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## COMPENSATION FOR 'IMMUNOTHERAPY' : THE END OF THE BEGINNING

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1. I have blogged in the past about the Immunotherapy costs in mesothelioma claims. It will be recalled that the *legal* difficulties associated with this family of therapies were:
  - Immunotherapy may not have been commenced or even recommended at the time of settlement
  - The length of time that the treatment would be utilised is wholly unknowable in advance
  - The unit cost of the treatment could be very high (some drugs, in combination are being charged at £200,000+ per annum)
  - Which particular drugs would be administered in the future cannot be known with absolute certainty in advance given that Mesothelioma UK believe that the clinical situation is changing generally every 6 weeks or so
  - Even the definition of 'immunotherapy' is not straightforward: many drugs are better considered to be targeted treatments rather than immunotherapy proper. In the rest of this post I shall continue to refer to the family of drugs as 'immunotherapy'
  
2. Meanwhile if the problem of Immunotherapy was complex, the victim's needs arising out of compensation for its costs remained straightforward, namely:
  - To have access to funds which permitted immunotherapy to be obtained as required for however long, with whatever drugs has been recommended by their treating oncologist and at whatever cost
  - To be freed from having to administer those funds directly
  
3. How these wishes are to be accommodated has become a source of significant dispute between the two sides of the litigation fence.
  
4. The principal sticking point has been the implementation of the general rule that medical expenses can be obtained only if they have been reasonably incurred (albeit whatever the actual outcome or level of success).
  - 4.1. We argued that, when properly analysed, the law was entirely clear: within the context of mesothelioma and its inevitable and painful death, *any* treatment recommended by the treating oncologist would be deemed reasonable. It followed, we said, that provided the treatment had in fact been so recommended, there was no need to insert a clause in any agreement regarding the cost of future provision to the effect that the insurer would only be liable for *reasonably* incurred expenses.
  - 4.2. The insurers on the other hand argued that such a clause was needed to avoid a 'blank cheque' liability.
  - 4.3. Some (but not all) insurers went further and argued that they should have the right to seek a determination of whether expenditure on immunotherapy had been reasonable and, if it was found not to have been, to have clawed back the damages already paid. Such an arrangement would have been particularly troubling since the reality was that given the

costs involved, in cases of doubt the victims would not incur the cost to avoid the risk to their other damages.

- 4.4. However, equally troubling was the stipulation (which many insurers insisted upon) that their own medic had the opportunity to opine on whether the recommendation by the *treating oncologist* that a particular form of immunotherapy should be provided, was reasonable. As I set out in my last blogpost it was very hard to see by what metric the value of extension of life could be measured in money's worth. Further it was equally hard to see how such an opinion could ethically be provided by the *medico-legal* expert instructed by the party whose legitimate interest it was to reduce the damages.
5. There were originally two methods obviously open to practitioners to try to settle claims whilst making provision for future immunotherapy costs. First, repeated interim payment applications and second, insurers' promises to pay direct.
6. I understand that the second option was tried in good faith on a number of early occasions but experience taught that it *could* be unsatisfactory. If there were delays in the payments being transferred from the insurer to the private health-care provider (ie who actually provided the immunotherapy) then the provider would (entirely reasonably) not provide credit and would simply state that it would not provide the drug instead. The first the victim would know was when he received the telephone call informing him that payment had been delayed. There was inadequate control for the victim and the 'not knowing' was a worry.
7. Interim payments are not perfect. They permit the argument of 'reasonableness' on each occasion; they are expensive and cumbersome and cannot be obtained for lengthy periods of time into the future since in order to obtain an interim payment to fund (say) the next 12 months of treatment, it would be necessary to show a very high likelihood that the victim would live that long – an impossibility.
8. However three longer term solutions have now been obtained for Claimants by partners of Irwin Mitchell in 3 separate offices, namely Ian Toft in Leeds, Alida Coates in Birmingham and Ian Bailey in London. The purpose of this blog is to outline them and provide a short guide to compare them.
9. The first solution was subsequently to be called the 'Scott' agreement. The intention behind the agreement was that it could be entered into by the parties at the beginning of litigation just as soon as liability was either conceded or proven (and hence, as a side-wind, the importance of *Bussey v Anglia Heating*). Ian Toft instructed Jeremy Roussak of Kings Chambers and I to seek agreement with insurers where the victim had commenced but terminated immunotherapy on the discovery of a separate tumour. He was, however, thought to be a possible candidate in the future. The model we used at the time was a consensual PPO. The form of the agreement was a Tomlin order. As usual, the interesting terms lay in the schedule.
  - 9.1. It was recited that there was accepted to be a realistic chance that at some stage in the future the victim would require immunotherapy albeit no one could say when that time would be, which treatment would be given, for how long at what cost.
  - 9.2. IM set up and administered a trust whose sole purpose would be 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 Mr Scott's travelling expenses would be paid. This was to be at the insurer's expense.

9.3. The trigger for payments would be Mr Scott's *treating* oncologist recommending the commencement of immunotherapy. Once the insurers were made aware of the trigger they would 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.

9.4. 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"*

9.5. 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.

10. Our belief was that this would quickly become the standard template because:

- 10.1. It could be signed as soon as liability was established and then the rest of the action could move onto settlement in the usual way;
- 10.2. It was extremely flexible and could cope with the victim changing drug regimes or even going into trials (which would be free of charge to the Defendant);
- 10.3. The insurer would never pay a penny more than the actual cost of the immunotherapy used
- 10.4. The victim had complete security of mind

Our belief turned out to be incorrect. There was a chorus of protest from the Defendants in subsequent meetings to the effect that no-one else would ever agree to these terms. This was unfortunate since the terms, if not consented to, could not be ordered by the Court.

11. A large number of JSMs then stalled on the issue of immunotherapy costs. Other ways had to be devised.

12. The second successful way has been referred to as a 'float' agreement. I recently concluded this instructed by Alida Coates in a case where the victim had already started to receive a form of immunotherapy. This agreement uses no PPO-like structure. Instead the insurers have agreed to pay for the setting up of a trust (in this case via a third party) into which an initial payment to the value of 3 months immunotherapy treatment is made. Thereafter the role of the Trust is to administer the payments out of immunotherapy charges. As each payment is made out, so the insurer 'tops up' the float and thus it is ensured that there can never be less

than 3 months supply available to the victim. This is important so that should there be any delay in payment, the victim has sufficient funds to carry on paying for treatment whilst 'chasing' or even enforcement of the agreement is carried out by Alida.

13. There are several features of the agreement which we think can be used a template to solve the 'reasonableness' conundrum

13.1. We formally conceded the principle that the insurer would only have an ongoing liability to pay for the cost of reasonable immunotherapy provision. However the parties then provided a cascade of reasonableness provisions as set out below:

- (a) Any drug from a named list would be deemed reasonable;
- (b) Any drug not on that list but which had been recommended by the treating oncologist; had completed a Phase II trial involving mesothelioma and which cost less than £250,000 per annum was deemed reasonable;
- (c) Any other drug outside those criteria which two nominated Oncologists agreed to be reasonable (a concession on our part);
- (d) Any drug falling outside (c) which the Court deemed reasonable on an expedited application. In the case of (d) the Defendant would fund the drug until such time as the Court found it to be unreasonable at which time the funding would stop but there would be no clawback.

13.2. At the end of the period of immunotherapy (ie when it stopped finally) or on death any money in the float would be paid back

14. Finally the third type of agreement was ordered by Consent by the Court today, namely a variable PPO again in a case where the victim is already receiving immunotherapy. Under this form of agreement, the present immunotherapy regime is to be paid into a trust pursuant to a PPO which is framed in standard terms by reference to the *Thompstone* model. The agreement sets out (in accordance with the evidence) which drugs are anticipated to constitute the second line of immunotherapy treatment. As the medical trigger in fact for this change will be demonstrable progression of the mesothelioma, this can act as the trigger for the variation of the PPO at which time a further application will be made to the Court in line with the Damages (Variation of Periodical Payments) Order 2005 (SI 2005/841) for a determination of the new cost. In fact the trust administering the present PPO payments will simply negotiate the new cost when the time comes. For the avoidance of doubt I do not believe that either *Willson v MOD* or *Curi v Colina* act as impediments to the use of the advancement of mesothelioma as a trigger for the variation since (a) those cases were determined under s32A Senior Courts Act 1981 and not the applicable Act here, namely the Damages Act 2006 and (b) because of dicta in *Farrugia v Burtenshaw* [2014] EWHC 1036 where, in considering the worsening of epilepsy as the trigger for a variable PPO stated:

*"I accept Mr Latimer-Sayer's submission that there is no difference in principle between (a) epilepsy developing in the first place, and (b) epilepsy worsening, such that a Claimant's care needs significantly increase.*

15. Should there be a third line of therapy or should the treating oncologist suggest a second line of immunotherapy different to the one presently anticipated then under an extended

liberty to apply, the victim can return to Court for further additional interim damages. Whilst the PPO pertains this provides security of payment and peace of mind.

16. No one solution will fit all circumstances. Of the three types of agreement (Scott, PPO and float) there may be other variations on the theme. Each case will have to be looked at intensely to see which model the factual circumstance most dictate. Given the sums of money involved and the importance of the issues, it is right and proper that bespoke solutions are provided and it is incumbent upon all who profess to practice in this area to have a firm grip of the underlying law, the latest medical developments and how solutions are being obtained as we go along.
17. Each of the solutions required pragmatism on both sides. It is notable that the last two solutions were arrived at with a single Defendant's firm (BLM) who were able, as we understand it, to co-ordinate between the partners in the two cases and leapt just as far as we did to reach agreement.
18. Further problems require to be ironed out and in my view the most flexible solution remains the Scott agreement.
19. Finally, three matters: first, I would like to record the significant assistance from Jeremy Roussak in all three cases; second, these agreements simply could not have been reached without the tenacity, dedication and sheer hard work of the above-named partners at Irwins. Third, I reiterate my closing remarks from the last blog. It is now clear that victims who are reliant upon the Diffuse Mesothelioma scheme are significantly disadvantaged compared to those with civil claims and the time will come when the scheme will need to be expanded since, insofar as it does not permit recovery of private immunotherapy costs, it no longer reflects practice in common law claims.

**MER QC**

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