talc-containing cosmetics already use the PLM and TEM/EDS/SAED methods for asbestos testing, we overestimate both the benefits and costs of this proposed rule.

[12] https://www.fda.gov/media/135069/download

5. Estimated Baseline Burden of Asbestos-Related Illnesses

The International Agency for Research on Cancer concluded in 2009 that there is sufficient evidence that inhalation exposure to asbestos causes mesothelioma and cancers of the lung, larynx, and ovaries (Ref. 2). According to the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program, in 2020 there were 1,218 new cases of mesothelioma, 83,538 new cases of lung cancer, 4,550 new cases of larynx cancer, and 8,815 new cases of ovarian cancer.[13] We present the breakdown of these new cases by age group for each cancer in Table 7. Almost all new cases of mesothelioma are attributable to inhalation exposure to asbestos.[14] We do not know the fraction of these cases that resulted from exposure to asbestos in talc-containing cosmetics. Because there are many pathways to lung, larynx, and ovarian cancer, we expect that the fraction of cases of these types of cancers attributable to exposure to asbestos in talc-containing cosmetics would be smaller than the fraction of mesothelioma cases attributable to asbestos in talc-containing cosmetics.

Table 7. Number of New Cases of Cancer in the U.S. in 2020

Age	Mesothelioma	Lung Cancer	Larynx Cancer	Ovarian Cancer
<15	0	13	0	66
15-39	33	443	35	749
40-64	234	22,726	1,955	3,897
65-74	341	30,018	1,524	2,141
75+	619	30,338	1,036	1,962
Total	1,218	83,538	4,550	8,815

FDA's CFSAN Adverse Event Reporting System (CAERS) is a passive surveillance system which receives adverse event reports from consumers, health practitioners, and industry. We surveyed the CAERS database for talc-related adverse events for cosmetics from 2018 to 2022. We present estimates from this data in Table 8. This data has limitations. For example, we do not know if asbestos contamination is the cause of the adverse events in these reports. Furthermore, passive reporting systems like CAERS tend to receive reports for only a fraction of actual adverse events.[15]

Table 8. Talc-Related Adverse Event Reports from CAERS (2018 to 2022)

Year	Death[a]	Cancer[a]	Mesothelioma[a]	Total Adverse Events
2018	1,824	3,612	372	4,991
2019	1,187	1,908	360	3,013
2020	1,813	1,616	266	3,391
2021	3,953	3,791	277	7,268
2022	1,149	4,909	170	5,586

[a] Outcomes are not mutually exclusive.

[13] Data available from https://seer.cancer.gov/statistics-network/explorer/application.html. Accessed July 6, 2023.
[14] Between 70 and 90 percent of pleural mesotheliomas in men are attributable to asbestos, though the proportion is uncertain for peritoneal mesothelioma and for women (Ref. 11).
[15] See Ref. 12 for a review of studies of underreporting of adverse drug reactions.

a. Value per Statistical Case of Talc-Related Illness

To illustrate the public health burden of asbestos-related illness, we estimate the expected value per statistical case of mesothelioma, lung cancer, larynx cancer, and ovarian cancer attributed to asbestos exposure, primarily through inhalation. Using the National Cancer Institute's SEER data for 2020, we present the 1-year, 3-year, 5-year, and 10-year relative survival rates for these cancers in Table 9.

Table 9. Relative Survival Rates of Asbestos-Related Illnesses (2020)

Type of Cancer	1-Year Survival Rate	3-Year Survival Rate	5-Year Survival Rate	10-Year Survival Rate
Mesothelioma	50.8%	23.2%	16.0%	10.5%
Lung Cancer	58.3%	38.9%	32.6%	25.2%
Larynx Cancer	84.6%	68.5%	61.0%	47.5%
Ovarian Cancer	80.0%	63.1%	53.1%	43.6%

The data presented is for all sexes, except for ovarian cancer which only includes people with ovaries.

For each of these types of cancer we assume that:

- A patient with an asbestos-related illness has a relative risk of dying in one year after diagnosis equal to 1 minus the 1-year survival rate, valued using the value per statistical life (VSL) discounted to year 1.
- A patient with an asbestos-related illness has a relative risk of dying three years after diagnosis equal to the 1-year survival rate minus the 3-year survival rate, valued using the VSL discounted to year 3.
- A patient with an asbestos-related illness has a relative risk of dying five years after diagnosis equal to the 3-year survival rate minus the 5-year survival rate, valued using the VSL discounted to year 5.
- A patient with an asbestos-related illness has a relative risk of dying ten years after diagnosis equal to the 5-year survival rate minus the 10-year survival rate, valued using the VSL discounted to year 10.

Given these assumptions, we present the relative mortality risk for one, three, five, and ten years after diagnosis for each asbestos-related illness in Table 10.

Table 10. Estimated Relative Mortality Risk of Asbestos-Related Illnesses, by Time Since Diagnosis

Type of Cancer	1 Year Since Diagnosis	3 Years Since Diagnosis	5 Years Since Diagnosis	10 Years Since Diagnosis
Mesothelioma	49.2%	27.6%	7.2%	5.5%
Lung Cancer	41.7%	19.4%	6.3%	7.4%
Larynx Cancer	15.4%	16.1%	7.5%	13.5%
Ovarian Cancer	20.0%	16.9%	10.0%	9.5%

The 2023 VSL ranges from $6.05 million to $19.75 million, with a primary estimate of $12.97 million. To estimate the expected value per statistical case of each asbestos-related illness at the

time of diagnosis, we first discount the VSL to the time of mortality, relative to the time of diagnosis. In Table 11, we present the VSL, discounted to one, three, five, and ten years after diagnosis, at a 7 percent discount rate and a 3 percent discount rate.[16]

Table 11. Value per Statistical Life Discounted to One, Three, Five, and Ten Years After Diagnosis ($m)

Years After Diagnosis	Discounted VSL (7%)			Discounted VSL (3%)		
	Low	Primary	High	Low	Primary	High
1	$5.72	$12.26	$18.66	$5.94	$12.73	$19.39
3	$5.10	$10.94	$16.66	$5.72	$12.27	$18.68
5	$4.56	$9.77	$14.88	$5.51	$11.82	$18.00
10	$3.43	$7.36	$11.21	$5.03	$10.78	$16.41

To estimate the expected value per statistical case of an asbestos-related illness, we take the sum over time of the product of the discounted VSL and the mortality risk in that year. For example, our primary estimate of expected value per statistical case of mesothelioma at a 7 percent discount rate is $10.16 million (($12.26 million discounted VSL × 49 percent mortality risk for year 1) + ($10.94 million discounted VSL × 28 percent mortality risk for year 3) + ($9.77 million discounted VSL × 7 percent mortality risk for year 5) + ($7.36 million discounted VSL × 6 percent mortality risk for year 10)). In Table 12, we present our estimates of the expected value per statistical case of each asbestos-related illness.

Table 12. Value per Statistical Case of Asbestos-Related Illness ($m)

Type of Cancer	Value per Statistical Case (7%)			Value per Statistical Case (3%)		
	Low	Primary	High	Low	Primary	High
Mesothelioma	$4.74	$10.16	$15.47	$5.18	$11.09	$16.89
Lung Cancer	$3.92	$8.39	$12.78	$4.31	$9.23	$14.06
Larynx Cancer	$2.51	$5.38	$8.19	$2.93	$6.28	$9.56
Ovarian Cancer	$2.79	$5.98	$9.10	$3.18	$6.83	$10.39

We note that we are unable to quantify the morbidity burden to patients who survive beyond ten years due to a lack of published literature describing the health-related quality-of-life impacts of different types of cancers. As a result, we underestimate the value per statistical case of asbestos-related illness. We request comment on the magnitude of the morbidity burden associated with asbestos-related illnesses and on our approach to estimating the value per statistical case.

b. Estimated Costs of Medical Care and Indirect Costs

Patients and insurers also incur the costs of medical care for these illnesses. To the extent that patients do not internalize medical costs paid by third parties, like insurers or government

[16] We discount VSL following the Health and Human Services guidance, Updating Value per Statistical Life (VSL) Estimates for Inflation and Changes in Real Income available here: https://aspe.hhs.gov/sites/default/files/2021-07/hhs-guidelines-appendix-d-vsl-update.pdf

programs, willingness-to-pay estimates like the VSL do not account for these costs. We summarize estimates of the costs of medical care for asbestos-related illness in Table 13. Borrelli et al. (2019) estimated that the average cost per mesothelioma hospitalization is $24,124 in 2014 dollars, or $29,608 in 2022 dollars (Ref. 13). These cost estimates do not include the costs of emerging medication therapies or outpatient care.

Sheehan et al. (2018) estimated the treatment costs of lung cancer by stage and type of treatment (Ref. 14). They found that cancer-attributable costs ranged from $802 to $7,469 per month during the initial treatment phase in 2017 dollars, or from $947 to $8,820 per month in 2022 dollars. In the continuing treatment phase, cancer-attributable costs ranged from $1,100 to $4,809 per month in 2017 dollars, or from $1,299 to $5,679 per month in 2022 dollars.

Gourin et al. (2014) estimated the total cost of initial and continuing treatment for larynx cancer over 5 years (Ref. 15). Initial treatment costs ranged from $71,346 to $118,921 over 5 years in 2012 dollars, or from $90,770 to $151,297 in 2022 dollars. Additional cancer-directed treatment costs ranged from $44,449 to $104,616 in 2012 dollars, or from $56,550 to $133,098 in 2022 dollars.

Bercow et al. (2017) estimated the cost of care during the first year of treatment of ovarian cancer (Ref. 16). They found that median total expenditures during the first year were $93,632 in 2012 dollars, or $119,123 in 2022. This estimate includes inpatient services, outpatient services, and outpatient drug costs during the first year of treatment, but no continuing costs beyond the first year of treatment.

Table 13. Estimates of the Costs of Medical Care, by Cancer Type (in 2022 dollars)

Type of Cancer	Type of Medical Cost	Low Estimate	High Estimate
Mesothelioma	Cost of Hospitalization	$30,590	$30,590
Lung Cancer	Cost of Initial Treatment Phase	$981	$9,133
Lung Cancer	Cost of Continuing Treatment Phase	$1,345	$5,881
Larynx Cancer	Cost of Initial Treatment Phase	$93,634	$156,070
Larynx Cancer	Additional Cancer Costs	$58,334	$137,297
Ovarian Cancer	First-Year Expenditures	$122,881	$122,881

Finally, beyond direct medical care costs, patients may incur additional indirect costs of treatment, like travel and lodging expenses for out-of-town treatments or caregiving costs. We were unable to identify any studies in the literature estimating these types of indirect costs of cancer treatment in the United States. We request comment on these indirect costs of medical care, and how they compare to direct costs.

E. Benefits of the Proposed Rule

In this section, we estimate the benefits of the proposed rule. The benefits of the proposed rule include reduced exposure to asbestos and cost savings from fewer recalls of talc-containing cosmetics. We discuss public health benefits from fewer asbestos-related illnesses qualitatively. We also discuss the cost savings to manufacturers of talc-containing cosmetics from fewer recalls each year.

1. Benefits from Reduced Exposure to Asbestos

To the extent that asbestos is present in talc-containing cosmetics products and to the extent that false negatives occur under baseline testing procedures, the proposed rule, if finalized, would reduce the rate of asbestos contamination in talc-containing cosmetics by reducing the number of false negative test results from the J4-1 method. The proposed rule would also reduce baseline rates of contamination by requiring that manufacturers test all batches or lots of talc-containing cosmetics or talc intended for use in cosmetic products using both PLM and TEM/EDS/SAED methods. However, we expect that some contamination in talc-containing cosmetics could remain due to sampling error or inadvertent unrepresentative sampling.

The International Agency for Research on Cancer concluded in 2009 that there is sufficient evidence that inhalation exposure to asbestos causes mesothelioma and cancers of the lung, larynx, and ovaries (Ref. 2). Therefore, we expect that a reduction in the rate of asbestos contamination in talc-containing cosmetics, would correspond with a reduction in the number of cases of mesothelioma and cancers of the lung, larynx, and ovaries caused by asbestos exposure.

We cannot estimate the total public health benefits of the proposed rule without knowing a population-level rate of contamination in talc-containing cosmetics or the probability of illness following exposure to asbestos in talc-containing cosmetics. Therefore, in Section II.L, we conduct a breakeven analysis determining the number of avoided cases of mesothelioma required for the benefits of this proposed rule to exceed the costs. We request comment and data that may facilitate a quantitative estimate of potential health benefits. In particular, we request data on the level of asbestos contamination in the population of talc-containing cosmetics in the United States and the magnitude of the risk of asbestos-related illnesses from exposure to asbestos in talc-containing cosmetics.

2. Benefits of Fewer Recalls of Talc-Containing Cosmetics

In addition to the potential public health benefits discussed in the previous section, we also estimate the cost savings to manufacturers from fewer recalls of talc-containing cosmetics. Manufacturers or distributors may voluntarily recall a cosmetic product from the market to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.[17] Between 2016 and 2022, there were, on average, 0.7 annual recalls of talc-containing cosmetic products, according to FDA's Office of Regulatory Affairs' internal data repository, with a low estimate of 0.0 recalls per year and a high estimate of 4.0 recalls per year. We assume that manufacturers would avoid between 0 percent and 100 percent of these recalls as a result of the proposed rule, if finalized. Therefore, we estimate that manufacturers would avoid between 0.0 recalls (0.0 recalls per year × 0 percent of recalls avoided) and 4.0 recalls (4.0 recalls per year × 100 percent recalls avoided) each year, with a primary estimate of 0.4 recalls (0.7 recalls per year × 50 percent of recalls avoided).

In a contract for FDA, Eastern Research Group estimated the cost of recalls in the cosmetic sector through a series of case studies (Ref. 17). They found that, in 2018 dollars, the cost of a

[17] See 21 CFR 7.40(a)

recall in the cosmetics sector ranged from $12,000 to $365,000, or from $14,345 to $436,341 in 2023 dollars. These costs include:

- Issue identification;
- Recall notification and communication;
- Product removal and destruction;
- Product replacement; and
- Corrective action.

Notably, these cost estimates do not include legal costs from lawsuits or lost product or company value. In Table 14, we present the annual benefits to manufacturers from fewer recalls of talc-containing cosmetics. The annual benefits of fewer recalls equal the annual avoided recalls times the average cost per cosmetics recall. We estimate that manufacturers would accrue benefits of between $0.00 million and $1.75 million annually, with a primary estimate of $0.08 million annually. We assume that these benefits would begin one year after the publication of the final rule.

Table 14. Annual Benefits from Avoided Recalls of Talc-Containing Cosmetic Products

Value	Low Estimate	Primary Estimate	High Estimate
Annual Recalls Avoided	0.0	0.4	4.0
Cost per Recall ($m)	$0.01	$0.23	$0.44
Annual Benefits from Avoided Recalls ($m)	$0.00	$0.08	$1.75

Given this assumption, the present value of benefits over 10 years would range from $0.00 million to $10.42 million at a 7 percent discount rate, with a primary estimate of $0.48 million. At a 3 percent discount rate, the present value of benefits over 10 years would range from $0.00 million to $12.25 million, with a primary estimate of $0.56 million. Annualized benefits would range from $0.00 million to $1.39 million at a 7 percent discount rate, with a primary estimate of $0.06 million, and from $0.00 million to $1.39 million at a 3 percent discount rate, with a primary estimate of $0.06 million.

F. Costs of the Proposed Rule

In this section, we discuss the costs of the proposed rule. The costs of the proposed rule include costs to read and understand the rule, asbestos testing costs, and costs of subsequent testing conducted on new batches of talc when an initial sample of talc tests positive for asbestos. We expect that talc producers, talc suppliers, and manufacturers of talc-containing cosmetics would all read and understand the rule. Talc suppliers would incur costs to test lots or batches of talc for asbestos, and manufacturers of talc-containing cosmetics would incur costs to maintain qualified talc-suppliers.

We anticipate talc suppliers may need to make small modifications to their written testing procedures. Additionally, if a talc supplier only supplies talc to manufacturers of talc-containing cosmetics and if the talc supplier ever has a batch of talc test positive for asbestos, they would have to establish a new commercial relationship with a manufacturer of non-cosmetic talc products to buy the talc contaminated with asbestos. We do not quantify these costs because we

believe these costs would be small, if any. We request comment on costs of making changes to the written testing procedure or potentially identifying a new buyer.

1. Costs to Read and Understand the Rule

We expect that manufacturers of talc-containing cosmetics, talc producers, and talc suppliers would incur costs to read and understand the rule. The proposed rule is approximately 10,000 words long. Following guidance from the Department of Health and Human Services, we assume a reading speed of between 200 and 250 words per minute (Ref. 18). Then, we expect that it would take an individual between 0.67 hours (10,000 words ÷ 250 words per minute ÷ 60 minutes per hour) and 0.83 hours (10,000 words ÷ 200 words per minute ÷ 60 minutes per hour) to read and understand the rule. We assume that between 2 and 4 lawyers would read the rule at each firm.

Based on the Bureau of Labor Statistics' 2023 National Industry-Specific Occupational Employment and Wage Estimates, the annual hourly wage for legal occupations in the Soap, Cleaning Compound, and Toilet Preparation Manufacturing industry was $65.[18] Assuming that overhead and benefits are approximately 100 percent of the hourly wage (Ref. 18), the fully loaded cost of labor for talc-containing cosmetic manufacturers is $129. Therefore, the cost for each manufacturer to read and understand the rule would range from $172 (0.67 hours per person × 2 people per firm × $129 per hour) to $431 (0.83 hours per person × 4 people per firm × $129 per hour). Given our estimate that there are between 763 and 841 manufacturers of talc-containing cosmetics on the market (Table 5), the total cost for such manufacturers to read and understand the rule would range from $0.13 million (763 firms × $172 per firm) to $0.36 million (841 firms × $431 per firm).

The Bureau of Labor Statistics' also estimates that the annual hourly wage for legal occupations in the Mining industry (excluding Oil and Gas Mining) was $93, for a fully loaded labor cost of $186.[19] Therefore, the cost for each talc producer or supplier to read and understand the rule would range from $247 (0.67 hours per person × 2 people per firm × $186 per hour) to $619 (0.83 hours per person × 4 people per firm × $186 per hour). Given that there are approximately 30 talc producers or supplier operating in the United States, the total cost for such firms to read and understand the rule would range from $0.01 million (30 firms × $247 per firm) to $0.02 million (30 firms × $619 per firm).

We assume that firms would incur these costs one time, in the year in which we publish the final rule. Given this assumption, the present value of costs over 10 years would range from $0.14 million to $0.38 million at both a 7 percent and 3 percent discount rate, with a primary estimate of $0.24 million. Annualized costs over 10 years would range from $0.02 million to $0.05 million at a 7 percent discount rate, with a primary estimate of $0.03 million, and from $0.02 million to $0.04 million at a 3 percent discount rate, with a primary estimate of $0.03 million.

[18] Based on wages for NAICS Code 3250A2, available here: https://www.bls.gov/oes/current/naics4_3250A2.htm#23-0000
[19] Based on wages for NAICS Code 212000, available here: https://www.bls.gov/oes/current/naics3_212000.htm#23-0000

2. Asbestos Testing Costs

In this section, we estimate the cost of asbestos testing for talc-containing cosmetic products. First, we estimate the number of new asbestos tests conducted under the proposed rule, if finalized. Then, we estimate the cost per asbestos test and the total cost of asbestos testing under the proposed rule.

a. Number of New Tests

First, we estimate the number of new tests conducted under the proposed rule. As described in the proposed rule, manufacturers of talc-containing cosmetics may rely on certificates of analysis from talc suppliers to meet asbestos testing requirements. Because relying on supplier testing is less costly for manufacturers than testing talc or talc-containing cosmetics themselves, we assume that all manufacturers choose this compliance option. Under this assumption, talc suppliers would regularly conduct asbestos testing on each batch or lot distributed to manufacturers of talc-containing cosmetics. Should a batch or lot test positive for asbestos, we expect that the supplier would test a different batch or lot to ensure it does not contain asbestos before supplying talc to the cosmetics manufacturer. We assume that between 0 percent and 25 percent of batches or lots of talc would test positive for asbestos. We request comment on this assumption.

In addition to this regular testing, each manufacturer would also maintain qualified suppliers by initially qualifying suppliers and subsequently testing the talc they receive from their suppliers annually to verify the validity of the certificates of analysis. To account for this testing, given the small number of talc suppliers on the market, we assume that each manufacturer would test, on average, one batch of talc each year. We request comment on this assumption. The annual number of new tests would then equal the number of batch or lot tests by talc suppliers plus the number verification tests by manufacturers of talc-containing cosmetics. We estimate the annual number of asbestos tests in Table 15.

Table 15. Estimated Number of Annual Asbestos Tests

Row Number	Variable	Low Estimate	Primary Estimate	High Estimate	Source
1	Talc Sold by Domestic Producers (metric tons)	560,000	560,000	560,000	Ref. 9
2	Talc Imports for Consumption (metric tons)	330,000	330,000	330,000	Ref. 9
3	Talc Exports (metric tons)	200,000	200,000	200,000	Ref. 9
4	Domestic Talc Consumption (metric tons)	690,000	690,000	690,000	Row 1 + Row 2 – Row 3
5	Share of Talc Sold by Domestic Producers for Cosmetics	0%	1%	2%	Footnote[20]

[20] From Table 2 in the Minerals Yearbooks from 2017 to 2021: https://www.usgs.gov/centers/national-minerals-information-center/talc-and-pyrophyllite-statistics-and-information. The low estimate is the minimum share of talc used by cosmetics manufacturers over the years 2017 to 2021. The high estimate is the maximum share of talc used by cosmetics manufacturers over the years 2017 to 2021. The primary estimate is the average share of talc used by cosmetics manufacturers over the years 2017 to 2021.

Row Number	Variable	Low Estimate	Primary Estimate	High Estimate	Source
6	Talc Consumption by Domestic Cosmetics Manufacturers (metric tons)	293	8,637	13,750	Row 4 × Row 5
7	Metric Tons per Lot	70	65	60	
8	Talc Supplied to Domestic Cosmetics Manufacturers (lots)	4	133	229	Row 6 ÷ Row 7
9	Ratio of Domestically Produced Cosmetics to Foreign Produced Cosmetics	2.59	2.59	2.59	VCRP
10	Talc Supplied to Foreign Cosmetics Manufacturers (lots)	2	51	89	Row 8 ÷ Row 9
11	Annual Initial Batch or Lot Tests	6	184	318	Row 8 + Row 10
12	Share of Positive Initial Batch or Lot Tests	0%	13%	25%	
13	Annual Subsequent Testing Conducted on New Batch or Lot	0	23	79	Row 11 × Row 12
14	Annual Verification Tests	763	801	841	Table 5
15	Total Annual Tests	769	986	1,158	Row 11 + Row 13 + Row 14

To calculate the number of annual asbestos tests, we first estimate the amount of talc consumption by domestic cosmetic manufacturers using data from the United States Geological Survey. In 2022, according to the USGS, domestic talc mines sold 560,000 metric tons of talc (Ref. 9). The United States exported 200,000 metric tons of talc and imported 330,000 metric tons of talc for consumption. Therefore, the total domestic consumption of talc was 690,000 metric tons.

Between 2017 to 2021, between 0 percent and 2 percent of United States talc was used in cosmetics manufacturing, with a primary estimate of 1 percent. We assume, therefore, approximately 1 percent of the total domestic consumption of talc, or 8,637 metric tons, was by cosmetic manufacturers. FDA subject matter experts suggest that the average batch or lot contains between 60 and 70 metric tons of talc. We request comment on the average batch or lot size of talc. Thus, the total talc supplied to domestic cosmetics manufacturers in 2022 was between 4 and 229 lots, with a primary estimate of 133 lots.

We use the ratio of talc-containing cosmetics produced by domestic manufacturers to talc-containing cosmetics produced by foreign manufacturers to estimate the amount of talc supplied to foreign manufacturers of cosmetics marketed in the United States. In the VCRP data, there are 2.59 products manufactured domestically for every one product manufactured internationally.[21] We assume that each internationally manufactured cosmetic product uses the

[21] Because listing products with the VCRP is voluntary, the data may not represent the complete population of talc-containing cosmetics. We expect that foreign manufacturers are less likely to voluntarily register with FDA. We believe, therefore, that we underestimate the amount of talc supplied to foreign cosmetic manufacturers.

same amount of talc annually as each domestically manufactured cosmetic product. Given this assumption, the amount of talc supplied to foreign manufacturers equals the amount of talc supplied to domestic manufacturers divided by the ratio of domestically manufactured cosmetics to internationally manufactured products. We therefore estimate that the amount of talc supplied to foreign manufacturers in 2022 ranged from 2 lots to 89 lots, with a primary estimate of 51 lots.

If we assume that the use of talc in cosmetics would remain constant over time, then the total number of initial tests regularly conducted each year by talc suppliers would range from 6 tests to 318 tests, with a primary estimate of 184 tests. If between 0 percent and 25 percent of these initial tests would be positive for asbestos, then the total number of subsequent tests regularly conducted on new batches of talc each year would range from 0 tests to 79 tests, with a primary estimate of 23 tests.

However, as noted in the U.S. Mineral Commodity Summary (Ref. 9), the use of talc in cosmetics has been declining over time, and we expect this trend to continue following the publication of this proposed rule, if finalized. Therefore, we likely overestimate the number of batch or lot tests conducted by talc suppliers.

We also assume that each manufacturer of talc-containing cosmetics would conduct one asbestos test each year to verify the validity of the certificates of analysis from their talc suppliers. We request comment on this assumption. Given the number of manufacturers of talc-containing cosmetics from Table 5, we estimate that manufacturers would conduct between 763 and 841 of these verification tests annually, with a primary estimate of 801 tests. The total number of tests conducted annually would therefore range from 769 to 1,238 tests, with a primary estimate of 1,009 tests.

b. Cost of Testing

To estimate that cost per test, we use information from FDA's contract with AMA Laboratory to conduct both PLM and TEM tests for asbestos. The contracted average cost per sample is $2,100 in 2022 dollars, including the cost to produce a full report. To account for uncertainty in the parameters of the testing protocol, we assume that the total cost to conduct asbestos testing on a lot or batch of talc would range from $2,000 to $5,000, including the cost to produce a certificate of analysis, or from $2,073 to $5,182 in 2023 dollars.

Multiplying the number of annual tests by the average cost per test yields an ongoing, annual cost of asbestos testing ranging from $1.61 million to $8.47 million, with a primary estimate of $4.41 million. We assume that manufacturers and suppliers would incur these costs annually starting one year following the publication of the final rule. The present value of costs over 10 years would range from $9.59 million to $50.59 million at a 7 percent discount rate, with a primary estimate of $26.34 million. At a 3 percent discount rate, the present value of costs over 10 years would range from $11.27 million to $59.47 million, with a primary estimate of $30.96 million. Annualized costs over 10 years would range from $1.28 million to $6.73 million at a 7 percent discount rate, with a primary estimate of $3.50 million, and from $1.28 million to $6.77 million at a 3 percent discount rate, with a primary estimate of $3.52 million.

As described in Section II.D, we assume that the number of baseline PLM and TEM tests per batch or lot of talc is zero. To the extent that suppliers test already test lots or batches using both

PLM and TEM, we overestimate the total testing costs associated with the proposed rule. We seek comment on current industry testing practices and associated costs.

G. Transfers Caused by the Proposed Rule

We do not anticipate any transfers in response to this proposed rule. We request comment on any potential transfers.

H. Summary of Benefits, Costs, and Transfers

The benefits of the proposed rule include public health benefits from reduced exposure to asbestos and cost savings from fewer recalls of talc-containing cosmetics. We discuss potential public health benefits from fewer asbestos-related illnesses qualitatively. We estimate that, at a 7 percent discount rate, each avoided case of mesothelioma would generate benefits of $10.16 million, each avoided case of lung case would generate benefits of $8.39 million, each avoided case of larynx cancer would generate benefits of $5.38 million, and each avoided case of ovarian cancer would generate benefits of $5.98 million, not included any costs of medical care associated with illness. We discuss the cost savings to manufacturers of talc-containing cosmetics from fewer recalls each year. We estimate that annualized costs savings over 10 years would equal $0.06 million at a 7 percent discount rate and $0.06 million at a 3 percent discount rate.

The costs of the proposed rule include costs to read and understand the rule, and asbestos testing costs. We expect that talc producers, talc suppliers, and manufacturers of talc-containing cosmetics would all read and understand the rule. We estimate that annualized costs to read and understand the rule over 10 years would equal $0.03 million at a 7 percent discount rate and $0.03 million at a 3 percent discount rate. Talc suppliers would incur costs to regularly test lots or batches of talc for asbestos and manufacturers of talc-containing cosmetics would incur costs to maintain qualified talc-suppliers. We estimate that annualized costs of asbestos testing over 10 years would equal $3.50 million at a 7 percent discount rate and $3.52 million at a 3 percent discount rate.

In Table 16, we summarize the benefits and costs of the proposed rule. The net monetized benefits of the proposed rule, if finalized, equal the sum of monetized benefits minus the sum of monetized costs. The net monetized benefits of the proposed rule, annualized over 10 years, would equal -$3.47 million at a 7 percent discount rate and -$3.49 million at a 3 percent discount rate. These estimates exclude qualitative benefits and costs, such as benefits from reduced exposure to asbestos.

Table 16. Summary of Annualized Benefits and Costs of the Proposed Rule over 10 Years ($m)

Impact	Type of Estimate	Primary Estimate (7%)	Primary Estimate (3%)
Benefits from reduced exposure to asbestos	Qualitative	N/A	N/A
Cost savings from fewer recalls of talc-containing cosmetics	Monetized	$0.06	$0.06
Cost to read and understand the rule	Monetized	$0.03	$0.03
Asbestos testing costs	Monetized	$3.50	$3.52
Net benefits	Monetized	($3.47)	($3.49)

Negative values in parentheses. Negative net benefits represent net costs.

I. Analysis of Regulatory Alternatives to the Proposed Rule

In this section, we discuss two regulatory alternatives to the proposed rule. First, we consider a regulatory alternative in which we require finished product testing of talc-containing cosmetics, rather than allowing manufacturers to rely on a certificate of analysis to satisfy the requirements of the proposed rule. Second, we consider a regulatory alternative in which we relax the requirement for initial supplier qualification and subsequent annual verification of certificates of analysis.

1. Finished Product Asbestos Testing

The proposed rule, if finalized, would allow manufacturers of talc-containing cosmetics to rely on certificates of analysis from talc suppliers in lieu of conducting testing themselves. The proposed rule would also allow manufacturers of talc-containing cosmetics to test talc instead of testing finished products. As an alternative to the proposed rule, we could remove these flexibilities and require manufacturers to conduct asbestos testing on finished talc-containing cosmetic products.

Under this regulatory alternative, we expect that manufacturers would test each batch or lot of finished talc-containing cosmetics products. Therefore, to estimate the asbestos testing costs under this regulatory alternative, we first need to estimate how many batches or lots of talc-containing cosmetics manufacturers produce each year. Because we do not have information on the average batch size of talc-containing cosmetics, we approximate the number of tests by assuming that the ratio of talc-containing cosmetic products to talc "products" equals the ratio of finished product tests to tests on talc by suppliers.

From Table 4, the number of talc-containing cosmetic products ranges from 13,764 to 14,155, with a primary estimate of 13,961. For the number of talc products, each talc supplier produces one product, bulk talc. Therefore, the total number of talc products equals 30, the number of talc suppliers. From Table 15, the total number of tests on talc from suppliers equals the number of batch or lot tests, which would range from 6 to 397, with a primary estimate of 207 tests. Finally, the number of finished product tests under this regulatory alternative equals the number of talc-containing cosmetic products divided by the number of number products times the number of tests by talc suppliers. We estimate the total number of annual finished product tests would then range from 2,660 to 187,413, with a primary estimate of 96,463. These estimates do not include the costs associated with any product destruction that would occur when a firm identifies asbestos in a finished product.

We assume that the average cost per asbestos test would range from $2,660 to $5,182. Then, the annual asbestos testing costs would range from $5.51 million to $971.11 million, with a primary estimate of $349.89 million. We summarize the annual costs of this alternative in Table 17, We assume that these costs would begin one year following the publication of the final rule.

Table 17. Annual Costs of Finished Product Asbestos Testing

Row Number	Value	Low Estimate	Primary Estimate	High Estimate	Source
1	Number of cosmetic products	13,764	13,961	14,155	Table 4
2	Number of talc products	30	30	30	Section II.D.2
3	Number of batch or lot tests by talc suppliers	6	207	397	Table 15
4	Number of finished product tests	2,660	96,463	187,413	Row 1 ÷ Row 2 × Row 3
5	Cost per test ($)	$2,073	$3,627	$5,182	Section II.F.2.b
6	Annual testing costs ($m)	$5.51	$349.89	$971.11	Row 4 × Row 5

The present value of asbestos testing costs over 10 years would range from $32.92 million to $5,798.80 million at a 7 percent discount rate, with a primary estimate of $2,089.28 million, and from $38.70 million to $6,816.91 million at a 3 percent discount rate, with a primary estimate of $2,456.10 million. Annualized costs would range from $4.38 million to $771.61 million at a 7 percent discount rate, with a primary estimate of $278.01 million, and from $4.40 million to $775.87 million at a 3 percent discount rate, with a primary estimate of $279.54 million. In Table 18, we summarize the benefits and costs of this regulatory alternative.

Table 18. Summary of Annualized Benefits and Costs with Finished Product Asbestos Testing over 10 Years ($m)

Impact	Type of Estimate	Primary Estimate (7%)	Primary Estimate (3%)
Benefits reduced exposure to asbestos	Qualitative	N/A	N/A
Cost savings from fewer recalls of talc-containing cosmetics	Monetized	$0.06	$0.06
Cost to read and understand the rule	Monetized	$0.03	$0.03
Asbestos testing costs	Monetized	$278.01	$279.54
Product destruction costs	Qualitative	N/A	N/A
Net benefits	Monetized	($277.97)	($279.51)

Negative values in parentheses. Negative net benefits represent net costs.

2. Maintaining Qualified Suppliers Without Any Verification Testing

The proposed rule, if finalized, would require manufacturers who choose to rely on a talc supplier's certificate of analysis to qualify the supplier by establishing the reliability of the supplier's certificate of analysis through initial verification of results of the supplier's tests for asbestos, and then to subsequently annually verify the reliability of the certificates of analysis provided by their talc suppliers through testing. As an alternative to the proposed rule, we could eliminate these requirements for verification testing.

In Table 15, we estimate that, under the proposed rule, manufacturers would conduct between 763 and 841 verification tests annually, with a primary estimate of 801 tests. If we did not require verification testing, the total number of tests would range from 6 tests to 397 tests, with a primary estimate of 207 tests. Assuming the cost to test a lot or batch of talc and prepare a certificate of analysis would range from $2,073 to $5,182 per test, the annual total testing cost in

this regulatory alternative would range from $0.01 million to $2.06 million, with a primary estimate of $0.75 million. We assume that suppliers would incur these costs annually starting one year after the publication of the final rule.

The present value of testing costs over 10 years would range from $0.07 million to $12.29 million at a 7 percent discount rate, with a primary estimate of $4.49 million, and from $0.08 million to $14.45 million at a 3 percent discount rate, with a primary estimate of $5.28 million. Annualized costs over 10 years would range from $0.01 million to $1.64 million at a 7 percent discount rate, with a primary estimate of $0.60 million, and from $0.01 million to $1.64 million at a 3 percent discount rate, with a primary estimate of $0.60 million. In Table 19, we summarize the benefits and costs of this regulatory alternative.

Table 19. Summary of Annualized Benefits and Costs with No Verification of Certificates of Analysis over 10 Years ($m)

Impact	Type of Estimate	Primary Estimate (7%)	Primary Estimate (3%)
Benefits from reduced exposure to asbestos	Qualitative	N/A	N/A
Cost savings from fewer recalls of talc-containing cosmetics	Monetized	$0.06	$0.06
Cost to read and understand the rule	Monetized	$0.03	$0.03
Asbestos testing costs	Monetized	$0.60	$0.60
Net benefits	Monetized	($0.57)	($0.56)

Negative values in parentheses. Negative net benefits represent net costs.

3. Verification Testing by Third-Party Certification Organization

The proposed rule, if finalized, would require manufacturers who choose to rely on a talc supplier's certificate of analysis to qualify the supplier by establishing the reliability of the supplier's certificate of analysis through initial verification of results of the supplier's tests for asbestos, and then to subsequently annually verify the reliability of the certificates of analysis provided by their talc suppliers through testing. As an alternative to the proposed rule, we could authorize a third-party certification organization to coordinate verification testing.

In Table 15, we estimate that, under the proposed rule, talc suppliers conduct between 6 and 397 regular asbestos tests each year, with a primary estimate of 207 tests. If a third-party certification organization organized this verification testing, then we assume that the organization would conduct one verification test per talc supplier annually, for an additional 30 asbestos tests per year (1 test per talc supplier × 30 talc suppliers). The total number of asbestos tests per year would then range from 36 tests to 427 tests, with a primary estimate of 237 tests. Assuming the cost to test a lot or batch of talc and prepare a certificate of analysis would range from $2,073 to $5,182 per test, the annual total testing cost in this regulatory alternative would range from $0.07 million to $2.21 million, with a primary estimate of $0.86 million. We assume that suppliers and the third-party certification organization would incur these costs annually starting one year after the publication of the final rule.

These estimates do not include any coordination costs associated with organizing third-party certification, including any costs for FDA to authorize such an organization.

The present value of testing costs over 10 years would range from $0.44 million to $13.22 million at a 7 percent discount rate, with a primary estimate of $5.14 million, and from $0.52 million to $15.54 million at a 3 percent discount rate, with a primary estimate of $6.04 million. Annualized costs over 10 years would range from $0.06 million to $1.76 million at a 7 percent discount rate, with a primary estimate of $0.68 million, and from $0.06 million to $1.77 million at a 3 percent discount rate, with a primary estimate of $0.69 million. In Table 20, we summarize the benefits and costs of this regulatory alternative.

Table 20 Summary of Annualized Benefits and Costs with Third-Party Verification Testing over 10 Years ($m)

Impact	Type of Estimate	Primary Estimate (7%)	Primary Estimate (3%)
Benefits from reduced exposure to asbestos	Qualitative	N/A	N/A
Cost savings from fewer recalls of talc-containing cosmetics	Monetized	$0.06	$0.06
Cost to read and understand the rule	Monetized	$0.03	$0.03
Asbestos testing costs	Monetized	$0.68	$0.68
Net benefits	Monetized	($0.65)	($0.65)

Negative values in parentheses. Negative net benefits represent net costs.

J. Distributional Effects

There is limited evidence suggesting that this proposed rule may benefit Black women more than other groups. Black women are more likely to apply talc to the genitals. An epidemiological survey of douching and genital talc use among women in the United States estimates that Non-Hispanic Black women were more likely to report using genital talc both between the ages of 10 and 13 and in the last 12 months than non-Hispanic White women or Hispanic/Latina women (Ref. 22). Zota et al. (2017) argue African American women face higher chemical exposures from vaginal douches and other feminine care products due to odor discrimination (Ref. 23).

Some evidence suggests an association between genital talc use and ovarian cancer. Taher et al. (2019) conducted a meta-analysis of relevant epidemiological research from 1982 to 2016 (Ref. 24). They found an association between genital talc use and epithelial ovarian cancer, with an odds ratio of 1.28. However, they found that the mechanism for this relationship is unclear. Asbestos contamination may be a contributing factor (Ref. 25), but studies in animals suggest alternative mechanisms. Therefore, we cannot conclusively determine whether the proposed rule would reduce rates of ovarian cancer in Black women more than in other groups from less use of genital talc contaminated with asbestos. We request comments on these possible distributional effects and any other distributional effects of this proposed rule.

More generally, there may be insights from a distributionally weighted analysis to account for diminishing marginal utility of income in accordance with Circular A-4 (see the Technical Appendix B) in this RIA.[22] Circular A-4 recommends a simple formula for computing weights based on income. The formula places larger weights on the dollar values of costs and benefits to

[22] See Circular A-4 Section 10(e), Weights and Benefit-Cost Analysis, for a more detailed description: https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf

low-income households and vice versa for high-income households. That is, the weights reflect the diminishing marginal utility of income: the finding from economics that an incremental (marginal) dollar increases the utility of a high-income person by less than it increases the utility of a low-income person. We request comment on application of income-weighting distributional analysis.

K. International Effects

The requirements of this proposed rule would apply to all firms that manufacture talc-containing cosmetics for sale to consumers in the United States. The rule would also impact talc suppliers, including international suppliers, that manufacturers rely on to provide certificates of analysis. As noted in Table 15, we estimate using VCRP data that the ratio of cosmetic products manufactured domestically to cosmetics products manufactured internationally is 2.59. Additionally, the U.S. Geological Survey estimates that there were talc imports of 330,000 metric tons in 2022 (Ref. 9). This proposed rule would create compliance costs for international talc suppliers and international firms that manufacture cosmetics for sale in the United States.

L. Uncertainty and Sensitivity Analysis

1. Breakeven Analysis

A significant source of uncertainty for this proposed rule is the magnitude of the risk reduction for asbestos-related illnesses. To illustrate the potential benefits of this proposed rule, if finalized, we conduct a breakeven analysis. In this analysis, summarized in Table 21, we estimate the number of avoided cases of mesothelioma required for the monetized benefits of this proposed rule to exceed the monetized costs. We choose mesothelioma because it is the type of cancer most associated with asbestos inhalation exposure. However, the requirement to test talc-containing cosmetic products using standardized testing methods for detecting and identifying asbestos that may be present as a contaminant in talc would, if such products are found to contain asbestos and are kept off the market, reduce the number of asbestos-contaminated talc-containing cosmetic products being sold to consumers—not only powdered talc products—which could reduce the risk of other types of cancers including cancers of the lung, larynx, and ovaries caused by asbestos exposure.

In Table 12 we estimated that the expected value per statistical case of mesothelioma at the time of illness onset would equal $10.16 million at a 7 percent discount rate and $11.09 million at a 3 percent discount rate. The latency period for mesothelioma following asbestos exposures ranges from 13 to 70 years (Ref. 7), for an average latency period of 41 years. To estimate the willingness-to-pay to reduce exposure to asbestos, we discount the value per statistical case from the time of disease onset to the time of the risk reduction; that is, the time of exposure to asbestos. We also account for the probability of an individual surviving between the time of exposure and the time of illness onset, unrelated to mortality associated with asbestos-related illnesses. Using conditional survival probabilities from the Centers for Disease Control's (CDC) Life Tables, if an individual is exposed to asbestos at age 34, the probability that they survive for 41 years until the time of illness onset is 68 percent.[23] Therefore, the willingness-to-pay at the time of the risk reduction is the willingness to pay today for a benefit in 41 years, multiplied by

[23] https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/NVSR/71-01/Table01.xlsx

the probability of surviving 41 years, which equals $0.67 million at a 7 percent discount rate and $3.49 million at a 3 percent discount rate.

Next, we calculate the annualized benefit of avoiding one asbestos exposure leading to mesothelioma each year for ten years, starting one year after the publication of the final rule. The annualized benefit of avoiding one asbestos exposure leading to mesothelioma annually equals $0.54 million at a 7 percent discount rate and $2.79 million at a 3 percent discount rate. The annualized net costs of the proposed rule equal $1.59 million at a 7 percent discount rate and $1.74 million at a 3 percent discount rate. Dividing the annualized costs of the proposed rule by the annualized benefit of avoiding one asbestos exposure leading to mesothelioma yields the number of avoided asbestos exposures leading to mesothelioma required for benefits to equal costs. We estimate that if the proposed rule would reduce the number of asbestos exposures leading to mesothelioma each year by more than 6.49 at a 7 percent discount rate or 1.25 at a 3 percent discount rate, then the benefits of the proposed rule would exceed its costs.

Table 21. Mesothelioma Breakeven Analysis

Row Number	Value	Primary Estimate (7%)	Primary Estimate (3%)	Source
1	Expected Value per Statistical Case ($m)	$10.16	$11.09	Table 12
2	Average Latency Period (Years)	41	41	Ref. 7
3	Probability of Surviving Latency Period	68%	68%	CDC Life Tables
4	Willingness-to-Pay for Risk Reduction ($m)	$0.67	$3.49	(Row 1 ÷ (1 + Discount Rate) ^ Row 2) × Row 3
5	Annualized Benefit of Avoiding 1 Exposure Leading to Mesothelioma per Year ($m)	$0.54	$2.79	Annualized Value of Row 4 over 10 Years, Annually Starting in Year 1
6	Annualized Net Costs of the Rule ($m)	$3.47	$3.49	Table 16
7	Avoided Exposures Required for Benefits to Exceed Costs	6.49	1.25	Row 6 ÷ Row 5

We note that, as described in Nardinelli (2018), breakeven analysis "may give the impression that we know whether net benefits [would] be positive or negative." (Ref. 26) As we detail in our benefits analysis, we are uncertain of the magnitude of any public health benefits from fewer exposures to asbestos and, consequently, whether the net benefits of this proposed rule would be positive or negative.

2. Alternative Discount Rate Analysis

In 2023, the Office of Management and Budget finalized new guidance for Regulatory Impact Analysis.[24] This new guidance recommends that Agencies use a 2 percent discount rate when discounting benefits, costs, and transfers over time. While this analysis predates the deadline for

[24] https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf

compliance with this new guidance, in this section we examine the sensitivity of our results using the 2 percent discount rate.

In Table 22, we present the value per statistical case of asbestos-related illness using a 2 percent discount rate.

Table 22. Value per Statistical Case of Asbestos-Related Illness at a 2 Percent Discount Rate ($m)

Type of Cancer	Low	Primary	High
Mesothelioma	$5.30	$11.36	$17.30
Lung Cancer	$4.42	$9.47	$14.43
Larynx Cancer	$3.05	$6.55	$9.97
Ovarian Cancer	$3.30	$7.08	$10.78

In Table 23, we present the annualized benefits and costs of the proposed rule at the alternative discount rate. The annualized benefits of the proposed rule over 10 years would range from $0.00 million to $1.40 million at a 2 percent discount rate, with a primary estimate of $0.06 million. The annualized costs of the proposed rule over 10 years would range from $1.30 million to $6.82 million at a 2 percent discount rate, with a primary estimate of $3.55 million.

Table 23. Summary of Annualized Benefits and Costs of the Proposed Rule over 10 Years at a 2 Percent Discount Rate ($m)

Impact	Type of Estimate	Low Estimate	Primary Estimate	High Estimate
Public health benefits from fewer asbestos-related illnesses	Qualitative	N/A	N/A	N/A
Cost savings from fewer recalls of talc-containing cosmetics	Monetized	$0.00	$0.06	$1.40
Cost to read and understand the rule	Monetized	$0.02	$0.03	$0.04
Asbestos testing costs	Monetized	$1.28	$3.53	$6.67
Net benefits	Monetized	($6.82)	($3.49)	$0.10

Negative values in parentheses. Negative net benefits represent net costs. The low estimate of net benefits equals the low estimate of benefits minus the high estimate of costs. The high estimate of net benefits equals the high estimate of benefits minus the low estimate of costs.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would impose small costs on affected firms, relative to annual revenue, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Small Entities

We use NAICS Code 325620, "Toilet Preparations Manufacturing," to characterize cosmetics manufacturers and NAICS Code 212390, "Nonmetallic Mining and Quarrying," to characterize talc producers and suppliers. Then, according to the Small Business Administration's size standards, a small cosmetics manufacturer is a firm with fewer than 1,250 employees and a small talc producer or supplier is a firm with fewer than 600 employees.[25]

In Table 24, we present data from the United States Census Bureau (Census) on the number of firms by employment size in these two industries in 2017.[26] We find that 87 percent of firms in the Nonmetallic Mining and Quarrying industry are small businesses and 97 percent of firms in the Toilet Preparations Manufacturing industry are small businesses.

Table 24. Number and Percent of Firms, by Employment Size and Industry

Employment	Nonmetallic Mining and Quarrying		Toilet Preparations Manufacturing	
	Number of Firms	Percent of Firms	Number of Firms	Percent of Firms
0-19 Employees	91	57%	623	67%
20-99 Employees	27	17%	183	20%
100-499 Employees	16	10%	71	8%
500-999 Employees	5	3%	17	2%
1,000-1,499 Employees	0	0%	3	0%
All Small	139	87%	897	97%
Total	159	100%	926	100%

B. Description of the Potential Impacts of the Rule on Small Entities

In Table 25, we estimate the average net costs per talc supplier and per manufacturer of talc-containing cosmetics over 10 years. As discussed in Section II.F.2, we assume that cosmetics manufacturers would rely on supplier testing rather than testing talc or talc-containing cosmetics themselves. Under this assumption, talc suppliers would incur costs in the first year after publication to read and understand the rule of $412 (0.74 hours per person to read and understand the rule × 3 people per firm × $186 supplier wage rate, from Section II.F.1) and would incur average asbestos testing costs of $25,061 annually thereafter (207 total asbestos tests by talc suppliers from Table 15 × $3,627 average cost per asbestos test ÷ 30 talc suppliers). Manufacturers of talc-containing cosmetics would incur costs in the first year after publication to read and understand the rule of $287 (0.74 hours per person to read and understand the rule × 3 people per firm × $129 manufacturer wage rate from Section II.F.1). Annually thereafter, manufacturers of talc-containing cosmetics would accrue recall cost savings of $100 ($0.08 million in total annual cost savings from Section II.E.2 ÷ 801 manufacturers from Table 5) and would incur average costs of $3,627 to annually verify the validity of certificates of analysis from suppliers. Annual net costs starting in year one would then equal $3,527 ($3,627 in asbestos testing costs - $100 in recall cost savings).

[25] https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.
[26] https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html

Table 25. Stream of Net Costs per Firm over 10 Years ($)

Year	Talc Suppliers	Manufacturers of Talc-Containing Cosmetics
0	$412	$287
1	$25,061	$3,527
2	$25,061	$3,527
3	$25,061	$3,527
4	$25,061	$3,527
5	$25,061	$3,527
6	$25,061	$3,527
7	$25,061	$3,527
8	$25,061	$3,527
9	$25,061	$3,527
Present Value (7%)	$150,061	$21,347
Present Value (3%)	$176,335	$25,044
Annualized Value (7%)	$19,968	$2,840
Annualized Value (3%)	$20,070	$2,850

Annualized net costs per firm would equal $19,968 for talc suppliers and $2,840 for manufacturers of talc-containing cosmetics at a 7 percent discount rate. In Table 26, we compare these annualized net costs to annual receipts, using data from Census. Even for the smallest firms, annualized net costs of the proposed rule represent less than two percent of annual receipts. We therefore propose to certify that this proposed rule will not have a significant impact on a substantial number of small entities.

Table 26. Comparison of Annual Receipts per Firm and Annualized Costs per Firm

Employment	Talc Suppliers		Manufacturers of Talc-Containing Cosmetics	
	Annual Receipts[a] ($m)	Annualized Net Costs as a Percent of Receipts[b]	Annual Receipts[a] ($m)	Annualized Net Costs as a Percent of Receipts[b]
0-19 Employees	$1.76	1.13%	$2.77	0.10%
20-99 Employees	$15.95	0.13%	$22.75	0.01%
100-499 Employees	$32.24	0.06%	$63.57	0.00%
500-999 Employees	$221.41	0.01%	$231.22	0.00%
1,000-1,499 Employees	N/A	N/A	Not Available	Not Available
All Small	$15.93	0.13%	$15.98	0.02%

[a] Annual receipts in millions of 2023 dollars.

[b] We use the annualized value of net costs at a 7 percent discount rate from Table 26 in this calculation.

IV. Appendices

A. Voluntary Cosmetic Registration Program Data

In Table 27, we present the number of products and the number of talc-containing products in the VCRP data for each product category and sub-category as of March 27, 2023. On that date, FDA stopped accepting submissions to the VCRP because of our plans to develop a program for submission of the facility registrations and product listings mandated by MoCRA.[27]

Table 27. Number of Products and Talc-Containing Products in the VCRP by Product Category

Category	Sub-Category	Number of Talc-Containing Products	Number of Products
Baby Products	Baby Shampoos	0	48
	Lotions, Oils, Powders, and Creams	3	141
	Other Baby Products	0	122
Bath Preparations	Bath Oils, Tablets, and Salts	0	420
	Bubble Baths	0	84
	Bath Capsules	1	7
	Other Bath Preparations	1	193
Eye Makeup Preparations	Eyebrow Pencil	34	162
	Eyeliner	20	313
	Eye Shadow	687	1,068
	Eye Lotion	1	249
	Eye Makeup Remover	0	60
	Mascara	24	231
	Other Eye Makeup Preparations	55	538
Fragrance Preparations	Colognes and Toilet Waters	0	560
	Perfumes	0	1,171
	Powders (Dusting and Talcum) (Excluding Aftershave Talc)	1	2
	Sachets	0	0
	Other Fragrance Preparations	0	1,308
Hair Preparations (Noncoloring)	Hair Conditioners	0	1,176
	Hair Sprays (Aerosol Fixatives)	0	206
	Hair Straighteners	0	44
	Permanent Waves	0	5
	Rinses (Noncoloring)	0	39
	Shampoos (Noncoloring)	0	1,238
	Tonics, Dressings, and Other Hair Grooming Aids	0	836
	Wave Sets	0	19
	Other Hair Preparations	2	625
Hair Coloring Preparations	Hair Dyes and Colors	0	454
	Hair Tints	4	17
	Hair Rinses (Coloring)	0	18

[27] https://www.fda.gov/food/cfsan-constituent-updates/fda-has-stopped-accepting-submissions-voluntary-cosmetic-registration-program-vcrp

Category	Sub-Category	Number of Talc-Containing Products	Number of Products
	Hair Shampoos (Coloring)	0	30
	Hair Color Sprays (Aerosol)	0	30
	Hair Lighteners with Color	0	5
	Hair Bleaches	2	23
	Other Hair Coloring Preparations	0	99
Makeup Preparations (Not Eye)	Blushers (All Types)	250	356
	Face Powders	227	368
	Foundations	51	353
	Leg and Body Paints	5	17
	Lipstick	100	1,644
	Makeup Bases	13	117
	Rouges	10	78
	Makeup Fixatives	1	28
	Other Makeup Preparations	70	644
Manicuring Preparations	Basecoats and Undercoats	0	68
	Cuticle Softeners	0	26
	Nail Creams and Lotions	0	10
	Nail Extenders	0	23
	Nail Polish and Enamel	2	690
	Nail Polish and Enamel Removers	0	38
	Other Manicuring Preparations	7	273
Oral Hygiene Products	Dentifrices (Aerosol, Liquid, Pastes, and Powders)	0	156
	Mouthwashes and Breath Fresheners (Liquids and Sprays)	0	80
	Other Oral Hygiene Products	0	119
Personal Cleanliness	Bath Soaps and Detergents	46	2,024
	Deodorants (Underarm)	33	460
	Douches	0	43
	Feminine Hygiene Deodorants	1	21
	Other Personal Cleanliness Products	4	479
Shaving Preparations	Aftershave Lotion	0	80
	Beard Softeners	0	45
	Men’s Talcum	0	0
	Preshave Lotions (All Types)	0	12
	Shaving Cream (Aerosol, Brushless, and Lather)	0	53
	Shaving Soap (Cakes, Sticks, etc.)	0	15
	Other Shaving Preparation Products	0	55
Skin Care Preparations (Creams, Lotions, Powder, and Sprays)	Cleansing (Cold Creams, Cleansing Lotions, Liquids, and Pads)	19	2,139
	Depilatories	0	117
	Face and Neck (Excluding Shaving Preparations)	17	2,670
	Body and Hand (Excluding Shaving Preparations)	4	1,064
	Foot Powders and Sprays	0	2
	Moisturizing	25	5,028
	Night	3	326

Category	Sub-Category	Number of Talc-Containing Products	Number of Products
	Paste Masks (Mud Packs)	6	273
	Skin Fresheners	0	215
	Other Skin Care Preparations	15	1,548
Suntan Preparations	Suntan Gels, Creams, and Liquids	0	52
	Indoor Tanning Preparations	1	34
	Other Suntan Preparations	0	19

Data accessed on April 6, 2023, containing submissions through March 27, 2023.

1. IRI Data

In Table 28, we present the IRI product categories used in our analysis matched to the product categories in the VCRP. When product categories did not align across databases, we used the closest possible match based on product characteristics. For example, the closest corollary to the VCRP sub-category "Leg and Body Paints" in the IRI data is the sub-category "Foundation."

To calculate the share of talc-containing products $share_i$ in each IRI sub-category i, we use the following formula:

$$share_i = \frac{\sum_{j \in C_i} n_j}{\sum_{j \in C_i} N_j}$$

where C_i is the set of VCRP product categories matched to IRI sub-category i, j indexes the VCRP sub-categories, n_j is the number of talc-containing products in the VCRP sub-category j, and N_j is the total number of products in the VCRP sub-category j.

Table 28. Share of Talc-Containing Products in IRI Product Sub-Categories

Category	Sub-Category	VCRP Sub-Category Matches	Share of Talc-Containing Products
Baby Needs	Baby Lotions	Lotions, Oils, Powders, and Creams	2.13%
	Baby Oils	Lotions, Oils, Powders, and Creams	2.13%
	Baby Ointment /Creams	Lotions, Oils, Powders, and Creams	2.13%
	Baby Powder	Lotions, Oils, Powders, and Creams	2.13%
	Baby Shampoo	Baby Shampoos	0.00%
	Baby Soaps	Other Baby Products	0.00%
	Baby Wipes	Other Baby Products	0.00%
Bath Products	Bath Fragrances /Bubble Baths	Bath Oils, Tablets, and Salts; Bubble Baths; Bath Capsules; Other Bath Preparations	0.28%
Cosmetics – Eye	Eye Brow Makeup	Eyebrow Pencil	20.99%
	Eye Combo	Other Eye Makeup Preparations	10.22%
	Eye Liner	Eyeliner	6.39%
	Eye Shadow	Eye Shadow	64.33%

Category	Sub-Category	VCRP Sub-Category Matches	Share of Talc-Containing Products
	Mascara	Mascara	10.39%
Cosmetics – Facial	Blush	Blushers (All Types); Rouges	52.73%
	Bronzer	Blushers (All Types)	70.22%
	Concealer	Foundations	14.45%
	Foundation	Foundations; Leg and Body Paints; Makeup Bases; Makeup Fixatives	13.15%
	Makeup Combo	Other Makeup Preparations	10.87%
	Powder	Face Powders	61.68%
Cosmetics – Lip	Lip Combo	Lipstick	6.08%
	Lip Gloss	Lipstick	6.08%
	Lip Liner	Lipstick	6.08%
	Lip Treatment	Lipstick	6.08%
	Lipstick	Lipstick	6.08%
Cosmetics – Nail	Artificial Nails and Accessories	Nail Extenders	0.00%
	Nail Polish	Nail Polish and Enamel; Basecoats and Undercoats	0.26%
	Nail Polish Removers	Nail Polish and Enamel Removers	0.00%
	Nail Treatment	Cuticle Softeners; Nail Creams and Lotions; Other Manicuring Preparations	2.27%
Cosmetics Accessories	Eyelash Adhesives	Other Eye Makeup Preparations	10.22%
	False Eyelashes and Adhesives	Other Eye Makeup Preparations	10.22%
	Makeup Remover (Lotion/Gel)	Eye Makeup Remover	0.00%
Deodorant	Deodorants	Feminine Deodorants; Deodorants (Underarm)	7.07%
Feminine Needs	Douches	Douches	0.00%
Foot Care Products	Food Care	Food Powders and Sprays	0.00%
Fragrances – Women's	Perfumes & Colognes/Body Powder	Cologne and Toilet Waters; Perfumes; Powders (Dusting and Talcum, Excluding Aftershave Talc); Other Fragrance Preparations	0.03%
	Women's Gift Packs	Cologne and Toilet Waters; Perfumes; Powders (Dusting and Talcum, Excluding Aftershave Talc); Other Fragrance Preparations	0.03%
Hair Coloring	Men's Hair Coloring	Hair Dyes and Colors; Hair Tins; Hair Rinses (Coloring); Hair Shampoos (Coloring); Hair Color Sprays (Aerosol); Hair Lighteners with Color; Hair Bleaches; Other Hair Coloring Preparations	0.89%
	Unisex Hair Coloring	Hair Dyes and Colors; Hair Tins; Hair Rinses (Coloring); Hair Shampoos (Coloring); Hair Color Sprays (Aerosol); Hair Lighteners with	0.89%

Category	Sub-Category	VCRP Sub-Category Matches	Share of Talc-Containing Products
		Color; Hair Bleaches; Other Hair Coloring Preparations	
	Women's Hair Coloring	Hair Dyes and Colors; Hair Tins; Hair Rinses (Coloring); Hair Shampoos (Coloring); Hair Color Sprays (Aerosol); Hair Lighteners with Color; Hair Bleaches; Other Hair Coloring Preparations	0.89%
Hair Conditioner	Hair Conditioner /Crème Rinse	Hair Conditioner	0.00%
Hair Growth Products	Hair Growth Products	Tonics, Dressings, and Other Hair Grooming Aids	0.00%
Hair Spray /Spritz	Hair Spray /Spritz	Hair Spray (Aerosol Fixative)	0.00%
Hair Styling Gel/Mouse	Hair Styling /Setting Gel /Mousse	Other Hair Preparations	0.32%
Hand & Body Lotion	Hand & Body Lotion	Body and Hand (Excluding Shave)	0.38%
Home Permanent /Relaxer Kits	Hair Relaxer Kits	Hair Straighteners	0.00%
	Home Permanent Kits	Wave Sets; Permanent Waves	0.00%
Moist Towelettes	Moist Towelettes	Other Personal Cleanliness Products	0.84%
Mouthwash	Mouthwash /Dental Rinse	Mouthwashes and Breath Fresheners	0.00%
Shampoo	Dandruff Shampoo	Shampoos (Non-Coloring)	0.00%
	Dry Shampoo	Shampoos (Non-Coloring); Other Hair Preparations	0.16%
	Regular Shampoo	Rinses (Non-Coloring); Shampoos (Non-Coloring)	0.00%
	Shampoo & Conditioner Combo Pack	Shampoos (Non-Coloring); Rinses (Non-Coloring); Hair Conditioner	0.00%
Shaving Cream	Shaving Cream	Shaving Cream; Shaving Soap; Other Sharing Preparation Products	0.00%
Shaving Lotion /Men's Fragrance	Men's Gift Pack Sets	Cologne and Toilet Waters; Perfumes; Powders (Dusting and Talcum, Excluding Aftershave Talc); Other Fragrance Preparations; Aftershave Lotion; Preshave Lotions (All Types); Beard Softeners	0.03%
	Shaving Lotion /Cologne/Talc	Cologne and Toilet Waters; Perfumes; Powders (Dusting and Talcum, Excluding Aftershave Talc); Other Fragrance	0.03%

Category	Sub-Category	VCRP Sub-Category Matches	Share of Talc-Containing Products
		Preparations; Aftershave Lotion; Preshave Lotions (All Types); Beard Softeners	
Skin Care	Body Anti-Aging	Body and Hand (Excluding Shave)	0.38%
	Depilatories	Depilatories	0.00%
	Facial Anti-Aging	Face and Neck (Excluding Shave); Moisturizing; Night; Eye Lotion; Other Skin Care Preparations	0.60%
	Facial Cleansing	Other Skin Care Preparations; Skin Fresheners; Paste Masks (Mud Packs); Cleaning	1.04%
	Facial Moisturizers	Face and Neck (Excluding Shave); Moisturizing; Night; Eye Lotion; Other Skin Care Preparations	0.60%
Soap	Deodorant Bar Soap	Bath Soaps and Detergents; Cleansing	1.62%
	Heavy Duty Hand Cleaner	Bath Soaps and Detergents; Cleansing	1.62%
	Liquid Body Wash/All Other	Bath Soaps and Detergents; Cleansing	1.62%
	Liquid Hand Soap	Bath Soaps and Detergents; Cleansing	1.62%
	Non-Deodorant Bar Soap	Bath Soaps and Detergents; Cleansing	1.62%
Suntan Products	Suntan Lotion & Oil	Suntan Gels, Creams, and Liquids; Body and Hand (Excluding Shave); Other Suntan Preparations	0.31%
Toothpaste	Tooth Bleaching /Whitening	Other Oral Hygiene Products	0.00%
	Toothpaste	Dentifrices (Aerosol, Liquid, Pastes, and Powders)	0.00%

B. Distributional Weighting

In this appendix, we discuss the potential effect of distributional weighting to account for diminishing marginal utility of income in accordance with Circular A-4.[28] Traditionally-weighted benefit-cost analysis (BCA) calculates the difference between the willingness to pay or accept of those who experience benefits from a regulation and the willingness to pay or accept, which underlies opportunity cost, of those who experience costs. In these analyses equal weight is applied to the dollar value of benefits and costs experienced by individuals and households, regardless of income.[29]

The distributional weighting procedure outlined in this technical appendix could be applied to our primary estimates. We only quantify costs and cost savings to talc suppliers and manufacturers of talc-containing cosmetics (so the estimates would apply to the same subpopulation and would only impact the magnitude of these estimates). Alternatively, the procedure could be applied to our breakeven analysis: the distributional weight on consumers of talc-containing cosmetic products would vary from the distributional weight on talc suppliers and manufacturers of talc-containing products. For this proposed rule, distributional weighting is measured by estimating the costs borne by consumers from higher prices via pass-through and the cost borne by firms which is distributionally weighted using household ownership of private firms and household and institutional ownership of U.S. equities of publicly traded firms.

We only discuss a hypothetical application of distributional weighting in this technical appendix, as these estimates are from a working paper that uses proprietary data not currently available to FDA economists. We request comments on this approach for distributional weighting.

Circular A-4 refers to the net benefit calculated in BCA as a measure of social welfare. However, this traditionally-weighted BCA does not fully account for the difference in the welfare impact on individuals of effects at different levels of the income distribution of benefits and costs. Because of the diminishing marginal utility of income, the same increase or decrease in welfare will be associated with fewer dollars when it accrues to a low-income person than when it accrues to a high-income person.

Circular A-4 recommends a formula for computing weights for households at different income levels (we will refer to this as distributionally-weighted), using a function of the ratio of median income to the income of the household. Applying these weights to the benefits and costs accruing to different groups accounts for diminishing marginal utility when aggregating those benefits and costs. These weights are greater than one for households below median income and less than one for households above. When these weights have been applied to the dollar value placed by households on the costs and benefits they experience, the result can be thought of as the dollar value that households would place on the costs and benefits they experience, if they had income equal to the median. Therefore, the distributionally-weighted BCA can be thought of as the net benefit of a regulation, accounting for the relative welfare a marginal dollar would produce for an income subgroup.

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[28] See Circular A-4 Section 10(e), Weights and Benefit-Cost Analysis, for a more detailed description: https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf

[29] Except insofar as income is implicitly reflected in market prices or other values extrapolated for purposes of monetization.

It is important to note that it is not possible to compute distributionally-weighted costs and benefits without first knowing the traditionally-weighted estimates of the costs and benefits to households at different income levels. For our primary estimates, we quantify costs and cost savings to industry, but we do not quantify or monetize public health benefits from fewer asbestos-related illnesses due to data limitations. However, it is possible to use the weighting methodology outlined in Circular A-4 to generate useful information about the effect of distributional weighting on the costs and benefits of the regulation, provided one has information on the distribution of income among the populations affected by the regulation and some proxy for the cost or benefit (hereafter, "impact") borne by households at different income levels. With this information, for each impact to each affected population, it is possible to compute the ratio of distributionally-weighted impact to traditionally-weighted impact, which we refer to as the "population weight" for the various impacts experienced by the various affected populations. For example, if the population weight for the benefit of a regulation to consumers is 1.5, it means that the distributionally-weighted benefit is 50 percent greater than the traditionally-weighted benefit. If the traditionally-weighted benefit were known, multiplying it by 1.5 would give the distributionally-weighted benefit. A higher coefficient indicates the benefit is disproportionately experienced by lower-income members of the affected population.

It is not necessary to know the dollar value of cost or benefit experienced by individual households to compute population weights. All that is necessary is to have an observable proxy for the cost or benefit per household that is directly proportional to the actual dollar value of the cost or benefit. For example, if a portion of the cost of compliance with a regulation is borne by consumers of the regulated good, it may be plausible to assume that the cost borne by any given household is proportional to the quantity of the regulated product they consume, which may be observable. Multiplying the quantity consumed by a household by its distributional weight provides a proxy for the distributionally-weighted cost borne by the household. The sum of the proxy across households provides a total traditionally-weighted cost proxy and the sum across households of the product of the proxy and the weight for each household provides what might be called the "distributionally-weighted proxy". The ratio of the total distributionally-weighted proxy to the total traditionally-weighted proxy will be the population weight for cost of compliance borne by consumers. [30]

Another potential impact of a policy could be the public health benefit to consumers of the regulated product, which could be estimated using VSL when the public health benefits impact mortality. Willingness to pay for risk reduction is generally lower among low-income households than among high-income households. In order to apply distributional weights in the

[30] Mathematically, let X_i be the (observed) annual exposure to talc-containing cosmetics for household i, let R_i be the (unobserved) dollar value of cost of compliance borne by household i as a result of the regulation, and let b be the (unobserved) cost of compliance per unit of exposure, which we assume is constant across exposure levels and across households. The (unweighted) cost burden for household i is $R_i = b \times X_i$.
The population weight on the cost to consumers is the ratio of the total weighted cost to the entire consumer population to the total unweighted cost to the entire consumer population. If w_i is the weight on household i, then the weighted cost to each household will be $w_i \times b \times X_i$. Thus, the total weighted cost will be $\sum_i w_i \times b \times X_i = b \times \sum_i w_i \times X_i$ and the total unweighted cost will be $\sum_i b \times X_i = b \times \sum_i X_i$. The population weight, W, will be,

$$W = \frac{b \times \sum_i w_i \times X_i}{b \times \sum_i X_i} = \frac{\sum_i w_i \times X_i}{\sum_i X_i}.$$

case of risk reduction monetized with VSL it is theoretically necessary to first compute the "income-adjusted" VSL for each household and then apply weights. Circular A-4 states that an acceptable alternative is to use the average VSL for all households, regardless of income. If the income elasticity of VSL is approximately equal to the income elasticity of marginal utility of income, this method will provide a close approximation of weighting. The literature on the income elasticity of VSL is inconclusive as to the relationship between the two elasticities. In the face of this uncertainty, we have chosen to adopt the average VSL method as an appropriate approximation of weighting.

1. An Application of Population Weights

To demonstrate a possible application of distributional weighting by income, we estimate weights for different subpopulations that could be affected by this proposed rule. We have not quantified costs or benefits for each of these distinct subpopulations, but this application or a similar application could be used to distributionally weight monetized costs and benefits for this regulatory impact analysis, if traditionally-weighted costs and benefits were known. More relevantly, the population-weighting exercise in this section will provide information about the relative effect of distributional weighting on benefits versus costs and a distributionally-weighted breakeven exercise that we believe is informative about the effects of the rule. These estimates are from a working paper titled *A Population-level Approach to Distributional Weighting* (Acland and Raphael 2024).[31] We request comment on our application of population weights following the approach of *A Population-level Approach to Distributional Weighting* working paper—including, but not limited to, methodology, data sources, and assumptions.

The benefits to consumers are through mortality risk reduction and could be measured in VSL. We do not additionally weight benefits from mortality risk reduction to consumers because, in accordance with Circular A-4, we treat VSL as implicitly income weighted and rely on an average VSL estimate. As discussed above, the result is that the population weight on risk reduction benefits to consumers is one.

The population weights on the cost of compliance to various stakeholders in regulated firms are computed. These include consumers (who would bear a portion of the cost of compliance in the form of price increases), owners of privately-held regulated firms, households that own shares of publicly-traded regulated firms, participants in defined-benefit pension plans that own shares in publicly-traded regulated firms and the beneficiaries of the activities of non-profits that own shares in publicly-traded regulated firms. Income and proxy data for these categories of stakeholders come from a proprietary dataset of consumer purchases of talc-containing powdered cosmetic products, the Survey of Consumer Finance, the ACS, and the Financial Accounts of the U.S. Full details of these data sources can be found in Acland and Raphael (2024). The cost of the regulation is the cost of compliance as presented in Section II.F.

[31] The full working paper *A Population-level Approach to Distributional Weighting* can be found at: https://gspp.berkeley.edu/research-and-impact/working-papers/a-population-level-approach-to-distributional-weighting

Some of this cost would be passed to consumers in the form of price increases. We estimate pass-through in accordance with standard theory, using the ratio of elasticity of supply and demand. Additionally, we believe it is informative to consider how distributional weighting would affect the cost of compliance under hypothetical scenarios in which consumers bear different proportions of the cost burden. It is assumed that any portion of the cost of compliance borne by any given consumer household would be proportional to the volume of regulated products they consume and that the portions borne by individuals and households in the other categories of stakeholders would be proportional to the market value of their ownership stake in regulated firms. The validity of these assumptions is discussed in Acland and Raphael (2024).

Note that in the case of non-profits, it is assumed that the value of shares owned accrues to those households who benefit from the activities of the non-profits that hold the shares. It is not possible to identify, even approximately, which non-profits hold shares or who ultimately benefits from their activities. Instead, we make the simplifying assumption that the traditionally-weighted dollar benefit generated by non-profits that hold shares is constant across all households.

Table 29 shows the population weights on the five categories of stakeholders: [32]

- consumers, W_{cons},
- owners of privately-held firms, W_{priv},
- households that own shares of publicly-traded firms, W_{hhpub},
- participants in defined-benefit pension plans that own shares of publicly-traded firms, W_{dbpub},
- beneficiaries of the activities of non-profit organizations that own shares of publicly-traded firms, W_{nppub}.

In addition to the population weights for each category of owners and shareholders of regulated firms, the proportion of the traditionally-weighted cost borne by each category was computed, using the same data sources as for the weights themselves. The share of regulated firms that are privately held was determined by an internet search for the ownership type of the firms that own the brands of each of the regulated products from the NielsenIQ's consumer panel Homescan data. It was not possible to determine the proportions of the three categories of shareholders among regulated firms specifically so the proportions among firms as a whole were used as proxies. Data came from the U.S. Financial Accounts. [33]

Using these proportions, the population weights on the three categories of shareholders in publicly-traded firms are proportionally weighted to compute a population weight on cost to all shareholders, W_{pub}. Then the population weights on shareholders and private business owners are proportionally weighted to compute a population weight on all firms, W_{firms}. Finally, the

[32] We note that some portion of the cost of compliance may be borne by employees of the regulated firms, if employers choose to pass the cost to employees in the form of wage or salary reduction. We do not estimate that here.
[33] Source U.S. Financial Accounts: https://www.federalreserve.gov/releases/z1/

population weights on consumers and firms are proportionally weighted to compute a population weight on costs to all stakeholders, W_{cost}.[34]

Table 29. Appendix B.2 Population Weights

	Population weight
Total cost	$W_{cost} = 1.957$[a]
Consumers	$W_{costcons} = 2.424$
Firms	$W_{firms} = 1.032$
Private	$W_{priv} = .641$
Public (shareholders)	$W_{pub} = 1.073$
Households	$W_{hhpub} = .447$
DB pension plans	$W_{dbpub} = .605$
Non-profits	$W_{nppub} = 2.044$

[a] The proportion of cost borne by firms is multiplied by the proportion of firms that are U.S. owned, $p_{US} = .690$.

The first result of note is that the population weight on total costs to consumers ($W_{cost} = 1.957$) is significantly greater than the weight on benefits to consumers, which is constrained to be one. This is largely because in the case of benefits to consumers, we are assuming that the benefit would be computed using average VSL, which means that in effect the benefits would already have been weighted. The weight on total cost to consumers is quite high, because consumers of regulated products are disproportionately lower income households.

Second, the population weight on cost to all firms is very close to one, suggesting that distributional weighting has little effect on costs to firms. It may be noteworthy, however, that it is not significantly less than one, given the fact that households who have ownership stakes in privately and publicly held companies are disproportionately higher income. The reason for this is that the proportion of shares held by non-profits is quite high and, under the assumption that the value generated by non-profit organizations is equally shared across all households in the population, the income distribution in the U.S. is sufficiently skewed to drive the population weight for this group of stakeholders above one. FDA requests comment on these assumptions, potential alternative assumptions, and empirical approaches that might enable FDA to produce a superior estimate.

[34] The proportions are as follows. The proportions of the three categories of shareholders among all shareholders are $p_{hhpub} = .510$, $p_{dbpub} = .110$, and $p_{nppub} = .381$. The proportions of private and public firms are $p_{priv} = .096$ and $p_{pub} = .904$. The proportion of cost burden borne by consumers and firms are $p_{cons} = .727$ and $p_{firms} = .273$, under the assumption that the burden is shared according to the relative elasticities of supply and demand. In the computation of W_{cost} the fact that 31 percent of the cost is borne by foreign firms is accounted for. Note that the burden on U.S. consumers of foreign firms is accounted for in W_{cons}.

V. References

1. **National Toxicology Program**, Report on Carcinogens, Fifteenth Edition. 2021. Available from: http://ntp.niehs.nih.gov/go/roc15.
2. **K. Straif, L. Benbrahim-Tallaa, R. Baan, Y. Grosse, B. Secretan, F. El Ghissassi, V. Bouvard, N. Guha, C. Freeman, L. Galichet, V. Cogliano, and W. H. O. International Agency for Research on Cancer Monograph Working Group**, A review of human carcinogens--Part C: metals, arsenic, dusts, and fibres. *Lancet Oncol*, 2009. **10**(5): p. 453-4. Available from: https://www.ncbi.nlm.nih.gov/pubmed/19418618.
3. **R.E.F. Gordon, Sean; Millette, James**, Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women. *International Journal of Occupational and Environmental Health*, 2014. **20**(4): p. 318-332. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883/.
4. **Cosmetic, Toiletry, and Fragrance Association**, Method J 4-1: Asbestiform Amphibole Minerals in Cosmetic Talc, in *Compendium of Cosmetic Ingredient Composition: Specifications*. 1976. Available from: https://www.cir-safety.org/sites/default/files/032013_web_w2.pdf.
5. **The U.S. Pharmacopeial Convention**, Revision Bulletin: Talc. 2011. Available from: https://www.usp.org/sites/default/files/usp/document/harmonization/excipients/m80360talc.pdf.
6. **Interagency Working Group on Asbestos in Consumer Products**, White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc. 2021. Available from: https://www.regulations.gov/document/FDA-2020-N-0025-0053.
7. **B.P. Lanphear and C.R. Buncher**, Latent period for malignant mesothelioma of occupational origin. *Journal of Occupational Medicine*, 1992: p. 718-721. Available from: https://www.jstor.org/stable/45015507.
8. **Euromonitor International**, Passport: Beauty and Personal Care in the US. 2023.
9. **U.S. Geological Survey**, Talc and Pyrophyllite Mineral Commodity Summary. 2023. Available from: http://pubs.usgs.gov/periodicals/mcs2023/mcs2023-talc.pdf.
10. **T. Stoiber, S. Fitzgerald, and N.S. Leiba**, Asbestos Contamination in Talc-Based Cosmetics: An Invisible Cancer Risk. *Environmental Health Insights*, 2020. **14**. Available from: https://journals.sagepub.com/doi/10.1177/1178630220976558.
11. **R.L. Attanoos, A. Churg, F. Galateau-Salle, A.R. Gibbs, and V.L. Roggli**, Malignant Mesothelioma and Its Non-Asbestos Causes. *Archives of Pathology and Laboratory Medicine*, 2018. **142**(6): p. 753-760. Available from: https://meridian.allenpress.com/aplm/article/142/6/753/65600/Malignant-Mesothelioma-and-Its-Non-Asbestos-Causes.
12. **L. Hazell and S.A.W. Shakir**, Under-Reporting of Adverse Drug Reactions: A Systematic Review. *Drug Safety*, 2006. **29**(5): p. 385-396. Available from: https://link.springer.com/article/10.2165/00002018-200629050-00003.
13. **E. Borrelli, Z. Babcock, and S. Kogut**, Costs of medical care for mesothelioma. *Rare Tumors*, 2019. **11**. Available from: https://journals.sagepub.com/doi/epub/10.1177/2036361319863498.
14. **D.F. Sheehan, S.D. Criss, Y. Chen, A. Eckel, L. Palazzo, A.C. Tramontano, C. Hur, L.E. Cipriano, and C.Y. Kong**, Lung cancer costs by treatment strategy and phase of

care among patients enrolled in Medicare. *Cancer Medicine*, 2018. **8**(1): p. 94-103. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1002/cam4.1896.
15. **C.G. Gourin, S.M. Dy, R.J. Herbert, A.L. Blackford, H. Quon, A.A. Forastiere, D.W. Eisele, and K.D. Frick**, Treatment, Survival, and Costs of Laryngeal Cancer Care in the Elderly. *The Laryngoscope*, 2014. **124**(8): p. 1827-1835. Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/lary.24574.
16. **A.S. Bercow, L. Chen, S. Chaterjee, A.I. Tergas, J.Y. Hou, W.M. Burke, C.V. Ananth, A.I. Neugut, D.L. Hershamn, and J.D. Wright**, Cost of Care for the Initial Management of Ovarian Cancer. *Obstetrics & Gynecology*, 2017. **130**(6): p. 1269-1275. Available from: https://journals.lww.com/greenjournal/Fulltext/2017/12000/Cost_of_Care_for_the_Initial_Management_of_Ovarian.12.aspx.
17. **Eastern Research Group**, Recall Cost Cast Studies. 2020.
18. **U.S. Department of Health and Human Services**, Guidelines for Regulatory Impact Analysis. 2016. Available from: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171981/HHS_RIAGuidance.pdf.
19. **S.V. deMars, Jaap**, USP's Iterative Approach to Standards Development and the "Emerging Standards" Concept. *Stimuli to the Revision Process*, 2022. Available from: https://www.usp.org/sites/default/files/usp/document/about/annual-report/usp-iterative-approach-to-standards-development-and-the-emerging-standards-concept.pdf.
20. **Grant Thornton LLP**, Consolidated Financial Statements and Report of Independent Certified Public Accountants: United States Pharmacopeial Convention and Subsidiaries. 2018. Available from: https://www.usp.org/sites/default/files/usp/document/about/usp-fs-2018.pdf.
21. **Eastern Research Group**, Sunscreen Drug Formulations for Over-the-Counter Human Use. 2010.
22. **K.M. O'Brien, K. Ogunsina, N. Wentzensen, and D.P. Sandler**, Douching and Genital Talc Use: Patterns of Use and Reliability of Self-reported Exposure. *Epidemiology*, 2023. **34**: p. 376-384. Available from: https://journals.lww.com/epidem/Fulltext/2023/05000/Douching_and_Genital_Talc_Use__Patterns_of_Use_and.9.aspx.
23. **A.R. Zota and B. Shamsunder**, The environmental injustice of beauty: framing chemical exposures from beauty products as a health disparities concern. *American Journal of Obstetrics & Gynecology*, 2017. **217**(4): p. 418.e1-418.e6. Available from: https://www.sciencedirect.com/science/article/pii/S0002937817308621.
24. **M.K. Taher, N. Farhat, N.A. Karyakina, N. Shilnikova, S. Ramoju, C.A. Gravel, K. Krishnan, D. Mattison, S.-W. Wen, and D. Krewski**, Critical review of the association between perineal use of talc powder and risk of ovarian cancer. *Reproductive Toxicology*, 2019. **90**: p. 88-101. Available from: https://www.sciencedirect.com/science/article/pii/S0890623818306373.
25. **H. Langseth, S.E. Hankinson, J. Siemiatycki, and E. Weiderpass**, Perineal use of talc and risk of ovarian cancer. *Journal of Epidemiology & Community Health*, 2008. **62**: p. 358-360. Available from: https://jech.bmj.com/content/jech/62/4/358.full.pdf.
26. **C. Nardinelli**, Some Pitfalls of Practical Benefit-Cost Analysis. *Journal of Benefit-Cost Analysis*, 2018. **9**(3). Available from: https://www.cambridge.org/core/journals/journal-

of-benefit-cost-analysis/article/some-pitfalls-of-practical-benefitcost-analysis/1F140D2D8B010BF4B1F57596A64AFE5E.