



Mesothelioma And The Dilemma Of The Prospect And Effect Of Immunotherapy

Michael Rawlinson QC

1. Given the number of different diseases with which it is associated, asbestos might reasonably be thought to be as versatile at killing the humans who inhaled it, as it was in meeting the perceived needs of British industry throughout the 20th Century.
2. If comparisons are permissible, then perhaps the most frightening of asbestos' manifestations is mesothelioma: the cancer of the linings of the chest and peritoneum. Owing to the widespread historic use of amosite insulation boards within the UK, this country (which boasts only c. 1% of the world's population) sees 20% of the world's incidence of mesothelioma. Indeed, the chance of a male born in the 1940s contracting this disease is now around 1 in 170.
3. Until recently swift death following diagnosis was almost inevitable: indeed, if a victim lived 'too long' after the diagnosis, then questions would often be raised about the accuracy of that very diagnosis. But we live in strange and wonderful times and consultant chest physicians of great eminence have begun to express (suitably dignified) excitement regarding new therapies called immunotherapy/biological therapies (referred to collectively here as "immunotherapy") when they have been applied to mesothelioma victims. The manner in which these new therapies work is beyond the scope of this blog (and to be honest, the comprehension of this blogger) but cases such as that of the redoubtable Mavis Nye, whose mesothelioma appears to have disappeared following such therapy, has caused not only a great stir but also an equal challenge to those who act on behalf of such victims.
4. Before outlining the challenge, a little more background is required. Mesothelioma victims lucky enough to be referred to the correct Oncologist will be told that whilst immunotherapy is not right for everyone, it could be that their Mesothelioma may be stabilised (for a while at least – no one is ever told to expect the result which has apparently obtained in Mavis Nye's case) by immunotherapy. But here the uncertainties begin to manifest: usually such therapy will only be applied once first line chemotherapy has been undertaken and when, thereafter, the cancer has once again begun to advance; but only if at that stage the victim's health status is still otherwise good and only if they can afford it, because such therapy is not available on the NHS. This is not to criticise the NHS – they ration scarce resources according to NICE guidelines and so far, there is insufficient evidence of the effectiveness of immunotherapy in mesothelioma cases to permit NICE to recommend it in such cases. One reason for this is that the drugs are in their infancy so far as their use against mesothelioma is concerned. Yet they appear to *be* effective in a significant number of cases for a significant period of time.
5. If you now talk to an oncologist about the likely immunotherapy treatments to be given to a mesothelioma victim, you will be told about a large number of potential drugs, used either singly or in combination and at widely different prices. So far the most expensive of these is pembrolizumab (Keytruda) at around £120,000 per annum. Such oncologists would also tell

you that results from trials are emerging all the time and one cannot know what the landscape will be in even 2 years time. So a person who is given Keytruda today and who, as a result, is alive in (say) 2 years time, may be well enough to transfer onto another therapy which is unproven (indeed, perhaps unknown) today but which may by then be realised to yield great benefit.

6. Now, let us move from a consideration of the medicine to the dilemma which is created for those advising both victims and insurers as a result of this medicine. Suppose you are acting for a victim who has just received his (or her) diagnosis and is very early in their treatment; let us say they are just going through the front line chemotherapy now. You look at their exposure history and, upon reviewing it, you see that it is clear and that therefore breach of duty should be easily provable against an employer whose insurer is both known and solvent. All looks set fair for an early settlement. But what are you to do about immunotherapy? You cannot yet know whether the victim is suitable for such treatment and, even if they are, which drug (or combination of drugs) will be prescribed or at what cost or for how long? Many immunotherapy courses require fresh scanning to be undertaken very regularly to ensure that the tumour has not advanced, a sign that the immunotherapy should either be stopped completely or changed.
7. It would appear, in theory, that you have only two options: first to wait to see what is prescribed and then claim an interim payment for that amount or, second to guess. Neither is a very attractive option for either the victim or the lawyer. Equally unattractive to the insurer is an unfocussed claim for some estimated amount of damages (added without evidence) to every schedule of loss.
8. In recent months insurers have approached the problem by making an offer to claimants, namely to make direct payments to the immunotherapy provider, on condition that the insurer's own medico-legal expert has the right to say that the provision is not in the victim's interest (and thereafter the insurer can seek a determination from the court that it may withdraw funding). This was undoubtedly a bona fide attempt to answer the problem. There can be a place for such agreements (for example if the paying party cannot prove reasonable security of payment for the purpose of a periodical payment order, or the provision is already being made and working well and is overseen by a medico-legal expert who could just as easily have been the treating oncologist etc.) but anyone who does so will need to satisfy themselves that two potential issues are being considered:
 - 8.1. That there are safeguards to prevent either the payer making deals with the provider over the head of the victim such that only a cheaper option is being paid for as opposed to a more expensive and experimental one which would otherwise be sanctioned by the treating oncologist if 'money was no object' Further, that there should be arrangements whereby the victim is informed when each payment is made

so as to avoid any (unknown to him) dispute arising between the insurer and the provider leading to the funds not being provided. Without this protection and knowledge the first the victim would know of any problem would be when the provider raised the issue of the shortfall. The victim, who should only have their own health to worry over, would then be left to negotiate between two commercial organisations as to why the payments had dried up and to negotiate the continuation of the therapy notwithstanding the drying up of funds etc.

- 8.2. The ethics of permitting review and objection by an oncologist or chest physician instructed by the insurer need to be considered. Such a medic, however personally honourable¹ would necessarily be being instructed by the party (the insurer) whose legitimate interest is to reduce costs where it can. What therefore is the ethical status of any objection raised to a suggested treatment where it arises from that standpoint and particularly where the suggestion being objected to is one which is necessarily being made by the patient's treating (NHS) oncologist. The treating oncologist is someone who will be in a better position to consider matters because that oncologist will have access not just to records but also to the patient himself. Upon what basis would the medico-legal expert then express a contrary view? On the basis that, when viewed in the round, the victim's potential extension of life really wasn't worth the cost? The protection afforded to the Defendant by such an arrangement would, it seems to me, be largely illusory.
9. I was asked by Irwin Mitchell to look at this problem 3 months ago and it seemed to me that there were only three viable options available to victims, namely to seek to persuade insurers to enter into a Periodical Payment Order ("PPO") or a Structured Settlement or, alternatively, to invite insurers to submit to repeated applications for interim payments to cover the provision of the immunotherapy costs for as long as they were required.
10. None of above solutions is without its problems but being flexible with existing forms of legal process has always been the hallmark of asbestos litigation, given the dilemmas of life and death which it daily throws up. What gave me the impetus to press on with the PPO idea was the knowledge that something needed to be done to fix what, as I hope I have demonstrated above, is a real and practical dilemma.
11. Since a PPO is, of course, an open-ended commitment to make payments for as long as is needed and since an insurer could credibly (if not necessarily correctly) argue that in its detail the situation we face neatly fits neither a stepped nor a variable PPO, why should any insurer enter into such an agreement voluntarily? The answer is that because such an agreement is, in the long run, a highly efficient method of dealing with the dilemma for insurers as well. If, upon proof by a Claimant that *at the moment of settlement*, there exists *now* a realistic chance

¹ And almost all of the candidates for this role have the anxious care of their own patient lists and all are honourable.

that at *some point in the future* immunotherapy will be recommended, then an insurer who enters into a PPO agreement as part of an overall settlement acquires two very significant benefits:

- 11.1. First, no case is ever delayed (and hence no costs are incurred as a result of such delay) by waiting to see whether immunotherapy is provided and with what effect etc.
- 11.2. Second, no payment is ever made by the insurer against the future risk that immunotherapy is to be provided *if in fact* no such immunotherapy is *in fact never* provided ie they will not have to add (say) £50,000 to each claim to ‘buy off’ the risk of immunotherapy being provided at some nebulous point in the future.

Finally it would be recognised by most properly advised insurers that there are two very powerful legal weapons lying in the hands of Claimants’ lawyers when one considers their ability to enforce payment from the tortfeasor for medical costs:

- 11.3. The law is that, provided such treatment is recommended by a reputable relevant expert, then the cost of that treatment is recoverable even if it is unsuccessful. In reality, where the prize at stake is longer life or longer healthy life, then there will be very little short of the positively harmful which the Court will consider not have been reasonable to attempt.
 - 11.4. If a proposed treatment is reasonable then it is no defence for an insurer to say that it could either be obtained more cheaply in another way (*Rialis*) or that it is available on the NHS (*s2(4) Law Reform (Personal Injury) Act 1948*)
12. I was therefore excited (genuinely!) to be instructed by Ian Toft of Irwin Mitchell, Leeds together with Jeremy Roussak of Kings Chambers, Manchester, in a case where the proposal of a PPO could be put to an insurer. Last week the proposal was accepted. A partly anonymised form of the Agreement can be obtained from either Ian (Ian.Toft@Irwinmitchell.com) or Jeremy (Roussak@kingschambers.com) should one be desired. Our client in that case was Mr Scott. He wanted to keep the terms of his order which are not relevant to the PPO confidential and the Court has so ordered, but he did want his name attached to the draft model agreement and this was permitted by the Court: and so what follows is both a description of and the terms of a draft Scott agreement.
13. The essence of the agreement was as follows:
- 13.1. A Tomlin form of order was used. As usual, the interesting terms lay in the Schedule to the order.

- 13.2. It was recited in the Schedule that there was accepted to exist now a realistic chance that at some stage in the future Mr Scott would require immunotherapy albeit no one could say when that time would be; which treatment would be given; for how long and at what cost.
- 13.3. Irwin Mitchell would set up and administer a trust whose sole purpose is to receive and then pay to the provider the costs of immunotherapy provision (with associated expenses such as blood tests and scanning) as and when such payments were demanded by the provider and received from the insurer. In addition such travelling expenses as Mr Scott would incur would also be paid. This trust is to be administered at the insurer's reasonable expense.
- 13.4. The trigger for payments is the victim's *treating* oncologist recommending immunotherapy. Once the insurers were made aware of that the trigger had occurred they will then pay £130,000 in quarterly instalments for as long as required. The figure alighted on was the figure for the provision of Keytruda. However a *quid pro quo* was agreed in that should the actual figure be less than that, a reverse indemnity would be provided (ie the IM Trust would repay to the insurer the money) and conversely should the treatment cost be higher then an additional 'top up' would be made by the insurer to the IM Trust. This would continue for as long as necessary but if the treatment stopped temporarily or otherwise changed the insurer would be informed and payments adjusted
- 13.5. There was no future role within the agreement for any expert employed by the insurer. Thus there was no provision for second guessing or countermanding the treating oncologist's recommendations (providing the treating expert was of good repute). This was made clear by the following clause within the agreement
- "For the avoidance of doubt the only ground upon which such objection can be taken by the Insurer is that the new sum does not actually represent the cost to be levied by the health provider to the Claimant. The Insurer shall not seek to argue that the continued provision of immunotherapy is rendered irrecoverable or unreasonable by reason of the fact or amount of the new sum"*
- 13.6. Payments would cease at such time as either the treating Oncologist considered that immunotherapy should be stopped permanently or the patient sadly died. Any excess remaining in the Trust would be repaid to the insurers.

14. Any insurer who seeks to object that this agreement could not be ordered by the Court can be answered in one of three ways:
 - 14.1. The agreement does not in fact offend either the Damages Act 1996 nor CPR Part 41 nor yet the Damages (Variation of Periodical Payments) Order 2005/841;
 - 14.2. Alternatively, the Court could without fear of reasoned contradiction impose upon a defendant a variable PPO which was triggered by the worsening of the condition represented by the advance of the cancer after front line chemotherapy had been administered and at a fixed figure equivalent to the most expensive treatment envisaged: the model agreement we entered into is a far more benevolent regime to the insurer than such an approach².
 - 14.3. Finally, if the insurers really wish, victims can simply settle all parts of the claim except that for immunotherapy, adjourn and then make multiple applications for interim payments as and when for as long as they live; and that would not be a happy solution for anyone.
15. Our agreement with the insurers in his case has provided peace of mind to the victim that any immunotherapy treatment will always be paid for as and when he needs it. The insurers who have agreed to it are, if I may say so, to be congratulated for their pragmatic, helpful and realistic approach. I hope others follow suit. It is for this reason that we make available the template for use for any who wish to do so. We do not claim that there is any magic in the wording but it should at least provide a starting point in other cases.
16. There is one final issue to consider. If the present agreement becomes widely adopted then there will grow a divide between those victims who possess good claims for compensation (and hence who can obtain immunotherapy via the Scott model agreement such as has been entered into in this case) and those victims who do not have such claims and are limited to making applications under the Diffuse Mesothelioma scheme (who cannot). Thus we quickly reach the highly uncomfortable position that whether a victim lives 12 months or 5 years may depend on the whether or not an insurer can be traced for his employment: a happenstance which is wholly out of the victim's control and which essentially amounts to a lottery on life. Since the intention of the scheme was to award average damages to its applicants, the time

² Insurers may seek to argue that the advancement of the cancer is not a 'deterioration' for the purpose of Article 2 of the Damages (Variation of Periodical Payments) Order 2005/841 on the grounds that the very diagnosis of mesothelioma necessarily encompasses death and that there can be no deterioration beyond death. That, to my mind, misses the point. Assuming death now to be inevitable, death is, when properly analysed not the condition but the outcome of the condition. Thus any deterioration in the manifestations of the condition 'on the way' to death can clearly be a deterioration which can trigger the payment of a PPO.

has come to consider whether the scheme should also be expanded to include the facility to enter into such agreements as were entered into in this case. This will require additional capital of course.

17. I hope this has both interested and helped you

MICHAEL RAWLINSON QC³

³ *I gratefully acknowledge both the editing skills and input of Jeremy Roussak in relation to this document. Any errors are, however, mine alone*

THE MODEL 'SCOTT' AGREEMENT

BEFORE the Honourable Mr[s] Justice

UPON HEARING Leading & Junior Counsel for the Claimant and Leading Counsel for the
Defendants

DRAFT MINUTE OF ORDER

PART I: PREAMBLE

WHEREAS

- 1 The Claimant was born on [XXXXXX] and is of full capacity.
- 2 The Claimant has brought proceedings against the Defendants for damages arising out of their tortious exposure of him to respirable asbestos dust whereby he has developed mesothelioma from which, at some indeterminate date, he will die.
- 3 Following diagnosis the Claimant underwent [XX] cycles of chemotherapy, with beneficial but transient effect.
- 4 [Set out treatment history to date – in terms of prior Chemotherapy/Immunotherapy provision etc]

- 5 There is a realistic (meaning more than fanciful) chance that the Claimant’s treating oncologist, [Insert name of treating oncologist] (references to whom are to be read as including any consultant oncologist who replaces him in advising the Claimant), will advise immuno- or like therapy, where it is administered within the United Kingdom of Great Britain and Northern Ireland with the intention of combating the primary mesothelioma and/or metastases thereof (“future immunotherapy”).
- 6 The parties have compromised all aspects of the claim save for the additional special damages claim arising out of future immunotherapy.
- 7 The Claimant seeks the provision of the additional damages by way of a Periodical Payment Order.
- 8 The circumstances in which the additional damages become payable and the form in which they are paid are set out in the Schedule attached to this Tomlin Order.
- 9 The Defendants is insured for the purpose of this claim by [Insert name of insurer] (“the Insurer”), a company whose conduct is regulated by the FSA under reference number [insert number].
- 10 At the time of this Order, the parties do not know if the Claimant will in fact require future immunotherapy, if he does, when it might start, for how long it might continue, if it might stop and then re-start or what its ultimate private cost might be.
- 11 The Insurer has agreed to fund future immunotherapy as advised by [Name of treating oncologist] without medical oversight by any clinician appointed on their behalf and subject only to the provisions of the Schedule hereto.

AND UPON THE CLAIMANT’S SOLICITORS UNDERTAKING

- 12 To set up, as soon as practicable, a Personal Injury Trust (“the Trust”) to be administered by [Name of professional trustee] (“the Trustees”). The purpose of the Trust is to receive

any payments made under the Schedule to this Order and to disburse them to whichever health provider renders a bill for the provision of future immunotherapy and/or associated medical expenses and to the Claimant himself in respect of reasonably incurred costs arising out of his future immunotherapy.

- 13 To provide to the Insurer the names and professional addresses of the Trustees and details of the Trust's bank account on a date no later than the Trigger Date, which is defined as the first date on which the Claimant sends to the Defendants evidence that [Name of treating Oncologist] recommends that further immunotherapy should be provided.
- 14 Not to permit disbursements of any amounts from the Trust which do not relate to
 - a the cost of the immunotherapy provision itself;
 - b any cost of related medical scanning, screening and review undertaken for the purpose of assessing progress and the continued medical justification for the provision of immunotherapy;
 - c out of pocket expenditure incurred by the Claimant in respect of undergoing the therapy and screening reviews.
- 15 Insofar as they constitute a trustee of the Trust, to ensure the winding up of the Trust as soon as practicable either after "the End Date", being defined as the earlier of
 - a the death of the Claimant; or
 - b the date upon which [Name of treating Oncologist] states that there is no further justification for the continuing provision of further immunotherapy.

AND UPON THE DEFENDANTS UNDERTAKING

- 16 To pay the reasonable costs of the Trustees in carrying out their duties under paragraphs 12 to 15 above upon presentation of a bill setting out those costs whether they be ongoing (insofar as they arise before the End Date) or final (insofar as they arise after the End Date).

AND UPON BOTH PARTIES ACKNOWLEDGING

- 17 Any claims for breach of contract arising from an alleged breach of the terms set out in the Schedule to this order may, unless the Court orders otherwise, be dealt with by way of an application to the Court without the need to start a new claim.
- 18 This is a final order for the purposes of the calculation of success fee arising out of the Claimant's retainer, CFA agreement and ATE policy.

AND UPON THE COURT BEING SATISFIED

- 19 The continuity of payment under this Order is reasonably secure pursuant to Section 2(3) of the Damages Act 1996 and/or pursuant to Section 2(4)(b) of the Damages Act 1996 in that the Insurer are protected by a scheme under Section 213 of the Financial Services and Markets Act 2000.
- 20 The periodical payments listed below and which are to be paid into the Trust are to be paid free of taxation under sections 731–734 of the Income Tax (Trading and Other Income) Act 2005.

PART II: THE ORDER

BY CONSENT IT IS ORDERED THAT

- 21 All further proceedings in this case be stayed upon the terms set out in the Schedule to this order dated and signed by Leading and Junior Counsel for each party the original of which has been retained by the Claimant's solicitors and a copy of which has been retained by the Defendants' solicitors, except for the purpose of enforcing those terms.
- 22 The Defendants' liability to the Claimant in respect of all heads of claim save for those arising out of future immunotherapy is assessed in the agreed sum of £xxx which said sum is to be discharged in the following manner:
- a there shall be credit given for the sum of £aaa paid by way of interim payment of damages to date;

- b** there shall be credit given for the sum of £bbb repayable to the Compensation Recovery Unit;
- c** the balance of £ccc shall be paid by the Defendants to the Claimant by 4pm 10th November 2017.

23 Upon the occurrence of the Trigger Date the Defendants shall pay, in addition to those sums set out in paragraph 22 above, those sums as specified in the attached Schedule by way of damages for the provision of future immunotherapy. There shall be no indexation of the additional payments and in this regard the Court applies section 2(9) of the Damages Act 1996 rather than section 2(8).

24 The Defendants shall pay the Claimant's costs of this action to be assessed on the standard basis if not agreed. By way of further partial discharge of this liability (the Defendants having already paid £xxx), the Defendants shall pay to the Claimant the sum of £aaa as an interim payment pursuant to CPR 44.2(8) by 4pm on 10th November 2017.

25 The parties may apply to the court to enforce the terms upon which this case has been stayed, to include for the avoidance of doubt the resolution of any dispute regarding the reasonableness of the costs claimed under paragraph 16 of this Order, without the need to bring a new claim.

PART III: THE SCHEDULE

- 1 The condition precedent for the Insurer to make payments under this Schedule is the occurrence of the Trigger Date.
- 2 The balance of the paragraphs in this Schedule are each to be read with the incorporated proviso that no liability arises to act under each or all of them if the Trigger Date has not occurred.
- 3 Each sum payable as calculated under this Schedule is a “periodical payment” and is made subject to the conditions set out in this Schedule.
- 4 The periodical payments shall continue to be made until the End Date as defined in paragraph 15 of this Order. Once the End Date has been passed and without prejudice to the continuing liability to make payments in respect of immunotherapy which has been provided prior to the End Date but for which no payment had yet been made, no further liability in respect of immunotherapy costs will arise under this Order.
- 5 There shall be no minimum number of payments made.
- 6 The Insurer will make the first payment under this Order within 14 days of the trigger date at the rate of £130,000 per annum payable in 4 equal quarterly instalments. For the avoidance of doubt the first payment will be of £32,500 and each subsequent payment shall be in an equal sum paid no later than every 91 days thereafter.
- 7 The sums, and each of them, shall be paid by bank transfer into the account of the Trust. Any subsequent change in banking arrangements of the Trust shall be made known to the Insurer forthwith.

- 8** Every 6 months after the Trigger Date,
- a** the Trustees shall provide to the Insurers an account which shall itemise each payment made by the Trust since the previous account, with copies of invoices in respect thereof;
 - b** the Claimant’s solicitors shall provide to the Insurers updated medical records, which they shall take all reasonable steps to obtain.
- 9** In the event that a change in the nature of the future immunotherapy is envisaged, the Claimant’s solicitors will take all reasonable steps to obtain from [Insert the name of the Oncologist] a letter setting out
- a** the nature of the new treatment;
 - b** the method and frequency by which the treatment will be administered;
 - c** the costs involved in the treatment.
- 10** Should it become known to either party that the then current periodical payment does not reflect the charges being levied and expenses being incurred in the provision of the future immunotherapy, the following procedure shall apply.
- a** As soon as reasonably practicable the Trustees shall inform the Insurer of (a) that fact and (b) the new annualized cost of provision by writing to them at such address as shall have been provided to the Trustees for the purpose on a date no later than 14 days after the making of this order.
 - b** Within 7 days of receipt of such notification the Insurer shall set out whether or not it agrees to pay the new rate. If it does then the sum set out at paragraph 6 of this Schedule shall be adjusted (“the new sum”) and become payable in equal quarterly instalments as from the date of next payment due (that is 91 days since the payment of the last instalment).
 - c** If the Insurer does not agree to pay the new sum then the parties shall be entitled under the liberty to apply contained in this Order, the Damages Act 1996 and/or

the Damages (Variation of Periodical Payments) Order 2005 (SI 841/2005), for a determination from the Court (under a certificate of urgency) of what the new sum should be.

- 11 For the avoidance of doubt the only ground upon which such objection can be taken by the Insurer is that the new sum does not actually represent the cost to be levied by the health provider to the Claimant. The Insurer shall not seek to argue that the continued provision of immunotherapy is rendered irrecoverable or unreasonable by reason of the fact or amount of the new sum.
- 12 The fact of, and the reason for, the End Date having been reached shall be communicated by the Trustees to the Insurer as soon as reasonably practicable.
- 13 At the occurrence of the End Date the Trustees shall ensure payment of immunotherapy costs outstanding as at that date are met and then any residual amount remaining within the Trust shall be repaid to the Insurer forthwith together with an account.
- 14 The reasonable costs of this and all of the lawful functions carried out in connection with the Trust by the Trustees shall be paid by the Insurer to the Trustee within 30 days of their rendering an itemized bill. It shall be open to the Insurer to challenge such costs for reasonable cause should they so wish. If, however, they do so, then they shall at the same time as raising the challenge make payment of such sum as they do agree to forthwith. Any outstanding dispute may be returned to the Court for determination under the general liberty to apply contained within this Order.
- 15 The Defendants, the Insurer and the Claimant shall comply with and be bound by the terms, requirements and obligations set out in this Schedule.

[Name of Counsel]