For Immediate Release:
January 2, 2020
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Attorney General Balderas Files Suit Against Manufacturers of Talcum Powder

Santa Fe, NM----Attorney General Balderas today filed a lawsuit in the First Judicial District Court of New Mexico against four corporations that manufactured, advertised, and sold talcum powder products, including baby powder, which contained hazardous and carcinogenic asbestos to New Mexicans. The defendants named in the lawsuit are Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Valeant Pharmaceuticals International Corporation; and Valeant Pharmaceuticals North America LLC.

“Our office will take immediate action any time a corporation misleads a New Mexican consumer or endangers the health and safety of our families,” said Attorney General Balderas. “These products have been targeted at minority groups, especially Black and Hispanic women and children, with false messages about their safety, and I will hold these companies accountable.”

The affected products were sold under the names “Johnson’s Baby Powder,” “Johnson’s Medicated Powder,” and “Shower-to-Shower Talcum Powder.” The lawsuit alleges that, despite knowing for over forty years that the products contained carcinogenic asbestos and increased the risk of some types of cancer, the companies actively worked to conceal that risk from the public and from government regulators. Instead, the corporations marketed the products as “safe” and “healthful."

New Mexico is one of the first states in the nation to file a lawsuit against the companies for manufacturing and selling talcum powder contaminated with asbestos.

A copy of the complaint is attached.

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STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, *ex rel.*
HECTOR H. BALDERAS, Attorney General,

Plaintiff,

v. **No. _____**

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL CORPORATION; and VALEANT PHARMACEUTICALS NORTH AMERICA LLC,

Defendants.

PLAINTIFF'S COMPLAINT FOR DECLARATORY RELIEF, DAMAGES, RESTITUTION AND CIVIL PENALTIES

Plaintiff, the State of New Mexico (hereinafter "the State"), by and through its Attorney General, Hector Balderas, hereby brings this action against Defendants Johnson & Johnson ("J&J"); Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer"); Valeant Pharmaceuticals International Corporation, and Valeant Pharmaceuticals North America LLC, (collectively "Defendants"), and alleges, upon information and belief, as follows:

1. This is a civil action to obtain declaratory and equitable relief, damages, restitution, and civil penalties for violations of the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq*.; the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30-44-1, *et seq*.; the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq*.; and, for other common law and equitable causes of action stated herein by the New Mexico Attorney General in the exercise of his statutory powers. This action arises out of Defendants' wrongful marketing,

sale and promotion of Defendants' asbestos-containing talcum powder products, Johnson's Baby Powder ("JBP"), Johnson's Medicated Powder ("JMP"), and Shower to Shower ("S+S") (occ. collectively "Talc Products"). Plaintiff seeks to recover the costs of Defendants' Talc Products as well as the cost of treating asbestos-related cancers caused by those products, including, but not limited to, expenditures for:

a. Medical assistance provided under New Mexico's Medicaid Program pursuant to the Public Assistance Act, § 27-12-2 et seq. NMSA 1978 (1995 Repl. and 1996 Supp.);

b. Public employees' health insurance coverage costs pursuant to the Group Benefits Act, § 10-7B-6 VISA 1978 (1995 Repl.);

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, § 10-7C-3 NMSA 1978 (1995 Repl.);

d. Public employees and school board retirees' group health insurance costs from the Public School Insurance Fund, pursuant to the Public School Insurance Authority Act, § 22-2-6.6 (1993 Repl.);

e. Any other expenditures by the New Mexico Human Services Department, the New Mexico Department of Health, the New Mexico Department of Corrections, the Risk Management Division of the General Services Department, the Retiree Health Care Authority' and/or the Public Schools Insurance Authority; and

f. Patients who have received exposure to Defendants' Talc Products and/or treatment for illnesses related to those products in connection with expenditures made by the above-described State programs, agencies and/or departments (hereinafter collectively referred to as "State of New Mexico participants").

2. The State brings this action exclusively under the laws of the State of New Mexico. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

3. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual consumers may have against Defendants.

4. All preconditions necessary for averments of the causes of action alleged herein have been met.

PARTIES

A. Plaintiff

5. The State of New Mexico is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought for and on behalf of the State of New Mexico in its sovereign and *parens patriae* authority, by and through its duly elected Attorney General, Hector Balderas. The Attorney General, as chief legal officer of the State, is statutorily authorized to initiate and prosecute any and all suits deemed necessary for the protection of the interests and rights of the State. Attorney General Balderas is acting pursuant to his authority under, *inter alia*, NMSA 1978, Sections 8-5-1 *et seq.*; the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq.*; the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30--44-1, *et seq.*; and, the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq.*

B. Defendants

6. At all relevant times, Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, marketing, labeling, promoting, packaging, advertising, distributing, and/or selling Defendants' Talc Products, asbestos-containing talcum powder products, to individuals, health care providers and entities in the State of New Mexico, including the City and County of Santa Fe, State of New Mexico.

7. At all relevant times, Defendants have marketed and sold asbestos-containing talcum powder products to individuals and entities located within every county of the State of New Mexico.

8. The Defendant manufacturers and/or suppliers include: **JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER, INC.,** a subsidiary of JOHNSON & JOHNSON, for its Johnson's Baby Powder and Shower-to-Shower Talcum Powder Products, **VALEANT PHARMACEUTICALS INTERNATIONAL CORPORATION,** and **VALEANT PHARMACEUTICALS NORTH AMERICA LLC**.

9. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and may be served through its registered agent for service of process, Attention: Legal Department, One Johnson & Johnson Plaza, New Brunswick, NJ 08933, or wherever they may be found.

10. Defendant Johnson & Johnson Consumer Companies, Inc. is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and may be served through its registered agent for service of process,

Attention: Legal Department, One Johnson & Johnson Plaza, New Brunswick, NJ 08933, or wherever they may be found.

11. Defendant Valeant Pharmaceuticals International Corporation is a Delaware corporation with its principal place of business in Bridgewater, New Jersey, and may be served through its registered agent for service of process, United Agent Group Inc., 12 Christopher Way #200, Eatontown, NJ 07724, or wherever they may be found.

12. Defendant Valeant Pharmaceuticals North America LLC is a New Jersey limited liability company with its principal place of business in Bridgewater, New Jersey and may be served through its registered agent for service of process, United Agent Group Inc., 12 Christopher Way #200, Eatontown, NJ 07724, or wherever they may be found.

13. Reference to any and all Defendants includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

14. Upon information and belief, in committing the acts alleged herein, each and every managing agent, agent, representative, and/or employee of Defendants was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification, and authorization of Defendants and their directors, officers, and/or managing agents.

JURISDICTION & VENUE

15. Subject matter jurisdiction for this case is conferred upon this Court pursuant to, *inter alia,* Article VI, Section 13 of the New Mexico Constitution.

16. This Court has personal jurisdiction over Defendants because Defendants do business in New Mexico and/or have the requisite minimum contacts with New Mexico

necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also within the contemplation of the New Mexico "long arm" statute, NMSA 1978, Section 38-1-16 (1971).

17. Defendants did distribute, supply, market, sell, promote, advertise, fail to warn, and otherwise distribute Defendants' Talc Products and commit the wrongful acts and omissions described herein in New Mexico and specifically in Santa Fe County.

18. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. This action is brought by the State of New Mexico as the sole plaintiff, and no class action or mass action is raised herein. Any alleged class or mass action is expressly disavowed. To the extent that anything in this complaint is alleged to be to the contrary, this paragraph is controlling. Accordingly, any improvident and dilatory attempt by Defendants to remove this case to federal court on the basis of Section 1332 of Title 28, United States Code, would be without any reasonable legal basis in fact or law.

19. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues, do not turn on the substantial federal interpretation of federal law, nor do they raise a substantial federal question. Further, there is no federal question possibly raised herein that is potentially significant to the federal system as a whole as required for substantial federal question jurisdiction. *See Gunn v. Minton*, 568 U.S. 251 (2013). Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of New

Mexico. “Generally, a negligence claim requires the existence of a duty from a defendant to a plaintiff, breach of that duty, which is typically based upon a standard of reasonable care, and the breach being a proximate cause and cause in fact of the plaintiff's damages.” *Herrera v. Quality Pontiac*, 2003-NMSC-018, ¶ 6, 134 N.M. 43, 47–48, 73 P.3d 181, 185–86. With regard to the specifics of that duty, “[p]olicy determines duty.” *Torres v. State*, 1995-NMSC-025, ¶ 10, 119 N.M. 609, 612, 894 P.2d 386, 389; *see also Calkins v. Cox Estates*, 1990-NMSC-044, ¶ 5, 110 N.M. 59, 61, 792 P.2d 36, 38 (stating that the question of duty “must be decided as a matter of law by the judge, using established legal policy”). That is, “[t]he existence of a tort duty is a policy question that is answered by reference to legal precedent, statutes, and other principles of law.” *Herrera*, 2003-NMSC-018, ¶ 7 (citations omitted). Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Any alleged federal claim or federal question is expressly disavowed. To the extent that anything in this complaint is alleged to be to the contrary, this paragraph is controlling. Accordingly, any improvident and dilatory attempt by Defendants to remove this case to federal court on the basis of Section 1331 of Title 28, United States Code, would be without any reasonable legal basis in fact or law.

20. The State does not bring this case against, and does not direct anything in this complaint to, any agency of the United States, any officer of the United States, or any person acting under any officer of the United States. To the extent that any Defendant alleges that anything in this complaint could be construed to constitute an action against and/or directed to a federal officer or a person acting under a federal officer, any pleadings allegedly against and/or directed to a federal officer or a person acting under a federal office are expressly disavowed. Any alleged federal contractor liability is expressly disavowed. To the extent that anything in this complaint is alleged to

be to the contrary, this paragraph is controlling. Accordingly, any improvident and dilatory attempt by Defendants to remove this case to federal court on the basis of Section 1442 of Title 28, United States Code, would be without any reasonable legal basis in fact or law.

21. Venue is proper in this Court pursuant to NMSA 1978, Section 38-3-1 (1988), because the Office of the Attorney General and the seat of the State Government are situated in the City and County of Santa Fe, State of New Mexico, and the claims for relief asserted herein arose in large part in the City and County of Santa Fe, State of New Mexico. Venue is also proper in Santa Fe County pursuant to NMSA 1978, Section 57-12-8 because Defendants have used methods, acts, or practices in Santa Fe County which are unlawful under the Unfair Practices Act.

FACTUAL BACKGROUND

22. For decades, Defendants have manufactured JBP, JMP, and S+S containing Asbestos and Talc Containing Asbestiform Fibers that were and are continuing to be sold and marketed as safe for daily use by consumers to give off a pleasant smell, mask odors, prevent chaffing, and/or absorb moisture. Defendants' Talc Products were advertised as healthful for babies, children, and adults and to be applied regularly to maintain freshness, keep skin soft, mask odors with a fragrance, prevent chaffing, and/or absorb moisture.

23. Defendants and the Cosmetic, Toiletry & Fragrance Association ("CTFA") (n/k/a Personal Care Products Council) ("PCPC") made false statements to Plaintiff, the general public, news media, and government agencies that exercise regulatory authority over the cosmetic industry, including, but not limited to, the U.S. Food & Drug Administration ("FDA"), the National Institute of Occupational Health and Safety ("OSHA"), the National Institute for Occupational Safety and Health ("NIOSH"), the Mine Health and Safety Administration ("MHSA"), and the National Toxicology Program ("NTP"), which, in turn, proximately caused

Plaintiff's harm through intentional efforts to deceive the general public and regulatory authorities as to the safety of and presence of carcinogens, including Asbestos and Talc Containing Asbestiform Fibers in JBP, JMP, and S+S.[1]

24. Defendants and the CTFA, for decades, possessed medical and scientific data that raised concerns regarding the presence of carcinogens, including Asbestos and Talc Containing Asbestiform Fibers in JBP, JMP, and S+S, and that demonstrated the existence of health hazards to those exposed to Asbestos and Talc Containing Asbestiform Fibers in JBP, JMP, and S+S.

25. Talc is a hydrous magnesium silicate, inorganic material that is mined from the earth. It is used in the manufacture of goods, such as paper, plastic, paint and coatings, rubber, food, electric cable, ceramics, and cosmetics. In its loose form and as used in JBP, JMP, and S+S, talc is known as "talcum powder."

26. Geologists, Defendants, and the CTFA—as well as their suppliers, experts, agents and advisors—have long known that the deposits in the earth that are associated with talc are also associated with the formation of asbestos. "Asbestos" is a commercial and legal term, rather than a geologic or scientific term, referring to six now-regulated magnesium silicate minerals that occur in fibrous form, including the serpentine mineral chrysotile, and amphibole minerals such as actinolite, anthophyllite, tremolite, amosite and crocidolite. The United States Geological Survey on Commercial Talc production in 1965, as well as those dating back to the 1800s, note the presence of tremolite, anthophyllite and chrysotile commonly among those minerals found within talc deposits.

[1] Again, no federal claim or issue is raised in this complaint. To the extent any federal agency or action is discussed, it is to describe Defendants' *mens rea* and/or state the duty owed under New Mexico law, not to allege an independent federal cause of action or substantial federal question. *See, e.g., Herrera*, 2003-NMSC-018, ¶7.

27. Defendants and their talc suppliers, which have been and still are the largest talc producers and/or talc-containing product manufacturers in the world, admit that they have long employed and/or consulted with doctors, scientists, geologists, mineralogists, and toxicologists, and that they have long maintained extensive medical and scientific libraries and archives containing materials relating to the health hazards of talc and the presence of carcinogens, including asbestos and asbestiform talc, in talc and talc deposits.

28. Beginning in the 1930s, medical and scientific literature emerged indicating talc was commonly, if not invariably, contaminated with substances known or suspected of being carcinogenic, such as asbestos, silica, quartz, nickel, and arsenic. Within the next several decades, an ever-growing body of medical and scientific literature demonstrated that direct and secondary exposure to talc, including asbestos-containing talc, was hazardous to exposed persons' health in that it could cause lung disease, cancer, and death.

29. Defendants and their affiliates, employees, agents, and/or suppliers were members of the National Safety Council. In March of 1933, Waldemar C. Dreesen of the United States Public Health Service reported to the National Safety Council the results of a study conducted among tremolite, talc, and slate workers. The study indicated that the talc was a hydrous calcium magnesium silicate, being 45% talc and 45% tremolite, and the National Safety Council stated, "The results of the study seemed to indicate a relationship between the amount of dust inhaled and the effect of this dust on the lungs of the workers." As early as 1934, the National Safety Council was publishing that "a cause of severe pulmonary injury is asbestos, a silicate of magnesium." In the September 1935 issue of National Safely News, an article entitled "No Halfway Measures in Dust Control" by Arthur S. Johnson reported reduced lung capacity resulting from "asbestosis" and "similar conditions" that developed "from exposure to excess of

many mineral dusts relatively low in free silica content." The article further noted that claims for disabilities from workers who alleged exposure to "clay, talc, emery, and carborundum dusts" had "claims prosecuted successfully." The article concluded that "[i]n the absence of adequate diagnoses, occupational histories and a more satisfactory method of adjudicating claims than prosecution at common law, we must conclude that it is necessary to find a practical method for controlling all mineral dusts."

30. In 1936, the National Safety Council published an article entitled "Lesser Known Facts About Occupational Diseases" that found "exposure to asbestos fibers, present in the weaving and grinding of dry asbestos material, offers another type of dust which may cause fatalities among workers." In 1958, The New York Department of Labor published Industrial Code Rule No. 12 establishing regulations applying to all employees and employers relating to dangerous air contaminants and listing both asbestos and talc as such substances.

31. In 1968, a study presented at the American Industrial Hygiene Conference & Exposition and published in the American Industrial Hygiene Association Journal concluded that "[a]ll of the 22 talcum products analyzed have a fiber content...averaging 19%. The fibrous material was predominantly talc but contained minor amounts of tremolite, anthophyllite, and chrysotile as these are often present in fibrous talc mineral deposits...Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem." L. J. Cralley, et al., "Fibrous and Mineral Content of Cosmetic Talcum Products," 29 Am. Ind. Hyg. Assoc. J. 350-354 (1968). Defendants were aware of these findings.

32. In 1968, a scientific study of store-bought, commercially available talcum powders conducted by the Occupational Health Program, National Center for Urban Industrial Health, was published and presented by the Industrial Hygiene Association. Defendants were aware of this

study. The study revealed that, contrary to popular belief, talcum powders were not entirely pure, but rather contained various fibrous minerals, including tremolite, anthophyllite and chrysotile. The study explained that such fibrous content was not unexpected because these types of fibers are often present in fibrous talc mineral deposits. Available documents indicate that during the same year and in the years following, at least one company began testing store-bought talcum powders for asbestos content. Despite tests showing some talcum powders contained asbestos, there is no evidence that positive results or the brand names of contaminated products were communicated to any governmental agency, the media or the public.

33. A 1976 follow-up study conducted by researchers at Mount Sinai Hospital in New York concluded that "[t]he presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc...We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products." Rohl A.N., et al., "Consumer Talcums and Powders: Mineral and Chemical Characterization," 2 J. Toxicol. Environ. Health 255-284 (1976). The Mount Sinai study results were published by various newspapers, including the New York Times and the Washington Post, and Defendants were aware of same.

34. In the early 1970s, the FDA began an inquiry into whether to regulate and require warnings on talc-containing products. Defendants and the CTFA, that served as an exclusive lobbying and advocacy group representing companies engaged in the cosmetic products industry, repeatedly conspired and worked in concert to block efforts to label and warn consumers regarding the dangers (including Asbestos and Talc Containing Asbestiform Fibers hazards) associated with cosmetic talcum powder products, such as Defendants' JBP, JMP, and S+S.

35. In 1971, the New York City Environmental Protection Administration Air Resources Board conducted a study of two "leading" brands of talcum powder using transmission electron microscopy ("TEM") and X-ray diffraction ("XRD") analysis and found them to contain 5-25% tremolite and anthophyllite asbestos.

36. Soon thereafter, a symposium was held in August of 1971 at the FDA to discuss the issue of asbestos content of talcum powders with the talc industry, government officials, and doctors and scientists from Mt. Sinai Hospital, which was then the epicenter of the medical and scientific study of asbestos. Among other statements, participants, and attendees heard: that asbestos should be banned in talcum powders; models should be set up to measure the levels of exposure to asbestos experienced by persons using talcum powder containing asbestos at the lowest level of microscopic detection; that finding asbestos in talc and talcum powder is extremely difficult; and that the only truly reliable way to determine the asbestos content of talc and talcum powder is through TEM and electron diffraction. Defendants and the CTFA—aware of the foregoing and citing costs as well as their fear of the public learning that talc was contaminated with asbestos—ignored and completely rejected any measures to meaningfully test talc products to make sure they were free from asbestos, asbestiform talc, and other carcinogens.

37. After this 1971 symposium, Dr. Weissler of the FDA hired Dr. Seymour Z. Lewin to test commercially available talcum powders for asbestos. Dr. Lewin tested 195 samples and found asbestos of varying amounts in 43. Many of Dr. Lewin's positive results were eventually corroborated by Pfizer Inc. The results, however, were uncorroborated by two other laboratories, leading the FDA to the conclusion that XRD, optical and electron microscopy, and electron diffraction must be used to detect asbestos in talc and talcum powders.

38. Dr. Lewin of New York University disclosed twice in 1972 that asbestos had been found in cosmetic talc. In a report to the FDA on August 3, 1972, Dr. Lewin reported that of 195 talc products, 20 had tremolite, seven had chrysotile, nine had both tremolite and chrysotile, and seven had substantial percentages of one of both. XRD had been used as the first step in analysis and the presence of asbestos and was verified by the use of optical microscopy to disclose the presence of significant numbers of fibers. Shortly thereafter, Dr. Lewin reported to supplier Whittaker, Clark & Daniels, Inc. on September 30, 1972, that Italian talc 1615 contained about 2% tremolite and 0.5% chrysotile as determined with XRD and detailed microscopic exam. In a July 31, 1973 review of Dr. Lewin's testing of 195 talc samples, the FDA found "good semi-quantitative agreement" for tremolite on selected samples re-analyzed using optical microscope analysis by FDA and XRD by Pfizer. Agreement was not as good for chrysotile, but the review did warn that optical microscopy could "completely miss the presence of chrysotile if the fibers are submicroscopic, which may well be the case in finely-milled talc." In 1972, ES Laboratories reported that "1615" talc contained 1% chrysotile and that "4615" talc contained 3% chrysotile and 3% anthophyllite. An August 23, 1973 report by Johns-Manville on TEM analysis of commercial talcs reported that nine of fourteen samples contained chrysotile. Only five samples did not have detectable levels of chrysotile. Pages from the laboratory notebook of Colgate-Palmolive Co. scientist Paul Briscese from March 7, 1976, show that Old Regal (North Carolina) talc tested positive for tremolite, New Montana talc tested positive for anthophyllite and tremolite, and Italian talc tested positive for tremolite.

39. A December 10, 1973 report of the CTFA's Talc Subcommittee disclosed that optical microscope analyses of talcs from the Italian, Montana I and II, Alabama, Vermont, and North Carolina mines had failed the proposed FDA's method because of elevated chrysotile

concentrations. This same CTFA report also showed that several laboratories had reported chrysotile in many of the talc samples sent by the CTFA for evaluation of analytical methods as well as the several identifications of asbestos in talc mentioned.

40. On September 3, 1973, the FDA sent the CTFA a letter regarding various means of measuring asbestos in talc, stating that "conventional methods employing X-ray diffraction or differential thermal analysis are not sufficiently reliable to produce quantitative results of the desired precision." The FDA further advised the CTFA that it "has been exploring refractory optical microscopy as a means of measuring asbestos in talc." The CTFA responded to the FDA's public notice on its proposed optical microscopy method on December 26, 1973. The CTFA contended that the proposed method was not "reliable" for the detection of asbestos in talc, recommended a "collaborative effort between FDA and industry to develop such a method," and urged deferment of the proposed rule. Minutes of the CTFA's Talc Subcommittee meeting on March 15, 1976, indicate that the FDA's "Dr. Shaffner suggested the possibility of having industry report periodically on the results of its analysis to the FDA." Dr. Estrin of CTFA responded that "the subcommittee would give serious consideration to this suggestion." Contemporaneously, evidence began to emerge from testing conducted by various regulatory agencies revealing that asbestos was being found in food, beer and drugs, including intravenously injected medicines. In 1972, and later in 1973, the FDA filed notices of proposed rulemaking requiring talc used in food, food packing, and drugs to be completely free of asbestos. These were some of the same "grades" of talc used by Defendants.

41. The talc industry's response, including that of the Defendants, was swift and well-coordinated through the CTFA, with which Defendants conspired and worked in concert to purposely create a flawed, voluntary testing and surveillance methodology for detecting asbestos

in talc and block efforts to label and warn consumers regarding the dangers associated with Defendants' Talc Products, including Defendants' JBP, JMP, and S+S products.

42. Regarding the FDA's proposed 1972 rule-making, the FDA Director of Product Development and Cosmetics, Dr. Schaffner, invited representatives of the talc industry to a meeting in August of 1972 to discuss the results of Dr. Lewin's study and inform them that the FDA was preparing to release a "Proposed Statement of Policy On Asbestos in Cosmetics Containing Talc." Dr. Schaffner explained that he was duty-bound and must publicize the brand names of the talcum powders that contained asbestos. CTFA's president, Dr. Merritt, strongly objected to the FDA alerting the general public and publishing the brand names of the talcum powders, as it would cause the manufacturers "economic hardship." Dr. Merritt also threatened to sue the FDA to prevent the disclosure of the brand names. As a result, the FDA, Defendants and CTFA never revealed or publicized the brand names of the talcum powders that contained asbestos, much to the detriment of the Plaintiff and the general public.

43. In 1973, the CTFA created a talc subcommittee and the Scientific Advisory Committee to develop a testing methodology for detecting asbestos in talc. Initially, the CTFA designated a group of its members to test talc grades used in talcum powder utilizing the methodology proposed by the FDA in its notice of rulemaking. Six samples of talc used in commercially available talcum powders, plus one talc sample purposely spiked with tremolite and chrysotile, were circulated among the members, including representatives of Defendants. Of the eight participating members, four found asbestos in every sample, three did not find asbestos in any sample (including the spiked sample), and one found asbestos only in the spiked sample. In conclusion, all members agreed that the best and most reliable method of detecting asbestos in talc is not optical microscopy, but rather TEM and electron diffraction. The same members,

however, dispensed with this analytical method, claiming TEM and electron diffraction equipment was too expensive, despite Defendants then owning or having unfettered access to the same.

44. From there, the difference between what Defendants and the CTFA knew diverged from what they were representing to the FDA. Defendants, the CTFA, and others in the industry knew that there was no such thing as "asbestos-free" talc—only talc in which asbestos could not be detected using the prevailing, most economic analytical methodology, XRD, which at the time could not accurately identify chrysotile asbestos in talc, nor detect tremolite asbestos contamination levels below 2-5%.

45. Defendants and the CTFA also did not disclose to the FDA that the overwhelming majority of talcum powder manufacturers and sellers were not testing their products for asbestos, and even if they were testing, it was done only superficially—only four or so grams per 20 tons of shipment and pre-processed talc, as an example. Defendants and the CTFA also failed to inform the FDA that they were not testing off-the-shelf talc powder products, but rather old samples that were never from the actual end products. Defendants also hid from the FDA that they were limiting their testing of talc to only one type of asbestos fiber to the exclusion of all other fiber types that are commonly found in talc deposits. What is more, to the extent Defendants found asbestos in their samples, these positive results were not reported to the FDA. Instead, on their behalf, the CTFA sent letters to the FDA in March of 1976 fraudulently claiming that industry-testing had shown all talcum powder products to be completely free of asbestos.

46. Beginning in 1975 and 1976, researchers at the New York Air Resources Board, Mt. Sinai School of Medicine, and the FDA became increasingly concerned that the CTFA, Defendants, and the cosmetic industries were too slow to address the issue of asbestos in talc and

talcum powders. Defendants had not issued any recalls, or provided consumer warnings, or informed the FDA of any effort to ensure that talcum powders on the market did not contain asbestos, or developed a reliable methodology or protocol for ensuring that talc and talcum powder did not contain asbestos or asbestiform talc.[2]

47. Taking matters into their own hands, Mt. Sinai Hospital researchers published a follow-up article to Dr. Lewin's 1971 study that demonstrated that some of Defendants' talcum powders contained over 20% asbestos. The researchers concluded that "[t]he presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc. . . We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products." The results of the Mount Sinai study were known to the Defendants and published the same year by the New York Times and the Washington Post.

48. Defendants and the CTFA responded to these developments by falsely claiming that the industry was doing "everything" it could to solve the problem; by issuing press releases falsely claiming that chrysotile had never been found in talcum powders; and by intentionally suppressing data that showed tremolite was commonly found in talc and talcum powder.

49. CTFA subsequently began in earnest to produce a voluntary protocol and methodology that would provide Defendants cover from both lawsuits and regulation. Egregiously, as concerned media members, citizens, and regulators began asking more questions

[2] Again, no federal claim or issue is raised in this complaint. To the extent any federal agency or action is discussed, it is to describe Defendants' *mens rea* and/or state the duty owed under New Mexico law, not to allege an independent federal cause of action or substantial federal question. *See, e.g., Herrera*, 2003-NMSC-018, ¶7.

about which other brands of talcum powder contained asbestos, Defendants and the CTFA falsely represented that talcum powders have never contained asbestos or asbestiform talc.

50. Defendants, their talc suppliers, and third parties funded by Defendants collectively met with and corresponded with the CTFA, as well as collectively met with the FDA and other government agencies, to individually and collectively advocate for the use of "voluntary" XRD testing of miniscule portions of the tons of talc to be used in consumer products. Defendants' "voluntary" method—that was developed collectively by Defendants and CTFA and advocated to the FDA in lieu of regulations requiring asbestos labeling or warnings on talcum powder products—was inadequate because levels of asbestos contamination in talc commonly fell below the detection limit of the testing methods. Defendants and CTFA also knew that asbestos contamination was not uniformly distributed, such that the miniscule amounts tested would not reveal the true level of contamination in talc products, including in Defendants' Talc Products.

51. In support of its voluntary XRD methodology, which was finally published in 1977, the CTFA produced letters to the FDA written by its members, including Defendants, identifying tests conducted showing talcum powder products did not contain asbestos. The CTFA, Defendants and other talc product producers, however, never informed the FDA of the hundreds of positive tests showing talc and talcum powders contained asbestos and other carcinogens.

52. The CTFA's "Method J4-1," published on October 7, 1976, states that TEM-SAED "offers greater sensitivity, but is not presented since it is unsuitable for normal quality control applications." The published method, rather, relies on XRD with "the level of detection of amphibole by this method [being] 0.5% and above." The CTFA met with and corresponded with Defendants and third parties, to individually and collectively advocate to the FDA for the

use of inadequate XRD testing on miniscule portions of the tons of talc obtained from the mining sources to be used in the consumer products, followed by fewer "periodic" tests by TEM. This voluntary method was developed by the CTFA and Defendants, and was advocated to the FDA by the CTFA and Defendants in lieu of regulations requiring labeling and warnings on talcum powder products, even though the CTFA and Defendants knew that the J4-1 method would not reveal the true level of asbestos in the talc that reached consumers. In fact, the first "round robin" tests, which analyzed a "CTFA Tremolite-Spiked Talc," resulted in six of seven participating laboratories failing to detect the tremolite. In other words, 84% of the industry's laboratories failed to detect asbestos in a sample known to contain tremolite asbestos while using the CTFA's own J4-1 method. There is no evidence that CTFA or Defendants ever shared this remarkable failure with the FDA or the public.

53. Minutes of the CTFA's Talc Subcommittee from February 24, 1975, stated: "It was agreed, however, that chrysotile is never found in cosmetic talcs, based on numerous analyses by several investigators..." When referring to the challenge of chrysotile detection, an article entitled "Talc" in the January/March 1976 CTFA Cosmetic Journal, states that "The only known backup method for a positive identification in this event, is [TEM] with selected area diffraction." However, "despite many efforts, the committee had been unable to find a sample of cosmetic talc containing naturally occurring asbestos...it was asked, 'Why should we test for chrysotile if there isn't any?'"

54. The CTFA's Specification for Cosmetic Talc, revised on October 7, 1976, falsely represented that no fibrous asbestos was detected in cosmetic talc. Even after 1976, the CTFA and Defendants continued to obtain and/or receive results of testing performed internally and externally indicating the presence of asbestos and other carcinogens in the talc being used to

manufacture cosmetic products. However, the CTFA and Defendants continued to represent that no asbestos was detected in cosmetic talc. These material representations adversely and directly affected the FDA's attempt to adequately test consumer talc for asbestos and regulate cosmetics.

55. The most sensitive method of identifying or detecting asbestos in cosmetic talc, TEM-SAED, was not used because the CTFA represented that its "ultra sensitivity could be a problem" and that it was too expensive to use. Instead, its J4-1 method relied on XRD alone for detection of asbestos at greater concentrations than 0.5%, a concentration that could allow more than a billion asbestos fibers per gram of talc to be passed off as "asbestos-free."

56. Defendants and CTFA made and published such representations, claiming that their testing method was adequate, that they were ensuring that talcum powder products were safe, including JBP, JMP, and S+S, and that the talc reaching consumers, including via the Defendants' Talc Products, were "safe," despite having substantial knowledge and evidence to the contrary. Defendants intentionally and knowingly did so to avoid FDA and other governmental regulations that would have required them to place warnings regarding the Asbestos and Talc Containing Asbestiform Fibers content of their JBP, JMP and S+S products, and thereby inform the public in this State, as well as the State of New Mexico, that JBP, JMP and S+S contain Asbestos and Talc Containing Asbestiform Fibers.

57. The CTFA then published an article in 1979 stating it conducted over three thousand tests of talcum powders and none of them found chrysotile. The article and report failed to disclose whether the talcum powders tested contained tremolite, anthophyllite, or any other form of asbestos. This publication of half-truths was conveyed to the FDA and the public with the purpose of preventing regulations of cosmetic products. Thereafter the CTFA's methodology

became the standard by which nearly all talc was analyzed by the entire industry, including talc used in cosmetic and hygiene products today.

58. Between 1970 and the 1990s, tests conducted by and on behalf of Defendants and the talc industry continued to show that talc and talcum powder products contained asbestos. None of these positive tests has ever been produced or made known to any regulatory agency, and their existence became known only because of civil litigation. Defendants intentionally and knowingly hid the results to avoid FDA regulations that might have required Defendants to place warnings regarding the asbestos content of their products, including their Talc Products, and thereby inform the public that JBP, JMP and S+S contained Asbestos and Talc Containing Asbestiform Fibers.

59. Defendants' and the CTFA's decision to hide these positive results and the inadequacies of their testing protocols continued through the 1980s, 1990s, and 2000s, even when various government agencies raised concerns about the safety of talc, including the issue of asbestos content.

60. To this day, many talc-containing products presently on the market, including Defendants' Talc Products, contain Asbestos and Talc Containing Asbestiform Fibers. Instead of publicizing this fact, Defendants and the CTFA continue to deny all the above to protect their pecuniary interests, to the severe detriment of the public, including Plaintiff.

61. Since at least 1979, Defendants have conducted a campaign to convince the public that their products are regulated by the FDA, that their tests are conducted pursuant to FDA regulations, and that talcum powder products are, therefore, safe. Nothing could be further from the truth; the FDA has never been assigned a budget by Congress to regulate cosmetics, including asbestos and other carcinogens in talcum powders. Defendants' professed concerns for the safety of their products have always been voluntary and under the auspices of the CTFA, a private

industry group, that in its 40 years has banned few ingredients in all cosmetics ever sold in the United States. Indeed, as of today, asbestos-containing talc in cosmetics is not among them.

62. Defendants (and other entities in the talc industry and cosmetic industries, including the CTFA), individually and collectively, failed to report to the FDA and other regulatory agencies, tests performed both internally and by outside laboratories confirming the presence of Asbestos and Talc Containing Asbestiform Fibers in both their finished products, including JBP, JMP, and S+S, as well as in shipments of raw talc from suppliers (or in talc J&J supplied from its own mines).

63. Defendants, and even the outside laboratories, including McCrone Associates, sent letters to the CTFA, to be and which were forwarded to the FDA, stating that results of testing of talc used by them after 1972 had not revealed the presence of amphibole or chrysotile asbestos, when in fact all of these entities had received or performed tests indicating the contrary when such false representations were made.

64. After 1976, Defendants and the CTFA continued to obtain and/or receive results of testing performed internally and externally indicating the presence of Asbestos and Talc Containing Asbestiform Fibers in JBP, JMP, and S+S. Defendants chose not to place any warning on their JBP, JMP, and S+S or ever disclose the fact that these products contain Asbestos or Talc Containing Asbestiform Fibers, at any point, up to and including the present, despite the clear hazard and direct information that their JBP, JMP, and S+S did, and continues to, contain Asbestos or Talc Containing Asbestiform Fibers.

65. Defendants and the CTFA, collectively and through explicit agreement and consciously parallel behavior, controlled industry standards regarding the testing, manufacture, sale, distribution, and use of talcum powder products, and controlled the level of knowledge and

information available to the public, including Plaintiff, regarding the hazards of exposure to carcinogens, including Asbestos and Talc Containing Asbestiform Fibers, from JBP, JMP, and S+S.

66. Defendants and the CTFA, through agreement and consciously parallel behavior, knowingly and intentionally released, published and disseminated invalid, inaccurate, outdated, and misleading scientific data; literature and test reports containing misinformation and false statements regarding the health risks associated with the use of talc and talcum powder products, including JBP, JMP, and S+S, to which the consuming public in this State have been exposed.

67. Defendants and the CTFA, while cognizant of the aforementioned data, deliberately chose to ignore the health and safety issues raised in said data and embarked upon a plan of deception intended to deprive the State and the public at large in this State and elsewhere, of alarming medical and scientific findings, many of which remained in Defendants' exclusive possession and under their exclusive control.

68. Defendants and the CTFA conspired and/or acted in concert with each other and/or with other entities through agreement and consciously parallel behavior:

a. to withhold from users of their products including Plaintiff and the general consuming public of this State—and from persons who they knew and should have known would be exposed thereto—information regarding the health risks of inhaling and/or ingesting and/or perineal (genital) application of JBP, JMP, and S+S containing Asbestos and Talc Containing Asbestiform Fibers;

b. to eliminate, suppress, or prevent investigation into the health hazards of exposure to asbestos and other carcinogens in talc and talcum powder products;

c. to ensure that asbestos-containing talc and talcum powder products became

widely used in commerce, irrespective of the potential and actual risk of harm to the users and consumers from the asbestos and other carcinogens therein; and

d. to falsely represent that talc and talcum powder products, including those of Defendants, were safe and healthful for use by consumers and the general consuming public of this State.

69. Plaintiff reasonably and in good faith relied upon the false and fraudulent representations made by Defendants and the CTFA regarding the hazards of talc and talcum powder products that contained asbestos and other carcinogens, and was, therefore, deprived of an opportunity to make informed decisions concerning said products.

70. The CTFA, as well as Defendants and other entities in the talc industry and cosmetic industries, individually and collectively, failed to report to the FDA tests performed both internally and by outside laboratories confirming the presence of asbestos in Defendants' and other CTFA members' finished products as well as talc shipments from talc suppliers and other sources that were used to produce finished products. Instead, the CTFA sent letters to the FDA stating that results of testing of talc used by the industry after 1972 had not revealed the presence of amphiboles or chrysotile, when in fact all of these entities had received or performed tests indicating the contrary by 1976, when such intentionally false misrepresentations were made.

71. The CTFA and Defendants made and published such representations claiming that their collective testing method was adequate, they were ensuring that talcum powder products, including JBP, JMP, and S+S, were safe, and that their testing of talc reaching consumers was "safe," despite knowing the contrary.

72. The FDA and other regulatory bodies, and ultimately Plaintiff and the general

consuming public of this State, directly and/or indirectly relied upon the CTFA's and Defendants' false representations regarding the safety of cosmetic talc.[3] In fact, an FDA letter dated January 11, 1979, states: "In cooperation with scientists from industry, our scientists have been making progress in the development of such regulatory methods." The continuing lack of FDA awareness regarding the CTFA's and Defendants' misrepresentations was obvious seven years later. In a response to a citizen petition to require an asbestos warning label on cosmetic talc, on July 11, 1986, the FDA states that an "analytical methodology was sufficiently developed" to ensure that "such talc [is] free of fibrous amphibole..." The CTFA'S J4-1 method has continued for the past four decades to be the cosmetic talc industry's method for "ensuring" "asbestos-free" talc. The use of TEM, recognized by the CTFA as offering "greater sensitivity" for asbestos, continued to increase over the following decades as its advantages were applied to more matrices. In 1990, Kremer and Millette published a TEM method for analysis of asbestos in talc with a theoretical detection limit of about 0.00005%. Despite such improvements in analytical techniques, the cosmetic talc industry, including Defendants, continues, four decades later, to use and promote its antiquated and wholly inadequate J4-1 method.

73. The CTFA and Defendants, collectively and through explicit agreement and consciously parallel behavior, controlled industry standards regarding the testing, manufacture, sale, marketing, distribution, and use of asbestos-containing talcum powder products, and controlled the level of knowledge and information available to the public in this State regarding the hazards of exposure to Asbestos and Talc with Asbestiform Fibers and other carcinogens

[3] Again, no federal claim or issue is raised in this complaint. New Mexico does not bring a cause of action for fraud against the FDA. To the extent any federal agency or action is discussed, it is to describe Defendants' *mens rea* and/or state the duty owed under New Mexico law, not to allege an independent federal cause of action or substantial federal question. *See, e.g., Herrera,* 2003-NMSC-018, ¶7.

from talc and talc-containing products, including JBP, JMP, and S+S.

74. The CTFA and Defendants, through agreement and consciously parallel behavior, intentionally failed to warn potential users, including Plaintiff and the general consuming public in this State, of the serious bodily harm and/or death which might result from the inhalation and/or ingestion and/or perineal (genital) application of Asbestos and Talc Containing Asbestiform Fibers from their JBP, JMP, and S+S products.

75. The CTFA and Defendants, through agreement and consciously parallel behavior, knowingly and intentionally released, published and disseminated invalid, inaccurate, outdated and misleading scientific data, literature and test reports containing misinformation and false statements regarding the health risks associated with the use of talc and talcum powder, and specifically talc and talcum powder used in the production of JBP, JMP, and S+S products to which the Plaintiff and the general consuming public in this State were exposed.

76. The CTFA and Defendants, through agreement and consciously parallel behavior, suppressed, altered, changed, destroyed and/or revised reports, data, tests, studies and other documents regarding the potential presence of asbestos and other carcinogens in talc and talc-containing products, including Defendants' JBP, JMP, and S+S products to which the consuming public in this State was exposed.

77. As recently as 2016, Defendants made material misrepresentations to the FDA regarding Asbestos and Talc Containing Asbestiform Fibers in its talcum powder products.

78. Similarly, Defendants have concealed their knowledge that exposure to Defendants' Talc Products places women at risk for developing ovarian cancer. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales.

79. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. This study found a 92% increased risk in ovarian cancer with women who reported genital talc use. Shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson came and visited Dr .Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powders about the ovarian cancer risks so that women can make an informed decision about their health.

80. Since 1982, there have been approximately twenty-two (22) additional epidemiologic studies providing data regarding the association of talc and ovarian cancer. Nearly all of these studies have reported an elevated risk for ovarian cancer associated with genital talc use in women.

81. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., *et al*. Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.

82. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the genital area before their cancer diagnosis. The study showed a 50% increase in risk of ovarian cancer in women that used talcum powder on their genital area and a positive dose-response relationship. Whittemore AS, *et al*. Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am. J. Epidemiol*. 1988 Dec; 128(6):1228-40.

83. A 1989 study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls, and found a 29% increased risk in ovarian cancer with women who reported genital

talcum powder use more than once each week. Booth, M., *et al*. Risk factors for ovarian cancer: a case-control study. *Br J Cancer*. 1989 Oct; 60(4):592-8.

84. In 1992, a case-control study found a statistically significant 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et al*. Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol*. 1992 Jul; 80(1):19-26.

85. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% increased risk of ovarian cancer of women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. *et al*. Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol*. 1992 Apr; 45(1):20-5.

86. In an August 5, 1992 document entitled "Johnson's Baby Powder...Major Opportunities," the Johnson & Johnson (J&J) defendants recognized and discussed that Johnson's Baby Powder® sales were in decline. The producers of talc products soon implemented a marketing strategy that specifically targeted African-American and Hispanic women within the State of New Mexico.

87. To "grow the franchise," the company implemented a strategy of targeting African-American and Hispanic women because its internal studies showed these two ethnicities used Johnson's Baby Powder® at higher rates than women of other ethnicities. In the same document, J&J acknowledged that: "Negative publicity from health community on talc continues ... cancer linkage." The racially targeted strategy implemented by J&J has and continues to disproportionately affect the citizens of New Mexico because approximately forty-eight (48%) of New Mexico's population is comprised of African-American and Hispanic individuals.

88. Despite the potential catastrophic health consequences, the companies that manufacture and sell talc products have concealed and failed to warn consumers about the dangers associated with their Talc Products. Instead, these companies not only intended, but encouraged women to use their Talc Products in the manner most likely to result in an increased risk of ovarian cancer.

89. Meanwhile, J&J expressly and impliedly represented to these communities, and the public, at large that Defendants' Talc Products were safe. J&J's misrepresentations and omissions regarding the safety of Defendants' Talc Products have resulted in residents of the State of New Mexico using Defendants' Talc Products in a potentially lethal way without any knowledge of the danger.

90. In 1995, the largest study of its kind to date found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talc in the abdominal or perineal area. Purdie, D., *et al.* Reproductive and other factors and risk of epithelial ovarian cancer: An Australian case-control study. Survey of Women's Health Study Group. *Int J Cancer*. 1995 Sep 15; 62(6):678-84.

91. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. *See* Shushan, A., *et al*. Human menopausal gonadotropin and the risk of epithelial ovarian cancer. *Fertil. Steril.* 1996 Jan; 65(1):13-8.

92. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Cook, LS, *et al.* Perineal powder exposure

and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.

93. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc via sanitary napkins to their perineal area. Chang, S, *et al.* Perineal talc exposure and risk of ovarian carcinoma. *Cancer*. 1997 Jun 15; 79(12):2396-401.

94. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., *et al.* Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am J Obstet Gynecol*. 1998 Aug; 179(2):403-10.

95. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, *et al.* Genital talc exposure and risk of ovarian cancer. *Int J Cancer*. 1999 May 5; 81(3):351-56.

96. In 2000, a case-control study of over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, *et al.* Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology*. 2000 Mar; 11(2):111-7.

97. In 2004, a case-control study of nearly 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study also examined women's use of

cornstarch powders as an alternative to talc, and found no increased risk in ovarian cancer in women in the cornstarch group, further supporting the causal connection between genital talc use and ovarian cancer. Mills, PK, *et al*. Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer*. 2004 Nov 10; 112(3):458-64.

98. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a general 36% statistically significant increased risk of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a strong dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer, adding further support to the causal relationship. Gates, MA, *et al.* Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev*. 2008 Sep; 17(9):2436-44.

99. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, *et al.* Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int. J Cancer*. 2009 Mar 15; 124(6):1409-15.

100. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, *et al.* Genital powder exposure and the risk of epithelial ovarian cancer. *Cancer Causes Control*. 2011 May; 22(5):737-42.

101. In June of 2013, a pooled analysis of over 18,000 women in eight case-control studies found a 20% to 30% increased risk of women developing epithelial ovarian cancer

from genital powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence." Terry, KL, *et al.* Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev Res (Phila).* 2013 Aug; 6(8):811-21.

102. In 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity. Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers.

103. In response to the United States National Toxicology Program's study, the CTFA formed the Talc Interested Party Task Force (TIPTF). Defendants were members of the CTFA. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend talc use at all costs and to prevent regulation of any type over this industry. The TIPTF hired scientists to perform biased research regarding the safety of talc, members of the TIPTF edited scientific reports of the scientists hired by this group prior to the submission of these scientific reports to governmental agencies, members of the TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on regulatory bodies regarding talc. All of these activities have been well coordinated and planned by these companies and organizations over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer.

104. On November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O, Ralph Larson, informing his company that studies as far back as 1960's ". . . show[ ] conclusively that the frequent use of talcum powder in the genital area

pose[] a serious health risk of ovarian cancer." The letter cited a recent study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that J&J withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based body powders about ovarian cancer risk they pose.

105. In 1996, the condom industry stopped dusting condoms with talc due to the growing health concerns.

106. In February of 2006, the International Association for the Research of Cancer (IARC) part of the World Health Organization published a paper whereby they classified perineal use of talc-based body powder as a "Group 2B" human carcinogen. IARC which is universally accepted as the international authority on cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women from perineal use of talc. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%. IARC concluded with this "Evaluation": "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." By definition "Limited evidence of carcinogenicity" means "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."

107. In approximately 2006, the Canadian government under The Hazardous Products Act and associated Controlled Products Regulations classified talc as a "D2A," "very toxic," 51 "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A".

108. In 2006, Imerys Talc (the supplier to J&J and other manufacturers as well) began placing a warning on the Material Safety Data Sheets (MSDS) it provided to Defendants regarding the talc it sold to them to be used in the Products. These MSDSs not only provided the warning information about the IARC classification but also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc as well.

109. Defendants, by contrast, have elected not to warn or inform the FDA, Plaintiff, or this State's consumers of any of the serious, known cancer risks long associated with Defendants' Talc Products. Instead, Defendants persist in denying the danger, maintaining focus all the while not on people, but on profits.

COUNT I

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

110. The State repeats and reiterates the allegations previously set forth herein.

111. Generally speaking, the statute of limitations does not run against the State. Independently, any allegedly applicable limitations period is tolled.

A. Continuing Conduct

112. Plaintiff, State of New Mexico, contends it continues to suffer harm from the unlawful actions by Defendants.

113. The continued tortious conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing has not ceased.

B. Equitable Estoppel

114. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff the true risks associated with exposure to Defendants' Talc Products.

115. As a result of Defendants' actions, Plaintiff and, upon information and belief, State of New Mexico participants, and health care providers within the State of New Mexico, were unaware, and could not reasonably have known, have ascertained, or have learned through reasonable diligence, the true risks associated with exposure to JBP, JMP, and S+S and/or the damages resulting from the Defendants' wrongful acts, and/or that the concealment of those risks was the direct and proximate result of Defendants' acts and omissions.

116. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of JBP, JMP, and S+S. Defendants were under a duty to disclose the true character, quality, and nature of JBP, JMP, and S+S because this was non-public information over which Defendants had and continue to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, State of New Mexico participants, and health care providers within the State of New Mexico. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of their wrongful and fraudulent conduct.

117. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing and unlawful conduct alleged herein. Because of the fraudulent acts of concealment of wrongdoing and unlawful conduct by Defendants, Plaintiff could not have reasonably discovered the wrongdoing and unlawful conduct, nor was the damage resulting from Defendants' wrongful acts capable of ascertainment by Plaintiff, nor, upon information and belief, State of New Mexico participants, and/or health care providers within the State of New Mexico. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable product, notwithstanding the known or reasonably known risks. Plaintiff, State of New Mexico participants, and health care providers within the State of New Mexico could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

COUNT II

VIOLATIONS OF THE NEW MEXICO UNFAIR PRACTICES ACT [NMSA 1978, Section 57-12-21]

118. The State repeats and reiterates the allegations previously set forth herein.

119. Defendants engaged in a course of repeated and willful conduct, through the acts and omissions described above.

120. The Attorney General is authorized to bring an action in the name of the State to remedy violations of the Unfair Practices Act. NMSA 1978, §§ 57-12-8(A), 57-12-15. This action is proper in this Court because Defendants are using, have used, and are about to use practices that are unlawful under the Act. NMSA 1978, § 57-12-8(A).

121. Defendants irresponsibly marketed and sold asbestos-containing talcum powder knowing that the products served no medical purpose.

122. Defendants' willful and repeated acts and omissions relating to JBP, JMP, and S+S, as described above, constitute unfair methods of competition, and they constitute unfair or deceptive acts or practices in the conduct of commerce, both of which violate the New Mexico Unfair Practices Act, NMSA 1978, Section 57-12-2. These acts and omissions include, but are not limited to, the following:

a. Defendants represented that JBP, JMP, and S+S have characteristics, uses and benefits that they do not have in violation of NMSA 1978, Section 57-12-2(D)(5).

b. Defendants represented that JBP, JMP, and S+S were safe and effective products when such representations were untrue, false and misleading, in violation of NMSA 1978, Section 57-12-2(D)(7).

c. Defendants engaged in conduct using exaggeration, innuendo or ambiguity as to material facts regarding the risk-benefit profile of JBP, JMP, and S+S which created a likelihood of confusion and misunderstanding in violation of NMSA 1978, Section 57-12-2(D)(14).

d. Defendants made deceptive representations of material facts regarding JBP, JMP, and S+S in violation of NMSA 1978, Section 57-12-2(D)(14).

e. Defendants' promotional activities regarding JBP, JMP, and S+S, including publishing and distributing statements which were misleading and deceptive, and which omitted material information necessary to make the statements not be misleading and deceptive, or tending to deceive, were in violation of NMSA 1978, Section 57-12-2(D)(14).

f. Defendants specifically promoted JBP, JMP, and S+S as safe for babies and adults and failed to disclose that JBP, JMP, and S+S posed serious increased risks for mesothelioma, ovarian cancer, and other cancers in violation of NMSA 1978, Section 57-12-2(D)(5), and NMSA 1978, Section 57-12-2(D)(14).

g. Defendants' conduct constitutes an unconscionable trade practice in that they took advantage of the lack of knowledge of the State, New Mexico health care professionals, and State of New Mexico participants regarding JBP's and S+S's risk-benefit profile in violation of NMSA 1978, Section 57-12-2(E)(1).

h. Defendants' conduct constitutes an unconscionable trade practice in that it resulted in a gross disparity between the value received and the price paid, in violation of NMSA 1978, Section 57-12-2(E)(2).

123. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient, to misleading and deceptive information regarding JBP, JMP, and S+S communicated in any manner by a sales representative constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

124. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to a misleading and/or deceptive print advertisement regarding JBP, JMP, and S+S constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

125. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to a misleading and/or deceptive brochure regarding JBP, JMP, and S+S constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

126. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to other misleading and/or deceptive information regarding JBP, JMP, and S+S, provided directly or indirectly by Defendants, e.g., by means of package labeling, "Dear Healthcare Provider" letters, CD-ROMs, DVDs, dinners sponsored by Defendants, PowerPoint presentations, promotional items, continuing medical education materials and events sponsored by Defendants and meetings sponsored by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

127. Each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations constitutes a separate, distinct, knowing and willful violation of the Unfair Practices Act.

128. Each sale of JBP, JMP, and S+S in New Mexico without an adequate warning constitutes a separate and distinct violation of the Unfair Practices Act.

129. Each exposure of a New Mexico resident to JBP, JMP, and S+S resulting from the aforementioned conduct of Defendants constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

130. Defendants' violations of the Unfair Practices Act were and continue to be willful.

131. Unless enjoined from doing so, Defendants will continue to violate the New Mexico Unfair Practices Act.

132. The State of New Mexico and its citizens have suffered and will continue to suffer substantial damage and injury as a direct and proximate result of Defendants' wrongful conduct and violations of the New Mexico Unfair Practices Act.

133. The State of New Mexico seeks as damages the reimbursement of all monies paid for JBP, JMP, and S+S by the State of New Mexico.

134. The State of New Mexico also seeks restitution for all monies paid for JBP, JMP, and S+S in connection with State of New Mexico programs and/or by state agencies and/or departments.

135. The State of New Mexico also seeks all recoverable penalties under Section 57-12-11 for violations of the New Mexico Unfair Practices Act.

COUNT III

VIOLATION OF THE NEW MEXICO MEDICAID FRAUD ACT [NMSA 1978, Section 30-44-7]

136. The State repeats and reiterates the allegations previously set forth herein.

137. Pursuant to NMSA 1978, Section 30-44-7(A), Medicaid fraud consists of, *inter alia*:

(3) presenting or causing to be presented for allowance or payment with intent that a claim be relied upon for the expenditure of public money any false, fraudulent excessive, multiple or incomplete claim for furnishing treatment, services or goods; or

(4) executing or conspiring to execute a plan or action to:

(a) defraud a state ... funded or mandated managed health care plan in connection with the delivery of or payment for health care benefits, including engaging in any intentionally deceptive marketing practice in connection with proposing, offering, selling, soliciting or providing any health care service in a state ...funded or mandated managed health care plan; or

(b) obtain by means of false or fraudulent representation or promise anything of value in connection with delivery of or payment for health care benefits that are in whole or in part paid for or reimbursed or subsidized by a state ...funded or mandated managed health care plan.

138. In failing to disclose the true facts regarding safety and efficacy of JBP, JMP, and S+S, Defendants committed violations of subsections (3) and (4) of NMSA 1978, Section 30-44-7(A) in connection with the State's Medicaid program. On information and belief, Defendants' clinical research and publication strategies were directed and influenced largely by marketing and profiteering concerns rather than by medical or safety concerns, and Defendants' management directed the company's so-called scientific research rather than enabling independent analysis. Defendants repeatedly failed to disclose important safety information; they improperly and deceptively influenced the medical and scientific literature and the perception of JBP, JMP, and S+S within the medical community; they consistently hid or downplayed JBP's and S+S's risks; they formed deceptive and misleading promotional relationships with other manufacturers and suppliers for the purpose of promoting their products and deceiving the FDA; they engaged in the virtual ghostwriting of medical and scientific articles; and they engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein. Defendants marketed JBP, JMP, and S+S as safe and effective with the intent that New Mexico residents and the State rely on their representations so that the Defendants' JBP, JMP, and S+S would still be available for sale and subsequently purchased in New Mexico.

139. In addition, Defendants, through their control and manipulation of studies and research publications, their submission of false and misleading information to the FDA, their failure to adequately warn of JBP's and S+S's true risks in their labeling and other marketing materials, and their false and deceptive marketing, caused false and misleading information regarding the safety and efficacy of JBP, JMP, and S+S to be reasonably relied upon by the State of New Mexico.

140. As a result of Defendants' fraudulent marketing of JBP, JMP, and S+S, the New Mexico Medicaid program has paid for JBP, JMP, and S+S. As a result, Defendants have been illegally enriched at the expense of the New Mexico Medicaid program. Further, the New Mexico Medicaid program has been required and will be required to pay the costs of treatment for Medicaid recipients actively harmed by Defendants' actions. Because of the dangerous risks associated with exposure to JBP, JMP, and S+S, which the Defendants concealed and misrepresented, the products were essentially worthless, lacking medical value, and in fact caused ovarian cancer and other cancers as well as mesothelioma and death.

141. In making representations that JBP, JMP, and S+S had any efficacy at all, Defendants acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information. Defendants' wrongful conduct resulted in charges to the New Mexico Medicaid program for goods or services that were so deficient as to be worthless.

142. Each claim submitted for JBP, JMP, and S+S for payment by the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

143. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to misleading and deceptive information regarding JBP, JMP, and/or S+S in connection with the New Mexico Medicaid program communicated in any manner by a sales representative constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

144. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to a misleading and/or deceptive print advertisement

regarding JBP, JMP, and S+S in connection with the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

145. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to a misleading and/or deceptive brochure regarding JBP, JMP, and S+S in connection with the New Mexico Medicaid program constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

146. Each exposure of a state employee or contractor, New Mexico health care professional, or New Mexico patient to other misleading and/or deceptive information regarding JBP, JMP, and S+S in connection with the New Mexico Medicaid program, provided directly or indirectly by Defendants, e.g., by means of package labeling, "Dear Healthcare Provider" letters, CD-ROMs, DVDs, dinners sponsored by Defendants, PowerPoint presentations, promotional items, and events sponsored by Defendants and meetings sponsored by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 30-44-8.

147. Each piece of marketing material used or disseminated in New Mexico in connection with the New Mexico Medicaid program which contained false or deceptive representations constitutes a separate, distinct, knowing and willful violation of the Medicaid Fraud Act.

148. Each purchase of JBP, JMP, and S+S in New Mexico without an adequate warning constitutes a separate and distinct violation of the New Mexico Medicaid Fraud Act.

149. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and its citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Medicaid Fraud Act.

150. Pursuant to the New Mexico Medicaid Fraud Act, the State is entitled to reimbursement for all monies paid for JBP, JMP, and S+S in connection with the New Mexico Medicaid Program, a civil penalty of three times the amount of excess payments, a civil penalty of ten thousand dollars ($10,000) for each false or fraudulent claim submitted or representation made, reasonable attorneys' fees, interest, and all other fees and costs of investigation and enforcement of civil remedies.

COUNT IV

VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT [NMSA 1978, Section 44-9-3]

151. The State repeats and reiterates the allegations previously set forth herein.

152. Defendants' knowing and repeated acts and omissions relating to JBP, JMP, and S+S, as described above, violate the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Section 44-9-3.

153. The State of New Mexico received claims for payment for JBP, JMP, and S+S from Defendants and from third-party vendors through various State programs and institutions. Among the claims for payment received by the State of New Mexico, the New Mexico Children, Youth and Families Department payed reimbursement to foster families for purchasing JBP, JMP, and S+S, and public healthcare facilities including, but not limited to, the University of New Mexico Hospital, purchased JBP, JMP, and S+S.

154. In failing to disclose the true facts regarding safety and efficacy of JBP, JMP, and S+S, Defendants knowingly presented, or caused to be presented, false claims for payment or approval, in violation of NMSA 1978, Section 44-9-3A(1).

155. On information and belief, Defendants' clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and Defendants' management directed the company's so-called scientific research rather than enabling independent analysis. Defendants repeatedly failed to disclose important safety information; they improperly and deceptively influenced the medical and scientific literature and the perception of talc and talcum powder products within the medical community; they consistently denied the presence of asbestos in JBP, JMP, and S+S and denied risks associated with the products; they formed deceptive and misleading promotional relationships with other manufacturers and suppliers for the purpose of promoting their products and deceiving the FDA; they engaged in misleading marketing to the State and its residents, participants in State programs, and/or the State of New Mexico that misrepresented the safety and efficacy of JBP, JMP, and S+S; they engaged in the virtual ghostwriting of medical and scientific articles; and they engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein. Defendants marketed JBP, JMP, and S+S as safe and effective despite knowing that the marketing was false or misleading.

156. The claims submitted to the State of New Mexico were false, misleading or fraudulent because Defendants knowingly concealed and misrepresented the dangerous risks associated with exposure to JBP, JMP, and S+S. Instead, the products were essentially worthless, lacking medical value, and in fact caused ovarian cancer and other cancers as well as mesothelioma and death.

157. In failing to disclose the true facts regarding safety and efficacy of JBP, JMP, and S+S, Defendants knowingly presented, or caused to be presented, false claims for payment or approval, in violation of NMSA 1978, Section 44-9-3(A)(1).

158. In making representations that JBP, JMP, and S+S had any efficacy at all, and in failing to disclose the true facts regarding safety and efficacy of JBP, JMP, and S+S, Defendants knowingly made, used, or caused to be made or used, false, misleading or fraudulent statements to obtain or support the approval of, or the payment on, false or fraudulent claims, in violation of NMSA 1978, Section 44-9-3(A)(2).

159. By engaging in the wrongful conduct described herein, Defendants conspired among themselves, and with the CTFA, to defraud the State by obtaining approval or payment on false or fraudulent claims in violation of NMSA 1978, Section 44-9-3(A)(3).

160. In addition, Defendants, through their control and manipulation of studies and research publications, their submission of false and misleading information to the FDA, their failure to adequately warn of JBP's and S+S's true risks in their labeling and other marketing material, and their false and deceptive marketing conducted by Defendants' lobbyists and company "scientists," caused false, misleading or fraudulent claims to be submitted to the State of New Mexico based on false and misleading information regarding the safety and efficacy of JBP, JMP, and S+S.

162. The State of New Mexico has been sustained damages becauseDefendants presented or caused to be presented false, misleading, or fraudulent claims for payment for JBP, JMP, and S+S. The State of New Mexico has made payments to Defendants and to third parties for the purchase of JBP, JMP, and S+S because of false, misleading, or fraudulent claims which Defendants presented or caused to be presented to the State of . The State of New Mexico has also paid substantial sums for injuries and services related to JBP, JMP, and S+S, asbestos-containing products that have no medical value and instead increase the risk of mesothelioma and ovarian cancer for those exposed. As a result, Defendants have been illegally enriched at the expense of

the State of New Mexico. Further, the State of New Mexico has been required and will be required to pay the costs of treatment of New Mexico residents actively harmed by Defendants' actions.

163. In making representations that JBP, JMP, and S+S had any medical efficacy at all, and in failing to disclose the true facts regarding safety and efficacy of JBP, JMP, and S+S, Defendants acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information. Defendants' wrongful conduct resulted in charges to the State of New Mexico for goods or services that were so deficient as to be worthless.

164. Each claim for JBP, JMP, and/or S+S presented to the State of New Mexico or to a contractor, grantee, or other recipient of state funds constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

165. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional, or State of New Mexico participant to misleading and deceptive information regarding JBP, JMP, and/or S+S communicated in any manner by a sales representative made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for JBP, JMP, and/or S+S constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

166. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional, or State of New Mexico participant to a misleading and/or deceptive print advertisement regarding JBP, JMP, and/or S+S made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for JBP, JMP, and/or S+S constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

167. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional, or State of New Mexico participant to a misleading and/or deceptive brochure regarding JBP, JMP, and/or S+S made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for JBP, JMP, and/or S+S constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

168. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional, or State of New Mexico participant to other misleading and/or deceptive information regarding JBP, JMP, and/or S+S made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for JBP, JMP, and/or S+S constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

169. In addition to, or in the alternative, each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations regarding JBP, JMP, and/or S+S made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for JBP, JMP, and/or S+S constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

170. In addition to, or in the alternative, each sale of JBP, JMP, and/or S+S in New Mexico in connection with State of New Mexico programs without an adequate warning constitutes a separate and distinct violation of the New Mexico Fraud Against Taxpayer's Act.

171. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and its citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Fraud Against Taxpayer's Act.

172. Pursuant to the New Mexico Fraud Against Taxpayer's Act, the State is entitled to three times the amount of damages sustained by the State because of Defendants' violations of the

New Mexico Fraud Against Taxpayer's Act, a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation, reasonable attorneys' fees, and costs.

COUNT V

FRAUD AND NEGLIGENT MISREPRESENTATION

173. The State repeats and reiterates the allegations previously set forth herein.

174. Defendants' warnings of JBP's and S+S's side effects contained false representations and/or failed to accurately represent the material facts of the full range and severity of risks and adverse reactions associated with the product.

175. Defendants' representations and assertions related to JBP, JMP, and S+S to the State of New Mexico, health care providers, and State of New Mexico participants contained false representations as to the safety of JBP, JMP, and S+S and their defective design.

176. Defendants were negligent in not making accurate representations regarding the risk of mesothelioma, ovarian cancer and other cancers associated with the use of JBP, JMP, and S+S.

177. Defendants knew or reasonably should have known through adequate testing that the representations made to the State with regard to the safety and efficacy of JBP, JMP, and S+S were false or incomplete, and misrepresented the material facts of the products' unsafe and defective condition.

178. The State, through its programs, departments and agencies, expended substantial sums for injuries caused by JBP, JMP, and S+S which expenditures were directly caused by the fraudulent and misleading statements of the Defendant.

179. Defendants willfully, knowingly and deceptively withheld material facts regarding the risk of mesothelioma, ovarian cancer, and other cancers associated with the use of JBP, JMP, and S+S from the State of New Mexico, health care professionals, and State of New Mexico participants.

180. Defendants intentionally withheld information regarding the safety risks associated with JBP, JMP, and S+S with the intent to induce the State of New Mexico, health care professionals, and State of New Mexico participants to purchase and use the products.

181. The State of New Mexico, health care professionals, and State of New Mexico participants were justified in their reliance on Defendants to educate them as to the risk of mesothelioma, ovarian cancer, and other cancers associated with JBP, JMP, and S+S use and exposure.

182. In addition, Defendants, through their control and manipulation of studies and research publications, its submission of false and misleading information to the FDA, its failure to adequately warn of JBP's and S+S's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by Defendants' sales representatives, lobbyists, and company "scientists," caused false and misleading information regarding the safety and efficacy of JBP, JMP, and S+S to be reasonably relied upon by the State of New Mexico.

183. Defendants' aggressive promotions have induced a misallocation of State funds through a pattern of fraudulent conducts. Defendants made or caused false claims, statements and representations of material fact to be made in connection with the State of New Mexico programs and/or in connection with expenditures made by State agencies and/or departments. In addition, Defendants knowingly and willfully concealed or failed to disclose material facts, events and/or transactions which affected Defendants' entitlement to payment, reimbursement, or benefits under

the State's programs or by State agencies and/or departments, and/or the amount of payment, reimbursement, or benefit to which the Defendant was entitled for services, goods, or assistance rendered in connection with the State's programs and/or to State agencies and/or departments. Defendants' scheme included the implementation of intentionally deceptive marketing practices. Defendants intended that their fraudulent promotion be relied upon for the continued sale of its products which resulted in the expenditure of public money.

184. Each of Defendants' misleading and deceptive statements, representations, and advertisements related to JBP, JMP, and S+S was material to the State's reimbursement for the products.

185. As a proximate and legal result of Defendants' fraudulent misrepresentations, the State of New Mexico has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

COUNT VI

NEGLIGENCE

186. The State repeats and reiterates the allegations previously set forth herein.

187. Defendants owed a duty to exercise reasonable care in the testing, marketing, manufacture, sales, labeling, and/or distribution of JBP, JMP, and S+S, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented risks for mesothelioma, ovarian cancer, and other cancers. Defendants owed this duty to the State of New Mexico, which expended State funds for the use of JBP, JMP, and S+S in the State of New Mexico.

188. Defendants breached this duty, as they were negligent in the testing, marketing, manufacture, sale, labeling, and distribution of JBP, JMP, and S+S.

189. Defendants further negligently, carelessly, recklessly, willfully, and/or intentionally engaged in the following conduct:

a. Failing to adequately train their sales force;

b. Supplying a product that they knew, or should have known, contained inadequate warnings of risks that were known to, or based on facts available to Defendants;

c. Supplying a product lacking sufficient warnings and/or instructions when they knew, or should have known, the risks associated with JBP, JMP, and S+S were not generally known by the State of New Mexico, health care providers, and patients;

d. Misrepresenting the safety and efficacy of JBP, JMP, and S+S;

e. Failing to disclose the true facts regarding the safety and efficacy of JBP, JMP, and S+S;

f. Failing to remove JBP, JMP, and S+S from the market when Defendants knew or should have known of the dangerous and defective condition of the products; and

g. Continuing to promote, market and sell JBP, JMP, and S+S after Defendants knew, or should have known, of the serious risks associated with the products' use.

190. Defendants' negligent, careless, reckless, willful, and/or intentional conduct was the proximate cause of the injuries and damages sustained by the State.

191. At all relevant times, Defendants knew, or should have known, that JBP, JMP, and S+S were and are hazardous to human health.

192. JBP, JMP, and S+S are abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with the products greatly outweigh any claimed utility.

193. As a direct result of the unreasonable marketing practices of Defendants, JBP, JMP, and S+S were, and are, defective and unreasonably dangerous.

194. JBP, JMP, and S+S reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed, and sold by Defendants. At the time JBP, JMP, and S+S were sold or placed on the market, they were in a defective condition and unreasonably dangerous to anyone exposed to them.

195. State of New Mexico participants used JBP, JMP, and S+S in the manner in which they were intended to be used, without any substantive alteration or change in the product.

196. Due to the negligent, careless, reckless, willful, and/or intentional conduct of Defendants, as set forth above, the State dispensed substantial sums of State funds in purchasing JBP, JMP, and S+S and was also forced and will be forced to expend even more money for the care and treatment of State of New Mexico participants injured by JBP, JMP, and S+S, all of which was foreseeable to Defendant.

197. As a direct and proximate result of Defendants' negligence, the State of New Mexico has suffered and will suffer damages and is therefore entitled to recover those damages.

198. The reprehensible nature of Defendants' conduct further entitles the State to an award of punitive damages.

COUNT VII

UNJUST ENRICHMENT

199. The State repeats and reiterates the allegations previously set forth herein.

200. Defendants knowingly, willfully, and intentionally marketed and promoted JBP, JMP, and S+S in a false and deceptive manner.

201. Defendants knowingly, willfully, and intentionally withheld information from the State, health care professionals and State of New Mexico participants regarding the risks associated with exposure to JBP, JMP, and S+S.

202. The State paid, reimbursed or otherwise conferred a benefit upon Defendants that directly resulted from the Defendants' fraudulent marketing practices.

203. Further, Defendants have been unjustly enriched as a result of their fraudulent marketing practices.

204. Plaintiff is entitled to restitution to the extent of the increased revenue received by Defendants from JBP, JMP, and S+S sales that were reimbursed by the State and which resulted from Defendants' deceptive and illegal marketing program.

PUNITIVE DAMAGES

205. The State repeats and reiterates the allegations previously set forth herein.

206. By engaging in the above-described conduct, Defendants acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations. Defendants' conduct also was willful, reckless, and/or fraudulent. *See Clay v. Ferrellgas, Inc.*, 1994-NMSC-080, ¶ 12, 118 N.M. 266, 881 P.2d 11 ("To be liable for punitive damages, a wrongdoer must have some culpable mental state, . . and the wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level . . . .") (citations omitted).

207. Here, Defendants were marketing and selling dangerous asbestos-containing talcum powder products which Defendants knew contained asbestos and knew would be used as

designed on a daily basis all over the consumer's body, including the genital area. Because of the level of danger posed by, and indeed visited upon consumers and the State by these dangerous products, Defendants owed a high duty of care to ensure that the risks and dangers of these products were disclosed and explained to consumers. Defendants chose profit over people, and over the safety of the community, and an award of punitive damages is appropriate, as punishment and as deterrence.

208. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of New Mexico, prays for judgment against Defendants as follows:

A. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Unfair Practices Act, §57-12-1, et seq.;

B. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Medicaid Fraud Act, §30-44-2, et seq.;

C. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Fraud Against Taxpayers Act §44-9-3, et seq.;

D. Grant permanent injunctive relief and award restitution against Defendants pursuant to §57-12-8(B) NMSA 1978;

E. Award the State its damages as set forth herein;

F. Award the State restitution as set forth herein;

G. Award maximum civil penalties as provided by law;

H. Award the State punitive damages;

I. Award the State the costs of prosecuting this action, together with interest, including prejudgment interest, and reasonable attorneys' fees in connection with the prosecution of this case; and

J. Grant such further relief as this Court may deem just and proper under the circumstances.

DATED: January 2, 2020

Respectfully Submitted,

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