

EXAMINING THE PUBLIC HEALTH RISKS OF CARCINOGENS IN CONSUMER PRODUCTS

HEARING

BEFORE THE
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OF THE

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AND REFORM

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EXAMINING THE PUBLIC HEALTH RISKS OF CARCINOGENS IN CONSUMER PRODUCTS

Tuesday, March 12, 2019

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND REFORM
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:06 a.m., in room 2154, Rayburn House Office Building, Hon. Raja Krishnamoorthi presiding.

Present: Representatives Krishnamoorthi, DeSaulnier, Khanna, Pressley, Tlaib, Connolly, Gomez, Cloud, Grothman, and Miller.

Mr. KRISHNAMOORTHY. Good morning. The subcommittee will come to order.

Without objection, the Chair is authorized to declare a recess of the committee at any time.

This hearing is entitled, “Examining the Public Health Risks of Carcinogens in Consumer Products.”

I now recognize myself for five minutes to give an opening statement.

Today marks our subcommittee’s first hearing. The Subcommittee on Economic and Consumer Policy was created to focus attention on the pocketbook issues that matter the most to Americans, economic opportunity and fairness, consumer health and safety, and the overall quality of life. We will do this first and foremost by asking tough questions and following the facts wherever they lead.

Today our focus is on a group of widely used personal care consumer products that contain talc, a mineral that manufacturers put in baby powder for infants, make-up for teenage girls, and personal care products for people of all ages.

Now, why is this issue important right now? First, recent reports claim that Johnson & Johnson, a large maker of personal care products, was aware for decades that its talc products sometimes contained asbestos, a carcinogen that has killed thousands of miners and shipyard workers. And separately, the FDA recently issued advisories regarding cosmetics marketed by Justice and Claire’s to children, also containing asbestos.

Let’s be clear: there is no question that exposure to asbestos is hazardous to human health, and geologists know that asbestos can be found in rock formations that also contain talc. Yet, the FDA cannot order any manufacturers to recall these personal care or cosmetics products that potentially contain asbestos. The question is why?

Because a loophole in the statute that empowers the FDA to regulate personal care products and cosmetics does not allow the FDA to require necessary recalls. Thankfully, some manufacturers like Claire's have volunteered to recall products the FDA has found to contain asbestos, which I thoroughly commend. But FDA authority generally remains weak. In fact, product recalls, mandatory risk labeling, and adverse event reports are just a few of the processes in which compliance with FDA guidelines is entirely voluntary for the cosmetics industry.

This is a statutory problem that needs reform, and I expect the Energy and Commerce Committee, under the leadership of Chairman Frank Pallone, will focus like a laser on that problem to protect consumers. But juries across America are not waiting for Congress to act. In fact, juries have awarded verdicts to victims and survivors who have suffered or died from ovarian cancer that was possibly caused by talcum baby powder. Many of those juries have assessed punitive damages against manufacturers for failing to warn consumers of talcum powder's ovarian cancer risk.

Today we are joined by women and their families from across the country who suffer from ovarian cancer which they attribute to long-time use of talcum baby powder. One of these families is the Browning family from my home state of Illinois. Anthony and Elisa Browning, thank you both for being here today on behalf of your mother, Gloria Browning. I extend my sincerest condolences to you and your family.

Additionally, one of our witnesses today, Mr. Salter, is the surviving son of a deceased ovarian cancer patient. He will testify to what he and his mother's doctors believe caused his mother's death. Mr. Salter, I extend our sympathies to you as well, and I want to personally thank you for joining us here today.

We will also hear from a distinguished epidemiologist, Dr. Anne McTiernan, who has conducted extensive analyses of the scientific data on talc and asbestos.

We will also hear from the Environmental Working Group, which is devoted to consumer health and education, to help us evaluate the problems in the Federal regulation of personal care products.

We are also listening to what the largest maker of talcum body powders, Johnson & Johnson, says about the safety of their products. In preparing for this hearing, my staff has discussed the company's detection methods, manufacturing and mining processes, and the health risk data with senior executives and their company, and we will continue to gather facts from them as well.

The average adult uses nine personal care products daily in this country, nine. Consumers use these products trusting that they are safe and will not harm themselves or their families. Today's hearing is just our first step in protecting consumers from potentially carcinogenic products. The American people deserve nothing less.

Now the Chair recognizes the ranking member, Mr. Cloud of Texas, for five minutes for an opening statement.

Mr. Cloud?

Mr. CLOUD. Thank you, Mr. Chairman.

Thank you, everyone, for being here.

Let me say at the outset congratulations, Chairman, on your chairmanship and on this first meeting of the subcommittee. I do look forward to working with you.

Mr. KRISHNAMOORTHY. Thank you.

Mr. CLOUD. I know we are just getting to know each other, but I know enough about both of us to know that our most important role is that of being a father, and because of that we keep in mind our families and the families we represent, and that is one of the things that makes this such an important issue today.

The issue we are discussing today is particularly important not only because of the potential harm for individuals but because of how commonplace consumer products are. I am confident that everyone in this room has used several consumer products this morning, or at least I hope so—

[Laughter.]

Mr. CLOUD [continuing]. the safety of which we largely take for granted.

When a problem like the potential contamination of consumer products with carcinogens becomes apparent, one of the first questions that comes to mind is what is the Federal Government's role in addressing it?

I think we can all agree on this: a company knowingly puts contaminated products on the marketplace for consumers to buy and use, that is a bad actor, and bad actors should be held accountable.

The government should engage in fact-finding and determine the level of risk posed to consumers by these contaminated processes, which is a process I hope we begin today.

Any Federal Government action should be guided by the best available science and based on real, quantifiable risk to consumers, not by fear or desire to simply act. It should be tailored to the problem at hand and designed to limit unintended or secondary consequences.

We need only to look at recent history to find instances of government regulation having the opposite effect from what was intended. In our response to the 2008 financial crisis, Congress took the expansive action and passed Dodd-Frank to address banks that were too big to fail. But according to the Wall Street Journal, the three largest U.S. banks by assets have taken up more than \$2.4 trillion of domestic deposits over the last 10 years. That growth is more than the total assets held by the eight largest banks in 2007, the year before the crisis began. In other words, we took banks that were too big to fail and we made them bigger.

Why does this happen? It happens because regulatory complexity favors large, established companies who can better absorb new compliance costs. It creates barriers to entry, so there are fewer new companies being formed, and it drives consolidation, concentrating risk into fewer institutions that have bigger roles in the economy.

So as we work on this very real situation, I hope we can keep in mind scalable solutions, as opposed to a one-size-fits-all approach, and I do thank our witnesses for appearing before this subcommittee today. I look forward to your testimony. Thank you for being here.

Mr. Chairman, I yield back.

[Prepared Statement of Mr. Cloud follows:]

**WRITTEN TESTIMONY OF RANKING MEMBER MICHAEL CLOUD
COMMITTEE ON OVERSIGHT AND REFORM SUBCOMMITTEE
ON ECONOMIC AND CONSUMER POLICY U.S. HOUSE OF REPRESENTATIVES**

March 12, 2019

- Thank you, Mr. Chairman, and thank you everyone for being here for the first hearing of this subcommittee in the 116th Congress.
- I look forward to working with you, Mr. Chairman, and all Members of this subcommittee over the coming years to address issues facing American consumers and our economy.
- The issue we are discussing today is particularly important. Not only because of the potential for harm to individuals, but because of how commonplace consumer products are.
- I am confident that everyone in this room has used several consumer products this morning, the safety of which we largely take for granted.
- When a problem like the potential contamination of consumer products with carcinogens becomes apparent, one of the first questions that comes to mind is what the Federal Government should do about it.
- There are those of us who prefer the government to take an active role in responding to a problem such as this, while others prefer a more limited role.
- But I think we can all agree on this: If a company knowingly puts contaminated products out in the marketplace for consumers to buy and use, that is a bad actor and bad actors should be held accountable.
- The government should engage in factfinding and determine the level of risk posed to consumers by these contaminated products, which is a process I hope we begin today.
- If allegations of wrongdoing are substantiated, the government should act in a measured and responsible manner.
- Any Federal Government action should be guided by the best-available science and based on real and quantifiable risks to consumers, not by fear or a desire simply to act.
- It should be tailored to the problem at hand and designed to limit unintended or secondary consequences.
- We need only look at our recent history to find instances of government regulation having the opposite effect from what was intended.
- In response to the 2008 financial crisis, Congress took expansive action and passed Dodd-Frank to address banks that were “too big to fail.”
- But according to the Wall Street Journal, the three largest U.S. banks by assets have taken in more than \$2.4 trillion of domestic deposits over the past 10 years.¹
- That growth is more than the total assets held by the eight largest banks in 2007, the year before the crisis began.²
- In other words, we took the banks that were already too big to fail, and we made them much larger.
- Why? Because regulatory complexity favors large, established companies who can better absorb new compliance costs.
- It creates barriers to entry, so there are fewer new companies being formed, and it drives consolidation, concentrating risk into fewer institutions who have bigger roles in the economy.
- We must avoid falling into the same trap if Congress is to act in response to the problem before us today.
- I thank our witnesses for appearing before our subcommittee today and I look forward to their testimony.
- Mr. Chairman, I yield back.

¹Rachel Louis Ensign, *Biggest Three Banks Gobble Up \$2.4 Trillion in New Deposits Since Crisis*, WALL STREET J. (Mar. 22, 2018), <https://www.wsj.com/articles/biggest-three-banks-gobble-up-2-4-trillion-in-new-deposits-since-crisis-152171001>.

²*Id.*

Mr. KRISHNAMOORTHY. Thank you, Mr. Cloud.

Now I want to welcome our witnesses: Dr. Anne McTiernan, M.D., Ph.D., a member of the Fred Hutchinson Cancer Research Center; Scott Faber, the Vice President of Government Affairs at the Environmental Working Group; and Marvin Salter, who is the son of a deceased ovarian cancer patient.

If the witnesses will please rise, I will begin by swearing you in. If you could put up your right hand, please?

[Witnesses sworn.]

Mr. KRISHNAMOORTHY. Let the record show that the witnesses answered in the affirmative.

You may put your right hands down.

Let the record show that the witnesses have answered in the affirmative. Thank you, and please be seated.

The microphones are sensitive, so please speak directly into them.

There is a timing system here. Counting down from five, you start with the green light, and then you go to yellow light and red light. But unlike with stop lights, you have to speed up when you see yellow, not slow down.

Without objection, your written statements will be made part of the record.

With that, Dr. McTiernan, you are now recognized to give an oral presentation of your testimony for five minutes.

STATEMENT OF ANNE McTIERNAN, M.D., PH.D.

Dr. McTIERNAN. Chairman Krishnamoorthi, Ranking Member Cloud, and members of the subcommittee, good morning and thank you for inviting me. My name is Dr. Anne McTiernan. I am a cancer prevention researcher in the Epidemiology Program, Division of Public Health Sciences, at the Fred Hutchinson Cancer Research Center in Seattle, Washington. I am also a Research Professor in the University of Washington Schools of Public Health and Medicine. I am not representing the Fred Hutchinson or the University of Washington in my presentation of testimony this morning to the subcommittee.

I am an internal medicine physician and an epidemiologist. My research focuses on cancer epidemiology and prevention, particularly cancers in women. I was asked to give testimony today because I have conducted a thorough and systematic review of the science linking use of talcum powder products with risk for ovarian cancer. As part of this review, I prepared an expert report on behalf of consumers for an ongoing multi-district litigation on talcum powder products as causes of ovarian cancer.

My scientific review focused primarily on the epidemiologic research. Epidemiologists look at large groups of people with a disease and compare them to people without that disease to look for what might be causing the disease.

The American Cancer Society and the U.S. National Cancer Institute estimate that in 2019, over 22,000 women will receive a diagnosis of ovarian cancer, and over 13,000 will die of ovarian cancer. There is no established method for screening for ovarian cancer. As a result, most women are diagnosed at an advanced, less treatable stage. There is also no method established for preventing ovarian cancer other than surgical removal of the ovaries. Therefore, it is critical to identify causes of ovarian cancer in order to prevent this serious disease.

My review identified 38 high-quality epidemiologic studies conducted over the past 40 years. These studies asked women about their use of talcum powder products in the genital area and tested associations with risk of ovarian cancer. Together, these studies included over 14,000 women with ovarian cancer, and particularly epithelial cancer, which is the most common type, and an even greater number of women without ovarian cancer. Most of these studies were conducted in the United States.

Ovarian cancer is thought to develop over years. Therefore, a woman's experience in her younger and middle years can affect her risk of ovarian cancer decades later. Women have reported use of talcum powder products on sanitary napkins, underwear, and directly to the genital area. In some studies, over 4 in 10 women report ever regularly using these products in the genital area.

Summarizing data from all of the published studies consistently shows that women who had ever used talcum powder products in the genital area had a statistically significant 22 to 31 percent increased risk of developing epithelial ovarian cancer compared with women who had never used them. Evidence suggests that these associations hold across diverse race and ethnic groups.

These combined analyses also showed that increasing exposure to these products was associated with increasing risk of ovarian cancer.

We know from laboratory and clinical studies as well as in humans that talc can migrate from the genital area up to the area of the ovaries and the fallopian tubes. Talc has been shown to cause inflammatory responses in the human body. We know that elevated levels of inflammation are associated with increased risk of ovarian cancer. And all of this provides a biologically plausible pathway by which talcum powder products can cause ovarian cancer.

So given the frequency with which asbestos has been found in cosmetic and personal talc products, I reviewed the literature in asbestos as well, and in 2012 the International Agency for Research on Cancer stated that a causal association between asbestos and cancer of the ovary was clearly established. That agency has also classified fibrous talc as a Class 1 carcinogen, the most dangerous type of carcinogen.

Given the high prevalence of use of talcum powder products, this level of increase can have profound effects on clinical events and public health. Women need to know about the risks of using talcum powder products in their genital areas. All consumers need to be warned about the contents of these products, including asbestos and fibrous talc, so they can make informed decisions about use.

Thank you for the opportunity to provide this testimony. I would be happy to answer any questions you may have.

[Prepared Statement of Dr. McTiernan available on: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/McTiernan-Statement.pdf>]

Mr. KRISHNAMOORTHY. Thank you, Dr. McTiernan.

Now, Mr. Faber?

STATEMENT OF SCOTT FABER

Mr. FABER. Thank you, Mr. Chairman, Ranking Member Cloud, and members of the committee. Let me start by thanking you for holding this hearing, and let me thank the people sitting behind me who have been personally impacted and who are willing to share their stories.

The recent news that asbestos was found in facial powders marketed to teens is something that should concern all of us. Unfortunately, cosmetics purchased at stores like Claire's and Justice are not the only products that are likely to contain asbestos. There is always some risk that the products produced with talc will contain this dangerous carcinogen.

EWG has found more than 2,000 cosmetics and other personal care products that contain talc, including more than 1,000 loose powders or pressed powders that could pose a risk of being inhaled or absorbed. Even small amounts of asbestos and talc can cause mesothelioma or other diseases many years after exposure.

It is not a secret that talc can contain asbestos. Companies have known of this risk since at least the 1950's. Nevertheless, as Commissioner Gottlieb said last week, cosmetic companies have no duty to test for products made with talc for asbestos or to share those test results with FDA, and have no duty to warn consumers of this potential risk.

Asbestos is not the only contaminant or chemical of concern in personal care products. Since 2009, cosmetics manufacturers themselves have reported using 88 chemicals linked to cancer, birth defects, or reproductive harm in both men and women. Nevertheless, the FDA is not now required to review and regulate, if necessary, these chemicals, and has very limited authority to do so.

While Congress has given the FDA the authority to review and regulate chemicals in food, in colors, in pesticides, Congress has not given the FDA the same power or the resources necessary to address chemicals of concern in cosmetics.

As a result, cosmetics have largely fallen into a regulatory black hole. While the FDA has only banned or restricted nine chemicals in cosmetics for safety reasons, more than 40 other nations have banned or restricted more than 1,400 chemicals in cosmetics and other personal care products.

While other categories subject to FDA oversight, categories like drugs, medical devices or food, must register with the FDA, must report ingredients, must report adverse events, cosmetics manufacturers do not have to register with the FDA, do not have to report ingredients, do not have to report adverse events. When products in other categories subject to FDA oversight harm consumers, FDA can stop their production and order a recall. But as we learned last week, FDA can only ask a cosmetics company to recall contaminated products.

Since the 1950's, Congress has tried to give FDA the power to oversee the safety of these everyday products but has so far been stymied, but that may be changing now that cosmetics companies, large and small, have endorsed bipartisan legislation to give FDA these basic powers.

All of us use personal care products every day. Women use on average 12 products that contain 168 unique chemicals. Men use on average six products that contain 85 different chemicals. Most Americans assume that these everyday products are safe, but they would be wrong. That is why I am so grateful, Mr. Chairman, that you are holding this hearing today.

Thank you. I am happy to take your questions.

[Prepared Statement of Mr. Faber is available on: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Scott%20Faber-Testimony.pdf>]

Mr. KRISHNAMOORTHY. Thank you, Mr. Faber.

Mr. Salter, could you present your testimony?

STATEMENT OF MARVIN SALTER

Mr. SALTER. Good morning, Chairman Krishnamoorthi, Ranking Member Cloud, and members of the subcommittee. It is a great honor for me to address this subcommittee on behalf of my mother, the late Jacqueline Salter Fox. My mother departed this life on October 6, 2015. Her death came suddenly. At that time, she was doing well. She felt at that point in her battle against ovarian cancer that she was winning. Her exact words were: "God wasn't done with me yet." But as we came to learn, like many women who suffer from this deadly disease, victories can be short-lived, and celebrations are often cut short. Her disease recurred with a vengeance, and my mom lost that fight.

My mother had me when she was 16 years old, and we were all we had. In many ways, we grew up together. We saw hard times, but we always weathered the storm together. Her illness and eventual death was a storm neither of us were ready for and one from which I remain devastated.

I sincerely believe that Johnson & Johnson took my mother's life. We believed in the company, and in that product specifically. My mother was a true fan. It was a staple in our house and a necessary part of our hygienic routine. It was as natural for her as brushing her teeth every single day. Baby powder was always in our bathroom cabinets or on our bedroom dressers. It was wherever we were getting dressed. We never realized that what we were using could possibly be harmful. Had we known then what we know now, we never would have brought this into our household.

Prior to her diagnosis my mother, like so many other women, had no symptoms whatsoever. She was diagnosed with late-stage ovarian cancer in April 2013. It was a rough time for us, but my mother was the type of woman who never let bad news overtake her joy. She was confident she would beat this disease. She approached her treatment with a positive attitude and a big smile. She smiled through her surgery. She smiled through her chemotherapy and even the hair loss that it caused. She cheered up the other patients, even though her own body was wracked with pain and fatigue. She spent her time just as she had spent her life, serving and caring for others. Her spirit was never broken, despite what was happening to her body. She smiled through it all.

At some point she learned that her over 30 years of use of baby powder could have been responsible for her disease. I was not involved in her decision to file a lawsuit, but I supported my mother fully. She told me it was important for her to bring awareness to women about the risk of cancer. She did not want any more women going through what she did. Unfortunately, she did not make her trial. Because I knew how important it was for her, it was important for me to continue that fight. I wanted to make sure that her voice was heard, and I wanted Johnson & Johnson to know her name. I wanted them to know what a wonderful woman she was and how unfair it was that she was no longer with her family.

The trial was eye-opening. The evidence put forth against Johnson & Johnson was substantial. They lied to us all. They knew the cancer risks associated with their products but chose to cover it up instead. They protected their products and profits while putting innocent lives at risk. Each day revealed new details about exactly how much they knew and when they knew it.

Testing of my mother's tissue revealed the presence of talc. I learned how talc migrates up the female pelvic system and causes chronic inflammation at the surface of the ovaries. I learned how talc particles can infiltrate the lymphatic system and spread throughout the body. I learned that talc is a mineral often found with heavy metals and asbestos, which are known to be cancer-causing.

In the end, the jury saw things as we did. Despite having passed, my mom accomplished her goal of helping educate women everywhere that baby powder is a serious threat to all women.

There have been more trials since my mother's. More juries have seen all the evidence. More news outlets have reported on this issue. The truth is finally coming

out, but justice has not been served. Johnson & Johnson has yet to take ownership for what they have done, and they have yet to take one step to make amends to all of us whose lives have been turned upside down because we trusted in this company when they said their product was safe. Johnson & Johnson continues to market and sell a product they know to be harmful, and they continue to lie and cover up the truth about its safety. It is past time for Johnson & Johnson to do the right thing.

All my mother wanted is for women to know the risks of using baby powder. Johnson & Johnson could voluntarily add a warning to their product today, or better yet, stop selling it altogether. After all this time, it is safe to assume that Johnson & Johnson will not do what needs to be done to protect the public.

I ask that this body use whatever power in its disposal to assist in bringing about justice for my mother and for all women and families who have been adversely affected by ovarian cancer caused by Johnson & Johnson's baby powder.

Thank you.

[Prepared Statement of Mr. Salter is available on: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Marvin%20Salter-Testimony.pdf>]

Mr. KRISHNAMOORTHY. Thank you, Mr. Salter.

I now will begin the questioning. I recognize myself for five minutes for questions.

Dr. McTiernan, I would like to kind of unpack some of what you had to say with regard to the link between talcum powder use and cancer.

Could you explain a little bit about the process by which talcum powder would lead to ovarian cancer?

Dr. McTIERNAN. We know from studies in humans that women who use these products have a higher risk of developing cancer. So the question is how could this be occurring?

One possible way is we know that talc can migrate to the fallopian tubes or ovaries, both of which can initiate the cancer cell developing.

One plausible mechanism is inflammation because talc has been shown to cause an inflammation when it is inside the human body, including in various parts of the body, and that inflammation can induce carcinogenesis. So that is one possible mechanism. But other studies, cell studies where talc has been applied to cells shows that there are some other mechanisms that could also be working.

Mr. KRISHNAMOORTHY. How frequently would one have to use talcum powder for cancer-related inflammation to begin to occur? I think you called it carcinogenesis.

Dr. McTIERNAN. It is really not clear how frequently somebody would need to use this product. Theoretically, if one dose is in the particular area and causes an inflammation, that could be sufficient. But when you have more doses, when a person has used this more often and longer, the likelihood of that being introduced into the peritoneal area around the fallopian tubes or ovaries, that likelihood increases. We do not know. There is no particular threshold. There is nothing that says this amount is safe, this amount is not safe.

Mr. KRISHNAMOORTHY. I would like to point to a statement that Johnson & Johnson submitted to us yesterday. They said, "Decades of independent scientific testing has confirmed that Johnson & Johnson's cosmetic talc and Johnson's baby powder are safe, are not contaminated with asbestos, and do not cause cancer."

Without objection, I would like to enter this letter into the record.

[The information referred to is in the Appendix section.]

Mr. KRISHNAMOORTHY. Dr. McTiernan, do you agree with the statement that I just made, quoting from Johnson & Johnson's letter to us?

Dr. McTIERNAN. I do not agree in the science aspect of it. I have not seen any of the particular data they are talking about. They are probably talking about two things. One is the epidemiologic studies. I interpret those data that the use of these products increases risk of ovarian cancer, as do many of the very large combined studies.

The other part of that statement I believe had to do with testing the product, and while I have not conducted those sorts of tests myself, I saw when I was doing my expert report, I saw both published data and information from the companies that suggested that some of those products could have asbestos or other substances that could be carcinogenic, as well as the talc itself.

Mr. KRISHNAMOORTHY. Thank you.

Before my next question, without objection, I want to enter into the record a letter from Felipe Aviles from Palatine, Illinois, who states that his daughter Jeannette regularly used talcum powder in her hygienic routine.

Without objection, I would like to enter her statement into the record, or her father's statement into the record.

[The information referred to is in the Appendix section.]

Mr. KRISHNAMOORTHY. "This past December, Jeannette felt severe abdominal pain. She then got a biopsy and discovered that she had mesothelioma. On January 18th, 2019, Jeannette was admitted to the University of Chicago Hospital. She never left and passed away on February 4th, 2019. She was sick, diagnosed, and gone all within a few months."

Without objection, I am also entering into the record a joint letter from 10 additional Chicago residents who are relatives of individuals whose lives have been taken or whose health has suffered after years of talcum powder.

[The information referred to is in the Appendix section.]

Mr. KRISHNAMOORTHY. I see that my time is about to expire, so I would like to yield back and I would like to call—I am going to ask Mr. Grothman if you have questions.

Mr. GROTHMAN. Okay. This is a question for any one of the three of you. It was prompted by Mr. Salter's testimony.

You say all along Johnson & Johnson knew the connections between talc and cancer. Is that true? You said all along that Johnson & Johnson knew the connection between talc or baby powder and cancer. Is that true?

Mr. SALTER. Yes, I would say that is correct. Obviously, we had our trial back in 2016, so I was privy to a lot of the evidence that was put forth that showed that they knew about it as early as the '80's.

Mr. GROTHMAN. Could you expand a little bit on that, like what type of testing, or they knew there was correlation between their product and cancer?

Mr. SALTER. I am not familiar with exactly what type of testing was done, but I was only a witness to some of the documents that were presented during trial.

Mr. GROTHMAN. Okay. Does either Dr. McTiernan or Mr. Faber know a little bit how much they were covering up, what they were covering up, and how long they were covering up?

Mr. FABER. Thank you for the question, Mr. Grothman. As Mr. Salter mentioned, there is a great deal of documentary evidence showing that a number of companies, including Johnson & Johnson, found positive test results of their talc for the presence of asbestos fibers going back to the late 1960's and early 1970's. I am happy to share those results with you.

Mr. GROTHMAN. That is fine. They did not care? Any followup studies that maybe we ought to reduce that in the product?

Mr. FABER. So, at the time, these results were shared by a number of parties with FDA. FDA considered whether or not to regulate talc or to come up with a system to ensure that talc was free of asbestos, and ultimately in 1976, under pressure from industry, FDA agreed to allow industry to self-regulate provided they used a particular testing method that could detect some but not all of the asbestos that might be present in talc.

Mr. GROTHMAN. And you think asbestos is what causes the cancer?

Mr. FABER. There is no doubt whatsoever that asbestos can contribute to mesothelioma and other forms of cancer and disease. That is why, beginning in 1972, OSHA set standards for asbestos. That is why more than 50 other nations, although not yet the United States, have banned the use of asbestos.

Mr. GROTHMAN. Johnson & Johnson also makes pharmaceuticals?

Mr. FABER. That is correct.

Mr. GROTHMAN. Is there any reason you would think they would be any more careful with pharmaceuticals than they are with these other products?

Mr. FABER. That is a great question.

Mr. GROTHMAN. Does that morality spread throughout the company?

Mr. FABER. So, as I am sure you know, Mr. Grothman, pharmaceutical drugs are subject to premarket review by FDA. By contrast, personal care products like talc are not. So we essentially rely on an honor system. We trust companies to monitor or to test for the presence of asbestos. We trust companies to test the products that are sent to them for asbestos. We trust these companies to conduct marketplace surveillance. But they have no need to do those tests or—

Mr. GROTHMAN. Would common sense—and I hate to say this, but would common sense tell you that when you are putting something on your skin, that there is the potential over time to have something bad happen?

Mr. FABER. Mr. Grothman, most consumers assume, and there has been a lot of research done on this question, that FDA has actually reviewed these products for safety before we put them on our bodies every day. I think if you walked outside the Rayburn Building and asked anyone on the street, they would assume that shampoos, soaps, lotions have been tested and regulated by the FDA.

Mr. GROTHMAN. To you and Dr. McTiernan, one more general question. Juries can always reach conclusions that are wrong, I suppose. But in both of your opinions, is there any doubt in your mind that the baby powder that was sold by Johnson

& Johnson has a connection to cancer? I mean, do you feel, after looking at the evidence, that that is something that is subject to debate?

Dr. McTIERNAN. I can answer from my review of the scientific literature. I believe that talcum powder products do cause ovarian cancer, yes. It is clear. There have been 24 case-control studies that have been conducted over the last 40 years. Over 14,000 women with ovarian cancer have been interviewed for these studies and have given information, and even more women without ovarian cancer, and the results are really consistent. So I do believe, yes, that those products—

Mr. GROTHMAN. Is it off the market now?

Dr. McTIERNAN. Pardon?

Mr. GROTHMAN. Is it off the market now? The product, is it off the market now?

Dr. McTIERNAN. No, this is still on the market.

Mr. GROTHMAN. It is still on the market as almost a proven carcinogen?

Mr. FABER. There are now at least 2,000 products that contain talc that are available for sale today, of which more than 1,000 are loose powders or pressed powders, therefore posing the risk of—things that are used around the nose and mouth that might be inhaled. It only takes one fiber lodged in the lung to contribute to mesothelioma decades later, and that is why many organizations and, frankly, many countries have required some sort of warning label, especially for children under the age of 3, when using these products that contain talc.

Mr. KRISHNAMOORTHY. Thank you. Your time has expired, Mr. Grothman.

I would just say that I do not think that common sense would dictate that when people apply things to their skin, that they would ever expect cancer. I just do not see that happening.

Anyway, the next person up is Ms. Tlaib. You have five minutes.

Ms. TLAIB. Thank you, Chairman.

And thank you, all three of you, so much.

Mr. Salter, thank you so much. My father had cancer, and he passed on at 67 of cardiac arrest, but I was very, very much appreciative of your honesty and your testimony, and I thank her so much for bringing attention to this. This will truly always be her legacy, to be able to at least protect other women.

Today's hearing is significant. I think people are not realizing corporate greed is a type of cancer in our democracy right now, and it is true. People are questioning the science, questioning real, actual data that says exposure to these products hurts our families, our residents.

Just last week, the Food and Drug Administration issued a safety alert confirming that asbestos was found in make-up product samples from stores like Claire's and Justice, which are the stores that my residents go to, working folks, working families. They do not go to the bourgeois Macy's counter. I am being serious. These are targeting working-class people, companies that manufacture and sell these make-up products to young girls, many of them of color.

The FDA safety alert states, and I quote, "The FDA requested that Claire's recall their products because they should not be used by consumers. Claire's has refused to comply with the FDA's request, and the agency does not have authority to mandate a recall." However, later on after that, Claire's has since voluntarily complied.

But even reading that just now, it shook me. And I know I am new, but before I came here I honestly thought FDA has got it covered, EPA has got it covered. I see what happened in Flint, in Michigan.

So being here, the products mentioned and the safety alerts include eye shadows. I mean, these are things that I see my nieces—the younger girls are starting to put all kinds of stuff on their face. I was not allowed to wear make-up until I was 18, but it is true, it is changing because they are really focusing on our young girls.

So, Mr. Faber, your organization has devoted so much to helping consumers make right decisions. I know the Ecology Center in Michigan, I sat on their board for years testing car seats that had toxins in them, kids' car seats.

Corporate greed is so dangerous. It makes us look blindly at the science, at real data and information. It is not like we do not want you—we want you to do well. We support—who does not? But we do not want it in exchange for people dying.

So in the context of makers of talcum baby powder and so forth, if you were to make a decision, if you were in my spot, what are some of the specific things? I mean, you had mentioned 40 other countries had 1,400 restricted already? And I think—what is ours? How many you said?

Mr. FABER. Nine.

Ms. TLAIB. Nine, and you just said 2,000 products are on the market right now. What would you ask us to do on behalf of our residents right now at this point?

Mr. FABER. Well, the good news is that Chairman Pallone, Chairman of the Energy and Commerce Committee, is now working with Congressman Shimkus to craft legislation that would give the FDA these basic powers to order a recall if a product

is contaminated, to review ingredients if the ingredients have been linked to cancer or reproductive harm.

The other good news is that many of the companies that in the '70's fought giving FDA this power now support bipartisan legislation like the kind being developed by Mr. Pallone and Mr. Shimkus to give FDA these basic powers, the ability to know whether or not something is contaminated, to order a recall, to stop the production of contaminated products, all powers that FDA has for other categories but does not have today for cosmetics.

Ms. TLAIB. I read—and I do not know if my colleagues know this, but I believe that this is a \$62 billion industry in America right now, and they cannot just put a disclaimer, anything, any information out there right now, education on what these products are. But to think that asbestos, asbestos, which is living, breathing in your body—it takes a while; it is like a slow death—is in these products is unbelievable.

I want to ask maybe afterwards if we can talk. I really want to put these products on my congressional website. I want to see if my colleagues will not let me do that, because I want to put it on my website and provide this information to these young girls and try to increase education, because I cannot wait for this legislation to pass for people to stop dying.

Thank you so much.

Mr. KRISHNAMOORTHY. Thank you, Ms. Tlaib.

Mrs. Miller, you have five minutes.

Mrs. MILLER. Thank you, Chairman Krishnamoorthi and Ranking Member Cloud. And thank you to all of you all for being here today.

Mr. Salter, I grieve with you. I understand the tight bonds there are between a mother and a son. I also held my mother-in-law when she lost her 34-year-old son, and I grieve with you. It is very sad.

Like many of my colleagues here today, I am troubled by the findings and the experiences that we have heard. For years, consumers have utilized products that contain talc without so much as a second thought. We have used it ourselves. I have bought products from both Claire's and used baby powder for years and years, and used it on my children as well.

It is even more concerning that people have known about these carcinogens in the products and have put them on store shelves regardless.

Mr. Faber, I agree that we need oversight to ensure that products put on store shelves are safe. However, we must also ensure that regulations placed on these companies are not so stringent that they may halt production altogether. It is such a fine line to walk.

How would you suggest that we ensure more testing is done without stifling the research and the innovation that it takes?

Mr. FABER. Thank you for the question. We work very closely with companies like J&J, Proctor & Gamble, Revlon, Estee Lauder and L'Oreal, as well as many small companies who are the real innovators in this industry, to craft legislation that would give FDA the power to review and, if necessary, regulate contaminants linked to cancer, birth defects, or reproductive harm, but would recognize the differences between very large companies like Proctor & Gamble and very small companies that are going to provide the most innovative products in our economy.

I think the evidence that FDA can provide this oversight is all of the success we already see in the drug sector, the medical device sector, among food companies. I do not think it is hard to imagine striking a balance where FDA can ensure that these everyday products do not contain ingredients linked to cancer or reproductive harm, and that we continue to have many of these everyday products in our homes.

There is certainly going to be cases where chemicals or contaminants are so dangerous that they should not be allowed in these everyday products. But there are literally thousands and thousands of ingredients available to formulators, and companies make products every day that do not include many of the chemicals and contaminants that I have mentioned in my testimony.

Mrs. MILLER. Is there a way to ensure that companies institute stringent testing procedures rather than relying upon the FDA?

Mr. FABER. We have relied on self-regulation now for more than 60 years. When Congress first began to consider whether or not to give these powers to FDA in the 1950's, and when Congress gave FDA the power to regulate chemicals in food in 1958 and chemicals in colors in 1960, we instead chose to rely on industry self-regulation with regards to cosmetics.

I think today's testimony and the support of so many cosmetic companies for more regulation is evidence that relying on self-regulation no longer makes sense.

Mrs. MILLER. What steps can Congress take to help empower companies and the FDA to utilize safe products?

Mr. FABER. The first step is giving FDA the power to identify those ingredients that have been linked to cancer or birth defects and reproductive harms and making an assessment of whether or not, first and foremost, those ingredients and contaminants should be in these products at all, or whether they should be restricted to other levels, as more than 40 other countries have done.

For the most part, most countries, when they look at these questions of the safety of these ingredients, have decided to restrict them to levels at which they would not pose any harm. That is certainly not the case for a contaminant like asbestos. There is simply no safe level of asbestos. If we cannot sell products that are free from asbestos, they should not be sold at all. But for most of the ingredients that have been regulated around the globe, countries like Canada, countries in Europe, countries in Southeast Asia, Korea, Japan, Australia, have generally taken the step of restricting chemicals to certain amounts so that we are not exposed to so much of that chemical that we would be at an increased risk of cancer or other serious harms.

Mrs. MILLER. Thank you. I yield back the rest of my time.

Mr. KRISHNAMOORTHY. Thank you, Mrs. Miller.

Ms. Pressley, you have five minutes.

Ms. PRESSLEY. I want to thank all of the witnesses for joining us again today. Mr. Salter, I echo the sentiments of my colleagues. Death is a certainty of life. However, her death was premature and could have been avoided, and evidence supports that there was what I would consider to be predatory marketing, and understanding that black women are, I think, the number-one consumers of beauty products, and specifically of this powder. So I thank you for turning your pain into activism and to making sure that no other family knows the pain that you do.

It is important to note that amongst the hundreds of thousands, if not millions of women that have used Johnson & Johnson talcum powder, the product was particularly popular with women of color. Johnson & Johnson tailored their marketing strategy to women of color almost 30 years ago. An internal memo that I would like to enter into the record, dated August 5th, 1992, entitled "Johnson's Baby Powder: Major Opportunity," shows a usage of 52 percent among African Americans, and 37.6 percent usage rate among Hispanics. This memo also details a plan to implement an Hispanic media program and to launch a black print media marketing effort accordingly.

Mr. Chair, I would like to submit this memo into the record.

Dr. McTiernan, in your meta-analysis, you surveyed the landscape of studies conducted on the safety of Johnson & Johnson's talcum powder. Is that correct?

Dr. McTIERNAN. Yes, that is correct.

Ms. PRESSLEY. Do any studies prior to the 1992 memo which I just submitted confirm the link between the use of talcum powder and ovarian cancer?

Dr. McTIERNAN. Yes, definitely. Studies as early as 1982 found an increased risk, up to two times increased risk of ovarian cancer in women who were using these products.

Ms. PRESSLEY. And is that for any use, and were black women disproportionately at risk? I think that report that you are referencing indicated that black women were three times more likely to develop ovarian cancer based upon their usage. Is that correct?

Dr. McTIERNAN. That study did not have enough black women to make specific comments on them in that paper. There were some later studies, in 2016, 2015. One focused only on black women, and they did find increased risk of at least 50 percent for ever use of talcum powder products and risk of ovarian cancer. Another study was able to look at both black and Latino women, as well as white women, and found similar increased risk.

So it really seems, at least for these ethnic groups, for blacks, Latinas, and white women, it has been shown to increase risk.

Ms. PRESSLEY. So anyone was at risk that was using talcum powder in their genital peritoneal, but women of color were seen at a higher risk because the studies indicated that they used it more.

Dr. McTIERNAN. Definitely. The study that focused on them, at least 50 percent were using those regularly.

Ms. PRESSLEY. Okay. So for well over half-a-century, tests confirm instances in which Johnson & Johnson's talcum powder was contaminated, and yet the company moved forward with aggressively marketing its potentially dangerous product to women of color despite these consequences.

Furthermore, a study by George Washington University even found that black women in particular again used talcum powders in the genital area at higher rates than the rest of the population. From Johnson & Johnson's documented early '90's marketing acumen, I must assume that they did know this, Okay?

So how could talcum powder use in the genital area over an extended time period lead to ovarian cancer? Why specifically?

Dr. McTIERNAN. The exact mechanism still needs to be studied, but we have several potential. One is inflammation, that talc or the other constituents in it can get in around the fallopian tubes and ovaries, can cause inflammation, and we know that inflammation can cause cancer. There are some other potential mechanisms that have been studied in ovarian cancer cells or in ovarian cells, and these look like many of the hallmarks of cancer that can occur from application of talc.

Ms. PRESSLEY. And just for the record I would like to state that every consumer wants to be respected for their purchasing power and marketed to, but nobody wants to be harmed and hurt by companies pedaling dangerous products in the process. It is really just inexcusable, and I look forward to continuing to work with my colleagues and the subcommittee to lead the charge and to make sure that companies are held accountable in this regard.

Mr. Salter, were there any warning labels placed on any of the talc products your mother used, warning of the increased risk of ovarian cancer?

Mr. SALTER. No, not one single one. Obviously, we used it from generation to generation, my grandmother, and my grandmother's grandmother, my mom. So obviously, in the African American community, it is a staple for usage for hygienic freshness, and not one single time has there been any label that stated or highlighted the risk of using this product whatsoever.

Ms. PRESSLEY. And do you believe that women have the right to know the facts about the cancer risks associated with talcum powder products?

Mr. SALTER. Oh, without a doubt. You know, I feel that if we had known that, my mother may still be here among countless other women who are battling this disease right now. They could have at least been given the option to choose to use this product or not knowing that risk, but they did not have the option to do so.

Mr. KRISHNAMOORTHY. Your time has expired. Thank you, Ms. Pressley.

Ms. PRESSLEY. Thank you.

Mr. KRISHNAMOORTHY. Mr. Cloud, five minutes.

Mr. CLOUD. Thanks again for being here.

One of the things, as we look for a solution in this, and I guess it is the puzzle for me, is the FDA approval process can tend to be politicized. We talk about the regulation of the food industry, but we know that there are carcinogens still in food that is available on the market. We can look at the opioid crisis that was in large part driven not by illegal drugs but by legal drugs.

So what happens a lot of times in the regulatory environment is that it actually favors the bad actors in the sense that the companies most likely to be helped in a situation like this would be a Johnson & Johnson. I think it is two-thirds—the industry has 3.6 million domestic jobs. Two-thirds of those are in companies with less than 50 employees. I think labeling is probably an easy solution, but when it comes down to granting FDA expansive new regulatory authority, how do we do that in a way that is properly scalable and effective?

Mr. FABER. Thank you. Thank you for your question.

To be clear, the legislation that has been introduced in the Senate by Senator Feinstein and Senator Collins and that is being developed now by Chairman Pallone and Mr. Shimkus does not anticipate creating a premarket review program like we have for pharmaceutical drugs or devices. The Feinstein-Collins bill and the drafts that are being developed by others simply imagine that FDA would be given the power to review the most controversial ingredients in personal care products and then set a limit on those ingredients. Formulators would then be given a limit around which to reformulate their products if indeed those particular chemicals were in those products.

I want to emphasize that most of the 88 chemicals that companies themselves have reported that are linked to cancer or birth defects or reproductive harm in men and women are not in most products. They are in some products. And in most cases, when other countries have looked at these chemicals, they have not simply banned them but placed restrictions around them, around which formulators have to reformulate.

So I think—I just want to be very clear that we are not imagining, no one is proposing to my knowledge a premarket review program but instead giving rules of the road to cosmetic and other personal care companies that they would have to reformulate around, in particular giving FDA the power, if necessary, to require a warning. In this case, a warning would seem to be a sort of obvious solution. Mrs. Dingell has introduced legislation in past Congresses to require a warning. Some companies have now begun to put warnings related to ovarian cancer on these talc-containing products.

And even if there is a very small amount of asbestos present—and again, the detection methods we have now cannot ultimately prove that a product is asbestos free—a warning would at least alert consumers to this potential risk and allow them to make their own choices.

Mr. CLOUD. That was going to be my next question in the sense of from a scientific standpoint, what testing mechanisms are there available? Asbestos is not always in talc. Is that right?

Mr. FABER. That is right.

Mr. CLOUD. Are there testing methods available to find out if—

Mr. FABER. I am not a geologist, but I will share that there are basically three testing methods available to determine whether or not asbestos has co-mineralized with talc, whether the talc might contain asbestos. One is called x-ray diffraction, the other is called polarized light microscopy or PLM, and the last one is called transmission electron microscopy or TEM. These detection methods get more and more refined, from XRD to PLD to TEM.

The important point is that none of them are an absolute guarantee that there is no asbestos present in the talc. They can magnify the sample to a level that is incredibly precise, but none of these methods can ever provide a guarantee that a talc-based product is completely free of asbestos.

Mr. CLOUD. Mr. Chairman, I have three documents from the Personal Care Products Council, a trade association that represents companies that make products such as cosmetics and baby powder. These documents are two statements by the association's President and CEO, Lezlee Westine, indicating their eagerness to work with the FDA and Congress. I ask unanimous consent to include these documents in the record.

Mr. KRISHNAMOORTHY. Without objection, so ordered.

[The information referred to is in the Appendix section.]

Mr. CLOUD. Thank you.

Mr. KRISHNAMOORTHY. And before I give Congressman Khanna his time, I acknowledge the memo Congresswoman Pressley submitted. It is, without objection, so ordered into the record. Thank you.

[The information referred to in is the Appendixsection.]

Mr. KRISHNAMOORTHY. Congressman Khanna, you have five minutes.

Mr. KHANNA. Thank you, Mr. Chairman.

I first want to recognize you, Mr. Salter. Thank you for being here. My heart goes out to you for your loss, and I appreciate your courage in showing up and trying to make a difference on this.

I want to focus my questions on Representative Pressley's memo that she introduced. I find it, frankly, quite shocking. As I understand the situation, by 1982 we understood the risks of some of the talcum powder and the link to cancer-causing activity, and yet Representative Pressley has a memo 10 years later, from 1992, that Johnson & Johnson is intentionally trying to sell more of this product to African Americans and the Hispanic American community.

Dr. McTiernan, do you think Johnson & Johnson acted in deliberate disregard of the risks? And how would you characterize that memo where they are deliberately selling a product to African Americans and Hispanics knowing some of these risks?

Dr. McTIERNAN. I have not seen the memo, but I do agree that it is questionable if there is an attempt to get people to use these products more if there is any amount of risk. Talcum powder products in the genital area is not required for health. It is not like a medication where you look at the benefit and risk of something and tell the person this is the benefit, this is the risk. We do not have that situation here. We have something that is not necessary for health, and so it was being marketed for other reasons.

So it concerns me that there would not be regulation that could oversee something like this. If there are risks to a product, we would like to be able to tell people what the risks are, and then realizing that for them the benefit may just be some other reason other than a health benefit.

Mr. KHANNA. Let me ask this, which any of the panelists can answer. Do you think Johnson & Johnson would have acted differently if we were talking about Caucasians and not African Americans or the Hispanic community?

Mr. SALTER. Could you repeat the question?

Mr. KHANNA. Sir, the memo that Representative Pressley presents is that Johnson & Johnson had a deliberate strategy to market this product to the African American community and to the Hispanic community knowing—one can only assume they knew because 10 years earlier there was a study linking this product to cancer. Do you think people there may have acted differently if the risk was to the Caucasian, to the white community as opposed to the African American and His-

panic community? Do you think they were more indifferent to some of the suffering because it was minority communities?

Mr. SALTER. Growing up in a less-than-perfect scenario where we did not grow up with a lot of money, poverty levels, tough life, but we made do with what we had, there were not a lot of resources that were available for us to learn more about different products, we did what other generations did. Products that were used by our forefathers, our great-grandmothers, great-great-grandmothers, that was the way of life.

Now, I have seen memos myself where J&J, Johnson & Johnson targeted those minorities, and personally I felt like they targeted because of lack of education, that those groups of people were easy targets. They used the product mostly, and they specifically targeted those people knowing the harm they were causing with their product, and they valued that over human life with profits.

So, yes, I think they would have treated Caucasians differently because of the money they were making targeting minorities.

Mr. KHANNA. I just want to say for the record that what you are saying is absolutely disgusting if Johnson & Johnson did that, targeting people who did not have an education.

Mr. SALTER. Yes, sir.

Mr. KHANNA. That is appalling.

Mr. FABER, do you have any comments?

Mr. FABER. I would just add that all of the companies that use talc were well aware of the presence or the potential presence of asbestos in talc going back to the 1970's. It was never a secret that talc could co-mineralize with asbestos. Ultimately, the companies were successful in persuading FDA to allow them to rely on a method of testing that could not rule out the presence of asbestos in talc.

I think it is critical to remember that when given the chance to require a warning, FDA declined to do so twice, even though it has required warnings on products that arguably pose less risk to consumers than products that would contain asbestos.

Mr. KHANNA. Thank you.

Mr. KRISHNAMOORTHY. Thank you, Mr. Khanna.

Our next questioner is Mr. Connelly. Five minutes, sir.

Mr. CONNELLY. Thank you, Mr. Chairman.

Welcome to our panel. Mr. Salter, I join with my colleagues in expressing deep sympathy to you and your family for your loss. I know that we are joined today by a number of people who care enough about this issue to be here today, and I welcome all of you, and particularly those of you from Virginia.

Mr. FABER, the Food and Drug Administration exists for what purpose?

Mr. FABER. To protect the safety of consumers.

Mr. CONNELLY. Protect the safety of consumers. So we expect that our FDA is looking at our food supply and our pharmaceutical supplies to ensure their safety. Is that correct?

Mr. FABER. That is correct.

Mr. CONNELLY. For example, I am going back but I think I am correct that the FDA did a great job, unlike Europe, in regulating thalidomide, and as a result the tragedies that occurred in Europe were minimized or did not occur here. Is that correct?

Mr. FABER. That is correct.

Mr. CONNELLY. So when it does its job, it can be a powerful force for consumer protection and consumer safety. Is that correct?

Mr. FABER. That is correct, sir.

Mr. CONNELLY. So when it comes to cosmetics, what does the law say the FDA can do, and/or what does it limit the FDA from doing?

Mr. FABER. The law that is in place now is simply the law that was enacted in 1938, which prohibits a product from being adulterated; that is, in general, prohibits a product from having a substance that would be akin to a poison that would have caused the sort of acute reaction that might send you to the hospital.

In general, the law has not given the FDA the authority to assess the chronic risks that might come from everyday use, from repeat exposure to chemicals applied to the body that might ultimately contribute to cancer or reproductive harm.

Mr. CONNELLY. So let me make sure I understand the distinction you are making. So if I had a cosmetic product loaded with cyanide, FDA would catch that and ban it.

Mr. FABER. Not exactly. That product would be adulterated. It would be, per se, illegal. If FDA were aware that the product was for sale, it could use its seizure powers to go into the marketplace and take those products off the market. But FDA could not stop me from producing it under its authorities under the FFDCA, nor could it order me to recall that product under the FFDCA.

Mr. CONNELLY. It would have to seize it.

Mr. FABER. It would have to go to the Department of Justice in order to get that product off the market.

Mr. CONNELLY. But that would be an immediate threat.

Mr. FABER. Correct.

Mr. CONNELLY. In this case, in terms of the adulteration of a cosmetic with traces of asbestos, that is not an immediate threat. That is a long-term cumulative threat to somebody's health. Is that correct?

Mr. FABER. FDA, in the statement that it released in response to finding asbestos in products sold in Claire's stores, did say that the presence of asbestos renders a product adulterated, and ultimately that is why they asked—didn't demand but asked Claire's to clear the market to recall that product, and to my knowledge that is the first time that FDA has said in that sort of statement that the presence of asbestos renders a product adulterated.

Mr. CONNELLY. When was that?

Mr. FABER. That was last week, sir.

Mr. CONNELLY. Last week. But we have testimony that Johnson & Johnson and FDA were aware of the risks of this adulteration going back to the 1970's. Is that correct?

Mr. FABER. That is correct.

Mr. CONNELLY. So why did it take over 40 years for FDA to take any kind of action that starts to look decisive?

Mr. FABER. Beginning in the early 1970's, once FDA was alerted to the presence of asbestos in talc products, FDA considered whether to require warnings or to otherwise regulate talc-containing products because of the risk that these products would include a carcinogen. Ultimately, FDA was persuaded that the new testing method developed by the industry's trade association would be sufficient to ensure that those products would be free from asbestos. The evidence shows that is simply not the case, that the testing method that was developed by what used to be called the CTFA and is now called the PCPC could not guarantee that those products would be asbestos free, and I think in retrospect the FDA would likely agree, if they were called to testify, that it was a mistake to rely on industry's assurances in 1976 that this testing method would guarantee that these products are safe.

Mr. CONNELLY. Mr. Chairman, my time is up, but I think this is a tragic case study that gives the lie to those who want to propound that the Federal Government's hobnailed boot is on the neck of business, and that if it would only let up, everything would be fine.

When we mindlessly deregulate or do not regulate to protect the public, this is what can happen. I hope we will all remember that, and frankly I hope this hearing will lead to some legislative direction that empowers FDA, especially in the cosmetic field.

I thank the Chair.

Mr. KRISHNAMOORTHY. Thank you, Mr. Connelly.

We are going to do a quick lightning round because a few members have a second round of questions, and we will keep these to two minutes this time. So please answer as briefly as you can.

I am going to start with Mr. Salter. You stated your mother used Johnson & Johnson's talcum powder for 35 years; correct?

Mr. SALTER. Yes, sir, since the day she was born, all her life. So longer than 35 years for sure.

Mr. KRISHNAMOORTHY. And your mother used it primarily for personal hygiene purposes. Is that right?

Mr. SALTER. Yes, Mr. Chairman, that is correct.

Mr. KRISHNAMOORTHY. And she did not receive any kind of warning—

Mr. SALTER. None whatsoever.

Mr. KRISHNAMOORTHY. And you believe that would have made a difference, at least a warning?

Mr. SALTER. Without a doubt. At least my mother would have had the choice to use the product or not use the product considering that she knew the risks of its usage.

Mr. KRISHNAMOORTHY. And what was her life like after diagnosis of the cancer?

Mr. SALTER. It was the most degrading process I have ever seen to watch a loved one deteriorate, and to think that that happened because of use of a product that is commonly sold on every single shelf in just about every store across this country is devastating. So it was a hard process, but she fought for her life, and she did it with a smile on her face.

Mr. KRISHNAMOORTHY. You know, you are representing a lot of people who are sitting behind you who are looking to you to voice their concerns. If you had something to say based on what you have heard today at this hearing, what would it be?

Mr. SALTER. I would say that awareness is key. So many people are blind to the fact that this product is harmful, and I am thankful that we are bringing light to the subject.

Mr. KRISHNAMOORTHY. Thank you, Mr. Salter.

Mr. SALTER. Thank you, Mr. Chairman.

Mr. KRISHNAMOORTHY. I yield back.

Mrs. Miller is going to have two minutes.

Mrs. MILLER. Thank you, Mr. Chairman.

I have had several thoughts listening today. I always pack baby powder with me everywhere I go, but I use it in my shoes for sweaty feet, just a habit I have had for years. I put it in tennis shoes, whatever. But it kind of reminds me that there is now a warning on cigarettes that the use of tobacco is harmful to your health, so I can understand that there are warnings that are available.

I had one more question really for Mr. Faber, but I stopped because my time was out, but it basically was along the same lines as before. I understand that the FDA has a voluntary cosmetic registration program which allows for reporting from companies to help increase safety for consumers. What suggestions would you have for increasing the participation in that program?

Mr. FABER. Well, I am glad to share that the vast majority of cosmetics companies, large and small, believe that registration should be required, in part so that FDA can alert them if an ingredient has been contaminated and it might have been used in one of their products.

I am also happy to share that, as Senator Feinstein and Senator Collins develop their bill, and I presume Mr. Pallone and Mr. Shimkus will as well, they have developed an abbreviated registration process for small companies who do not have the same resources as Proctor & Gamble or Estee Lauder or L'Oreal or other big companies.

So I think there is a way to allow FDA to know where companies are and what is in their products, and also to know if products are hurting people, as is sometimes the case, without placing significant burdens especially on the small innovators in the cosmetics industry.

Mrs. MILLER. Okay, thank you. I have run out again. Thank you.

Mr. KRISHNAMOORTHY. Thank you, Mrs. Miller.

Ms. Pressley?

Ms. PRESSLEY. Thank you, Mr. Chairman.

Your products still contain talc; is that correct? There is still talc in your products?

Mr. FABER. We found 2,000 products that are for sale today that contain talc, including more than 1,000 that are loose or pressed powders which are used around the face and mouth and are likely to be inhaled.

Ms. PRESSLEY. Including your baby products; correct?

Mr. FABER. There are still baby products that contain talc. There are also baby products that are made from corn starch. Many of the companies that sold baby powders and still sell baby powders made from talc also sell baby powders made from corn starch.

Ms. PRESSLEY. Excuse me. So in spite of the research and the science and the tragic loss of life, you still would lead us to believe that your products are safe for consumption?

Mr. FABER. I think what is important to remember is that these are discretionary products. I think that is what is ultimately the real tragedy of asbestos in talc, is that we are not talking about things that people need to survive—food, water—or even things people need to use to come to a meeting like this, shampoos and soaps and deodorants. These are the definition of discretionary products, and that is why a warning and further regulations would be—

Ms. PRESSLEY. I recognize you are not Johnson & Johnson, but I am just furious because what is the source of rebuke and retribution for these families? We cannot return their loved ones to them. So what can we do to make sure this tragedy does not happen again? I understand you are science in what you are offering, but I just do not know how the consumers can have any true trust and faith here that they are safe in the consumption of these products.

It is a person's prerogative, but if there is predatory marketing happening, there is a seduction happening here.

Mr. FABER. If I were in your shoes and in Commissioner Gottlieb's shoes, I would not wait another day to require a warning on all these products. FDA has twice refused to do so after receiving citizen petitions. They could tomorrow require a warn-

ing on any product that is containing talc so that consumers would know. That would be the first step and the easiest step we could take to protect consumers.

The next step would be to really better understand whether it is even possible to produce these products without containing asbestos, and help companies. And if not, then there are plenty of alternatives available, including alternatives made with corn starch.

Ms. PRESSLEY. Thank you, and that is what I was looking for, to be prescriptive about where we go from here to prevent this tragic loss of life from happening to any other families.

Mr. FABER. I appreciate your questions.

Ms. PRESSLEY. All right. Thank you.

Mr. KRISHNAMOORTHY. Thank you, Ms. Pressley.

No more questions. We are going to move to closing statements.

To conclude today's hearing, I want to thank our witnesses once again for discussing this critically important issue with our subcommittee. In Mr. Salter's case, thank you for discussing your family's personal tragedy.

My heart and my best wishes go out to all the families out here represented by all of you for the loss of your loved ones. And I want to thank all of you for traveling from all over the country to be here today with us.

I said it earlier but it bears repeating: the average adult in this country uses personal products nine times daily. Consumers use these products trusting that they are safe and will not cause harm to themselves or their loved ones.

Today's hearing was just our first step in protecting consumers from potentially hazardous or carcinogenic products. Following this hearing I will work diligently with my staff in order to determine the best next steps, including any need for a continuing investigation into the matters discussed this morning.

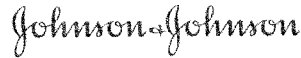
Thank you to everyone again for their time today.

Mr. CLOUD. I would just echo those thoughts. Thank you for being here. Thank you for your testimony. Thank you for the participation in this committee. And, Chairman, thank you for your leadership on this topic. I look forward to moving this forward. Thank you very much for being here.

Mr. KRISHNAMOORTHY. Thank you.

We are adjourned.

[Whereupon, at 11:25 a.m., the subcommittee was adjourned.]



March 11, 2019

Subcommittee on Economic and Consumer Policy,
Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Members of the Subcommittee:

Tomorrow's hearing on public health risks in consumer products raises significant and important public policy issues that deserve to be examined in a thorough, rigorous, and impartial manner. Johnson & Johnson has dedicated significant resources to providing the public with open and transparent information regarding Johnson's Baby Powder, cosmetic talc, and talc safety, including through a dedicated website, Facts About Talc, where the company has posted more than 1,500 documents of studies, letters, and other materials covering decades of information about cosmetic talc. This letter summarizes key information about talc safety and seeks to correct erroneous information that has been recently repeated by the media.

Johnson's Baby Powder Is Safe

The science is clear. Decades of independent scientific testing has confirmed that Johnson & Johnson's cosmetic talc and Johnson's Baby Powder are safe, are not contaminated with asbestos, and do not cause cancer. The FDA, global regulators, and leading independent labs have collectively tested Johnson & Johnson's cosmetic talc for decades and repeatedly affirmed that it does not contain asbestos.

Indeed, just last week, the FDA restated its findings from an earlier study in which it tested both Johnson's Baby Powder and the cosmetic talc supplied to Johnson & Johnson, in addition to 34 other cosmetics products. Using "the most sensitive techniques available," the FDA found that none of the products tested, including Johnson's Baby Powder and the cosmetic talc used in Johnson's Baby Powder, contained asbestos.¹ Numerous global regulators have recently affirmed the safety of Johnson & Johnson's cosmetic talc products.² Likewise, scientists from Harvard, MIT, Princeton, Dartmouth, Mt. Sinai Medical Center, the National Institute for Occupational Safety and Health, and many others have time and again confirmed

¹ Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition (Mar. 5, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm> (citing results from FDA's 2009-10 study, which surveyed over 34 products, including Johnson's Baby Powder, and linking to FDA's general webpage on talc, <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm>).

² See *Government of India Reaffirms the Safety of Johnson & Johnson's Talc* (Feb. 28, 2019), <https://www.factsabouttalc.com/assets/pdfs/news/Feb28-2019.pdf>; JFDA, "*Johnson Baby Powder*" Is Free from Carcinogens, Jordan News Agency (Dec. 17, 2018) (translation).

that Johnson & Johnson's cosmetic talc products do not contain asbestos.³ Multiple scientific, peer-reviewed studies of tens of thousands of men and women reflect that cosmetic talc does not cause cancer.⁴

Johnson & Johnson has been working cooperatively with regulators on these issues for decades. When media reports first raised issues regarding cosmetic talc in the 1970s, Johnson & Johnson worked swiftly with the FDA and leading scientists to demonstrate that its baby powder was safe.⁵ After performing its own testing, the FDA concluded, in 1976, that Johnson & Johnson's products were not contaminated with asbestos.⁶ Unfortunately, plaintiffs' lawyers and others have sought to misuse or mischaracterize historical documents in an attempt to rewrite history, but the facts and documentary record are clear.

Johnson & Johnson's Decades of Testing of Cosmetic Talc

In 1976, the cosmetics industry established a testing standard to ensure the safety of cosmetic talc, called the CTFA J4-1 specification, which was subsequently acknowledged by FDA as well. The J4-1 standard requires the use of x-ray diffraction (XRD), and, where necessary for additional screening, polarized light microscopy (PLM). Johnson & Johnson has used XRD and PLM for decades, and indeed, currently uses both methods in accordance with the United States Pharmacopeia recommendations for ensuring that pharmaceutical-grade talc is asbestos free. In addition to using XRD and PLM in accordance with the United States Pharmacopeia and J4-1 methods, Johnson & Johnson uses transmission electron microscopy (TEM) to assess its cosmetic talc.⁷ Johnson & Johnson tests the sites where its cosmetic talc is mined, the raw ore taken out of the earth, and the milled powder before it is bottled.⁸

In addition to Johnson & Johnson's own testing, independent experts and authorities have analyzed its sources and products. Government agencies such as the FDA and the National Institute for Occupational Safety and Health, leading labs including the McCrone Group, and scientists from world-class universities like Harvard and MIT have all confirmed that Johnson & Johnson's cosmetic talc products are safe and do not contain asbestos.

³ See, e.g., Boundy et al., Occupational Exposures to Non-Asbestiform Talc in Vermont *in* DUSTS AND DISEASE 365 (R. Lemen & J.M. Dement eds., 1979); Martin Buerger, REPORT TO DR. A. L. GOUDIE, (1972); R.C. Reynolds, X-RAY AND OPTICAL EXAMINATION OF TALC PRODUCTS (1971); Press Release, Mt. Sinai Medical Center, Statement by Dr. Thomas Chalmers (Mar. 23, 1976).

⁴ See, e.g., Rubino et al., *Mortality Study of Talc Miners and Millers*, 18 J. OCCUP. MED. 186 (1976); Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017); Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NATL. CANCER INST. 249 (2000); Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 AM. J. EPIDEMIOL. 45 (2010).

⁵ See, e.g., Letter from W. Nashed of Johnson & Johnson to FDA (Oct. 17, 1972).

⁶ See Memorandum from Ronald Yates, FDA, to Heinz Eiermann, FDA (Jan. 7, 1976).

⁷ See JOHNSON & JOHNSON RAW MATERIAL SPECIFICATION (2014).

⁸ See Fred Pooley, REPORT ON THE EXAMINATION OF ROCK SAMPLES FROM THE VERMONT TALC MINE (1972); Fred Pooley, AN EXAMINATION OF MINE SAMPLES AND RELEVANT POWDERS (1972); Memo from A. Frank to G. Lee on Audit Testing of Windsor 66 Talc for Asbestos (June 28, 1977).

FDA's Past Conclusions on Talc's Safety

Since the 1970s, the FDA has repeatedly examined talc safety and investigated allegations regarding public health and cosmetic talc. On each occasion, the FDA has concluded that Johnson & Johnson's products do not contain asbestos and do not cause cancer. In 1986, the FDA responded to a citizen petition and determined that cosmetic talc did not warrant a warning about the presence of asbestos. Importantly, the FDA determined that certain of the early analytical results from the early 1970s and before—many of the same materials cited by plaintiffs' lawyers and news reports today to suggest the presence of asbestos in talc—were of “questionable reliability” due to the lack of agreement around which methods were well-suited for analyzing cosmetic talc.⁹

In 2010, the FDA released the results of its own testing of talcum powder products and sources. The agency found that Johnson & Johnson's products and source materials did not contain asbestos.¹⁰ In 2014, after years of additional scientific research being published, the FDA concluded that cosmetic talc did not warrant warnings about cancer. The FDA reviewed decades of scientific investigations of possible links between ovarian cancer and talc and concluded that there was “no conclusive evidence to support” a causal connection between talc and ovarian cancer.¹¹

Cosmetic Talc Does Not Cause Cancer

Numerous epidemiological studies over several decades have examined whether differences in exposure to talc are associated with differences in disease occurrence. For example, studies have followed thousands of miners and millers working in talc production in Italy, Vermont, France, and elsewhere.¹² Because these personnel work in talc producing occupations, the miners and millers are exposed to talc at massively larger quantities than consumers. Yet these studies have not identified a single person with mesothelioma, the cancer associated with asbestos. These studies include workers dating to the 1920s and have been updated as recently as 2017, continuing to show no instances of mesothelioma.¹³

Additionally, several studies have examined whether there is a causal link between the use of cosmetic talc and ovarian cancer. Three large, prospective cohort studies of tens of thousands of women did not find any such link. In 2000 and 2010, the Nurses' Health Study, which considered more than 40,000 nurses who reported use of cosmetic talc as of 1982,

⁹ Letter from H.W. Swanson, FDA, to Phillippe Douillet, Docket No. 83P-0404 (July 11, 1986).

¹⁰ *Cosmetics Ingredients: Talc*, FDA (last updated Aug. 21, 2018).

¹¹ Letter from Steven Musser, FDA, to Dr. Samuel Epstein, Cancer Prevention Coalition, Docket Nos. 94P-0420, FDA-2008-0309-0001/CP (Apr. 1, 2014). FDA also observed that there is still no “cogent biological mechanism by which talc might lead to ovarian cancer.” *Id.*

¹² See, e.g., Rubino et al., *Mortality Study of Talc Miners and Millers*, 18 J. OCCUP. MED. 186 (1976), Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017), Selevan et al., *Mortality Patterns Among Miners and Millers of Non-Asbestiform Talc: Preliminary Report*, 2 J. ENV. PATH. & TOXIC. 273 (1979), Wild et al., *A Cohort Mortality and Nested Case-Control Study of French and Austrian Talc Workers*, 59 J. OCCUP. ENVIRON. MED. 98 (2002).

¹³ Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017).

concluded that the use of cosmetic talc had no overall effect on the occurrence of ovarian cancer.¹⁴ A separate study in 2014, and part of the Women's Health Initiative, considered more than 30,000 perineal users of cosmetic talc and concluded there is no increased risk of ovarian cancer from the use of cosmetic talc.¹⁵ In 2016, a third study, the Sister Study, considered nearly 6,000 women who were talc users and again found no association between cosmetic talc use and ovarian cancer.¹⁶

Litigation Results

Although Johnson & Johnson has both won and lost some jury trials, no jury verdict against Johnson & Johnson has been upheld on appeal. Johnson & Johnson has received six trial judgments in our favor. There have been nine judgments in favor of plaintiffs; three have been reversed, five are on or nearing appeal, and one reached a conclusion of zero damages. Additionally, dozens of lawsuits against Johnson & Johnson have been dismissed.

Commitment to Public Health and Safety

Johnson & Johnson recognizes that we have an obligation to our customers to ensure that our products are safe. And Johnson & Johnson expresses its deepest sympathies to the patients and families struggling with cancer. For that reason, Johnson & Johnson has gone above and beyond the industry standard when ensuring the safety of our cosmetic talc products. We support efforts to examine the science and evidence concerning talc safety in a thorough, rigorous, and impartial manner.

Nothing is more important to us than the safety of consumers and maintaining their trust in our products. We have long supported legislation to modernize the FDA's regulatory authority over cosmetics and personal care products, and believe this reform is essential to enabling the agency to increase its ability to protect the public. We are committed to continuing to work with Congress and the FDA to advance meaningful change.

We encourage the Subcommittee members, your staff, and the interested public to review the information and documents posted on Facts About Talc. Johnson & Johnson is committed to an open and transparent discussion about talc safety, and we thank the Subcommittee for its interest in this important matter.

Sincerely,
Johnson & Johnson

¹⁴ Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NATL. CANCER INST. 249 (2000); Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 AM. J. EPIDEMIOL. 45 (2010).

¹⁵ Houghton et al., *Perineal Powder Use and Risk of Ovarian Cancer*, J. NATL. CANCER INST., September 2014.

¹⁶ Gonzalez et al., *Douching, Talc Use, and Risk of Ovarian Cancer*, 27 EPIDEMIOLOGY 797 (2016). Notably, this group of women was already at a significantly higher risk than the normal population for developing ovarian cancer.

Felipe Aviles
784 East Pennsylvania Dr.
Palatine , IL 60074

March 11, 2019

House Committee on Oversight and Reform
Subcommittee on Economic and Consumer Policy
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Krishnamoorthi, Ranking Member Cloud and members of this Subcommittee:

I write to thank you for holding a hearing to examine the public health risks of carcinogens in consumer products, an issue my family is unfortunately all too familiar with. I am a resident of Palatine, Illinois. My beautiful daughter Jeannette suffered from peritoneal mesothelioma and died as a result of using talcum powder, a product that contained asbestos, a known carcinogen. I/we write to share with you our/my personal experience and to express my gratitude that the members of this Subcommittee are examining this important issue. I hope that the dangers of asbestos-containing talcum powder and the need for accountability is carefully considered.

Jeannette Aviles-Velasquez was born in North Chicago, Illinois on August 31, 1983. We were an Army family at the time, so our family moved a bit, but eventually returned to Illinois. Jeanette attended Zion Benton High School and eventually worked at Curion Corporation in Deerfield. In 2003 Jeannette was blessed to give birth to her son Alexander, known as Alex. She was a proud, protective and loving mother to Alex, their bond was strong and unbreakable.

In late November/early December of 2018 Jeanette had severe abdominal pain. She went to Northwest Community Hospital in Arlington Heights where they did a biopsy and discovered mesothelioma. She then went to University of Chicago and was admitted on January 18, 2019. She never left the hospital and died on February 4, 2019.

I have lost my beautiful daughter. Alex has lost his mother, the person who loved him most in his life and whom he loved deeply. At 15 years of age he has lost his mother and his life will never be the same. As his guardian and grandpa I will love and protect Alex with all my might, but I know I will never fill the emptiness that entered his life last month.

I write to you to ask that these harmful products are removed from the market and that those who harmed my daughter are held accountable. We used baby powder on her as a child, and in turn she used it on Alex when he was a baby. Her only exposure is through these cosmetic products. The

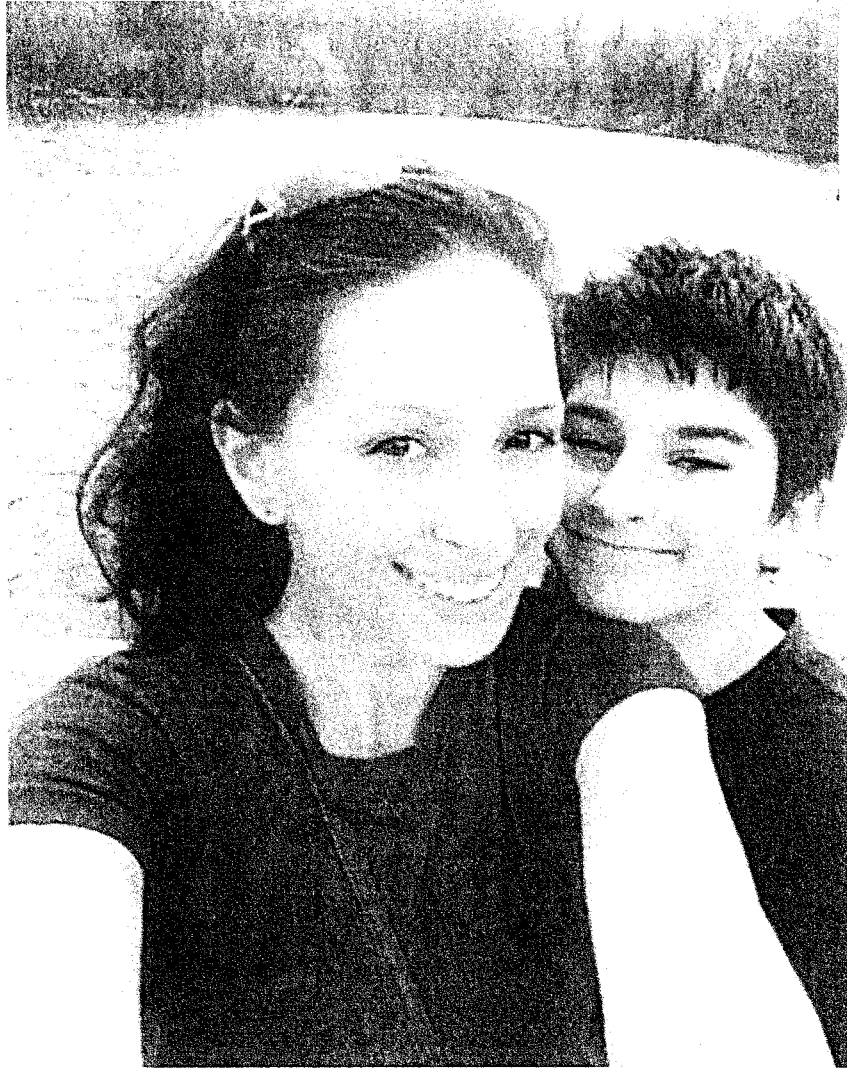
death and harm that results from these dangerous products is entirely preventable and should never happen in the first place – corporations should not be able to sell products that include such harmful ingredients.

I appreciate the opportunity to share Jeannette's story with you and hope that the members of the Subcommittee take it into consideration as they examine the need for better protection for consumers against dangerous products such as asbestos-laden talcum powder. I hope that by sharing this story we can prevent other people from getting hurt.

Thank you for your consideration of this important issue.

Sincerely,

Felipe Aviles



March 7, 2019

House Committee on Oversight and Reform
Subcommittee on Economic and Consumer Policy
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Krishnamoorthi, Ranking Member Cloud and distinguished members of this Subcommittee:

We are the families of the individuals whose lives have been taken or whose health has suffered tremendously from the use of an everyday consumer product – talcum powder – which contained a known carcinogen, asbestos. We are constituents of Illinois who have all suffered the pain of having ovarian cancer, mesothelioma or other asbestos-related disease rip apart our lives and those of our loved ones. We write to express our sincere gratitude to Chairman Krishnamoorthi, Ranking Member Cloud and members of this Subcommittee for looking into the public health risks of carcinogens in consumer products. It is our hope that our stories are heard, and the dangers of Johnson & Johnson Baby Powder are discussed at this hearing.

Over **22,000**; the number of new ovarian case each year.

Over **14,000**; the number of deaths from ovarian cancer each year.

0 = the health benefit to using talcum powder products.

Our choices are only as good as the information we have to make them. When it comes to the products we decide to use on ourselves, on our children, we trust that the companies who make those products have done their due diligence. We trust that they would tell us what we need to know to make the right choices for ourselves and our families. We trust them to do everything they can to keep us safe. We do not expect that a company that we grew up believing in, would betray us in such a horrific way. We did not expect that the use of a product as soft and gentle as baby powder could result in a disease so deadly.

It is alarming to discover just how little regulation there actually is over cosmetic products to ensure safety. Documents available in the public domain make clear that Johnson & Johnson's baby powder has tested positive for the presence of asbestos, a known carcinogen, and that they have known for decades that they cannot guarantee their products are asbestos-free. Despite their knowledge of the potential dangers that talcum powder posed to women, to this very day, the company continues to publicly assert that baby powder is asbestos-free and 100% safe. They continue to encourage the product's use on children and adult women. They continue to deny that baby powder is unsafe despite tremendous evidence to the contrary. For decades, we believed we could trust "the family company." Johnson & Johnson has betrayed that trust.

Cornstarch has been shown to be a safer alternative to talcum-based products. In fact, today on the shelves of stores throughout the country, Johnson & Johnson sells pure cornstarch products side-by-side with its Baby Powder; the only difference being one can cause harm, while the other

is harmless. However, Johnson & Johnson continues to allow consumers to unwittingly make an unsafe choice — by failing to provide important safety information and refusing to remove the unsafe product from the market. We must ask why. Why is talcum powder as an ingredient so much more important than human life? What will it take for this company to be held accountable for their actions?

We speak for our loved ones that lost their life and for those that have so far survived. Those so brave like Ms. Ann Smiley, a Chicago, Illinois native, who is currently fighting for justice together with others similarly harmed. She was diagnosed in 2016 with ovarian cancer and had to have a complete hysterectomy with five months of chemotherapy to follow. Those like Ms. Lois Slemper, a Virginia native, who said in her testimony that it was a “big mistake” to trust a company to use ingredients that were safe. We want to be heard, we want to educate the public and physicians to not use the products that cause so much harm.

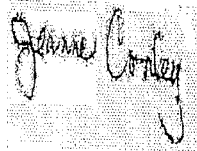
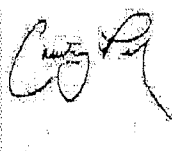
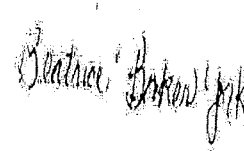
When you learn that you or your loved one has been diagnosed with ovarian cancer or mesothelioma, you cannot describe the emotional rollercoaster you go through. You are not only filled with fear, you are angry, and you are full of questions. Because the stage of the disease, everything happens pretty quickly. One day you learn of your diagnosis and just a few days later you find yourself, or your loved one, laying in the hospital bed recovering from surgery and doctor after doctor explaining what is going to happen next, how long you are expected to live afterwards, and what treatments you have to go through. Then those treatments begin. The chemotherapy that is administered is brutal, to say the least. To go from taking care of yourself and others to be the one taken care of is a bruise to your self-worth. The depression sets in, more drugs, more treatment. You lose your hair, you are so sick that you cannot get out of bed. Just going through the chemo treatment itself, you not only think you are going to die, but you also do not want to live. All of this because a company decided for me, or my loved one, to use an ingredient that was harmful — betrayal.

Johnson & Johnson has known of the dangers of talc for many years. Instead of doing the right thing — warn, or better yet, remove the baby powder from the market — they chose to put people in harm’s way. There are many documents that have been shown in the trials that demonstrate how Johnson & Johnson tried to create confusion and mislead consumers of their product. They targeted women of specific races, as well as obese women. Additionally, documents reveal that in the 1990’s the condom industry stopped dusting their products with talc due to the health risks. In the early 2000’s, an internal memo from the talc supplier describes their concern about litigation due to the harm being caused to consumers.

We write to you to tell our stories of how ovarian cancer or mesothelioma entered our lives one day and tore our worlds apart. How it mutilated our bodies and took our loved ones too soon. We write to express the sorrow of mourning the lives we once had and the anger of being lied to and deceived. We write for the ability for everyone to have the right to make an informed choice for themselves and to decide what risks they wish to take. We write to ask for these harmful ingredients to be removed from these products. And finally, we write to appeal for justice, in the hopes that those responsible for our collective harm are ultimately held accountable for their actions.

Cosmetic body powder has no therapeutic benefit. In light of the risk of life-threatening cancers, talcum powder products should be removed from the market or contain a warning which clearly informs consumers of the increased risk of ovarian cancer and mesothelioma.

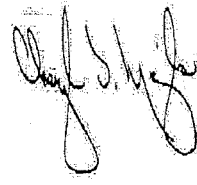
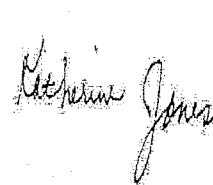
Sincerely,

Jeannie Conley

Courtney Peck

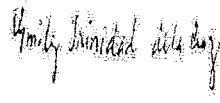
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Cheryl Mizak

Katherine Jones

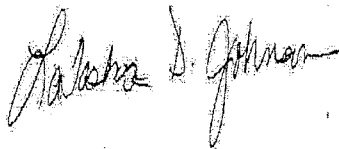
Ann Smiley

Emily J. Dela Cruz

Latasha Johnson

Sheila Barlow



Latasha Johnson

Jeannie Conley
Floor Chicago, Illinois
>xxxx insert “*Sister of ovarian cancer patient/victim etc.*” here<

Courtney Peck
Chicago, Illinois
....

Copy to
Blair/Lisa
(By Noon)

- JOHNSON'S BABY POWDER -

8/5/92

Major Opportunities

1. Continue to fully leverage the diaper rash claim against JBP cornstarch.
- Current household usage on Johnson's Baby Powder Pure Cornstarch has declined from 13% in 1989 to 8% in 1991. Continue to support diaper rash claim in order to rebuild product usage.
2. Investigate ethnic (African American, Hispanic) opportunities to grow the franchise.
- Johnson's Baby Powder has a high usage rate among African Americans (52.0%) and among Hispanics (37.6%). Additionally usage indices are high for African American and Hispanic females for JBP talc (139 and 101 respectively). Hispanic females also have a high index (151) against JBP cornstarch. The brand can increase volume in 1993 by targeting these groups.
The brand will institute an adult Hispanic tula program and potentially launch an adult Black print effort.

Major Obstacles

1. The franchise faces weakness on several key skus in factory sales and in consumption.

	<u>YTD % +/- YAG</u>	
	<u>JBP</u>	<u>JBP/CS</u>
9 OZ	-35.6%	-26.4%
14 OZ	-9.7%	+6.3%
24 OZ	-14.8%	-31.2%

- JBP 4 OZ is down -6% in all outlets; Drug distribution down 5 points versus YAG.
- JBP 9 OZ is down -13% due to Food and Drug outlets; Drug distribution down 3 points versus YAG.
- JBP 14 OZ is down -11% due to declines in Food and Drug outlets.
- JBP 24 OZ is up +1%; a -10% decline in Drug has been offset by a +9% gain in Mass; Drug distribution is down 7 points versus YAG.
- JBPCS 9 OZ is down -8% due to declines in Food and Drug

- JBPCS 24 OZ is down -7% due to declines in Drug and Mass; Mass distribution is down 9 points.

- To correct this trend, renewed focus is needed on 9 oz and ~~14~~ 24 oz sizes of the franchise. (Focus on building distribution in Drug and making these skus part of 1993 Ring Club.)

2. Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.
 - Investigate the addition of an additive to reduce dust.
 - Encourage the reduction of dust in use by developing advertorial copy and media strategy to promote proper way to powder and diaper a baby.
3. Little differentiation on JBP talc and cornstarch versus private label.
 - Implement temporary price roll-backs on JBP and JBPCS (using BSP funds) to achieve merchandisable price points and attack private label in the absence of value added news ~~long term~~ *(RHS, RHB)*
 - Investigate JBP medicated line extension as news for second half 1993/1994.
 - Evaluate "time release" formula and /or oatmeal as second half 1993 news.
4. Mennen competitive coupon pressures strong YTD.
 - Participate in broad based infant coupon programs to combat pressure from Mennen (Period 2 FSI).
5. Talc is adult focussed business in baby focussed line.
 - Longer term, investigate moving brand to a different franchise.
 - Short term, supplement infant plan with periodic adult promotional support
 - Period 5 "Adult" FSI

