

AUSTIN KNUDSEN
Montana Attorney General
Brent Mead
Deputy Solicitor General
Montana Department of Justice
215 N. Sanders
P.O. Box 201401
Helena, MT 59620-1401
brent.mead2@mt.gov
(406) 444-2026

Attorneys for Plaintiff

MONTANA FIRST JUDICIAL DISTRICT COURT, LEWIS AND CLARK COUNTY

THE STATE OF MONTANA,

Plaintiff,

v.

JOHNSON & JOHNSON,

Defendant.

Case No.

**COMPLAINT FOR INJUNCTIVE
AND MONETARY RELIEF**

Comes now the Plaintiff, State of Montana, and brings this action complaining of Defendant Johnson & Johnson (hereinafter referred to as “J&J”) for violating the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 through 30-14-144 as follows:

I. JURISDICTION AND STATUTORY AUTHORITY

1. This enforcement action is brought by Attorney General Austin Knudsen in the name of the State of Montana and in the public interest pursuant to the authority granted by his constitutional, statutory, and common law authority, including the authority granted to him by the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 through 30-14-144.

2. This Court has jurisdiction over the Defendant pursuant to Mont. R. Civ. P. 4(b)(1) the Defendant transacted business within Montana at all times relevant to this complaint.

3. Plaintiff has reason to believe that Defendant has caused and will cause immediate, irreparable injury, loss, and damage to the State of Montana. Therefore, these proceedings are in the public interest.

II. VENUE

4. Venue for this action properly lies in Lewis and Clark County, State of Montana, pursuant to Mont. Code Ann. 30-14-111(3) because the Defendant does not maintain a place of business in Montana. Venue is also proper in Lewis and Clark County because Defendant transacts business in Lewis and Clark County, or some of the transactions upon which this action is based occurred in Lewis and Clark County. Mont. Code Ann. 30-14-111(3).

5. Plaintiff has reason to believe that Defendants have caused and will cause immediate, irreparable injury, loss, and damage to the State of Montana by unlawfully dispensing prescription opioids. Therefore, these proceedings are in the public interest.

III. PARTIES

6. Plaintiff State of Montana is a sovereign State of the United States of America. Austin Knudsen is the Attorney General of the State of Montana. He is authorized by Montana law to sue on the State's behalf.

7. Defendant Johnson & Johnson is a New Jersey company, and its principal place of business and executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. J&J transacts business in Montana and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling Johnson's® Baby Powder® and Shower to Shower®.

IV. ACTS OF AGENTS

8. Whenever this Complaint alleges that Defendant did any act, it means that Defendant:

- a. Performed or participated in the act; or
- b. Its subsidiaries, officers, successors in interest, agents, partners, trustees, or employees performed or participated in the act on behalf of and under the authority of Defendant.

V. TRADE AND COMMERCE

9. J&J and its agents have, at all times described below, engaged in trade or commerce in the State as defined in Montana's Unfair Trade Practices and Consumer Protection Acts, Mont. Code Ann. §§ 30-14-101 through 30-14-144.

VI. FACTUAL ALLEGATIONS

10. Since the 1890s, J&J and various subsidiaries have manufactured, marketed, and sold talc body powder products such as Johnson's® Baby Powder and Shower to Shower® (collectively, "Talc Powder Products"). J&J marketed these products as safe for daily use by consumers all over their bodies, including female genitals. The products were marketed and intended to be used to maintain a fresh, dry, and clean feeling; to eliminate friction on the skin; and to absorb excess moisture. J&J's talc powder products were advertised as "clinically proven gentle and mild."

11. In advertisements, J&J at times encouraged primarily women and teenage girls to use Talc Powder Products to mask and avoid odors. Bottles of Johnson's® Baby Powder specifically stated, "for use every day to help feel soft, fresh and comfortable." Shower to Shower's® advertisements stated, "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh and comfortable throughout the day." In short, J&J knew and intended that women would use the Talc Powder Products on and in their genitals.

12. Since the 1980s, J&J knew of studies and other support information demonstrating that Talc Powder Products were sometimes tainted with carcinogenic asbestos and that women who used talc-based powders in the genital area had an increased risk of ovarian cancer compared to those

women who do not. At all pertinent times during these periods, feasible and safe alternatives to the Talc Products existed (e.g., cornstarch powders). Despite this knowledge, J&J continued marketing of Talc Powder Products as safe, pure, and gentle, and as suitable for use in and on female genitals.

13. J&J's knowledge of the potential presence of asbestos in its Talc Powder Products dates to at least the 1950s when J&J discovered that the chief source mine for talc in the U.S. market contained tremolite. Tremolite is one of the six different minerals that take the form of crystalline fibers known as asbestos. Through the 1960s, J&J searched for "clean" talc deposits but kept finding tremolite fibers in the deposits. As early as 1969, J&J expressed internal concern in a memo that the tremolite fibers in its talc posed a safety risk and that J&J would not be able to assure that its powders were safe to use if tremolite in more than "unavoidable trace amounts" were present.

14. In the 1970s, there was growing public awareness of the dangers of asbestos, with the Federal Food and Drug Administration ("FDA") recognizing asbestos as the primary cause of mesothelioma. During this time, J&J repeatedly met with the FDA and shared "evidence that their talc contains less than 1%, if any, asbestos."

15. Meanwhile, J&J's own scientists were conducting studies showing that J&J's talc contained trace amounts of asbestos fibers. J&J's research director warned that J&J should "protect our powder franchise" by eliminating as many tiny fibers that can be inhaled in airborne talc dust as possible, but that "no final product will ever be made which will be totally free from respirable particles."

16. Moreover, a 1973 J&J memo made clear that the company was "confident" that asbestiform minerals could be located even at a mine the company considered "very clean" and that talc used in J&J's baby powder at times contained identifiable amounts of tremolite and actinolite, two types of asbestos fibers.

17. J&J knew, from the results of funded studies, that asbestos was present in talc. However, citing costs and fear of public reaction, they failed to disclose this knowledge to the government, media, or the public. Instead, the lobbying organization Cosmetic Toiletry and Fragrance Association (hereinafter “CTFA”), which J&J was a part of, stated, “there is no basis to Petitioner's request that cosmetic talc products should bear warning labels to the effect that talcum powder causes cancer in laboratory animals or the ‘frequent talc application in the female genital area increases the risk of ovarian cancer.’”

18. J&J also engaged in an effort to influence research on talc safety. J&J commissioned a 1974 mortality study of Italian talc miners, which found no mesothelioma among the subject population. The study was then repeatedly published along with other J&J-commissioned studies, including one testing baby powder on a doll to show that powdering provided low exposure, touting the safety of talc without disclosing J&J's connections. J&J reported on the success of its efforts to influence in a 1977 internal report on J&J's “Defense of Talc Safety” strategy, noting that independent authorities had been “enjoy[ing] confirming reassurance” that cosmetic talc products were “free of hazard,” in part due to the effective dissemination of “favorable data from the various J&J sponsored studies” to the scientific and medical communities in the United States and Britain.

19. Meanwhile, a 1982 Harvard study found that the use of talc increased a woman's risk of ovarian cancer by 92%. The authors of that study advised J&J to place a warning on its talc products. It did not.

20. Since 1982, multiple studies found an increased risk of ovarian cancer caused by the use of talc products for feminine hygiene.

21. J&J took part in efforts to neutralize the effects of the studies. For instance, the United States National Toxicology Program published a study in 1993 on the toxicity of non-asbestiform talc

that found clear evidence of carcinogenic activity. In response, CTFA's Talc Interested Party Task Force TIPTF, a group of which J&J was a member, issued statements claiming these studies were insufficient to link between hygienic talc use and ovarian cancer.

22. Despite knowledge of the dangers associated with using its Talc Powder Products, J&J failed to warn consumers and continued to market Talc Powder Products for use in the manner most likely to increase the risk of ovarian cancer.

23. In the 1990s, J&J specifically targeted African American and Hispanic women in its marketing campaigns in order to reverse declines in sales of its baby powders. J&J's internal memo describing this marketing strategy acknowledged that baby powder had problems such as "negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage)."

24. By the 2000s, other manufacturers began placing warnings on their talc products about the risk of developing ovarian cancer as a result of genital talc use the safety documents provided to J&J by its current talc supplier included a statement that the International Agency for Research on Cancer "has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans." Despite knowing for over 30 years of studies linking the use of Talc Products in the genital area with increased risk of ovarian cancer, J&J continued to refuse to include any warning or information in its marketing of the Talc Products. Instead, J&J continued to market the products as safe for daily use on all areas of the body. For example, contemporaneous Shower to Shower® advertisements suggested that "a sprinkle a day keeps odors away" and that the product "can be used all over your body."

25. In 2012, J&J sold Shower to Shower to Valeant Pharmaceuticals North America, LLC, a wholly-owned subsidiary of Valeant International. In July 2018, Valeant International changed its

name to Bausch Health Companies, Inc (“Bausch”). In 2018, Bausch reformulated Shower to Shower by replacing talc with corn starch.

26. In October 2019, J&J recalled Johnson’s Baby Powder after the United States Food and Drug Administration discovered asbestos in a bottle. J&J finally discontinued the manufacturing, sale, and distribution of talc-based Johnson’s Baby Powder in May 2020 in the United States.

VII. VIOLATION OF THE MONTANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACTS LAW

27. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 26.

28. Defendant, in the course of marketing, promoting, selling, and distributing its talc products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under Montana’s Unfair Trade Practices and Consumer Protection Acts, Mont. Code Ann. §§ 30-14-101 through 30-14-144, when they misrepresent the sponsorship, approval, characteristics, benefits, or qualities of their talc powder products.

29. Defendant, in the course of marketing, promoting, selling, and distributing its talc products, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under Montana’s Unfair Trade Practices and Consumer Protection Acts, Mont. Code Ann. §§ 30-14-101 through 30-14-144, including but not limited to misrepresenting the safety of talc products.

30. At the time they engaged in the conduct described in this Complaint, Defendants knew or should have known that they were placing a dangerous product into the stream of commerce.

VIII. PRAYER FOR RELIEF

31. WHEREFORE, the State respectfully request that:

- a. Pursuant to Montana’s Unfair Trade Practices and Consumer Protection Acts, Mont. Code Ann. §§ 30-14-101 through 30-14-144, the Court permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in false, misleading, or deceptive practices in the marketing, promotion, selling, and distributing of their Talc Powder Products;
 - b. Pursuant to Mont. Code Ann. §§ 30-14-142(1), the Defendants be ordered to pay civil penalties in the amount of not more than \$10,000 for each and every violation of the Montana Unfair Trade Practices and Consumer Protection Acts;
 - c. Pursuant to Montana’s Unfair Trade Practices and Consumer Protection Acts, Mont. Code Ann. §§ 30-14-133(3) and 30-14-142(1), the Defendants be ordered to pay costs and reasonable attorneys’ fees incurred by the Montana DOJ in connection with the investigation and litigation of this matter; and
32. Plaintiff further requests that this Court grant all other relief to which the Plaintiff is entitled.

Dated this 11th day of June, 2024.

Respectfully submitted,



Brent Mead
Deputy Solicitor General