Talc and Ovarian Cancer

Supplementary questions and answers Prepared 20.10.97

Background

On 22nd October 1997, Face Value will air a programme, which will discuss a potential link between talc and ovarian cancer. This issue has been around for many years and there has been a full FDA review of all of the research available. This review has concluded that there is absolutely no causal link between talc and ovarian cancer. This is an industry matter and is not specific to Johnson's Baby powder. The CPTA has issued a full statement on the matter and Johnson & Johnson supports this statement.

The purpose of this document is to supplement the question and answer sheet already issued by J&J corporate. It covers issues specific to what may be aired during the Face Value programme. Any questions on the link to ovarian cancer or the similarities to asbestos are contained within the corporate Q&A also attached.

Above all, the company is absolutely sure that Johnson's Baby Powder is perfectly safe for use on any part of the body, in line with the directions on the pack. There is no link to ovarian cancer either implied or actual and this is the conclusion of the independent review carried out by the FDA. Trust and safety is the basis of our company reputation and if we believed there was even the slightest risk associated with the normal use of Johnson's Baby Powder, we would not hesitate to take the necessary action.

Questions and answers in response to recent publicity. (numbered from Q.38 onwards which follows the corporate Q&A sheet)

Q.38: If you are saying that there is no link to ovarian cancer then why did the programme suggest that there is - they wouldn't just make it up would they?

A.38: That is a good question and we have challenged ourselves on the same issue. We are entirely confident of the safety of our product and all we can do to reassure you is tell you the facts: and that is that there is absolutely no link between talc and ovarian cancer. This is the view expressed by the independent FDA working party who have reviewed all of the research and is supported by the CPTA.

Q.39: Are you saying that the research is not valid in its conclusions?

A.39: What is most important here is what the independent working party who have reviewed this research have concluded. They have concluded that there is no link to ovarian cancer either implied or actual . We have also carried out our own review of the data and we support the conclusions drawn by the FDA.

Q.40: Why did Johnson & Johnson decline to be interviewed by Face Value?

A.40: The talc issue is a general industry issue and is not specific to Johnson's Baby Powder. The CPTA issued an industry response to Face Value , which we support . We are more than happy to talk to our consumers directly (as

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- I am doing with you now) but it is not our corporate policy to talk to our consumers through the medium of television programmes like Face Value.
- Q.41: Why did the CPTA statement which J&J supports make no reference to the fact that the FDA went on to conclude that people should "err on the side of caution"?
- A.41. The written FDA statements, which the CPTA have relied on to draw their conclusions, do not contain any such reference. If this is a personal or subsequent view verbalised by any member of the FDA then they are entitled to express that view. Ultimately we all have to take whatever action is right for ourselves. What I can assure you of however, is that Johnson's Baby Powder is perfectly safe for normal use and that the FDA formal conclusions were that there is absolutely no link either implied or actual to ovarian cancer.
- Q.42: If you have known about this research since 1994 or before, why didn't you tell consumers before now or were you just worried about your sales?
- A.42: We believe that our first responsibility is always to our consumers. This research has always been in the public domain and we have made no attempt to hide it. We have made every attempt to understand its implications for our consumers and can assure you that independent reviews of the research carried out by the FDA have concluded that there are is no link to ovarian cancer. Trust is the basis of our company reputation and I can assure you that if there was the slightest risk to our consumers we would be the first to withdraw the product. We have done this before with Tylenol in the US.
- Q.43: If there is even the slightest risk of a link to ovarian cancer why do you say that the product is safe to use on babies, particularly on babies' bottoms?
- A.43: We can assure you that there is not even the slightest risk of a link to ovarian cancer. Independent studies have proven that talc cannot migrate from any area of the body to the ovaries. Johnson's Baby Powder is perfectly safe to use on your baby, in line with the normal directions on the pack.
- Q.44: Why would Face Value make a programme on this subject if there is nothing to it surely I should believe them more than I should believe you because they have the consumers' interests at heart?
- A.44: That is a great question and I cannot answer it for you. Our opinion is that it is the independent conclusions of the FDA working party that are the most reliable source of the truth in this matter. This working party concluded that there was absolutely no link between the use of talc and ovarian cancer. Ultimately you have to judge the accuracy of the information you have received from the media and from us. However, I can assure you that we always have our consumers' interests at heart and that if there was even the slightest risk we would act accordingly.
- Q.45: I don't care if you think that there is absolutely no risk. You should have made consumers aware of the issue there should be directions on the pack to indicate that it is not suitable for use on certain parts of the body. Are you going to do this in the future?
- A.45: Ultimately, it is not what we think that matters, but what independent sources such as the FDA think. We are extremely confident in the FDA working party conclusion that there is absolutely no risk of ovarian cancer. Johnson's Baby Powder is safe for use, in line with the normal directions on pack, on any

part of the body. Research has proven that talc cannot migrate from any part of the body to the ovaries. We are extremely confident in the safety of our product and see no need to make any changes to the current packaging.

Q.46: I have just been diagnosed with ovarian cancer and I have been using Johnson's Baby Powder for years. I am extremely angry that you knew about this years ago and that you did not inform the public. I want to know how you are going to compensate me.

A.46: I am extremely sorry to hear about your recent diagnosis. However I can assure you that there is absolutely no link between Johnson's Baby powder and ovarian cancer. This is not just our view but is supported by an independent review of all of the research available conducted by the FDA.

If the consumer is still unhappy with this response and insistent upon what we are going to do to compensate her then the appropriate response is...

Once again, I am very sorry to hear that you are suffering from ovarian cancer, however I can assure you that our product is not at fault. If you wish to take this further then that course of action is up to you and we will respond accordingly.

Q.47: How can you be totally sure that talc does not cause ovarian cancer? $\stackrel{\textstyle \sim}{\mathcal{N}}$

A.47: We are absolutely sure for a number of reasons: firstly, an independent review of all the research available, conducted by the FDA has concluded that there is no link between talc and ovarian cancer. Secondly, in the UK and the U.S where talc is commonly used, the incidence of ovarian cancer is 15 / 100,000 women whereas in Scandanavia where talc is not used by women the incidence of ovarian cancer is higher at 21 / 100,000 women. The higher incidence of ovarian cancer in Scandanavia is flinked to diet and has no connection to the use of talc. We can absolutely assure you that there is no known or implied link between talc and ovarian cancer. If there was we would be the first to take appropriate action for the safety of our consumers.

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