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RE: LIABILITY OF THE DEPARTMENT OF HEALTH AND OF THE CSM IN RESPECT OF PERSONAL INJURY CAUSED BY LICENSED MEDICINAL PRODUCTS

ADVICE

1. The need for this advice arises from two actions which are currently being pursued against the Crown. The first is the so called HIV Haemophiliacs Litigation, in which a Master Statement of Claim has been served alleging breaches of duty and negligence against the Department, both as Licensing Authority and as having responsibility for the provision of medical services under the National Health Scheme, the CSM and the Regional and other Health Authorities. The allegations against the Department as Licensing Authority and the CSM are based on failures to vary or revoke licences because of known risks of Hepatitis, the granting of licences to non-heat-treated Factor VIII concentrates and a failure to appreciate in time the AIDS risk. Similar allegations are made against the CSM in that it failed to give the necessary advice which would have led to the removal of the offending product from the market. It is said that the Department in its role as the body responsible for the provision of medical services (and the Welsh office, which fulfilled that role in Wales) failed in its duty in several respects in connection with the Blood Transfusion Service. It should have obviated the need to rely on foreign imported concentrates, it failed to recognise the need for and to require to be used non-heat-treated products, it failed to require the screening of donors and it failed to appreciate and to deal with the Hepatitis risk.

2. The second group of actions (although only one has so far materialised) is a claim by a Plaintiff who alleges that he has been injured by becoming addicted to valium (benzodiazepine). It is said that the Department and the CSM ought to have warned of the dangers of dependency.

3. These actions, or groups of actions, are not likely to be the last of such claims against the Department. Although in the pertussis vaccine and Opren actions, no claim was in the end pursued against the Department, claims were formulated. I gather some other actions may have been adumbrated and, having regard to the history of innovatory drugs and the greater awareness of damaging side-effects, helped with the increase readiness of persons injured [redacted] to join together for the purposes of litigation, such claims are likely to continue to be brought. Many, perhaps most, can be pursued against a drug company, at least where the drugs which have caused the damage can be limited to one manufacturer or the relevant manufacturers can be identified. The Haemophiliac action provides an example of claims where no alternative defendant can be found, save, perhaps, in individual cases, doctors who may have failed to follow proper practices or have ignored guidelines.

4. In these circumstances, and in the light of recent authorities tending to limit the extent of Anns v. London Borough of Merton [1978] AC 728, it seems to me that the time has come to reconsider whether there can be liability. I do not think that any cause of action for breach of statutory duty lies under either the Medicines

Act or the National Health Service Acts. The duties under the latter Acts is, broadly speaking, to provide and supervise a National Health Service. They are not directly concerned with safety of individuals and I do not believe that any Court would hold that the harm allegedly suffered by an individual such as a haemophiliac infected with AIDS was of the type which the statute was passed to prevent. Similarly, it seems to me that the duties under the Medicines Act, although concerned with safety, are not directed at protecting individuals from specific injury, but are directed at the public at large. Accordingly, there is no intention to benefit individuals. Furthermore, s.133(2)(a) of the 1968 Act expressly negates a civil action based on any alleged contravention of the Act. In any event, all duties owed under both sets of Acts are public law duties, owed to the public at large and as such to be enforced as necessary by public law remedies rather than actions for damages by individuals. If any cause of action exists, it must be one for breach of a common law duty of care which is superimposed upon the public law duty created by the relevant statute.

5. I think it is necessary to deal with the potential liability of the Department as Licensing Authority separately from that as responsible for the provision of medical services. The principles to be applied are, of course, the same, but there is scope for a different answer to result from their application. I shall deal with the CSM at the same time as the Licensing Authority, and with the various Health Authorities under the aegis of the Department carrying out its functions and the National Health Service Acts.

6. The general principles

6.1 In Jones v. Department of Employment [1988] 1 All ER 725 at 738f Glidewell LJ. summarised the test for the existence of a duty of care in a given situation as being whether it was "just and reasonable" that such duty should exist. But there must be, and are, guidelines to help the Court determine whether the existence of such a duty is just and reasonable. The "just and reasonable" approach is derived from the words of Lord Keith in Peabody Fund v. Sir Lindsay Parkinson [1985] AC 210 at 240, in which he pointed out that there must not only be a relationship of proximity but also circumstances in which such relationship can give rise to a duty of care. In the Council case Yuen Kum-Yu v. AG of Hong Kong [1987] 2 AER 705, Lord Keith refined this approach further by pointing out that in Anns, where referring to the need for proximity, Lord Wilberforce should not be taken to have intended that foreseeability of injury was all that was needed. There must, of course, be foreseeability, but there must also be a Plaintiff who is "so closely and directly affected by my act that I ought reasonably to have [him] in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question": per Lord Atkin in Donoghue v. Stevenson [1932] AC 562 at 580. Thus there must, as was emphasised in the Yuen Kum-Yu case, be the necessary directness and closeness of the relationship between the parties.

6.2 The surrounding circumstances will determine whether the necessary proximity exists in any given case. In the Yuen Kum-Yu case it was accepted that damages to future depositors was reasonably foreseeable, but no duty of care was owed because "further would-be

depositors cannot be regarded as the only persons whom the admissions should properly have in contemplation. In considering the question of removal from the register, the immediate and probably disastrous effect on existing depositors would be a very relevant factor": [1987] 2 AER at p.713b.

6.3 It seems, too, that their Lordships took into account in negating a duty of care that the decision whether or not to deregister the company lay very much within the discretionary sphere of the commissioner's functions. This, I think, hrcks back to the distinction drawn by Lord Wilberforce in Anns between the the policy and operational area. He said this ([1977] 2 All ER at p.500g):-

> "Most, indeed probably all, statutes relating to public authorities or public bodies contain in them a large area of policy. The courts call this "discretion", meaning that the decision is one for the authority and body to make, and not for the courts. Many statutes also prescribe or at least presuppose the practical execution of policy decisions: a convenient description of this is to say that in addition to the area of policy or discretion, there is an operational area. Although this distinction between the policy area and the operational area is convenient and illuminating, it is probably a distinction of degree; many "operational" powers or duties have in them some element of "discretion". It can safely be said that the more "operational" a power or duty may be, the easier it is to superimpose on it a common duty of care".

In Anns itself, there was liability for carrying out an inspection negligently; there would have been no liability if a decision had been made as a matter of policy (because of financial constraints or for whatever valid reason) to carry out no inspection at all: see p.501a-e. It was on this basis that Stuart-Smith J. was persuaded to strike out all the allegations in Kinnear follows (the pertussis vaccine damage cases) save those which related to alleged negligence

in failing to draw attention in the relevant leaflets disseminated by the Department to contra-indications to vaccination, which fell within the "operational" area.

6.4 But in addition there is no duty of care, even if the necessary proximity and foreseeability is established, if to admit such a duty would be contrary to public policy. That was recognised in the Yuen Kum-Yu case (see p.715h-716b) and, if it had been necessary, a duty of care might well have been denied on that ground. The argument, broadly speaking, was that it would inhibit the commissioner in carrying out his duty if he was to be constantly looking over his shoulder at the prospect of claims against him so that he was approaching his work in a detrimentally defensive frame of mind. This aspect was spelt out by the House of Lords in Hill v. Chief Constable of West Yorkshire [1988] 2 All ER 238, a case which, incidentally, also approved the Yuen Kum-Yeu approach to Anns. Lord Keith said this (p.243h):-

> "Potential existence of....liability may in many instances be in the general public interest, as lending towards the observance of a higher standard of care in the carrying on of various different types of activity....In some instances the imposition of liability may lead to the exercise of a function being carried on in a detrimentally defensive frame of mind..."

6.5 At both stages, the test for liability depends substantially upon a judicial reaction to the particular circumstances. It is therefore difficult to forecast accurately the likely outcome and it may be important to spell out adequately as a matter of evidence the reason for not imposing liability. Thus it is in my view sensible to seek to litigate the existence of a duty of care as a preliminary

issue rather than to seek to strike out the Statement of Claim as disclosing no reasonable cause of action, if such a course is considered desirable.

7. The Licensing Authority and the CSM

7.1 The exercise of their functions under the Medicines Act 1968 by both the Licensing Authority (LA) and the CSM is difficult and vital in the public interest. It is important that innovation in medical products should not be unduly held back, but safety must be paramount. All drugs have side effects which may be more or less harmful and a balance has to be struck between the benefit and the damage which may result from any particular product. Thus someone in some pain from condition A may be prepared, if that can be alleviated, to put up with discomfort from condition B caused by the drug which achieves such alleviation (cf. the Opren cases in respect of some known side effects). In Smith Kline French Laboratories v. Licensing Authority [1989] 1 All ER 578 Lord Templemen referred to the need for the LA to be able to refer to all information, however confidential, in discharging its duty to safeguard the health of the nation and ended his speech thus (p.590e):-

> "But in my opinion the LA should not be deterred from exercising its right and powers so as to ensure public safety and to ensure fairness to the applicants whether or not they resort to campaigns or litigation. The Courts should be reluctant to criticise the practices of the LA or to grant injunctions or orders or declarations against the LA which is endeavouring reasonably and conscientiously to discharge the onerous duties imposed by Parliament and is acting in good faith".

While that case did not concern a private law breach of duty of care, it is in my view important as an indication of the judicial attitude to public policy.

7.2 I have read an advice given by Gordon Slynn when Treasury Devil in 1974 in which he indicated that there probably is a duty of care owed by the CSM and, inferentially, by the LA to an injured user of a licensed medicinal product. I think it has been overtaken by the more recent authorities. Whether or not there is in either case sufficient proximity to impose a duty of care, it seems to me that there are very powerful public policy grounds which serve to negative the existence of such a duty. It is vital that the CSM and the LA should exercise a judgment which is in no way affected by extraneous considerations such as the fear of possible liability. The US experience, which has led to conservatism in medical treatment, is by no means in the public interest. In any event, it seems to me that the key decisions whether or not to license and whether or not to revoke or suspend a licence are essentially in the area of policy and discretion and thus incapable of having common law duty of care superimposed.

7.3 If this is right, there is no alternative Defendant in the Haemophiliac cases and they will not be compensated through the courts. I note that a decision has been taken not to compensate them in other ways, for example a scheme such as applied by the Vaccine Damage Act. There is, I think, much to be said for some such scheme to compensate those who fall victim, through no fault of their own, to a medical disastor. But that is a political and not a legal

problem, although a sympathetic judge may be persuaded to take account of the absence of alternative compensation in deciding whether there is a duty of care, that being one of the surrounding circumstances.

7.4 I see no reason to distinguish between the LA and the CSM. Each is an essential party to a licensing decision on safety grounds. The LA has to make the final decision, but must take and will almost always act on the advice of the CSM. The functions of the CSM do not suggest that Parliament intended or envisaged that the individual members (for it is not a body corporate) should be potentially liable in negligence for its actions. Furthermore, the existence of confidential information will make litigation very difficult and may even operate unfairly against the Defendants, if they are unable, on grounds of confidentiality which must in the public interest be maintained, to put forward all the reasons which underlay their decision.

7.5 In all the circumstances, I am satisfied that a duty of care ought to be denied and a preliminary issue tried. It can be done relatively speedily and should be tried before discovery is given. It should, of course, be raised not only in the Haemophiliac cases but also in the valium action. I see no reason in principle why both should not be heard together on this point.

8. The Department and the Health Authorities as responsible for the provision of medical services

8.1 It is obvious that the scope for "operational" as opposed to "policy" decisions is greater in this sphere. Nevertheless, I think that in general the duties involved in running the Health Service and

in providing the relevant services thereunder are not such as would normally be expected to attract a duty of care to an individual who may be adversely affected when something goes wrong. Decisions which depend on allocation of limited resources and questions of priorities (eg. whether money spent on haemophiliacs will deprive those who need major transplants of the chance of life) are, as it seems to me, clearly within the realm of policy. I think, too, that public policy would tend to negative a duty of care, since the possibility of litigation should not play any part in the equation.

8.2 It is therefore important to identify the breaches of duty relied on in the Statement of Claim to see whether they can be said to exist. Self-sufficiency of the transfusion service (paragraph 83.1) is clearly a matter of resource allocation. The reliance on non-heat, treated concentrates, heat treatment and screening (83.2, 3 and 4) all seems to me to be policy decisions, which cannot be looked at in isolation and must have been influenced by the views of the LA and the CSM, who advised on safety. It must not be forgotten that before the advent of Factor VIII haemophiliacs were often doomed to an early death and excruciating pain. The risk of hepatitis was a small price to pay for the benefit of the treatment and the expense of obtaining other than non-heat-treated concentrates from overseas would have been very considerable and would have affected the ability of the Service to pay for the treatment of persons who were suffering in other ways. I think the same can properly be said of the Hepatitis and AIDS risks (83.5 and 6).

8.2 This is not, as I see it, a case where it is said that the Department did something in the teeth of advice from its own experts or contrary to its reasonable policy. What is in the main complained of is a failure to have the correct policy, because the side-effects of using the relevant concentrates were given insufficient weight. To say that other steps could have avoided the tragedy is to miss the point; the only question is whether what was in fact done could amount to a breach of a duty of care.

8.3 In paragraph 83.3 (ix) and (x) there are allegations that insufficient advice or instructions were given after late 1984. Those sort of allegations are closer, in my view, to the sort of matters which could give rise to a duty of care. If it could be shown that insufficient steps were taken to deal with a known problem (most particularly in giving adequate warnings), a duty of care is easier to impose. But many of the other allegations are clearly matters of policy (see eg. 83.4(ac) where what is criticised is the adoption of a policy "in the belief that the test methods are not sufficiently reliable").

8.4 In my opinion, the points can properly be taken that the DH does not owe a duty of care to an individual in carrying out its functions under the National Health Service Acts. There are, as it seems to me, strong public policy arguments in favour of this approach. Should a person who cannot get a heart transplant or whose operation is deferred because of lack of money be able to sue alleging that the DH was negligent in not allocating sufficient resources to his particular problem? The answer must be no. But that is what effectively underlies the claim in this case against the Department.

8.5 Even if the court is not prepared to go the whole way, some of the allegations ought to be struck out and I think that it is necessary to limit the action before discovery.

8.6 I see no reason to impose liability on the Health Authorities in respect of policy matters any more than on the Department. They cannot be liable in areas where the Department owes no duty of care. This aspect affects the Welsh Office, for whom we act, as well as the various Health Authorities. Of course, they may be vicariously liable for the errors of individual doctors, who may have acted negligently, but no such allegations are made in the master Statement of Claim. Similarly, if it could be shown that they ignored advice or instructions given by the Department, there might be liability (see eg. paragraph 92.3(s)). I would certainly hope that they would join in the denial of a duty of care. I would have no objection to counsel acting on their behalf seeing a copy of this advice, if those instructing me were to deem it desirable.

9. I should add that, from the information I have seen, I think that there are reasonable defences to all claims on the merits. But I am sure that the existence and, if it exists, the extent of any duty of care must be settled and these cases are the vehicles to enable that to be done. Once the decision has been made to leave it to the courts, it must be dealt with properly, taking all properly arguable points.

10. I have also considered whether the allegation made in the haemophiliac cases that there was negligence in failing to exclude the hepatitis virus is maintainable. I find the point very difficult. What is said, in effect, is that, if that virus had been removed, so would the unknown AIDS virus too. Of course, what was reasonable to cater for a non-fatal virus may be very different from what was reasonable to deal with a fatal virus But I do not see why in principle the claim should not be made, although it is arguable that there is no causative connection as a matter of law. On balance, I do not think an attempt to dispose of this allegation would succeed on a preliminary point, but it may be worth raising the argument at the same time as the others.

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ADVICE

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