

DRAFT

Mr A Davey - PS/MS(H)

From: Mr Hagger MB1
Date: October 1989
cc: Dr Jones MCA
Mr Wilson MCA
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VALIUM LITIGATION: DUTY OF CARE

1. The purpose of this submission is to:
 - a. inform Minister of the receipt of a writ in connection with the benzodiazepines Valium and Librium;
 - b. seek Minister's agreement to use the forthcoming Valium case to fight the issue of whether the Licensing Authority (LA) and its advisory committees have a duty of care to an individual.

The Valium Litigation

2. The LA and the Committee on Safety of Medicines (CSM) have received a writ and statement of claim which joins them and the Secretary of State for Defence and the manufacturers (Roche) of Valium in high court action in a claim for damages. The statement of claim alleges against the LA and the CSM damages for personal injuries and loss suffered as a consequence of negligence and/or breach of statutory duty.
3. The Plaintiff alleges that the CSM and LA should have known at all material times of the risk of benzodiazepine dependence and had a duty under the Medicines Act to warn all prescribing practitioners accordingly. It is also claimed that the LA and CSM were negligent and in breach of their duty in allowing the manufacturer to promote the drug as being relatively very safe.
4. Treasury Solicitor has indicated notice to defend. Officials are currently listing documents in anticipation of an Order for Discovery.

Duty of Care

5. During the Opren case Counsel considered whether it might be appropriate to seek to have the case against the LA/CSM struck out on the grounds that neither had a duty of care; but the Opren case was already well advanced when this aspect was considered and no subsequent case has been considered appropriate. However Leading Counsel now advises that this current action on Valium would be a good case to take, as a preliminary issue, the argument that neither the Licensing Authority nor any of its advisory committees owes a duty of care to an individual. [A copy of this written Opinion is annexed.] *

* Not yet received from Council

6. In order to establish negligence it would be necessary for the plaintiff to show that there was a duty of care owed by the defendant. This would require both that it was reasonably foreseeable that harm would result in the absence of such care and that there was a sufficiently close relationship between the parties to give rise to such a duty. Counsel relied on 2 recent cases, one a Privy Council, the other a Court of Appeal, where it was held that a public body which was set up by a statute which was clearly intended to protect the public at large imposed no duty of care to individuals. These 2 cases depended on two arguments. The first is that there could not be a sufficiently close relationship between the "victim" and the statutory body because the duty is owed to the public at large not to individuals. In the case of the LA and its advisory committees it would be impossible to consider each and every individual when considering the licensing of products because every medicinal product has side effects which may affect individuals and the decision must be taken on the basis of a risk/benefit assessment for the generality of patients for whom the medicine is intended.

The second argument is that it would be contrary to public policy to make such bodies directly responsible to individuals because the threat of proceedings would have an inhibiting effect on decision-making and in finding experts to serve on advisory committees. It would put members in a "detrimentally defensive frame of mind" and in the case of members of CSM perhaps lead to valuable drugs not being licensed. It might also make it harder to find good people to serve on these committees.

7. If the 'no duty to care' arguments were successfully deployed in the Valium case they would establish a precedent which could be deployed in other cases where the LA and/or the CSM are defendants, and in discouraging plaintiffs from attempting to involve the LA or CSM in litigation. At present, only 1 writ issued, but if we don't take argument, likely whole Benzo group will join in. From the operational standpoint there would be considerable benefits to the MCA in such an outcome as the opportunity costs of defending actions can be very high in terms of diverting considerable scarce manpower resources from more productive work over lengthy periods. Litigation, or threats of it, against the LA/CSM appear to be becoming more frequent. The CSM would also welcome such an outcome though there is no sign as yet that they are in practice reacting over-defensively in licensing advice nor do we think the risk of litigation is putting off good candidates from accepting invitations to serve as members.

8. The Minister will, however, wish to consider possible presentational problems against running this line of argument. It might be seen as an attempt by the LA and its advisers to absolve themselves in law from responsibility for their actions and as preventing individuals from having any course of redress in the courts where they considered the LA or the CSM were at fault. In cases where the plaintiffs had attracted much public sympathy there could be political consequences to be weighed. Where many plaintiffs had essentially similar cases eg in Opren and the pending HIV cases it may in any case be more difficult to apply the 'no duty of care to the individual' argument.

9. In addition it is necessary to consider the circumstances where the Secretary of State may be involved in the same litigation both as the licensing authority and as the Minister for the NHS eg as in the impending HIV case where he is involved as the Licensing Authority and the Minister responsible for the supply of blood products.

Conclusion

10. The Minister is invited to:

- a. note that a writ has been received in the case of the tranquillisers Valium and also Librium;
- b. to decide whether Counsel should be briefed in the Valium litigation to argue the case, as a preliminary issue, that the LA and its advisory committees do not have a duty to care to the individual.

The case for taking the issue is both to clarify the law in this area and potentially to save time and resources in fighting such actions in future. It would also remove a possible undesirable pressure on the advisory committees (though there is no evidence so far that they are offering 'over defensive' advice). But there are presentational/political arguments against which the Minister will wish to weigh.

11. An early decision would be helpful as the preliminary times must be clarified as soon as possible.

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