The United Kingdom Parliament

Examination of Witnesses (Questions 160-179)

THURSDAY 24 JUNE 1999

MRS ANN DOWLING, MR JOHN ELDER, MS KARIN PAPPENHEIM, DR REG PEART, MR WILLIAM POWELL AND MR DAVID THROWER

160. We will probably come back to you later on with some specific questions about your experiences because obviously you have exercised your right to go through the procedures. As a Committee, I think we are interested in why you feel the procedures have not worked in your circumstances. Can I thank you for the moment? We will certainly come back to you in a moment or two.
(*Mr Elder*) The reason why they have not worked and they will not work is because it is an internal investigation, from start to finish.

161. Your key concern is that external mechanisms ought to be introduced in some way?
(*Mr Elder*) They have to be. There can be no question about that.

162. Ms Pappenheim, would you like to say a little bit more about your own concerns? Can you keep them reasonably precise and relate them to our terms of reference? We are anxious to learn from the experiences of you and your colleagues, the patients you represent, in looking at what we recommend as to changes that might be brought in by the government.
(*Ms Pappenheim*) I will start by briefly outlining that haemophilia is a very rare condition. It is an inherited, life-long condition, a bleeding disorder, and the major effect of it is internal bleeding which, if untreated, will damage joints and is life threatening. The situation that we are here to speak about today is the one that has arisen from the use of blood products to treat people with haemophilia for their condition. That treatment began in the late sixties and went on through the seventies and eighties. During that time, those blood products were contaminated with HIV and hepatitis A, B and C. The effect of that is that over 95 per cent of the patient group treated during that era were infected with combinations of those viruses. We have had a long term problem with that treatment, leading in this instance to infection of this patient group who already had a serious, life-long, medical condition. They have been infected with two life threatening viruses through their NHS treatment. It is important to state that in 1985 and 1986 viral inactivation procedures were put in place to prevent future transmission of HIV and hepatitis through blood products, but we still know that there are viruses such as TTV, which is a recently identified one, and hepatitis A, which actually escaped that inactivation process. We cannot be entirely confident to this day that blood products are 100 per cent safe, because we already know that some viruses are escaping the inactivation processes. What has happened as a result of the HIV and hepatitis C infection, which is what we primarily want to focus on, is that by the time inactivation was put in place, as I said earlier, over 95 per cent of the patient group treated had been infected. 4,800 people with haemophilia have been infected with hepatitis C and of those 1,200 were also infected with HIV. Many have lost their lives. Over 700 have died of AIDS already and at least 90 have died of hepatitis related liver disease. Of course, we now have a patient group of survivors who are still struggling with the consequences. Hepatitis C has a far longer progression than HIV. It is a 20 to 40 year progression, but in its end stages it damages the liver and leads to liver cirrhosis and liver cancer. Treatments for both of those viruses, as you will appreciate, are very complex and difficult, particularly for the groups of patients who have haemophilia, HIV and hepatitis. The treatment prospects are really very uncertain and treatments in themselves have massive side effects which can be completely disabling. To summarise the end results, many of these patients have had seriously impaired health and still have declining health today. They have suffered actual loss of earnings as a result of course because many, many have had to give up work and are no longer able to continue work because of that. Also, they are suffering the stigma of living with these viruses. What we really wanted to highlight—and this is where we get on to the meat of your inquiry—is the fact that there have been no effective, national procedures to pick up on this widespread treatment failure that took place over a long period of time. Unlike other countries—and we can look at Canada and Ireland—where people also suffer the effects of contaminated blood, the governments in those countries have undertaken inquiries to establish exactly what happened, what might have been done, what the impact has been and, very importantly, to learn lessons for the future. In this country, there has been no systematic investigation. It has been piecemeal and I think one of the strongest issues to be raised today is that picking up the pieces from this disaster has been largely left to self help. Patients have formed themselves into self help groups where they have tried to share information and find out about how to live with these viruses. The Haemophilia Society as a charity has been left very much in the role of trying to provide support, information and advice but there has been no systematic approach to actually ensuring that every single infected patient has been correctly identified, tested, treated and followed up. One of the things we want to flag up very, very strongly is that the previous government undertook a look back study of patients who had been infected with hepatitis C through transfusions. There were obvious reasons for doing that, because they had to find them, but an assumption was apparently made that all haemophilia patients would be located, tested, treated and

counselled by their haemophilia centres. You can see from the evidence that we have presented here—and you can talk to many, many of our members to find out—that they have not all been correctly identified, tested, treated, advised and counselled. We have in here a case history of a young man of 28 who has only within the last ten months, although it is believed he has been infected with hepatitis C for 17 years, been properly tested and told about his condition. Obviously, one of the sources of anguish and anger for our patient group is that, because there was no systematic approach to locating, testing and advising everyone, some people lived with very dangerous viruses which they could transmit, without being given information that would allow them to protect those closest to them, to avoid sexual transmission to partners and to make lifestyle changes, for instance those with hepatitis C, who should have known that drinking alcohol is not a good thing for their health. You will see from the evidence that we have presented that the approach to the follow up has been haphazard. Certainly we are not here today to blame clinicians and nurses working in haemophilia because I think one of the points we would like to flag up is that this disaster has had a terrible impact on doctors and nurses as well. Many have seen their entire patient group at a particular haemophilia centre die and become seriously ill. That has been traumatic and stressful for them. We are certainly not here to make an attack but what we are here to do is to flag up the issue of whose responsibility was it. Was it sufficient to allow individual clinicians to advise patients off their own bat, because this is what has happened to a couple of individuals we know. Fortunately, they were warned by a doctor or a nurse who was in a position to know the medical research and had warned them that there was contamination in the blood product. Should it have been left to individual clinicians, doctors and nurses like that? Was it the responsibility of the Department of Health? Was it the responsibility of the professional medical bodies representing those clinicians? I think what our patient group feels is that they have been let down by all and that there has been no attempt to take the comprehensive approach to picking up the pieces of this disaster. Obviously, that is one of the lessons that we hope would be learned. We would hope that today, with increased emphasis on clinical governance, with the existence of the National Institute of Clinical Excellence—I stress "hope" because we do not know this; we do not know that if such a thing happened tomorrow action would be any different, but I think I cannot express strongly enough the loss of confidence, the anger, the disappointment of this particular patient group who have been infected through their treatment and have not had adequate redress.

Dr Stoate

163. I appreciate that your group has had very significant health problems and has suffered enormously because of the problems you have outlined extremely succinctly and very well. Do you feel as though this should never have happened at all or do you feel that, the infection with viruses having happened, it should have been handled differently? I am not quite sure where your complaint is. Is it that it should have been stopped in some way; it should never have happened, or is it that, having happened, the response was wrong?
(*Ms Pappenheim*) It is a very complicated issue because we are obviously looking at a patient group with a serious medical condition. For those with severe haemophilia, treatment was essential. However, there is an issue of people who had mild haemophilia who may only have required treatment perhaps two or three times in a lifetime and some of the particular anger of those patients is that they feel that, had they been told of the risks of accepting blood products for a condition which they might have overcome—they could have gone home and they could have sat with ice packs—there were other ways, if you had mild haemophilia, of tackling the problems. Clearly that kind of issue might not apply when you have severe haemophilia so one of these issues is about why there was not advice and information at the time to allow patients to make an informed choice about accepting treatment if there was another option.

164. You think the medical knowledge was there but it was not being given to the patients? There is clearly a possibility that the medical knowledge was wrong or the medical knowledge just was not available, but you are saying the medical knowledge was there but it was not being applied?
(*Ms Pappenheim*) We are looking at a long period from the beginning of the seventies, when blood products began to be widely used, right the way up until 1985/1986 when inactivation processes were implemented. Obviously, medical and scientific knowledge was evolving throughout that time. In the case of hepatitis C, it was known only as a non-A, non-B virus in the seventies, but it was known to exist. Signs were coming through. They were being reported on in the medical literature, so there was an evolving state of knowledge which could have been flagged up. This is where we are raising the question again about was it the responsibility of an individual clinician who had read the medical research to say, "I would like to warn you about this". Was it the responsibility of the Department of Health to issue a circular to say, "Only treat in certain circumstances"? Was it the responsibility of the royal colleges? These are some of the questions that our patients are still asking today. That is one set of questions. The other is why there has still been no adequate follow up action, why no redress. There is really very little that the courts can do to resolve this problem and seeking justice, seeking recompense, has come down to campaigning and lobbying by patients within the patient group of the Haemophilia Society. This is very starkly contrasted with other countries where they have done an inquiry; they have uncovered the facts; they have put the picture together. Certainly they have responded, as in Ireland, very close at hand, by providing at least some form of financial recompense for the loss that these people have sustained. I think the point on that which we really want to flag up very strongly for this Committee is that this patient group have been told many times that they are allegedly the victims of non-negligent harm. The question we want to raise is what should be done in a situation where you have a large number of patients who have apparently suffered the effects of non-negligent harm, where we are being told that action through the courts will not work and the government has been at great pains to distance itself from responsibility because it continues to refer to this as inadvertent and non-negligent harm.

165. There is clearly a difference between no full compensation, which is one aspect which you are perfectly right to press for if that is what you want. The alternative is compensation for damage done—in other words, by a named individual, a hospital or a trust. Are you saying that you wish to take action against named individuals who have treated people wrongly, or are you saying that you would like full compensation from the government for sufferers of this disease?
(*Ms Pappenheim*) I think we want the government to take action because there has been a very unequal

response. We are dealing particularly with two viruses, as we have said in our submission, HIV and hepatitis C. In terms of HIV, quite rightly after considerable pressure, after campaigning, after 900 people with haemophilia and HIV went to court in a mass action, the previous government in 1987/1988 set up a financial assistance scheme. That was never described as compensation because the government distanced itself and accepted no responsibility. Money that was provided was on an ex gratia basis in recognition of a tragedy. However, the patients with hepatitis C, of whom there are now some 3,000, have not been addressed in the same way. Our very strong view is that this is a completely unequal response. It is unjustifiable to have divided the patient group. It has caused immense anger and anguish. Hepatitis C clearly is a different virus to HIV, but it has extreme health consequences; it carries stigma, it is disabling and it has created actual financial loss for people unable to work. Going back to your question, we feel that the previous government made a partial response after massive public pressure and pressure in the courts. They set up a financial assistance scheme to provide some measure of recompense for HIV. One of the reasons that they were forced to do that was because of the dramatic progression of HIV. Deaths were happening at the rate of one a week. It is perhaps both the misfortune and fortune of those with hepatitis C that their virus did not progress. It is a much longer progression, but for a number of reasons—that may be one of them—they were not included in that original focus. It is that group who are still left struggling with the health consequences and left asking time and time again why has the government such an unequal response to a group of patients who have all been infected through the same type of treatment, used in the same era for the same condition. That is the point which we really want to flag up. There seems to be no justification for responding partially, and quite rightly, to those with a devastating virus, HIV, but leaving aside completely those with hepatitis C.

Julia Drown

166. You said that blood products might not be safe today and the inactivation process might not affect a couple of viruses. Do you feel that patients today are being warned of those risks?
(*Ms Pappenheim*) I think patients today are incredibly alert and haemophilia patients have become one of the best informed patient groups out there, because of this experience. Therefore, we provide information on the existence of TTV, for instance. There is a constant described by the Department of Health as "theoretical" risk of CJD because, as you will be aware, there is no screening test for CJD. Whilst blood products are obviously massively safer than they were in the era we are talking about now, there is no guarantee of 100 per cent safety and they still carry that theoretical risk of CJD. This is the reason why, as a patient group, we have campaigned for access to synthetic recombinant treatment which really should be a choice for all patients so that they can avoid, albeit a theoretical risk, an unknown, unquantified risk of other blood borne viruses.

167. If you were not warning patients, would you feel there was adequate warning being given to patients?
(*Ms Pappenheim*) That is a difficult question to answer. It will depend very much on the stance of individual clinicians and nurses and how proactive they are in discussing treatment options. I think the point we have flagged up in our evidence is that, with regard to HIV and hepatitis particularly, over the period after the infection, for instance, tests were carried out on patients without their consent; they were not given information on the result in many cases. One would hope that things have moved on, but we are still talking about, even in the last couple of weeks, patients in touch with the Society who are only just getting the results of their tests for these viruses and quite clearly, once given the results, were not given a full counselling or information session on what the implications are, not least the fact that they are highly unlikely to be able to get mortgages and life assurance again. It is not only a health impact; it is your whole life that will be affected.

Chairman

168. Dr Peart, can I bring you in to say a little more about the background to your group? Obviously, I have personally met a number of your colleagues. Can you explain to my Committee colleagues broadly the concerns that you have as a group, as they tie into our terms of reference for the areas we are examining?
(*Dr Peart*) I am very much aware that, because of the very long term, wide ranging and very complex nature of the benzodiazepine problems, some of my written submission was outside the remit of this inquiry, but I have prepared a statement in which I have attempted to distil it to be consistent with the terms of reference and some of the definitions in the *Oxford English Dictionary*. In the interests of time and because of my drug induced cognitive impairment, I would very much like, with the Committee's permission, to read this statement. I think it will serve to produce a much more precise statement, one with greater content, and be much more informative.

169. So long as it is not too long.
(*Dr Peart*) It will be less than the previous speaker. The adverse clinical incident I wish to talk about is 40 years of misprescribing, misdiagnosis and mistreatment. In the late 1970s, Professor Lader of the Institute of Psychiatry warned that the biggest medical epidemic of the 1980s was in the making. This has happened. A much better way of describing the whole incident, I believe, is it is simply chemical rape of the body, mind and soul. Investigation of this incident has been very limited. It is limited to medical publications on a worldwide basis, but these are very restricted in scope and there have been very few epidemiological studies. The CRM issued guidelines for drug data sheets in 1980 and the CSM published guidelines for prescribing in 1988. The Institute of Psychiatry also published a similar set in the same year. the outcome of these investigations was at best to have a very marginal impact. Questions like what happened, why did it happen, why is it ongoing have largely been unanswered. Another important question is simply why have there been so few investigations. I think the answer must be associated with vested interests. From the 1960s onwards, patients bombarded their doctors with complaints about these drugs. By the late 1970s, independent authorities had estimated about one million people were addicted to these drugs. This figure has remained about the same to this day. It is of interest to not that for valium, the most widely used of these drugs, only 16 reports of addiction were received by the MCA via the yellow card system. That is from 1963 to 1996. The usefulness and effectiveness of this system must be in grave doubt when massive under-reporting of drug adverse reactions has been going on for so long. One point is clear. The system does not work for the patient, but it appears to work hand in glove with

vested interests.

170. Could you explain who you specifically regard as the vested interests? Are you talking about the drug companies?
(*Dr Peart*) Very much so the drug companies but, to quite a large extent, the Committee of Safety of Medicines and the MCA and also, as I will elaborate on, the medical profession itself, the prescribers. Decades of little or no response to patients' complaints were finally picked up by the media. This no doubt forced the hand of the CSM into issuing guidelines in 1988. Patients, tired of stonewalling by their prescribers, were reluctant to take action against them because, like any addict, they wanted to safeguard their access to and supply of their drugs. Instead, thousands of letters of complaint were written to the drug companies, the CSM, the MCA, the Department of Health, the BMA, the GMC, MPs and ministers. Most patients simply wanted recognition, acceptance and treatment of the problem. As this was not forthcoming, many finally resorted to legal action. Others, like myself, tried to get access to their medical records. I was refused access by my GP on the grounds that he needed permission from all of the doctors who treated me.

171. Is this since the law changed with regard to access to medical records?
(*Dr Peart*) That was in about 1988.

172. It predates the recent legislation.
(*Dr Peart*) Probably, but the interesting point on this issue is that one of the psychiatrists, the major one who treated me, simply replied to my doctor stating that all communication should be via the Medical Defence Union. I therefore started legal action myself and joined the action group against the drug companies. This legal action really was a disaster from beginning to end and it confirmed that the English legal system is incompetent and incapable of running group actions for medical negligence. Over £15 million was spent, not a penny going to the claimants. It turned out simply to be a money making machine for members of the legal and medical professions. Briefly, the reasons for its failure include defence tactics to run up the claimants' costs, bias by the presiding judge, Mr Justice Kennedy, a strong conflict of interest by our own case experts who are also prescribers—they were very hostile to both claimants and to the generic experts who were supposedly briefing them. Many sufferers have tried to obtain state benefits, including disability living allowance, because of the very long term and debilitating adverse reactions to these drugs. Few have succeeded due to the refusal of prescribers to recognise and diagnose problems caused by these drugs. A sick note quoting benzodiazepine addiction is an absolute rarity. The few who get benefits like DLA are granted them for reasons other than the cause—i.e., it is the symptoms of the problem like depression and agoraphobia. It is interesting to note that the DLA handbook in 1988 contains no reference to prescription drug addiction. The phraseology used for other addiction rules out the inclusion of the iatrogenic addiction. The biggest barrier to patients obtaining recognition, acceptance and treatment for this problem is the prescribers themselves, those whose clinical judgment, I might add, created the problem in the first place. Voluntary support groups get little or no cooperation from doctors. They refuse to display information in surgeries or give verbal information to patients. Most surgeries, if not all, have lists of benzodiazepine users and databases and it would be very easy for prescribers to notify patients of support and voluntary organisations. By definition, relatives and carers are in the same boat. They are unable to be supportive and in many cases their actions are destructive because they are aided and abetted by misinformation from prescribers. There appears to be a lack of will to open up and to do something about this problem by statutory sector services. Quite often, health authorities are keen to work within government guidelines and directions from the Department of Health and with the voluntary sector, but the inward looking stance by the statutory services, especially the National Health Service, means the response to complaints is very much one of a statement of "it is up to the clinical judgment of the prescribers". This mantra is taken up by the prescribers, by the National Health Service, by the MCA and other authorities. It does seem that the old precept "first do no harm" has been turned on its head.

Mr Lewis

173. That was very helpful and clear. Thank you. I am interested to know whether you feel and whether the group of people that you represent feel that these drugs have any place at all in the treatment of people with mental health problems or mental illness; and whether there are perhaps other people who have received this kind of medication who would say that it has actually made a positive difference to the quality of their lives. I know it is very difficult to be objective.
(*Dr Peart*) I believe, and many of our members believe, that within the current guidelines they are of significant value. That is for very short term use and for quite serious conditions. I do know of people who fit into that category and they would certainly make such a statement. I think there is another aspect to these drugs which is seldom addressed and that is a very wide ranging individual sensitivity to the drugs. Some people can take the drugs and within a matter of days, or certainly a week, they can become addicted to them. Others can go for many months and only very slowly develop dependency or addiction. It is an issue that, right the way through from clinical trials to the prescriber, does not seem to be addressed at all.

174. What you are saying is that there will be groups of people who have a similar condition where doctors may feel it appropriate to prescribe this form of medication, but no regard has been taken in the past in terms of factors connected with individual. The doctor has looked at a group of people. They seem to have similar symptoms. Therefore, this kind of medication would appear to be the most appropriate intervention and most appropriate response, but really beyond that there has not really been any attempt to look at anything else connected with the individual or their history, their likelihood to become dependent or addictive. Is that what you are saying?
(*Dr Peart*) Very much so and very strongly so. In fact, once patients become addicted and hooked on these drugs the prescribers invariably continue to treat the symptoms rather than looking at any original problem. The treatment ends up by being one, like polypharmacy, of treating symptoms only, ignoring the original complaint.

175. Is it your view that, based on research and evidence, it is possible for doctors to identify easily those people who it would be, in terms of the balance of risk, unwise to prescribe this medication for?
(*Dr Peart*) No, I am not of that opinion at all because the probability of any individual becoming addicted to these drugs is not dependent upon the individual characteristics or problems. It is simply a biochemical problem. All aspects of addiction can basically be explained in terms of biochemistry and the nature of the drug.

176. You have said that you feel in some cases it is appropriate for doctors to prescribe this medication?
(*Dr Peart*) For short term use, yes.

177. You have also said that you are concerned that maybe there are some people, even in the short term, who can become addicted?
(*Dr Peart*) Yes.

178. What I am a bit unclear about is, based on your experiences, do you feel doctors can be expected to identify those people who are likely to become addicted, even after a short period of time of being on that medication?
(*Dr Peart*) I do not think that doctors can pre-predict or predict. I believe that most doctors should be able to diagnose the symptoms of dependence as soon as they occur, whether after one or two weeks or after six or seven months.

179. Your contention is that basically once that becomes clear very quickly what has happened over the years is that doctors have avoided dealing with that and have just continued prescribing?
(*Dr Peart*) Yes, irrespective.

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