

Zumbiehl Janine CHBS

From: Bayliss Matthew GBGU
Sent: Dienstag, 31. März 2009 16:07
To: Nadel Alan USGR; Sullivan Jonathan Dale CHBS; 'jwolff@fulbright.com'
Subject: FW: Paraquat

CONFIDENTIAL AND LEGALLY PRIVILEGED COMMUNICATION

Dear all

Widnes Mortality Study

I attach the response from Martin Wilks to my request for his comments on the thoughts and questions from Tony Cherry.

Regards,

Matthew

From: Wilks Martin CHBS
Sent: 31 March 2009 14:39
To: Bayliss Matthew GBGU
Subject: RE: Paraquat

CONFIDENTIAL AND LEGALLY PRIVILEGED COMMUNICATION

Matthew,

Please find my initial thoughts on the points raised by Tony Cherry inserted into the text below. I suggest we discuss this further next Monday.

Regards

Martin

From: Bayliss Matthew GBGU
Sent: Montag, 30. März 2009 20:23
To: Wilks Martin CHBS
Subject: Paraquat

Confidential & Legally Privileged Communication

Martin,

Widnes Mortality Study

The following are the thoughts and questions from our UK external counsel, Tony Cherry, in relation to the proposal to carry out and to publish a new mortality study.

Just two points for clarification:

- By way of background, I merely explained that, in the US, there has been a suggestion of a possible link between paraquat and Parkinsons Disease. This is what Tony refers to below paragraph 3 as the "America Paper".

- In addition to the recent Widnes skin claim (Morgan), the Durnford Medical Centre (the Widnes Skin clinic) has just received a request for information from solicitors acting for Mr Tommy Mercer "in a claim for compensation against his former employers in respect of his diagnosis of Bowen's Disease".

Response from Tony Cherry:

- Efficacy of the proposed study. The plant was very strongly unionised and there wasn't much job flexibility so I'm not sure that everyone who was exposed to bipyridyl and the tarry by-products of its manufacture would necessarily have been exposed to paraquat in its finished form. I'm wondering how they propose to establish who was exposed to what within the study. Any lack of clarity about this could be a substantial risk. I wouldn't recommend consulting the cohort. As noted below, claims would be dangerously easy to stir up.

It is important to clarify that we are not talking about a single study, but potentially about two: one is concerned with analysis of death certificates as done in the Paddle investigation. The other one would be an investigation in the living population. There is general agreement that the first – while very limited in scope – should be carried out and published while the second one has been discussed with a number of external experts who are advising us that it is not likely to be feasible. Exposure is of course a critical issue. We are working from the original classification made by John Osborn and used in the original Paddle et al. 1991 paper. This information is limited and allows at best qualitative classification. It is doubtful whether there is additional information which would help.

- Residues in the finished product. Important to remember that the chemical route to Paraquat used at Huddersfield always (and in the final years at Widnes) was completely different. Therefore I'd be interested to know the latency period which is being suggested for the development of Parkinsons - if it's more than twenty years then there could theoretically be some association with residues from the HTS/LTS/Mag processes - if not it's the "new" chemistry we need to be concerned with and there has been a careful strategy to keep the new process "clean" from claims.

There seems to be a general view in the scientific community that environmental exposures would have to act for decades in order to influence the manifestation of the disease. In that sense, 'negative' data from the Widnes cohort would provide some degree of reassurance.

- Generally, I see a lot of risk associated with this for modest potential benefit, because it's so hard to prove a negative. If the mortality study showed no excess of Parkinsons it would help to refute the American paper but it couldn't specifically contradict it. The epidemiologists would no doubt argue about all the usual variables. However, it may confirm the findings or throw up some wholly unpredicted excess cause of death which would give us a new set of problems. I think it would be difficult to limit the study to Parkinsons in practice. For example, how would they address multiple/complex causes of death? What would you do if the team told you that although they were not formally investigating "x" they had seen evidence which suggested if they did report on "x" there would be an excess?

The limitations of this sort of study are fully appreciated. It will not be able to disprove an association between paraquat exposure and PD. Nevertheless, it will allow us to answer the question 'have you looked at your own workforce' which will no doubt be one of the first to be asked in any litigation. As far as the mortality study is concerned, the data have been monitored over the years by John Tomenson and we know that there is no excess of PD mentioned on death certificates. As for other disease outcomes, this has to be considered very carefully in terms of what to study and publish. However, in previous updates for occupational health purposes no relevant excess causes of death have been identified.

- The risks are amplified because this group is already identified as a cohort with a potential health problem - that's why they are being monitored in the first place. Do you have a clear strategy for what you would tell them if the study did reveal some excess mortality? Tommy Mercer's continuing interest in possible claims is a useful reminder of how easy it would be to reignite a major problem at Widnes. Note, his solicitors are referring to Bowens disease, so I'd be specially wary of including this. I suppose there's no way his solicitors could have got wind of this proposed study, is there?

As stated above, the question of studying the living population is complex and does not appear feasible. The mortality study does not require contact with any of the living cohort members, but a publication will of course establish our interest in this area and will therefore need managing.

- On a purely practical point, I don't think it's possible to die of solar keratoses (or similar marks however caused), so I wouldn't expect the mortality study to show anything about that. It's worth remembering that this whole Widnes problem would never have happened if the concerns in the seventies had been merely about keratoses. It was because Bowra raised the spectre of skin cancer that it caught light.
- I'm particularly worried about the Geoff Paddle report and the lung cancer issue. Geoff was an ICI employee, (can't remember whether he went with the Zeneca divestment or stayed) producing reports in the old ICI style of looking at every possible issue. Lung cancer is incredibly common in the population at large compared to other cancers, with a wide variety of causes of which smoking remains a chief one. My memory of what was decided about Geoff's work at the time is rather vague now, but I suspect it was because it was such a small effect in relation to such a common cancer that the decision was taken not to do more work. I think Clive was involved the last time I remember discussing it in about 2001/2002. My view would remain the same now and I wouldn't do it.

Paddle recommended a follow-up on the modest excess of lung cancers seen in the original study. This was done and internally reported and the excess had disappeared. The concerns over the rationale for the work done in the 1970s and 1980s are valid, but that's water under the bridge. We are now faced with a new issue for which questions are asked concerning our workforce. We believe that these need addressing and that the outcome of the limited work proposed at the moment will be helpful in doing this.

should be grateful if you would let me have your comments on the above response from Tony Cherry.

When you respond, could I please ask you to respond only to me without copying anyone else.

I look forward to hearing from you.

Regards,

Matthew