

**Enquiries please contact:**

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**Ref:** H:/Julia/letters/Roaccutane/ [REDACTED]

**Date:** 26 January 2001

[REDACTED]  
127 Lower Baggot Street  
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Dear [REDACTED]

We are sorry that diary problems prevented us from doing so by the end of November, as we had intended, but, with apologies for the delay, we now write to respond to your letter of 4 August 2000 (with enclosures) about the drug roaccutane.

**General observations**

2. We should like to begin by making a few general points.
3. First, we must put it on record that neither the Trust nor the University has institutionally participated in any sort of 'cover up' of the side effects of roaccutane. Indeed, your contention (in paragraph 2 of your submission of 4 August) that, together with a number of named individuals, both bodies have been party to such a cover up leads us to wonder whether - at least in the context of the prosecution of academic research - you might perhaps have misunderstood the relationship between the Trust and the University on the one hand and individual scientists on the other. In talking about the Trust and the University you are talking about corporate entities, and it would make sense to talk about such entities being parties to covering up scientific data only if you referring to the decisions *either* of properly constituted decision-making bodies within the institution *or* of senior corporate officers. For the avoidance of doubt, we must make it clear that neither institution has been party to a cover up, and we note that, in your detailed submission, you do not in fact offer any evidence or argument to support your contention that the Trust and the University are themselves parties to the cover up in which you seem to think Professor Cunliffe and some of his colleagues have been engaged.
4. Secondly, we think it would be helpful if we reiterated the approach which we have adopted (and are adopting) to the concerns which you have raised about Professor Cunliffe and his colleagues. As we sought to explain in our letter of 1 December 1999, many of the questions and issues which you have raised in your correspondence with us over the past two and a half years do not lie within the jurisdiction of either the Trust or the University. In particular, it is not for either body to reach a corporate view on the efficacy or safety of roaccutane. Again as we sought to explain in our letter of 1 December 1999, we can as institutions intervene in the process of scientific debate only if we have good reason to suspect some

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kind of misconduct or impropriety. In a nutshell (and at the risk of over simplification), the issue for us in the present context is not whether Professor Cunliffe's judgement about the efficacy and safety of roaccutane is right or wrong but rather whether he and other employees of ours have, as scientists, conducted themselves honestly and with integrity.

5. Thirdly, we must emphasise that, as well as having a general obligation to promote the proper conduct of science, we also have duties to our employees (and ex-employees). We do, for example, have a duty to protect researchers from mischievous, frivolous and malicious allegations and from allegations which are without substance. This is the main reason why, as a matter of general policy, we would not instigate a full investigation and hearing of any allegations of misconduct unless and until preliminary screening has established that there is a *prima facie* case to investigate. It is our understanding that other scientific institutions adopt the same practice.
6. Fourthly, we note that it is a theme of your allegations that Professor Cunliffe and his colleagues have somehow been in the pay of Roche, your implication being that Professor Cunliffe and his colleagues have been influenced in what they have said and published about roaccutane by a relationship with Roche. In this connection, we should make the point that there is a distinction to be drawn between professional and personal relationships; it is one thing for a piece of research to be funded by a pharmaceutical company, and another for a scientist to receive personal benefits from such a company. We would remind you that a good deal of medical research in this country is funded by pharmaceutical companies, and that such companies sponsor or otherwise provide support for a significant proportion of medical conferences across the world. In the interests of clarity and accuracy, it is important to distinguish between a company's payment of emoluments to an individual and its commissioning of research in that individual's laboratory. It is important, in other words, to address the question whether the individual derives any material *personal* benefit from the pharmaceutical company in question. We note, however, that you fail to draw that distinction in your submission.
7. Finally, we feel bound to point out that the allegations which you make against Professor Cunliffe and his colleagues are extremely serious and, in our view, potentially libellous and actionable. No doubt you are aware of this.

#### **The next steps**

8. As we have explained previously, the University and the Trust have already had your allegations screened. On the basis of your original submission, the screeners concluded that there were no *prima facie* grounds for considering that Professor Cunliffe had perpetrated any scientific misconduct. In addition, the Trust's internal audit service carried out an audit of the Leeds Foundation for Dermatological Research, and in respect of Professor Cunliffe's own affairs, and similarly found no evidence of malpractice.
9. Nonetheless, we note that your submission of 4 August covers ground not covered in your original approach to us; and, so as to err on the safe side, we have decided therefore to refer your submission of 4 August 2000 to the screeners for review. On the assumption that your submission of 4 August constitutes a comprehensive

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and consolidated statement of your concerns (insofar as they relate to our staff), and that it subsumes your previous submissions, we are asking the screeners to produce a consolidated report, subsuming their original report to us.

10. We are asking the screeners to address two questions on the basis of your submission of 4 August 2000:

- ◆ Is there, in their judgement, a *prima facie* case that Professor Cunliffe, or any of the other scientists cited in your submission of 4 August, knowingly and with an intent to deceive suppressed or misrepresented data about the side-effects of roaccutane?
- ◆ Is there, in their judgement, any *prima facie* evidence of any impropriety in the relationship between Professor Cunliffe and his colleagues on the one hand and Roche on the other?

No doubt you will let us know if you think any of your specific issues are not covered by these general questions.

11. As Miss Roper explained in her letter of 25 September, we have already sent a copy of your submission of 4 August to the doctors cited in your submission, inviting responses from them. Responses received are being referred to the screeners. We are still awaiting one response.

12. We will of course let you know the outcome of this further screening stage when it is concluded (and see our comments below on the timetable).

### Specific points

13. In the meantime, and pending a further report from the screeners, we would comment as follows on the specific questions you raise in paragraph 13 of your submission of 4 August 2000.

#### *Financial questions (your points 1 and 11)*

14. You ask for details about the financial and other benefits received by the Trust and the University and by a number of specified individuals. Subject to 15 below, we have already given you this information (insofar as it can be obtained without disproportionate cost) in respect of the University corporately; and, as we have explained above, the Trust's internal auditors have already fully investigated the financial arrangements of the Leeds Foundation for Dermatological Research, as well as Professor Cunliffe's own accounts, and have found no evidence of any malpractice or impropriety. Unless and until the screeners find that there is *prima facie* evidence of any malpractice or impropriety, we do not consider that we would be justified in disclosing additional financial information.

15. On a point of detail, and in response to your letter of 8 August 2000, we acknowledge that there was an error in our letter of 3 August 2000. We said in that letter that, since 1987, the University had been awarded research grants and contracts from the Leeds Foundation for Dermatological Research totalling £520k. In fact, the figure of £520k relates to research grants and contracts in support of

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Professor Cunliffe's work; across the institution as a whole, a total of some £2.1 million was received by the University from the Foundation in the period 1999-2000.

#### *Identity of the screeners (your point III)*

16. As we have sought to explain previously, we do not, as a matter of general policy, release or otherwise disclose the names of assessors appointed to carry out the preliminary screening of any allegations of misconduct. This policy is intended to protect the screeners from undue pressure (from any direction). We would, however, make two further points:
- As we have already explained to you, neither of the screeners in this case has or has had any kind of personal or professional relationship with Roche; and, while one of the screeners is a senior employee of the University, the other is independent of both the Trust and the University (we are, however, paying him an honorarium for his time and trouble).
  - In the event that we decide to initiate a full investigation (see 17 below), the names of any committee established for that purpose would be made public.

#### *Appointment of an investigating committee (your points IV, V, VII, VIII, IX & XI)*

17. We will decide how to proceed further when we have a further, consolidated report from the screeners on the basis set out in 8-10 above; but, for the avoidance of doubt, we must make it plain that we will not establish an investigating committee unless and until the screeners deliver a positive answer to either or both of the questions being asked of them (see 10 above). We must make it plain too that, whereas the screeners' delivering a positive answer is *necessary* condition for the establishment of an investigating committee, it is not in itself a *sufficient* condition. There would be other options open to us.

#### *Internal audit (your point VI)*

18. The findings of internal audit investigations are not public documents as they contain confidential information relating to individual employees. If you wish to contact the Leeds Foundation for Dermatological Research directly, they will be obliged to let you have a copy of their audited accounts.

#### *Survey by Professor Cunliffe (your point X)*

19. You refer to a survey conducted by Professor Cunliffe and we would be grateful for clarification of the survey to which you refer.

#### **Timetable**

20. We are, of course, conscious that it is some two and a half years since you first wrote to us; and we are naturally anxious to ensure that the questions you have raised in relation to our staff (and ex-employees) are resolved as quickly as possible, in the interests of all parties. Nonetheless, we must emphasise that the processes we have set in train will take some time to complete, and that we do not consider ourselves bound by any deadlines you may set. We have asked the

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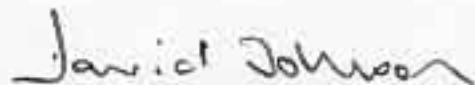
screeners to aim to report back to us by the end of April (or earlier if possible), but we cannot at this stage guarantee that it will be practicable for the screeners to meet that deadline.

### Questions for you

21. In general, we suspect that there is little to be gained by entering into further correspondence with you before the screeners have reported. There is however one point on which we would be grateful to receive your confirmation as soon as possible. As we said in our letter of 1 December 1999, we are not prepared to embark upon an endless dialogue or to consider an endless series of allegations. In this connection, we should be grateful if you would, for the avoidance of any possible doubt, confirm that your submission of 4 August 2000 contains all matters you wish us to consider.

We look forward to hearing from you on this basis.

Yours sincerely



**DAVID JOHNSON**  
Chief Executive



**PIERRE GUILLOU**  
Dean of the Medical School

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