

NARRATIVE
TALC – NTP REGULATORY CHALLENGE

Good morning everyone. My name is Steve Jarvis and I am responsible for Health, Safety, and Environmental matters for Luzenac America.

This morning...it is my distinct pleasure to present to you a summary of our most recent regulatory challenge involving the National Toxicology Program and their review of talc for potential listing in the 10th Report on Carcinogens.

But first....for those who may not know exactly what we doI'd like to introduce you to Luzenac America.

SLIDE 1

Luzenac America is part of the Luzenac Group of Companies. Headquartered in France, Luzenac Group is the world largest commercial producer of talc products.

In North America..... Luzenac America operates 4 talc mines and 8 talc milling operations.....We have large operations based in Ontario, Vermont, and Montana. Luzenac America is

1



headquartered in Denver Colorado where we also have our Research and Development Center.

Luzenac America mines and processes around a half-a-million tons per year generating approximately ^{Redacted} in sales.

Our major markets are talc sales to paper, polymers and paint markets..... and to a lesser degree, personal care products.....

You might be interested to know that we produce all the baby powder for Johnson & Johnson – including the talc for their popular adult product, Shower-to-Shower. As an interesting aside, would you believe that Luzenac talc also goes into Cipro?? It's True!.....

SLIDE 2

Our major regulatory challenge..... a challenge I might add that Luzenac absolutely could not afford to losecame from the NTP.

The NTP was authorized by the United States Congress to coordinate interagency toxicological testing and to publish the formal "Report on Carcinogens" which comes out about every 18-24 months..... To be listed in the RoC can be

devastating to a substance because of mandatory labeling requirements by OSHA and Proposition 65 in California.

In early 2000, NTP nominated talc for possible listing in the RoC because back in the early 1990's, the NTP published the results of a 2-year talc inhalation study on rats and mice and concluded that talc caused lung tumors in female rats.....

More on that in a minute.

SLIDE 3

A listing of talc in the RoC would have devastating consequences for the talc market worldwide.

First of all.....we would see a virtual immediate loss of our sales to the personal care market – around \$10 Million in sales in the first year.

Secondly.....because of the carcinogenic labeling requirements, we would likely suffer a deterioration of sales in all markets....perhaps anywhere from 20% to 50% of all remaining sales by year-three.

Additionally, a listing in the U.S. by NTP would likely trigger a carcinogenic status for talc in Europe and the Far East.

And finally..... because of our consumer product exposure, civil litigation would likely skyrocket.

As I mentioned, simply devastating consequences.

SLIDE 4

Now realistically..... there are some health issues with talc. For nearly 20 years, epidemiologists have been finding a weak, but persistent statistical link between the hygienic use of talc and ovarian cancer. However..... the studies are weakened by no one being able to offer any feasible “causal” explanations as to how and why talc would cause ovarian cancer.....but not a multitude of other cancers in the human anatomy.

As I mentioned, there is the 1992 rodent study by NTP, which found lung tumors in female rats. However, many other leading experts discount this finding claiming the tumors were a result of lung overload - simply too much inert dust in the lungs triggering an traumatic auto-immune response from the rats.

And finally, there is the long-held public perception that all talc contains asbestos. And even if it

doesn't, they are so similar chemically, that talc probably behaves like asbestos.

So these are some of the primary issues and concerns that served as the backdrop for the NTP review.

SLIDE 5

Okay....so here's what happened.

NTP announces in early 2000 that talc is going to be review. While this announcement catches us off guard, we are not alarmed.

But then, in October of 2000, NTP issues their draft report on talc and announces that the first two formal reviews resulted in votes to list talc as a carcinogen. The combined vote was 13-2 to list.

The entire talc industry, as well as companies like J&J were absolutely, positively, unquestionably, flabbergasted..... We simply could not believe it.

But now we had only two months to prepare for the third NTP review meeting..... a public meeting of the influential Board of Scientific Counselors Subcommittee. This occurred in December of last

year and we achieved a very dramatic turnaround. The BSC subcommittee voted 7-3 **not** to list talc.

And finally.....we fast-forward to this past June for the fourth and final review process. We see the NTP Executive Committee took the unprecedented action to actually **“stop”** the review process on talc and send it back to the beginning. They did this by deferring a final vote on talc.

And make no mistake about it, they knew if they proceeded with a listing nomination for talc, Luzenac America was going to challenge them in Federal Court.....and as the facts lay out, NTP would likely lose. Of that we are fairly certain!

SLIDE 6

Our successful defense strategy was threefold.

First.....we continued to work through the auspices of the CTFA – the Washington based trade association for the cosmetics industry. As you might imagine, Luzenac and Johnson & Johnson wield considerable influence on the talc subcommittee.

Secondly.....and this was our secret weapon, engage the services of the Washington based

Center for Regulatory Effectiveness, CRE. Since its formation in 1996 by several ex-high ranking officials in the OMB, CRE has grown into a nationally recognized...and relatively respected... regulatory watchdog organization. Federal agencies frequently come to them for assistance. CRE has also taken NTP to court.

And thirdly, we decided to be aggressive. This was a fight we simply could not lose. As such, we retained expert legal counsel to ensure we would have a solid foundation for a legal challenge if necessary.....it was the same firm which assisted CRE in their court battle with NTP.....and we also became very aggressive in our communication with NTP and other federal agencies. When didn't let the windows of "formal comment periods" become restrictive. We sent e-mails, faxes, overnight letters, and even telephones calls to key players in this battle....right up until hours before the final Executive Committee meeting.

And we believe these strategies paid-off.

SLIDE 7

While we certainly would have preferred a total victory – where NTP declared talc was not a human carcinogen.....we were relieved to at least get the review process “derailed” for now.....at least we have some “breathing space” to prepare a thorough, scientific defense of talc.

One of the issues we plan to focus on is demonstrating to NTP that virtually all of the epidemiology studies they previously used must be declared invalid for use in assessing talc “not containing asbestos”. This will be an expansion of the “Fatal Flaw” defense Luzenac employed in the first review on talc.

Additionally, we believe the latest epidemiology study which IS valid with regard to talc quality....it's called the Gertig study.....and which also happens to be the largest study as well..... shows no increased risk of ovarian cancer. The significance of this study must be more heavily weighted than prior studies.

Any predictions at this point? Hard to say...but our hard fought victory this past year has given us some confidence and direction.

One last point.....lest we get complacent..
.....regardless of what happens with NTP, we
also have to keep an eye out for IARC. IARC
reviewed talc back in 1986 and concluded there
was insufficient evidence of talc carcinogenicity in
humans. We are hoping that this NTP activity
doesn't stimulate IARC conduct an "end-run"
around NTP declare talc a possible human
carcinogen.....because I think you all know,
we do not have the ability to become an active
participant in that relatively "closed" process.

Thank you for your time.