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IN THE COMPETITION APPEAL TRIBUNAL Case No. 1016/1/1/03

New Court,
Chair Street,
London WC2A.2JT

29 September, 2003

Before:
SIR CHRISTOPHER BELLAMY
(President)
PROFESSOR PETER GRINYER
MR GRAHAM MATHER

BETWEEN:

GENZYME LIMITED ("Genzyme")

Applicant

and

THE OFFICE OF FAIR TRADING ("OFT")

Respondent

Mr David Vaughan CBE QC and Mr Aidan Robertson appeared for the applicant.

Mr Rhodri Thompson QC and Mr Jon Turner appeared for the respondent.

Transcribed from the shorthand notes of
Harry Counsell & Co
Clifford's Inn, Fetter Lane, London EC2A.1LD
Telephone: 0207 269 0370

PROCEEDINGS

DAY THREE

THE PRESIDENT: Good morning.

MR THOMPSON: Good morning, gentlemen. As I think I flagged at the end of Friday, we looked again at the timing but, consistently with our general approach we have decided to keep the general shape of our presentation as it was. I propose to take about an hour now to deal with the two factual points which I characterised as points 2 and 3 in the outline on Friday.

If all goes to plan Mr Turner will then take most of the rest of the morning on the issues of abuse and then, hopefully, briefly after lunch I will deal with the answers to the Tribunal's questions and the issue of the direction, which I hope will enable us to fit in what needs to be fitted in today.

THE PRESIDENT: Before you just go on, Mr Thompson, there is just one point on the transcript from Friday that we would like to develop at some point, not necessarily now but at some point convenient to you, which is about exclusive distribution. It is on page 75, lines 32 and 33, as part of your argument you said that:

"The possibility of an exclusive arrangement between Genzyme and the Homecare Services provider would therefore not arise and could not be sustained if it did arise as the NHS buyer would make its own arrangements."

What we need to be clear about is whether you are attacking as part of the abuse the existence of an exclusive distribution in favour of Healthcare at Home from March, 2000 to 5th May, 2001 and, if so, how that fits in with the general case that is being made.

MR THOMPSON: Yes, I think we will come to that in relation to the questions. That was particularly one of the things that was raised.

MR VAUGHAN: But before my friend does start, so you get an idea of how we see the day planning out. We would expect to deal with about half our reply during the afternoon.I think it is pretty clear we will not finish today and therefore we would need to find another date convenient to the Panel and others for an extra day.

THE PRESIDENT: I see, so you have moved away a bit from putting everything in writing.

MR VAUGHAN: We have moved away from the brief, short, sharp---

THE PRESIDENT: The short, sharp, killer final---

MR VAUGHAN: I think we want to cover things in a bit more detail.

THE PRESIDENT: Yes, so we may need another day later on.

MR VAUGHAN: Half day, yes. The other thing is we have served another witness statement of Mr Morland, picking up some of the points that have arisen over the previous 2 days. Thank you.

THE PRESIDENT: Yes. Mr Thompson?

MR THOMPSON: I do not know if the Tribunal has the note that I handed up on Friday afternoon.

THE PRESIDENT: Yes, we do, yes.

MR THOMPSON: I think we can move straight to page 2, and proposition 1. I think I heralded one amendment, it says "prescribing pharmacist", and it should read "dispensing", and I think it would also be helpful to add the words "by that pharmacist" in the bracket at the end. The point being that in reality Homecare Service providers are, in fact, pharmacists and they, in fact, incur the cost of homecare services.

THE PRESIDENT: Perhaps you are coming to this, it has seemed sometimes that in the decision the decision is equating the role normally performed by the community pharmacist with the role, in fact, performed by the two specialist pharmacists we have got in this case in Burton-on-Trent and Oxford. I do not know if that is still part of the OFT's case, but it seems to the Tribunal that it is not a particularly exact analogy.

MR THOMPSON: I can quite see that there are issues about what is done, so it might be said that there is wholesaling of a rather attenuated kind, given the additional work that is done by the homecare services provider after the initial dispensing of the drug either in Oxford or Burton-on-Trent. The point I am making here is simply that the cost of that additional work is paid for by the pharmacist, it is a cost of the homecare services provider,and that is, in my submission, a matter of relevance, when you come to the operation of the Drug Tariff and whether or not it is appropriate that this cost should be included in the reimbursement provided to the pharmacist under the Drug Tariff.

The other point that Mr Turner has just reminded me, and I think I heralded it in my questions of Mr Browlee, the fact is, and it is a point stressed both by Genzyme, and Healthcare at Home that these are, in fact, real community pharmacists, and they have to be real community pharmacists under the NHS Act to be entitled to reimbursement under the Drug Tariff because that is how the scheme works.

THE PRESIDENT: But when you say they are "real community pharmacists", what do you mean - they are stocking up the drugs available to people who bring in prescriptions?

MR THOMPSON: Yes, they are pharmacists in the community and have been appointed on that basis. In the case of Genzyme, Mr Dorodra, you will recall, gives evidence that he is a community pharmacist not on site at Genzyme's institution but he is up at Rose Hill in Oxford, and he is in fact a community pharmacist, and so he is reimbursed as such, and it is necessary to the operation of the Drug Tariff that he should be.

The points I was going to go through, if I just go through the headings, are the internal documentation, not all of which is it necessary to go to, the basic pricing evidence that appears in the documents, the correspondence with third parties, and the theoretical position, and then finally the question of whether or not the Department of Health were misled in 1999/2000 which is a point that is really developed in the second report of Professor Yarrow, or the second report of Professor Yarrow, and the second statement of Mr Williams.

If we take the first point, I think it would be useful to turn up some of these documents just to show precisely the passages we rely on.

THE PRESIDENT: Yes, you take us to anything you want to take us to, Mr Thompson.

MR THOMPSON: If one looks first of all at bundle 31. It is the OFT's core bundle, tab 2, page 61, and it is really the first sub paragraph there, and this is Mr Cortvriend, who you will recall at this stage has been responsible for marketing Cerezyme since 1993, writing to Mr Van Heek, there is a letter from Mr Van Heek to Mr Manuel which appears in the bundle at pages 3 to 6. Mr Van Heek is vice-president, or general manager, Europe for Genzyme, or he was in 1993 and as far as I know he still was in 1997, although I do not think that matters.

Mr Cortvriend is explaining what happened and he refers to a letter of 4th May, 1993 and that is also in the bundle, and in fact that is the letter that I have referred to at page 3, where Mr Van Heek has been explaining to Mr Manuel of the Gaucher's Association that, contrary to appearances---

THE PRESIDENT: Shall we just look at that first?

MR THOMPSON: It is quite a long letter, and it is not in very good typeface.

THE PRESIDENT: That is at page 3.

MR THOMPSON: It is.

THE PRESIDENT: 1993, it is coming from the Netherlands?

MR THOMPSON: Yes.

THE PRESIDENT: I see. This is Ceredase, now presumably, is it not?

MR THOMPSON: Indeed. I think the relevant part is on the second page of the letter, where Mr Van Heek describes what would happen. At that time it is the third paragraph, where it says "This company..." and he is talking about Caremark. "This company would act on our behalf as distributors/wholesaler and at the same time as dispensing pharmacy int he price of £2.90 their fee is included. For other services they provide specifically for patients treated away from their hospital home care nurse and sundry materials such as infusion set and saline, not prescribed by a GP, they would charge an additional 7p per unit".

So at that time the idea was that the wholesaling cost would be integrated at £2.90 and an additional 7p would be added on as a nursing cost, effectively.

THE PRESIDENT: Yes.

MR THOMPSON: And for various ancillaries.

Then Mr Cortvriend comments on the letter, and says: "Your letter of 4th May talked about end prices to the FHSAs..." actually I have not found that reference. I am sorry, that is on page 6 of the letter. Under "Germany" there is a sentence saying: "These prices.." and he sets out a number of prices "...compared to the UK between £2.90 and £2.97. These are end prices to the FSHA." So that is how Mr Van Meek has

presented to Mr Manuel at that stage. It would be a 2.90 price with a 7p add-on.

THE PRESIDENT: It looks as if Mr Manuel is complaining that Ceredase is more expensive int he UK than it is in Europe, it seems to be the context in which this is arising.

MR THOMPSON: I think the historical position, if I may just explain, has been that they had been supply direct to patients at $3.50, and they were proposing at this stage to put it up to $4.50, and Mr Manuel was clearly unhappy with this, $4.50 equating to 2.90 or 2.97 I think.

Perhaps just by way of background it is worth looking at the very first page in the bundle, which is at about the same time as the letter from Mr Van Heek. You will see in parallel to Mr Van Heek's explanations to Mr Manuel there was, in fact, a letter - it seems to have been a preliminary letter of engagement from Mr Cortvriend to Mr Dibley of Unicare, which became Caremark, setting out a rather different arrangement. The relevant part is the middle two paragraphs on the first page. In the first paragraph they put priority to the issue of being a community pharmacy. And say "They would like you to act as a dispensing pharmacist for the supply of Ceredase, and the distributor for hospital supply of Ceredase from April 1993 in the UK". Then they set out a rather different pricing structure "With regard to the community pharmacy supply of Ceradase via FB10 prescriptions, we intend that the price be 2.97 per unit to the customer and that you be charged 2.67 per unit. "So that seems to be where the idea of the whole cost being included as a single figure, a 30p discount or service fee being paid to Caremark was first introduced.

MR. MATHER: That is the implementation of his phrase in the letter to Mr. Manuel, "Their fee is included".

MR. THOMPSON: I do not think we necessarily need to go into this in detail, but in 1996 and 1997 Mr. Manuel expressed some grievance that he had understood that a maximum of 7p was going to be added on, whereas in fact a 30p fee was actually being added on.

MR. MATHER: Are they not two different concepts, the first being, "Their fee is included" and the second, "They will charge an additional 7p", or am I missing something?

MR. THOMPSON: I think is when we get back to where I started, which is where Mr. Cortvriend and Mr. Van Heek tried to unpick this material with the benefit of hindsight, which is the document at which we first looked at page 61.

THE PRESIDENT: I do not think we have really looked at the document at page 61 yet.

MR. THOMPSON: That is the context to this document.

Mr. Cortvriend says, "I am still not sure how we should proceed. Your letter of 4th May 1993 talked about end prices to the FHSAs, but this could be interpreted as just the cost of the drug." Then the words upon which we primarily rely, "... except that the

way in which Caremark operate is by including the whole package under the heading of 'Drug Costs' when they bill the Health Service." We say that that is a clear recognition that what Caremark was doing was bundling its whole cost of its homecare supply in with the cost of the drug and that that was the reality of the situation as it had been in place at least at some time prior to 1997 and, apparently, going right back to 1993.

THE PRESIDENT: That is what he says in the first sentence. Then in the second sentence he says that he told Mr. Manuel something a bit different in 1996; is that right?

MR. THOMPSON: Yes, and that is the point that I think Mr. Manuel complained about, because that appears to suggest that the matter was segregated, whereas, in fact, as Mr. Manuel discovered in 1996 it was not, it was all treated as part of the drug cost.

THE PRESIDENT: Where is the letter of 12th November 1996?

MR. THOMPSON: That is at page 19. Since we are into this, I am afraid we then need to go through the document in slightly more detail, because it goes back to the correspondence at pages 7 to 9, to which I referred Mr. Brownlee briefly on Friday. You will see, first of all on page 7, the first paragraph, Mr. Cortvriend informing Mr. Manuel that the price is going to be £2.63 per unit. Then you will see, two pages further on, page 9, Mr. Termeer informing Mr. Manuel that the price is going to be £2.73 per unit.

THE PRESIDENT: I think the easiest thing, Mr. Thompson, is for you to tell us what conclusion you want us to draw from this particular exchange between 1993 and 1997.

MR. THOMPSON: The basic point that I am making is that in the correspondence it is clear that in 1993 and 1994 a price of £2.63 and then £2.73 was identified as the price for Ceredase as supplied in the United Kingdom.

In parallel to that, arrangements were made with Caremark for additional services to be provided at a cost of, apparently, 30p. How exactly it worked is slightly obscure - and this is an obscurity that appears both in the evidence and, I am afraid, in the decision, but it is not material to any issue - there is evidence from Mr. Cortvriend that the initial price for homecare services was £2.97.

THE PRESIDENT: You mean the drug including homecare services?

MR. THOMPSON: The price charged to the NHS when homecare services were provided was £2.97. That figure seems to derive from the first letter to Caremark of 26th March 1993 and possibly also Mr. Van Heek's letter of about the same time. However, the obscurity arises because it is clearly implicit in the first letter to Caremark that its fee, if I might put it in that way, would be 30p, whereas it is clear from the letter of 27th May that the basic price for the drug was £2.63. If you add 30p to 2.63, you come to a figure of 2.93 rather than 2.97 and it is obscure whether Caremark in fact received a

34p fee and 2.97, which seems to be what Mr. Cortvriend implies, or whether it had received a 30p fee and 2.93 or indeed some other figure. There is nothing in the primary documents hat explains what the actual arrangement for Caremark was prior to October 1995.

If the Tribunal can bear with me for one paragraph of submissions, a further complication is the VAT point, which Mr. Cortvriend explains was the reason why a lower price was charged to hospitals than was charged for homecare services, because the effect of the £2.63 price identified at page 7, when VAT is added on, is that the cost to hospitals for purchases of Ceredase was £3.09: £2.63 plus 17.5% is in fact £3.09.

MR. MATHER: And hospitals paid that price.

MR. THOMPSON: They paid that price and they had no means of recovering the VAT, so that was the actual cost to the hospital. Mr. Cortvriend says that the reason for the difference was the VAT saving. We do not know from the primary documents what the actual charge for homecare services was until the beginning of 1995. You may recall that I showed Mr Brownlee a document from beginning of 1995 the Homecare Services price had been £3.099.

THE PRESIDENT: Can you just remind us what that document was?

MR THOMPSON: Yes, it is in a different bundle, unfortunately, bundle 37, tab 28, pages 289 and 291. So that is what happens, and that is what we can see from the primary documents. We have asked, but we have not received any primary documents available to us prior to the beginning of 1995, and it is obviously a somewhat historical inquiry.

THE PRESIDENT: Yes, I'm probably going to confuse the issue even more, but in the bundle that we have got in front of us at the moment, at page 12 there is something from a little later in 1995, October, 1995 which indicates that Caremark will be invoiced at the current price, in the third paragraph, £3.09 pence per unit, and a service charge, representing a discount of 36 pence per unit be invoiced to Genzyme.

MR THOMPSON: With respect, I am very grateful because I think that is where clarity finally arrives on this question. In my submission it is clear from this that by this date the arrangement was, as it were, crystallised. The price of £3.09p was established as the headline cost of the drug. The hospital price of 2.73 was established as well, giving an actual cost to hospitals of 3.21p. Now, it's the 17.5 per cent. to £2.73, that's what you get. Caremark was adding on 36p for its costs as explained by Mr Cortvriend to Mr Van Heek in 1997, and was receiving those 36p either as a discount as is stated there or later as a service fee as it appears in the Healthcare at Home Healthcare at Home documents for provision of the homecare service from the point of dispensing as a community pharmacist.

We say that looking at their internal documents, and then the correspondence, it is plain that what had been done is that Genzyme had bundled the cost of Homecare

Service from the point of dispensing as part of the drug cost.

THE PRESIDENT: Just to quibble a little bit, I am not quite sure it is necessarily, if you mean from the point of dispensing in a physical sense that may be true, but it depends what this service is that Caremark is providing, but it is presumably providing the holding of the drug, dealing with the prescription and all the onward things from there, it is just dealing with everything that happens after dispensing, there is a bit that happens before dispensing that it is dealing with as well.

MR THOMPSON: There amy have been some storage issues, because as I understand it, until the events of May, 2001 Genzyme was responsible for delivery of the product to the community pharmacy, and so although there would have been storage that would have been no different in kind from storage in the community pharmacy, and effectively Caremark picked up the ball at the point of dispensing, and then incurred costs, and 36p was paid to Caremark to reflect those costs, which is what we say is a bundle price.

There is a small, but potentially significant exchange of correspondence at pages 13 through to 31, where two individuals who are intimately concerned with marketing of Ceredase in the United Kingdom, and then Cerezyme, Professor Cox, and Mr Manuel of the Gaucher's Association inquired about what the cost was and their initial understanding was that it was £2.73, although Professor Cox wrongly states it as £2.72.

I understand Mr Turner would be taking the Tribunal to some of these documents in relation to abuse. If I could simply summarise, particularly Mr Manuel, complained bitterly that he had been informed in 1994 that the price for Ceredase was 2.73, and this arrangement of including Caremark's costs had never been explained to him, and the Office relies on this correspondence in this connection to confirm that the initial understanding was that the drug price was 2.73 and not 3.09 pence.

I think, in the way of these things, that is dealt with in A, B and C of my note, down to (iv) under C.

THE PRESIDENT: Just before that, do you want to take us to (ii) under A, "Proposal for GH"?

MR THOMPSON: That is a very short point which I could take you to now, yes that would be convenient. That is in the same bundle.

THE PRESIDENT: It is probably chronologically slightly different, is it not, this is the earlier?

MR THOMPSON: It is, it is an important document we rely on for various purposes, and it may be appropriate to look at it now. It is at page 77---

THE PRESIDENT: In the same bundle?

MR THOMPSON: Yes, tab 2 in the OFT core bundle. It may be worth just glancing at

page 67. It is quite curiously headed "Office of Fair Trading Section 26 Notice", but it is actually underneath described as "Contents: Plan Formulation and Sign Off", it is actually a document setting out the plans for Homecare Services, and this is a document we describe on, as it were, my second point, or rely on my second point, because it sets out what Genzyme Homecare was intended to be and how it was intended to work. But the document we rely on here is at page 77 and following, and in particular the executive summary on the second page. This was a document which was presumably put to the management of Genzyme as a proposal for the setting up of Genzyme Homecare. We rely on the first paragraph of the executive summary, the last sentence. It says: "Genzyme pays entirely for the cost of home provision. It is included in the cost of Cerezyme to the NHS at the agreed price. We just state that as a bald acceptance of the OFT's case in this issue. The same statement is made further down on the other side of the page, top paragraph on the same page, it is exactly the same statement that is made.

THE PRESIDENT: That is November, 2000.

MR THOMPSON: Yes. There we say again Genzyme was looking back at the situation and was explaining that the OFT's case is basically correct.

THE PRESIDENT: Yes.

MR THOMPSON: If we then look at the DoH correspondence, which is (iv) under C, I imagine that the Tribunal is reasonably familiar with that correspondence. I do not know if it will be worth looking at that again. The points that we primarily rely on are the description by Mr Cortvriend of the nature of the service provided by Healthcare at Home at this stage.

THE PRESIDENT: We had better quickly look at, I think, Mr Thompson.

MR THOMPSON: In the same bundle, page 34, I think, is the clearest statement, the letter from Mr Cortvriend, which starts at page 33. He is describing why Genzyme is seeking special treatment, and on the second page, the first paragraph he again sets out the position clearly. "Our price of £618 is the price which our homecare provider, Healthcare at Home Ltd supplies the product to the NHS.However this, as I pointed out does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients even to the extent of thrice weekly visits to patients' homes to administer two hour infusions. In addition Home delivery and ancillary such as water for injection and infusion pumps and lines, needles, swabs etc. are all provided as part of this service together with fridges for storage of drug etc." So there they were stating that this was part of the---

THE PRESIDENT: This is the letter I think Mr Brownlee took us back to on Friday.

MR THOMPSON: It is part of the drug cost, and the price is actually quantified at page 40. This is where they actually quantified in response to the Department's request, and you

will see that the actual calculation is relation to classes identified in the Healthcare at Home agreement, and you will see it is "Home, Home Delivery Support, Nurse Visits, Waste, Homecare in summary", so all that was clearly included as the add-on cost which was being identified, and then that was quantified as 33.9p by Genzyme in the bottom column of figures. There is a list price of £3.9p and then they identify the element of that which is actually homecare services as 33.9p, and it is excluding hospital deliveries, so there again they clearly state essentially what the OFT's case is.

THE PRESIDENT: And at this stage that is what they are essentially paying to Healthcare at Home; is that right?

MR. THOMPSON: Yes, the on-cost of those dispensing, apart from the fees included in the drug tariff.

If we then move on to the theoretical position - I have done it under three headings - the usual meaning of the NHS list price, which is obviously a matter that has been explored in some detail with Mr. Brownlee on Friday. The only point of which I think it may be worth just reminding ourselves is at bundle 37, tab 32. I hope that the Tribunal's bundles were amended to include

Mr. Brownlee's second statement. I have, at the back of tab 32, three pages 3381 to 3383. This is the nub of the controversy.

Mr. Brownlee sets out his statement that he made in his first witness statement and then he summarises some points made, particularly by Professor Yarrow, and then he clarifies the situation at paragraphs 4 and 5 and, in particular, at paragraph 6 he refers to the passage at which we have looked from Mr. Cortvriend and says: "We did not understand this description to be equivalent to the normal wholesaling function for which allowance is conventionally made under PPRS. That is the essential reason why we accepted their argument that a 4.5% price cut should not be applied to their nominal list price of £3.09 but rather to the lower figure of £2.55." So that was what he understood at the time; and we submit that that was essentially correct.

MR. MATHER: Mr. Thompson, I wonder if you can help me. Just as I was turning to those pages my eye fell upon page 42 in tab 1, bundle 31, which seems relevant to this general area. It is the letter to Mr. McIan. I was just wondering - if you were aware of this - whether a reply was ever received and, if so, where we would find that.

MR. THOMPSON: We are not aware of any reply. You will appreciate that at about this time there were also letters written to the Office of Fair Trading and it may be that the two were subsumed in one another, but I cannot give an answer as to whether there was a formal reply.

MR. MATHER: Thank you very much.

MR. THOMPSON: The reason I hesitate is that some of these letters were copied to the OFT and vice-versa. It does not appear that this one was. There was a parallel letter, a

shorter letter, which I think was copied to the Office of Fair Trading, but I cannot find that at the moment.

THE PRESIDENT: Just while we are on the various points being discussed in relation to community pharmacy, dispensing and so forth, would it be fair to say that in the normal case when a medicine is dispensed by the community pharmacy it does at that point, as it were, reach the patient, that is to say, the patient has got the medicine or somebody on his behalf has collected it? In this case, even though these two pharmacies in Burton-on-Trent and Oxford may be community pharmacies in the sense that they are dealing with the general public for other things, when they dispense Cerezyme we know it has not got to the patient: it has still got a very long way to go. The question as to whether there is a read over from the conventional case to the case we have actually got arises for that reason as well.

MR. THOMPSON: Indeed. I do not think anyone can take away from Mr. Brownlee's evidence that he regards this as a categorical area. I think the highest we can put it is this. You may recall I asked Mr. Brownlee about all the costs being tangled and I think his answer was that, in those circumstances, he probably would have disallowed the cost.

THE PRESIDENT: That is exactly what he said, but it is, to say the least, a grey area. What I am not clear about, Mr. Thompson - and I just raise this at the moment - is how far this question of what the NHS list price does or does not include is essential to your argument. Supposing, for the sake of argument, it was a grey area as to what in the normal sense the NHS list price did or did not include, does your argument still remain, "It does not actually matter what it does or does not include, we have still got a situation where there is one price for, effectively, two things: the drug and the service and they should be separated"?

MR. THOMPSON: Obviously, I have given this matter quite a bit of thought in the last week and it does seem to me that there is a fundamental point of principle that Professor Yarrow's arguments, however persuasive they may be - or not, as we say - does not address, namely, that these are costs that are being incurred by the pharmacist and, as such, as a matter of principle, should not be reimbursed out of the NHS list price. The list price is intended to reimburse the pharmacist at the point of dispensing for the cost of the drug, which is the cost of manufacture and the cost of wholesaling, bringing the drug to that pharmacist.

THE PRESIDENT: That is where it gets more difficult. I probably did not put my question very clearly. Let me have another go. Supposing it is not very clear, or at least not sufficiently clear, what the NHS list price is supposed to include in a case like this. In other words, supposing one cannot be unequivocal as to what the NHS list price is in some sense supposed to include or not include, not least because no-one has ever

defined what the NHS list price is, let alone defined it in a rather atypical situation like we have got here. Supposing we have got that situation. Is it central to your argument to identify what the NHS list price does or does not include; or does your essential bundling argument still stand, whatever it includes in terms of the National Health Service Acts, the drug tariff and the arrangements for prescriptions and reimbursement of prescriptions? Does it matter to you what is or is not included? Because your essential argument is that there is included in the drug price one price for two different things and it is anti-competitive to bundle them together. That is an argument that one would have thought can be stated without us needing to go into what the NHS does or does not include.

MR. THOMPSON: I think that is certainly true. The reason why it really does matter - and I think it is a question you put to me on Friday - "Is it not obvious that it is a bundled price?" - you may recall that Mr. Vaughan - it is another theme that runs through the Genzyme documents - argues that this is all de minimis, we are talking about 42 people receiving nursing homecare and that the most the bundling relates to is the free provision of occasional nursing care to very few people. That is where Professor Yarrow adds in some points about supermarket checkouts and small incidental free additions.

Our point is that that is a travesty of what happened. All of Caremark's costs, whatever they may be, were added on to the price of the drug that Genzyme stated to the NHS in 1993 and 1994 and identified again to the DOH in 1999 and 2000.

THE PRESIDENT: I think what you are saying is this. In a sense, we have got into this whole issue of the NHS list price partly, at least, in response to the argument that was put against you by Genzyme, which says, "The NHS list price conventionally includes delivery - that covers most of it - and the rest is de minimis, so over and out."

MR. THOMPSON: Yes.

THE PRESIDENT: That is the essential argument. You then feel that you need to counter that by going into, in more detail, what the NHS list price does include.

MR. THOMPSON: Yes. Can I put it in another way? Supposing Genzyme came along and said, "We are going to bear all these costs ourselves as a manufacturer's cost", then it might be a more difficult question for Mr. Brownlee to say, "We're going to disallow that anyway, because that is not of a kind that is conventionally allowed." It is a completely different thing to say that the costs that Caremark is actually incurring and that Genzyme is not incurring at all should be put onto the list price so that Caremark should have to try and get the money back out of Genzyme.

THE PRESIDENT: Is that a fair distinction? In this case and in the later case of Healthcare at Home, Genzyme was paying Caremark and, subsequently, Healthcare at Home a fee, 33p, which you could have said was a cost to Genzyme. You could have expressed it

as a discount, but you have actually expressed it as a fee paid, so the manufacturer is incurring that cost. In other words, he is paying someone for, among other things, the process of getting the drug from the pharmacy to the patient's home. One point on which Mr. Brownlee left matters open was how the PPRS would work in such a situation.

MR. THOMPSON: Indeed, at that time that was what was happening, but of course our complaint there is that that put Genzyme in charge of the situation.

THE PRESIDENT: I know what the complaint is, but the complaint seems to me to be capable of being stated without necessarily having to analyse in great detail the arrangements for reimbursement of pharmacies under the NHS, which is what the NHS list price is primarily directed to.

MR. THOMPSON: In my submission, that is certainly correct, but the OFT's point is one of principle and also one of fact: that in reality these costs were not borne by Genzyme and were an additional cost added on to what Genzyme required for the drug.

THE PRESIDENT: You say they were not borne by Genzyme. Genzyme was paying Healthcare at Home. Why is that not a cost borne by Genzyme?

MR. THOMPSON: I am looking back to the original position in 1993. I agree that in the end Genzyme did meet them, but out of the NHS list price. So that was, as it were, after the bundling had taken place.

THE PRESIDENT: Let us go on.

MR. THOMPSON: Then D.2 is essentially the material that we have been discussing now. I do not think it is necessary to look this up. This is Mr. Derodra the Genzyme Homecare community pharmacist. At paragraphs 33-4 he explains that the pharmacist's remuneration does not normally include any payments for services. That is reflected in clauses 6 and 8 of Part 2 of the drug tariff, which I do not think it is necessary to look at, but that is how that works. That was confirmed by Mr. Brownlee in his evidence in response to some questions to me: that the drug tariff would not normally cover payments to pharmacists for additional services, even if those costs were quite small, as in the case, for example, of the dispensing fee.

THE PRESIDENT: Could I just say this? In general, we are a little bit hazy about the system for zero discount drugs?

MR THOMPSON: Yes, can I help you on that. You may recall that there is a document in the bundle, it is called "The Translucency Report". It is in the core bundles, and I did have a reference for this, but I have lost it. It is at the beginning of volume 2, which is bundle 38. It is the first tab in bundle 38 and at page 401, paragraph 6.3.6, you will see the matter is set out clearly. "Zero discount products distributed by a wholesaler, the wholesaler will retain the whole of the discount provided by the manufacturer to cover the extra costs of distribution. The zero discount products distributed directly by the

manufacturer, the manufacturer gives no discount to the pharmacist". The it sets out the unfairness of the pharmacist having to cough up any clawback in such circumstances.

The first instance, as I understand it, is where the product is difficult to wholesale for some reason, it is rather expensive and so it is not perceived that the wholesaler will give any discount on the 12.5 per cent. The second is the one we are dealing with here where, for whatever reason, the manufacturer refuses to give any discount at all to anybody and in this case that is why it is a zero discount drug.

MR MATHER: I seem to remember Mr Brownlee saying that sometimes pharmacists did receive discounts for zero discount drugs. Can you cast any light on that, if my recollection is correct?

MR THOMPSON: Well, there are issues of fact which I do not think in the wonderful world of the PPRS or the reimbursement regime are necessarily reflected in the reimbursement, and I think everyone accepts that the clawback is only a broad equivalent to what pharmacists actually get by way of discounts. I cannot remember that is the point that Mr Brownlee was making. There is a provision in the Drug Tariff that these are only zero discount drugs if you do not show that somebody actually got a discount, something to that effect. So again a zero discount drug is not always zero discount.

MR MATHER: Nothing is ever as it seems. Thank you very much, that does clarify that.

MR THOMPSON: I think that is right. I should add on the point of zero discounts, Mr Morland's statement of this morning also has some remarks about zero discount drugs at paragraphs 32 - 7, which I think are broadly consistent with what I have just said - I hope so. I think in relation to Professor Yarrow, we have made our points fairly forcibly in the pleadings, and I think I have said this morning the points he fundamentally overlooks are the fact that these costs are all scrambled up as part of the overall homecare service delivery. He appears to us to substantially under describe what is involved in homecare services.

THE PRESIDENT: When you say the costs are all scrambled up, what do you mean by that exactly?

MR THOMPSON: Even if he were right that there is some element that could be described as wholesaling, for example---

THE PRESIDENT: Or some analogy could be drawn?

MR THOMPSON: Yes. In fact, it is a single costed service, both internally, and one sees that from the proposal for Genzyme Homecare, and indeed for all the cost materials that have been produced, first of all by Dixon Wilson, you may recall there was a report which, I think, was referred to---

THE PRESIDENT: It was in the interim measures.

MR THOMPSON: Indeed, and Mr Williams as well. I do not think anyone has suggested

that the costings are based on the way Professor Yarrow puts it. He appears to us also to overlook the fact that these are costs actually borne by somebody else, either Healthcare at Home or Caremark or, at least, as a matter of cost allocation Genzyme Homecare, and it is only a matter of Genzyme's choice, whether it reimburses those costs.

We then look at the position about the Department of Health. I put it in blunt terms: were the Department of Health misled in 1999/2000? In my submission, that is the implication of the way that Professor Yarrow, and Mr Williams put it in their latest evidence. Mr Brownlee gives evidence that his understanding was that this was a bundled price, including non-standard elements that would not normally be in the NHS list price, but the value of those elements was 33.9p. It is clearly implicit in that evidence that Genzyme were saying that its return on the drug was actually £2.75 but its projected return would drop to £2.55 and that it was content for its projected return to be calculated on the basis that after the 4.5 per cent reduction it would go down to £2.43. That was the whole basis of what they were asking for, that is what they put to the Department of Health. But we are now told that that was all a transparent falsehood.

Secondly, the points of principle that are made, is this a bundled price? We say it clearly was and that the Department of Health was not being misled about that. The second point that Mr Williams now seeks to make is that because in fact Genzyme's Homecare service costs have dropped since 2000 means that it should now be permitted to argue that a higher stand alone price is justified. In response to that we say that Genzyme has benefitted on the bottom line from any savings in costs that it may have made, which we do not accept, but if it has made savings in costs we say that that is no basis for a price increase on the drug, the fact that it is saving money on its homecare services, we see no reason why the Department of Health should have accepted that as a reason why Genzyme should make a return of 2.80 or 2.90 or whatever on the drug, because in fact its homecare services are much cheaper than they said they were going to be in 1999.

Looking at the issues of quantum, the Tribunal already expressed some question marks about the 20p and you have heard what Mr Brownlee had to say about that with the benefit of hindsight. The other points, the actual costs of Homecare Services in 1999 were 33.9p on the basis of Genzyme's own figures. The historical costs, on the basis of what documents we do have, appear to have been between 30 and 36 pence per unit, and the contractually agreed homecare services costs for healthcare at home seem to have been 28.43p per unit, so it appears that Healthcare at Home, as it were, shared in the price cuts - approximately half in net terms of what the 12p price was accepted by Genzyme.

We then look at the projected costs. We have already said that is essentially irrelevant. There is the Dixon Wilson Report which was at least a proper report, and we have no explanation from Mr Williams as to why his version differs from the Dixon Wilson report or why he thought it appropriate to produce such a report at this late stage.

Then we have Mr Williams's second report, which I would like to take the Tribunal to briefly. It is bundle 37, tab 25. We have already made some gentle grumbles about the circumstances in which it was produced, but that is not the reason why I go to it now. The reason I go to it now, is that it appears to us to have some quite remarkable mistakes in it. The first is at page 252, paragraph 15B. Mr Williams states that there was a mistake in the argument advanced by the Department. He says "The actual costs for providing the service to Genzyme, post 1999, when they had brought it back in house were significantly lower than those incurred by HH. So he makes it clear that he is assuming that Genzyme Homecare have actually brought Homecare in-house, at the start of 2001, whereas the Tribunal will be well aware that in fact Healthcare at Home has been providing homecare services on a continuing basis, essentially at its own cost, for that period. It is a somewhat worrying feature in that it appears questionable what instructions Mr Williams has received about the actual fact, but it is also of considerable significance to the later cost calculations that he makes which seem to be on a completely false basis.

MR VAUGHAN: I am sorry, I can't resist it any more. Mr Williams was here on Friday. My friend knows perfectly well he was here on Friday, and if he wants to put those points they should be put, they are fundamental points, not construction or interpretation.

THE PRESIDENT: Let's see how we get on, Mr Vaughan.

MR THOMPSON: The second remarkable feature is at paragraph 26, when you will see a calculation of Healthcare at Home's costs. I am not entirely clear why this has been undertaken at this stage.

THE PRESIDENT: We need to be a bit careful about figures in this public hearing.

MR THOMPSON: I will not state the actual figure. You will see that the penultimate entry states a sum for the hospital discount, and in my submission it is self-evident that the hospital discount is not a coset of home services, and should not appear in that figure, so that Healthcare at Home's costs are quite dramatically overstated.

MR VAUGHAN: It is related to an analysis of the invoices.

THE PRESIDENT: Well we had a lot of evidence, or at least I had a lot of evidence, in the interim measures' proceedings about what the costs were, and there is, I think, one point in that judgment where one collects up the various bits of information one has, historically and otherwise about the sorts of margin homecare service providers in this

industry conventionally seem to earn, and the figure within a range seem to have a centre point of about 10 per cent. at the margin. That was the net result of the evidence at the interim measures stage.

MR THOMPSON: Yes, I am simply dealing with Mr Williams' report, because it has been put to us at a late stage as apparently showing that the Department made a great mistake. Paragraph 31, Mr Williams states that approximately two-thirds of Genzyme's sales of Cerezyme in 2002 were into the homecare sector rather than into NHS Hospitals. Then he states that implies approximately 4,300,000 were supplied into the homecare sector. Then in the next paragraph he estimates a cost which I will not state. Neither of the statements are transparently accurate, and neither of them have any obvious factual basis. The more important point is in paragraph 33, those figures are used to calculate Genzyme's homecare's costs per unit, and you will see that the full number of units and the full costs have been used for the purposes of that calculation, thus assuming that all the units delivered are delivered by Genzyme Homecare, i.e. approximately to 150 people, whereas the reality is they are delivered to 15 people. So taking a reasonable assumption that all Gaucher patients use approximately the same amount of Cerezyme, it is necessary to divide the number of units by 10 and to multiply the average cost by 10, suggesting that the Genzyme Homecare operation is extremely expensive, per unit.

Although we have asked for clarification---

THE PRESIDENT: Well that may well be the case on the small amount of volume that they have which raises a further issue about what you do to calculate the margin, what assumption do you make about volume, that is true.

MR THOMPSON: So we asked various questions of clarification. In particular we asked for the papers on which these calculations were made. We have had no satisfactory response although there was an offer that we should go up to Oxford and go over some documents, last Tuesday, I think, with Mr Williams. It appeared to us that that was not necessary or appropriate, in that this report plainly contains some gross errors.

The final point that Mr Williams makes is at paragraphs 36 to 41, where he compares the costs of homecare to the normal wholesaler margin, and you may recall that I put this to Mr Brownlee, to ask him whether it would be a relevant consideration in allowing or disallowing a cost, that it was more or less than the wholesaler margin. In my submission, that is entirely irrelevant. For example, the pharmacy fee is approximately 90p for dispensing £9000 worth of Cerezyme. It is not a relevant factor in deciding whether or not it is allowed. It is a cost to the pharmacist and it is not allowed.

I think you can take it that we are not impressed with Mr Williams' second report as a basis for the appeal.

The final point here is Genzyme's required rate of return, and I simply summarise some historical materials to indicate the type of rate of return that Genzyme appears to have been satisfied with since Ceredase and Cerezyme were launched, and that is (iv) on page 4.

THE PRESIDENT: You talk about required rate of return----

MR THOMPSON: That is not the right word - required return on the drug.

THE PRESIDENT: Revenue, you mean, or price?

MR THOMPSON: Price, I think, "rate of return" I agree is unfortunate.

THE PRESIDENT: "Price" may be better.

MR THOMPSON: Well, I think "return" for the drug. Initially it was $3.50, which is about £2. or £2.33, and you find that in the original statement of Mr Cortvriend. It was then 2.63 and you find that in the document we looked at. It was then 2.73 apparently from 1994 to 95. From 1995 - 98 under the arrangements of Caremark, it was 2.73. 1998/9 it was 2.75 and one finds that in the figures quoted to the Department of Health. Then there was a projected decline to 2.55 on the basis of the stated forecast increase in costs, then it was £2.43 from 1999/2000 after the 4.5 per cent price cut or, if one discounts the 20p as a bit of froth then it was £2.63 once the price cut had been imposed. Then the actual return in relation to Healthcare at Home was £2.69 after the 28.43 was deducted from the reduced price of 297.5. By way of comparison the return for hospital sales has been 2.73 continuously since 1994. That is what I wanted to say about bundling.

I have got a bit behind the time, but I will try and take the definition of homecare services relatively quickly because that is, I think, a point we have set out in considerable detail in our evidence.

The first point I would make - I have set out the references to the defence - under the heading "Demand Side Evidence" the Tribunal here heard directly from Mr Farrell so I will not take time over that. I would, however, like to show the Tribunal the specification for the Birmingham Children's Hospital. That is attached to our skeleton argument. It is bundle 45. It should be somewhere in your document 5; I do not know why.

THE PRESIDENT: Yes.

MR. THOMPSON: Birmingham Children's Hospital NHS Trust. You will see that it is a specification for homecare services, delivery of pharmaceuticals and associated services for patients in their own homes. Then there are general aims and the points on which I specific rely are under 2, "General management of all BCH packages." At 2.4 - ---

MR. VAUGHAN: Go to 2.2.

MR. THOMPSON: Yes, "The supplier will need to demonstrate their ability to provide and

manage a homecare service for different groups of patients." That is because this is a block contract specification.

MR. VAUGHAN: Just read it.

MR. THOMPSON: Then there are a number of conditions.

THE PRESIDENT: We have read the conditions, Mr. Vaughan.

MR. VAUGHAN: Thank you.

MR. THOMPSON: Paragraph 2.4 requires ISO 902 accreditation. At 2.5: "The supplier will need to demonstrate the ability to provide nursing care and training." At 2.6 there is a requirement for individual co-ordinators "... who will be responsible for integrating all aspects of the care packages for the patient." Then 2.7: "Relevant advice and information must be available 24 hours a day." 2.8: "Clinical advice to be given by named specialists only - BCH specialists only." 2.9: "The supplier will need to demonstrate the ability to monitor patient treatment adherence and concordance when appropriate." At 2.10 there are some requirements in relation to communication, but particularly the last sentence: "Emergency supply will be provided at the same cost as the normal service" and, indeed, 2.12: "The supplier will be able to supply patient care and support and information in languages such as Urdu." 2.15: "The supplier will ensure the service is patient-focused, taking into account individual patient needs, patient feedback and changes in circumstances." Then 3.3, the provision of equipment and services - 3.3, when a refrigerator is supplied. 3.6: "There must be explicit arrangements for the disposal of the hazardous waste", and then there are detailed requirements in that respect.

Then at 5 there are detailed requirements covering delivery schedules, storage and stock replenishment. In particular, the second sentence of paragraph 5.1: "Delivery schedules must be flexible and allow delivery to alternate addresses, e.g. workplace, GP surgery when required for parental convenience." 5.3 requires delivery dates to include evenings and weekends and says: "Deliveries will be made within one hour of the agreed time or the patient carers will be contacted to re-schedule the delivery." Then 5.5 is a provision for unpacking of refrigerated items. 5.7: "The service should be flexible enough to enable the patient to take holidays within the UK and abroad." 6 requires approval of subcontractors.

Then 8, provisions in relation to reporting to the trust. In particular 8.4 requires records and approval of clinical data. Then 9.2.2 on the next page sets out detailed requirements in relation to nursing.

You will see that this is all under the heading of general requirements for the specification. Then there are specific requirements further on for particular conditions.

I have taken that quite briefly but, in my submission, there is an instructive comparison when one looks at the other document, the terms and conditions for Polar

Speed, which you should find at the back of my skeleton argument. It is a shorter document in smaller type.

THE PRESIDENT: Just before we go there, Mr. Thompson, I am just glancing through this document and if you just look at the particular packages for the particular drugs you will see that for the one done under 9.1 there are 75 patients requiring homecare; under 9.2 there are 12, that is, at 9.2.5; at 9.3 there are 22; under 9.4 there are 75; under 9.5 there are 150; under 9.6 there are 9. Then 75 under 9.7 and under 9.8 - I cannot see it at the moment. Then they identify the number, yes.

Then 9.8.11 is quite interesting, because that is apparently covering the UK and Northern Ireland.

THE PRESIDENT: You want us to compare that with Polar Speed.

MR. THOMPSON: I am told that it is before the specification.

THE PRESIDENT: It is, yes. It is just before that.

MR. THOMPSON: It was not attached to mine for various reasons.

In my submission, there is quite a striking difference between these and it is particularly paragraph 6, the terms in relation to delivery, where all that is required is to use its reasonable endeavours to deliver.

At 7.1: "The company shall make one attempt to deliver", and there is actually provision for the goods to be disposed of after seven days. That is 7.3.

Then at 8, there is no obligation to provide any plant, equipment, machinery or labour for loading or unloading. "Any assistance given beyond the usual act of collection shall be at the sole risk of the client." That is paragraph 10. At paragraph 12.1.1, the liability is limited to £250.

We say that that tells quite an important story about what homecare services are, even in relation to home delivery, and that Polar Speed is not in the same business, which is not to say that Polar Speed is in any way a bad company: it is simply not in the same business as a homecare services provider.

If we then go on with the headings quite quickly, there are some internal documents which I have already showed you. This is under 3.3 on page 5 of the note. We have already glanced at the internal documents about the setting up of Genzyme Homecare.

The marketing materials relate to the way in which Genzyme Homecare was launched and the way in which it was described. I think there is one document I should take you to, which is the specification for the Manchester Children's Hospital, which is at bundle 31 in the OFT core bundle, tab 2, page 90. I think it is sufficient just to read the heading "Background". This seems to be a document which was produced by Genzyme Homecare as its specification for homecare services, rather than a document produced by Manchester for what it actually wanted. That is by the by and it is perhaps

a somewhat prejudicial comment.

Under the heading "Background", in the middle two paragraphs, it says: "Genzyme has now decided to take the service level to greater levels of excellency by creating its own in-house service. This service has been designed to provide first-class support to the Gaucher patient population, but also to lay the foundations for service provision to Fabry and other patients suffering from rare metabolic diseases. The service is clearly focused on this patient population. The philosophy is bespoke and flexible rather than call centre. Our team is highly experienced and all members possess outstanding professional and personal qualities which are the pre-requisite of any such peerless service."

Again, we say that Genzyme was clearly portraying itself as in the same type of business as the homecare services providers and not in the same type of business as, say, Polar Speed.

The same tale is told in various places in the Genzyme witness evidence. I have given the references to some items under sub-heading 5. I do not think we need to turn it up, but there is a long description of homecare services in the first statement of Miss Kelly at pages 655 to 662 of bundle 38, tab 45, but I think it would be worth just looking briefly at the oral statement of Miss Kelly at the hearing before the OFT, which is at the same OFT bundle, tab 3, pages 138-9.

You will see it starts on page 137. There is a question from Miss Fletcher at the bottom of the page, where she asks: "You spoke quite a lot about the 28 homecare patients. I want to ask a little bit more about the 85 self-administering patients. In particular, I was wondering if anyone could expand on what the delivery to those patients comprises. How specialised is it? Is there a degree to which there are waste disposal services involved and what do they comprise? And the extent to which nurses are available, at least on call or attend occasionally." Mr. Vaughan says he would like to deal with it, but in fact Miss Kelly ----

MR. VAUGHAN: I said that Miss Kelly should deal with it there and then.

MR. THOMPSON: Yes, so Miss Kelly deals with it.

MR. VAUGHAN: Do not misrepresent me.

MR. THOMPSON: Miss Kelly says, "On average, patients receive prescriptions for deliveries about once every two or three months. That is the average life of the prescription, shall we say. They visit their metabolic physician, in this case one of four centres. The doctor will make an assessment and then he will write a prescription against what he feels is their current clinical condition. I cannot speak for Healthcare at Home deliveries right now, because we have not been involved with them, so what their services are I cannot describe. I can certainly describe what our services are." Then there is a description of the delivery and of the refrigerator etc. Then the

Customer Services Department and waste disposal.

Then the passage on which I particularly rely in relation to nursing is at page 139, line 7: "As far as the nursing services are concerned, this is an apples and pears story, because patients are individuals and their needs are individual. For lots of patients who have been having treatment for a long time and who are doing really well, the most they have is an occasional phone call. For others, if they have a wobbly moment for various reasons or if they suddenly get a little bit sensitive, then we offer a respite service. In terms of who do we offer the medical support line to, it is anyone really - in the notes in the file that the patients get at home - the nurses carry a rotating bleep system, so there is always someone on call 24 hours a day. That cannot be necessarily just Gaucher related. You could have left your drug out of the fridge, you could have run out of needles. All those kinds of basic things that happen in hospitals as well, routine life, as well as happens to patients at home. There is someone at the end of the line in case you need to call them. I think that is where it is an advantage having some knowledge of metabolic disease, because you have an idea of how this should be going. It is not like chemotherapy. It is a different kind of environment. That describes from a practical point of view what happens to the patient at home."

MR. VAUGHAN: Would you go on? She goes on with this.

MR. THOMPSON: Yes, then there is more about ----

MR. VAUGHAN: The rest is in CB 37/38, where the full text is, not just this truncated bit. It is CB46, which is volume 38 - 45 and 46 - 45 is her witness statement.

MR. THOMPSON: There is a great deal and, indeed, the statement that Mr. Morland has put in this morning goes over a good deal of the same ground and, as it were, reiterates the bespoke and flexible nature of the service, which is, of course, something we rely on.

Then over the page. I do not think it is necessary to go to all this material, because it is very fully set out in the pleadings. We rely on a number of letters where Genzyme describes the nature of the service and quite a substantial amount of evidence in relation to, particularly, Healthcare at Home, Clinovia but also to the other two main players, which are set out on their websites, which are in the bundles and in the description in Mr. Jones' statements.

Then the only other point I would make relates to the implications of Professor Yarrow's theory that this is actually a rather standard form of delivery. It would appear from his theory that there must be a way in which Polar Speed could stand in for part of the service. The evidence before you is that there have been occasional instances in which that has been done in particular circumstances. But, in my submission, it is quite clear that Polar Speed cannot really step into the homecare services providers' shoes in any substantial sense; indeed, such a suggestion is inconsistent with the rationale for

the creation of Genzyme Homecare, because if that was right then they could simply have used Polar Speed or, indeed, on Professor Yarrow's theory, the local milkman, as far as one understands it, but there is no suggestion that Genzyme itself has ever considered that as a possibility. Indeed, Mr. Morland this morning said that that would be entirely out of the question. We say it is also totally inconsistent with the evidence we have been through.

There is a further point, which is my last point, the question of the downstream market definition, where I think Mr. Vaughan said yesterday that we had effectively conceded the point and this was fatal to our case: that we had conceded a point on that downstream market definition. I do not know whether the Tribunal is attracted to that line of argument.

THE PRESIDENT: Just remind me of what point it is that it is thought you have conceded?

MR. THOMPSON: You will recall in the defence, and particularly in our skeleton - and it reflects something that is in the decision - that the only reason why downstream homecare service delivery for Cerezyme is treated as a separate market is because of the pricing abuse on the upstream market. If it were not for that, the market would open up and the competing suppliers would be able to compete.

Mr. Vaughan appears to think that that is a concession that, as it were, our downstream market is a bit of a "try on" and that we do not actually believe in it.

In my submission, that is not correct. We have both the analysis of the MMC, which we say is essentially the same, and there is the ----

THE PRESIDENT: We have not gone to that yet. I think we ought to just quickly have a look at that.

MR. THOMPSON: It is bundle 38, tab 39. There is something in the introduction about this, but I think the clearest statement is the one to which I have referred, which is pages 436 to 437, paragraph 271. The first sentence, 271, makes a general point about homecare services: "In the case of the services considered in this inquiry, there is no substitutability on the demand side in the usual sense, because each treatment is specific to a particular condition, although it is possible for purchasers to re-define the requirement, for example by hospitals providing compounding and nursing services and contracting out only the delivery element."

So there are variations, but, because the product is different, from a demand side point of view one needs to look at each condition separately.

Then they go onto the supply side: "The issue of market definition therefore depends principally on the extent of supply side substitution, that is the ease and speed with which a producer of one product or service is able to offer another in response to a price rise or the opportunity to offer the service at a lower cost.

Then they ask the question whether the treatments are all in the same market,

at 2.72, and then at 2.75 " We believe it is necessary in the light of this evidence to draw a distinction between contracted and prescribed services. Prescribed services..." and that is in the MMC terminology, this is a prescribed service, "...the possibility of entry by service providers depends on their ability to establish a relationship with the product supplier, which is the sole source of remuneration and in effect to sell their services to them. The product suppliers therefore effectively have the discretion, if they so choose, to foreclose the supply of homecare services..."

Then, "...either by providing the services in-house, vertical integration, or establishing preferential relationships with individual service providers, vertical agreements, and in practice with the partial exemption of IG have done so. Such foreclosure clearly limits the scope for supply side substitution."

So we say that our analysis is entirely consistent with that and because of the particularly rigid market situation that prevails now, it is particularly appropriate to look at this market in isolation in terms of assessing market power and abuse of dominant position.

The second point we make is a point indeed that Genzyme makes from time to time, that the market definition question is a functional question, targeted at particular types of conduct, and we say that the case law on tying and bundling is entirely consistent with our approach.

For example in Tetrapak it would have been no answer to the case on abuse to say that the cardboard suppliers who were unable to enter the packaging markets could have gone and made cardboard, for example, for cereals or some other use. Likewise, the fact that the nails for Hilte nail guns, it was no answer to suggest that nail suppliers could have made nails for something else. Likewise Napier Brown would be ridiculous for British Sugar to have said but they could always deliver something else even if they cannot deliver our sugar, and the same in relation to Telemarketing. It would have been ridiculous to suggest that the abuse was eliminated because the marketing company excluded from Luxembourg television could, for example, have offered its services on French or Belgian television. We say, as a matter of principle, that it is a nonsensical argument.

From the point of view of technicality, the Genzyme relies on what is often called the cellophane fallacy, whereby market definition can be affected by pricing conduct of the dominant supplier on the market. I do not know whether the Tribunal wishes me to develop this point. We say that that is a quite different situation from the one that prevails here. Here we have an abuse on a different market, which is creating an insuperable barrier to entry on the downstream market. We say that there is absolutely no reason why the Office of Fair Trading should ignore that for the purposes of market definition. It is precisely the Office of Fair Trading's point that the conduct of

Genzyme is constraining the nature of competition on that downstream market.

Then finally, for good measure, if one applied a classical SNIP test and contemplated Genzyme increasing its bundled price by 5 p, for example, that would obviously make no difference, it would be no easier for a competitor to enter the market if Genzyme put up its prices slightly because the whole thing is a closed system, and they would still be unable to purchase the drug at lower than the bundled price. So we say on all grounds the definition is correct, and for a functional purpose is the correct market to look at.

Those were the points I was going to make. I will now hand over to Mr Turner.

THE PRESIDENT: Thank you, Mr Thompson.

MR THOMPSON: Do not worry.

THE PRESIDENT: It is probably the Tribunal's fault, or more particularly, the President's. Take your time, because I think we are going to have to have another hearing in any event. I do not want anyone on either side to feel rushed.

MR TURNER: That is of assistance, Sir. I propose to address the following issues. First, under the heading of "Abuse", the inter-relationship between the two abuses, bundling and margin squeeze, then to move on to the nature and extent of the harm that results from Genzyme's pricing policies, by reference to a few points in the key evidence; and finally, to look at the defence of "objective justification" that has been advanced by Genzyme, and to touch on some points in relation to four heads that have emerged, namely, that it is common practice in the industry to engage in this form of pricing, that Genzyme's pricing practices ensure a high quality of service to the patient, that Genzyme's pricing practices what they call "bringing the service in-house" is more cost effective than if there were conditions of competition; and finally, the idea of a tacit Department of Health approval of Genzyme's pricing practices.

If I may begin by turning to the link between the two abuses. This may be of particular significance in that it may bear on the question raised by the Tribunal which Mr Thompson is shortly to deal with, about whether the abuses really can be said to fall into two distinct segments, namely pre-May, 2001 and post-May, 2001.

In my submission one way of looking at the matter, which is useful and instructive, is to see the two abuses as really two sides of the same exclusionary coin, and to think of it in this way that bundling chokes off the demand from hospitals from independent homecare providers, because it is not economic for the hospitals to use anybody else.

From the other side the margin squeeze chokes off the supply from independent homecare providers, because it is no economic for them to supply homecare services in competition with Genzyme Homecare. In both cases the effect is

the same - the field is closed to everyone apart from Genzyme's chosen provider, and the difference between the situation pre-May, 2001 and post-May, 2001 when viewed in that way is that Genzyme Homecare has been substituted from May, 2001 as the chosen provider instead of Healthcare at home?

PROF GRINYER: But you see no difference in principle?

MR TURNER: In principle, no, that in-house operation is then within the magic circle. It does aggravate the position to some extent, that is true, in particular because of the market perception that Genzyme Homecare is identical to Genzyme the drug manufacturer. That was the source of some of the grievances that, for example, Professor Cox gave voice to.

It does not fundamentally alter the exclusionary analysis, and standing back what that means is that at all times, since the Act came into force, on 1st March, 2000, the customer - the NHS - has not had control over who supplies homecare to the Gaucher patients, or control over the terms of that supply.

THE PRESIDENT: So a choice of provider has been an abuse since the Act came into force. There is no exclusive distribution arrangements for this drug. In other words, the original agreement with healthcare at home became illegal on 1st March.

MR TURNER: To the extent that it was a symptom of that practice, yes.

THE PRESIDENT: Well, it was an exclusive distribution agreement to the extent that it meant that Genzyme prevented itself from supplying the drug to anyone except Healthcare at Home for distribution in the United Kingdom, that is an abuse?

MR TURNER: Yes, that was I think clause 2(3)(A) of the distribution agreement of February, 2000, and it would appear that to the extent that happened, that that would have been under it.

Now, if I may turn from that description to the adverse consequences of this situation in which the company, Genzyme, controls the provision of homecare which has obtained, as I say, since 1st March, 2000 at least, and there are at least three detrimental consequences. The first is that the NHS does not control the specification of the homecare service provided for its patients. It is Genzyme which does so,and Genzyme which has its own distinct views about the desirable scope and extent of the service that is to be offered, and if I may take you to one document in that connection, it is in the OFT core bundle, 31, at tab 3, page 129.

This is a document, an extract from which has appeared in submissions, but this is the full document. From Miss Kelly of Genzyme, to the representative of Healthcare at Home, dated February, 2000 - around the time of the renegotiation - and in particular in the second paragraph, regarding certain patients, Miss Kelly says "As we have discussed many times in the past, it is not the intention of the service funded by Genzyme to provide other than respite care for patients who are receiving Cerezyme

infusions at home." She goes on to explain the reasons for that and says "...whether the nurses are willing, as you describe, to take the patients home is not the point in question".

THE PRESIDENT: What is respite care there?

MR TURNER: Respite care, as I understand it----

THE PRESIDENT: Is that when the carer needs to have a break?

MR TURNER: I believe it is not. It appears from the extract from the oral hearing that Mr Thompson went to, but I will be corrected if I am wrong, it is the situation where a patient who is otherwise stabilised, has a "wobbly moment", as it was described, and there is a need for some further care to take place to met some crisis - for example, they lose confidence in re-cannulating, or cannot find a vein or something of that description.

Then the other paragraph three up from the bottom on that page: "It is the responsibility of the local hospital to undertake infusions if the patient is unsuitable or unwilling to self-infuse, or the carer, not Genzyme or Healthcare at Home. The very last time of writing, please instruct the nurses accordingly".

So what one sees there is that the company has its own strong views about the shape and contours of the service that is provided to patients, and Genzyme has, moreover, expressed some concern about the possibility of the specification for the service being defined by the NHS, as opposed to itself. One finds that, for example, just to provide the reference, on day one of the transcript in Mr Vaughan's submissions on page 63, at lines 14 to 23. You need not turn it up but I will simply quote what was said. "Mr Cox refers to tendering every two years, and so if that was the system, you do not know who is going to be carrying out the nursing services, from anywhere within the community. From anywhere in the community there may well be people who win the tender, so we would have no control whatsoever, we cannot guarantee it would be Healthcare at Home who wins the tender under the current procurement rules."

Then Professor Grinyer asked: "Is it your suggestion, Mr Vaughan, that you will have a better ability to control the quality of the homecare provision than, say, Mr Farrell or other providers dealing with tenders?" Mr Vaughan: "Yes, because we are just dealing with us. He wants to deal with all these on an equal basis."

In the same connection, I would refer briefly to the terms of the distribution agreement that was concluded in February 2000, which is highlighted at paragraph 6 of the OFT decision, and that distribution agreement the Tribunal may just want to look at in bundle 33 at annex 2 and there you will see the agreement. At paragraph 2.1, under the heading "Appointment": "Genzyme hereby appoints the distributor as its sole and exclusive distributor of product to users throughout the territory together with other services as may be requested by Genzyme subject to terms of this agreement".

Then one goes from there to paragraph 6.4 to 6.6: "Distributors shall provide the services specified in the distribution procedures agreement to each patient according to his designated patient group. Services shall be provided in compliance with all relevant regulations and professional guidelines, and the provision of the services referred to in clause 6.4 shall comply in all respects with the distribution procedures agreement.

6.6 relates to the amendment of that agreement. In fact, it appears that no such written agreement was ever concluded. So that what one has is simply the structure that you can observe and in conjunction with such indications as the communication from Miss Kelly to Healthcare at Home to which I have just referred.

That then deals with the specification, the shape of the homecare services. The second issue is that the customer does not have control over the ongoing quality of the service either, and this was a point that arose in the course of Mr Farrell's oral evidence, and is also dealt with in his statement. The President, Sir, you referred to the meeting note between Mr Farrell and the Office of Fair Trading in December, 2001 as Mr Farrell was giving evidence,and in that note under the heading "Advantages of an independent homecare provider..." I do not think we need to turn it up just for this point, Mr Farrell made the point that Trusts can make their own decision about the best homecare provider, and remove them if they are not performing well. He specifically identified that as the advantage of a system where he can choose.

The third point is that there is, under Genzyme's pricing policies, no price competition that can occur between service providers, which there could be if the NHS were allowed to put the business out, for example, to tender, or otherwise to negotiate.

In response to that point what is said against us is that the market is minuscule, and Mr Vaughan has referred to only 42 nursing patients on more than one occasion. But the point is, first, all Gaucher patients treated at home obviously are covered by the Homecare arrangements. Their needs vary and the service is dynamic. But far more importantly than that, as Mr Thompson was indicating, if the bundling is ended you will have potential competition, as matters stand, between three to four specialist homecare providers, taking place as part of their general homecare businesses across the range of treatment areas from oncology to Thalassaemia. No one has set themselves up specifically, it is true, to serve Gaucher patients, with the partial exception of Genzyme Homecare itself. But that is not to the point.

The point is that this is valuable incremental work for these companies, if the market is freed up and there is every reason to think that there would be active competition.

So those are the points of principal concern. What I turn to now is to demonstrate how those concerns briefly have manifested themselves in practice,

because Genzyme says in its skeleton argument that there was never any complaint form any source about Genzyme's conduct, while it had its exclusive distribution arrangements in place, with Healthcare at Home. Now, that is incorrect. There were strong concerns expressed by at least Professor Cox who wanted a choice, also by the Responsible Patients' Association, who wanted better service levels; and also - and it is in the decision - by a hospital in the North of England which wanted to switch to Fresenius,and was unable to do so. If I may, I will take you very shortly to each of those areas, starting with Professor Cox's concerns, and you will find this in the core bundle for the OFT, bundle 31, at tab 1.

If one goes first to page 13, this is page that Mr Thompson took you to for a slightly different purpose. You have here Professor Cox, June 1996, writing to Mr Cortvriend, asking him what the unit cost is when Caremark trains patients, and provides homecare assistance, and finally, would it not be possible for hospital pharmacies to import this licensed agent independently?

What this is saying is that Professor Cox, even at that stage, is inquiring about the possibility of obtaining the drug alone without it being coupled with the services provided then by Caremark that Genzyme supplied, along with the drug, and he looks forward to hearing form Mr Cortvriend.

Turning the page, you have the reply, 21st June, 1996 and the only part that I need go to is in the paragraph at the bottom of the first page, the first two paragraphs deal more with pricing. "At present we are convinced that Caremark, by virtue of their unique position in wholesaling, dispensing and providing homecare are offering the best possible deal to all concerned. If you feel that there is another way that this could be done which would free up more money to be spent on the active treatment itself, I would be very interested to hear about it. I do realise that in many areas of business competition can often help to bring prices down but for Ceradase I do not feel that this would happen, and the price to the patients during the learning curve, if new suppliers are involved could be considerable".

Over the page he addresses the possibility of a hospital pharmacy importing the product directly and he deals with that literally in terms of the hospital obtaining the drug from abroad, and that is his reply.

One goes from there to Mr Cox, taking up the baton again at page 16, if we turn the page, in September, 1996. He comes back and in the second paragraph asks Mr Cortvriend: "It would be extremely helpful if you were able to give a breakdown of the difference between 2.72 and £3.09p" - 2.72 is of course his error. "It would also be particularly helpful for me to know - I think you did explain it once - what the cost of the drug is if purchased directly from Genzyme, compared with that from Caremark. I look forward to hearing from you as soon as possible".

Finally, in this sequence, the reply is on the facing page, and it is the middle paragraph that matters. "Dear Professor Cox.." in the middle paragraph: "I am always happy to discuss alternative arrangements for the supply of Ceradase. I have yet to come across a means of accomplishing this in a manner that is more cost effective or offers an increase in patient benefits. I would also refer you to my letter of 21st June this year to which I have referred".

So that, from Professor Cox's point of view, shows his efforts to inquire about the possibility of an unbundling, or a decoupling, and the polite way in which he was rebuffed - that takes me back to the quotation from Tolstoy that stood at the head of Mr Thompson's submissions.

Turning then to the patients. The patients' association also expressed concerns, and the first document here, in the same bundle, is at page 19. This is the letter from Mr Cortvriend, to Mr Manuel of the Gaucher Association in November, 1996. In the first paragraph, he records that one of the concerns is reservations of the Association about the level of service being offered by Caremark, and then in the third paragraph he makes this point. "With regard to the quality of service which Caremark provide, I realise that the comments that were made during our meeting, there are some incidents which have caused concern among your members, and that need to be addressed. However, I would expect that if they were consistently falling down on some aspect of their service that we would certainly hear about it from doctors, pharmacists and patients in a loud and clear manner. In fact, remarkably few complaints have come to our attention, and I remain confident that Caremark provide a safe and efficient means of enabling patients to be treated in their own homes".

So here we have the first in a series of letters in which complaints about service were raised. It is picked up two pages on on page 21.

THE PRESIDENT: His case is that they have had very few complaints.

MR TURNER: At that stage he says "We have had very few complaints". It is then necessary to look at the reply - November, 1996, and to go immediately to (b) at the foot of that page which deals with services. Now, Mr Manuel begins, and the Tribunal can read it for yourselves, by saying that when they had met there was an agreement that Mr Cortvriend would review the situation and indeed there was some consideration as to whether the distribution could be taken by Genzyme in-house - a position on which the Gaucher's Association later expressed a rather different view.

Do I take it from your letter that you are either not going to review this----

THE PRESIDENT: Sorry, where are you, Mr Turner?

MR TURNER: At the bottom of that page, page 21, just going over the page now: "Do I take it from your letter that you are either not going to review this, or that you have reviewed it and decided to stay with Caremark. One member of our Executive has very

great experience of distribution delivery systems as well as good contacts in the pharmaceutical industry. I am sure it will not be very difficult for him to work out a business plan."

Then the material part: "I am astonished at your comments on the service of Caremark. You know full well that as a result of complaints that we received from patients about Caremark we carried out at our own cost a survey that service provided. The information was well distilled into a report, the conclusions of which were sent to Caremark and you. They were so concerned, presumably at the possibility of you withdrawing a lucrative contract, that they called a meeting with us at which they promised to review their procedure and confirmed that new systems would be put into place.

"From reports back to us, the position has not improved. Do you wish us on each subsequent occasion that we receive a comment from the patient about Caremark that we should refer these patients to you? Would you wish us now to canvass doctors over whether or not they are satisfied and to ask them to send their responses to you? It seems absurd that we should be required to carry out a management audit of a contract that Genzyme have awarded and which would otherwise cost either you or the company a considerable sum of money but had no alternative due to this stance taken by Genzyme in earlier correspondence."

Just to complete the picture, over the page to page 24, Mr. Termeer writes back and in the last but one paragraph on the first page he says half-way down: "I am satisfied, however, that through our European subsidiaries we currently charge a fair price for ----"

MR. VAUGHAN: Can you start at the beginning of that paragraph?

MR. TURNER: "We do not intend to charge a premium for Cerezyme, neither are we able at this stage to reduce the price. I know from our discussions in November that you have had a continuing concern about the price of Ceredase and additional costs incurred in Europe by ourselves. It is perfectly understandable that you challenge these. I am satisfied, however, that through our European subsidiaries we currently charge a fair price for Ceredase."

The part I wanted was after that: "Caremark's involvement as a homecare provider generates additional costs and we need to scrutinise these costs and we are in any case obliged to audit them at regular intervals. Martin Cortvriend has informed me that he will conduct a review of Caremark's activities before the year end, which will involve contact with all doctors and pharmacists involved with Ceredase prescribing."

So that takes us to the year end and we have now a promise of a review that is to take place.

As you see from the letter on page 30, which is from Mr. Manuel back to Mr.

Van Heek in February of the following year, that review did not take place. There is only a small extract from this letter at the foot of the first page. "The issue of the service provided by Caremark is an entirely independent factor" - it is talking from the price. "Henri's letter to me of 12th December 1996 indicated that Martin Cortvriend would be carrying out a review of Caremark prior to the end of this year. I do wonder whether that has been effected and with what result."

From there, the trail runs cold, apart from an important letter which you should have as document 62A or at page 62A in this tab.

MR. VAUGHAN: To be fair, can you go on with that correspondence?

MR. TURNER: My friend will come back to this, but I will take you to the ----

MR. VAUGHAN: But if my friend reads the correspondence and then leaves out the next letter, it seems a bit ----

THE PRESIDENT: Where is the next letter?

MR. VAUGHAN: At 28 and 29 from Mr. Van Heek.

THE PRESIDENT: This is the reply to --?

MR. VAUGHAN: To the one he previously ----

THE PRESIDENT: This letter of 14th February is the one to which we have just been referred and the letter before that is 24th January.

MR. VAUGHAN: My friend read out the 12th December 96.

MR. ROBERTSON: He read out the 24th February, but he missed out the letter to which it was a reply.

MR. TURNER: If I may, I do not believe I have left out anything material in the sequence and I am seeking to go only to what is material for the purpose of the argument. If there is anything that deals with this issue and, no doubt, my friends will take you to something if they say it is against me.

If I may go to page 62A, which is in tab 2, we have now jumped to the middle of June 1997, page 62A.

MR. VAUGHAN: We have not got it.

THE PRESIDENT: We have got a page 62 and then we have got a page 63.

MR. TURNER: I understood from the Treasury Solicitor that these were supplied.

THE PRESIDENT: Yes, right at the end of our tab 1, the last document in that tab, just before the insert.

MR. TURNER: I will share this with my friend. This is a communication to Mr. Van Heek from Mr. Cortvriend and we are now half-way through the following year. Under the heading "Caremark", he is saying that he has spoken with Jeremy Manuel this morning of the Gaucher's Association: "... we refer to the recent discussions and correspondence that he has had with us and we covered the following issues. 1. Caremark. I explained what we have done so far this year with regard to auditing

Caremark and that we would shortly be writing to the Gaucher Association with some details of this process and with information regarding the improvements that are being implemented at Caremark. He accepts that he cannot influence our choice of distributor/homecare provider but repeated that it is only right for him to press us to ensure a trouble-free service for patients, particularly when Caremark are being well paid for the provision of this service."

That concludes that short journey through those documents. The only point that I wanted to draw from that is that you see from it, over a significant period of time, concerns culminating in quite a strong expression of concern expressed by the Patient Association and an attitude, so far as Genzyme are concerned, that they can deal with it, in good faith they will deal with it, but, of course, as Mr. Cortvriend confirms in the final communication: "It is ultimately a matter for them."

So on an issue of clinical care and the quality of service that is being provided the attitude of the company, because of these arrangements, is that it is a matter for them to deal with.

The final area that I wanted to show the Tribunal involves only two documents and is where the NHS itself manifests a desire for choice which is thwarted by Genzyme's pricing policies in the early period. For this, if you will pick up again the core bundle, bundle 31, you should have a document inserted at the end of tab 1 as 60A.

THE PRESIDENT: Entitled "Fresenius Homecare Services."

MR. TURNER: This again is specifically referred to in the decision. It is one document at which the Tribunal may not have looked. August 1996. It is Fresenius writing to Genzyme to ask whether they might be engaged to provide homecare services for patients for a hospital in the North of England. I would invite the Tribunal to read it to yourselves.

THE PRESIDENT: Yes. (<u>After a pause for reading</u>): Yes.

MR. TURNER: Apparently, the Office asked if there was a reply to that letter, to complete the picture, and were told there was not a written reply; but if you turn to page 60D, a few pages on in that clip, at point 5 you will see that the Office asked if there was a reply and received the response which is set out in the second column: a telephone response. There was a meeting with Fresenius, interestingly, close to the end of 1997. The letter was dated August 1996.

Following the meeting, Genzyme decided not to take matters further with Fresenius because, inter alia, it was felt by Genzyme that the culture of Fresenius was wrong: there was a lack of commitment to the level of service required by Genzyme and Genzyme also felt that there was a lack of proper infrastructure.

So what one has there is a concrete case - or so it appears - of the desire by a

part of the NHS for what is now termed block contracting. Fresenius served other of their patients with other conditions and it was desired that Fresenius would also serve the Gaucher patients. The Genzyme exclusive arrangements stood in the way of that.

The final document, as an illustration of this problem, is a very recent example. That is in the defence file, 28. I do not know how the Tribunal's defence file is arranged. I am looking at a document which is at the end of Exhibit CHM4 to Mr. Munro's witness statement.

THE PRESIDENT: It has got a number of tabs in it; are you able to give us a tab number?

MR. TURNER: Yes, in my file it is tab 14, near the very end.

THE PRESIDENT: CHM3.

MR. TURNER: CHM3. I am sorry. The last document in that tab is a memorandum from a lady who is the clinical service unit manager at the Royal Berkshire Hospital. Again, the Tribunal might just want to read that for yourselves.

THE PRESIDENT (After a pause for reading): Yes.

MR. TURNER: It is a very recent example.

THE PRESIDENT: Has it got a date?

MR. TURNER: Yes, on the previous page. The 1st July 2003.

THE PRESIDENT: So this is post the decision.

MR. TURNER: This is post the decision. This arose out of something that came in the documents annexed to the notice of appeal, the witness statement of either Mr. Morland or Mr. Johnson about the position of Clinovia. What one gets from this document is that the bundling as much as anything else has, in this case, operated to cause the hospital concerned to think twice about using its preferred homecare provider, here Clinovia, for services for two Gaucher patients then being treated in hospital and Miss Bowring concludes by pointing out that when she has discovered that the cost of the service is included in the hospital drug it has made the move to Clinova as a provider not cost-effective. "Unfortunately, this has considerably muddied the waters and delayed our move to homecare for these two patients."

My point about that is this. It did involve Genzyme Homecare, but the position would have been exactly the same pre-May 2001 had the chosen provider, the Healthcare at Home, been in the saddle. The same difficulty would have arisen and the same difficulty about moving to Clinova would have arisen.

Sir, that is all I want to say about the downstream effects of the two abuses and how they co-mingle. I would like to turn now to address the upstream effects of the abuses. The point here is that if Genzyme or its chosen provider are supplying homecare to the patient, that makes it more difficult for a new competitor with a new drug to come in. This is because it means changing the homecare provider, to whom an attachment is often formed with the patient, as well as changing the drug. That might

cause distress to the patients and, as Mr. Cortvriend put it in 1996, they could pay a considerable price.

To appreciate the full strength of this point, it is necessary to bear in mind the particular context of this case. One comparison that Genzyme have drawn, for example, is with Fabry disease. It is appropriate to bear in mind that there is a material difference between the circumstances that apply to Gaucher's disease on the one hand and the circumstances in relation to Fabry disease.

As is pointed out in the decision - you will find the note at paragraph 265 - the enzyme replacement therapy drugs for Fabry disease both entered the market at the same time; Genzyme and TKT are both actively competing for new patients, who up to know have not had the option of treatment.

THE PRESIDENT: You have got competition on the drug, even if you have not got it on the distribution.

MR. TURNER: You have got competition, but from the patient's point of view and from the prescribing clinician's point of view it means there is not a well-established single drug in place at any one time from which a patient, when you are considering a new drug, would need to move. The position is rather different in that you have two drugs that came in at the same time.

More importantly perhaps even than that is that there are more significant potential side effects with the drugs for Fabry disease. That is common ground. You will find it, for example, at paragraph 5.14 of the written representations put in by Genzyme in the administrative procedure.

The implication of that is that in the case of Fabry disease, by comparison with Cerezyme, which is remarkably good so far as absence of side effects is concerned, there is again a higher possibility that the drug will not agree with them in any particular case, that there will be side effects, and that the occasion to move may be a more straightforward decision.

In the case of Cerezyme, with which we are concerned, we have a well-established and highly successful drug with few side effects, so that if in the medium term TKT or any other competitor emerges, for example, with a cheaper although equally efficacious drug, the clinician will probably - or at any rate may not - be faced with a situation where the patient is not doing well on Cerezyme.

Against that background, you turn to the evidence from the two leading Gaucher specialists in the country for adult patients, Professor Cox and Dr. Mater, both of whom express strong convergent views that if, in particular, Genzyme Homecare is serving all of the Gaucher patients that that will impact upon their clinical freedom to prescribe a new treatment: it will make it more difficult for them to persuade a patient to move to a new treatment and thereby cause difficulties for new entrants.

What is said here in Genzyme's recent skeleton is that this difficulty, if it is real, one would expect to have been voiced by Professor Cox at the outset, but it is not. In my submission, that is wrong and one sees quite clearly, if you go to the documents, that this is a concern that Professor Cox did voice from the outset.

Perhaps just before the short adjournment I will take you to the relevant pieces of correspondence. They are in bundle 39.

THE PRESIDENT: Of the core bundle?

MR. TURNER: Of Genzyme's. The relevant tab appears to be tab 69, page 1009 in the top right corner of the page. This is a letter to which Miss Mather drew attention.

THE PRESIDENT: We have already glanced at this.

MR. TURNER: The part that I want is in the last paragraph of the first page of this letter. The Tribunal can read it for yourselves, but he says, Professor Cox, that he is concerned that removal of the service from Healthcare at Home, which is an independent service provider, will lead to a lack of independence and so on. And he goes on in the last sentence to say, "The clinical freedom for prescription of other drugs related to Gaucher's disease either available now or that will come on-stream will be prejudiced by the sole provision of the service by the Genzyme company."

This then became a theme of Professor Cox's concerns and if you turn on a few pages to page 1013 you have his letter to the Office of Fair Trading. Mr. Thompson rightly points out that in relation to Miss Mather's question there may be an answer here. In the second paragraph, "I understand from the Department of Health, to whom I wrote on 29th March about my concerns as to the propriety of this move by Genzyme, that they have sent you a copy of my letter to them requesting advice." So what appears to have taken place is that the Department pushed this over to the Office of Fair Trading.

In the second paragraph of this letter, Professor Cox first of all makes clear how important he and
Dr. Mater between them are in relation to the population of Gaucher patients. He says half-way through that paragraph: "Between us, we take care of the great majority of adult patients with Gaucher's disease who are receiving enzyme treatment with Cerezyme in England. A small number of patients, principally children, receive the drug at two other centres. Approximately 85 patients receive the treatment here and I understand that at least 60 patients are being treated at the Royal Free Hospital. It is my understanding that about 175 patients are receiving treatment nationally."

Then he goes on: "It is my belief that the loss of an independent service provider would represent a significant future disadvantage to the access that Gaucher's patients would have to a variety of agents that are emerging specifically for their treatment and it is for that reason I am enclosing a copy of my correspondence here."

So, again, he puts that at the forefront of his concern: that he is worried about the loss of prescribing freedom.

"The Gaucher's Association, which represents the patients who receive this treatment, have had discussions with me about this matter and join me in their concerns about the proposed action by the Genzyme company that produces the drug for their members."

Then if one goes forward to the note of the meeting between Professor Cox and the Office of Fair Trading, which is on page 1017 and just dwell here for a moment because Genzyme infer from this that Professor Cox's view is that there ought to be tendering and a change in homecare providers every two to three years. In fact, I draw your attention to what he actually says, which is at paragraph 21 in the final bullet point. He expresses the view that if the provision of the drug was separated out from the provision of the service, then this would be tendered out and reviewed, probably every two to three years. I simply draw your attention to that to lay emphasis on the word "reviewed": it is not to say that there would be a change in service provider, only, as

Mr. Farrell confirmed in oral evidence, that there would be a review and that, no doubt, the best interests of the patient would dictate whether there was to be any change.

Finally, in my submission, an extremely important document in the case. I would invite the Tribunal to move on to page 1026, where you have a copy note of a meeting that took place between Genzyme's legal advisers and Professor Cox. It is a particularly valuable document because it appears that a faithful transcript was taken. It is an agreed note, as I understand it, as well.

Professor Cox in this note eloquently explains his concerns. If I could just mention which the key paragraphs are, the Tribunal will want to read this in their own time. On the second page, the penultimate paragraph, EFBP, which is the Perrott of Taylor Vinter, asking whether TC (Professor Cox) would personally be influenced by the identity of the homecare provider. It is that paragraph.

THE PRESIDENT: We are just speed reading it.

MR. TURNER: Yes.

THE PRESIDENT (<u>After a pause for reading</u>): The difficulties to which he refers in changing homecare service providers presumably apply whoever the homecare service provider is. That is to say, even if you had competing providers, once you have got a provider upon whom the patient becomes dependent or has a close relationship the more difficult it becomes to change it, presumably.

MR. TURNER: Yes, that would follow.

THE PRESIDENT: Your point is, at least you have got the option if the pricing is ----

MR. TURNER: Precisely. In his case, he is drawing attention to the fact that if the

representative of a company controls access to the patient group that that makes it difficult for a new company to come in. The point being that if, say, it was Healthcare at Home that were providing the service under an independent arrangement with the NHS, then there would be no difficulty because it would not be necessary to change the homecare service provider if one wanted to change the drug.

The point here is that, because it is Genzyme or Genzyme's representative providing the homecare service, changing the drug means changing the provider as well. That is the key problem.

If one turns the page and if the Tribunal would read the top paragraph and a half - KD is Professor Cox's hospital administrator, I believe.

THE PRESIDENT (After a pause for reading): It is apparently a problem for the NHS that they have to focus on the wishes of patients!

MR. TURNER: It is a difficulty for all of us that we have to deal with customers!

What is interesting is, half-way through the second paragraph, actually in the second sentence, three lines down: "EFBP stressing that since the treatment of Gaucher's is a very narrow field, individual clinicians, especially TC, are very influential." With respect, we totally endorse that point. It is precisely because of the narrowness of this field that the influence of this leading physician is so important.

Before we break, perhaps two other passages that I would ask the Tribunal to look at quickly and then, of course, you can read it to yourselves afterwards in full. At the foot of page 1029, page 4 of the note, perhaps if you will read from "KD adding that the Patients Association ..." two paragraphs up, just to the end, that will serve for present purposes.

THE PRESIDENT (After a pause for reading): The first of those paragraphs is expressing some reservation about the idea of the tendering procedure.

MR. TURNER: Yes.

THE PRESIDENT: That there are administrative difficulties and the patients do not like it very much.

MR. TURNER: Yes, I accept that. Of course, tendering is at an early stage. We are dealing with something which is not established yet at all and Professor Cox's views are developing on the subject. It does not affect, in my submission, the point, which is that the patients dislike discontinuity and that is a factor to be borne in mind.

THE PRESIDENT: Professor Cox was asked whether commercial tendering for the provision of homecare in connection with Cerezyme every three years would be undesirable. He responded by saying that he thought that was a fair statement.

MR. TURNER: Yes, and that may be contrasted with his discussion previously with the Office of Fair Trading in which he had mentioned tendering perhaps every two to three years. But here the point which he is really seeking to make is that discontinuity ----

THE PRESIDENT: He seems to have expressed somewhat divergent views on the two occasions; is that fair?

MR. TURNER: That is absolutely fair in relation to the question of tendering.

MR. GRINYER: But over the page and page 5, he is concerned with clinicians having the selection rather than Genzyme.

MR. TURNER: Yes. The point for the Tribunal to bear in mind is that, as Mr. Farrell confirmed in oral evidence, in the tendering process it is wrong to think of it as "the cheapest bid gets the business" sort of process. The clinician has an input. Who actually wins the business and how that business is then provided is a decision that will be taken in consultation with the clinicians. Insofar as Professor Cox here is expressing reservations about tendering, it is unclear the extent to which that may have been borne in mind. Certainly Mr. Farrell has made that absolutely clear. That is what happens with the haemophilia tender; that is what would naturally happen, as he sees things going forward.

THE PRESIDENT: Thank you, Mr. Turner.

(The luncheon adjournment)

THE PRESIDENT: Can I just say, so that people can be thinking about it that if we do need another date, perhaps a morning or something of that kind, at the moment the Tribunal is looking 6th October. It is somewhat difficult for us if we cannot do that day, because of diary and other commitments, that is what we are thinking of.

MR TURNER: For my part, Sir, that will be impossible.

THE PRESIDENT: Well, perhaps we can discuss it at the end of today and see where we are. I am just saying it now so people can take advice, make phone calls and all the rest of it.

Yes, Mr Turner?

MR TURNER: Sir, just to close off on the point that was being canvassed before the short adjournment in relation to Professor Cox's attitude towards tendering. I have mentioned in the course of Mr Farrell's oral evidence he had addressed what such tendering would involve and he had made clear in particular that two matters would be addressed, that the best interest of the patient would be at the forefront of the concern, and that the prescribing clinicians would also be closely consulted, and if I may just give you the transcript references. There was the question that you asked Mr Farrell, which appears at page 31, beginning at line 23 and going over to the top of the following page, page 32. Then in re-examination page 63 lines 14 to 18, and page 65 lines 17 to 23.

Returning to the significance of Professor Cox and Dr Mehta's view. Both Professor Cox and Dr Mehta have, of course, given witness statements in these proceedings and those are detailed, clear and strong. The purpose of the witness statements was made specifically known to enable Genzyme to challenge those in this

appeal. Genzyme have not wanted to cross-examine either of those clinicians, and their claim is that there is no need for them to do so because Genzyme does not doubt that they are sincere.

In my submission that is an insufficient answer in a procedure of this kind. The Tribunal h as seen that theirs is key evidence because of their position in this industry. They are the key prescribers, accounting for the great majority of patients and it is precisely what they personally will or will not do, and how they personally will or will not be affected that bears on the strength of the exclusionary effect. This is not therefore a matter of their credibility. Genzyme has had the opportunity to test the basis for their evidence, to challenge the grounds on which it is based, and they have declined that invitation.

What they have done, and this has been covered in the skeleton, so I shall deal with it shortly, is to adduce evidence from certain other specialists, including materials from the two Fabry specialists, from whom they have obtained materials, and principally from a Dr Walldek.

If I may just turn to that briefly. We have already made the point in the skeleton that adducing that evidence in any event does not affect the centrality of Professor Cox and Dr Mehta's evidence.

The second point is that for what it is worth in substance it does not touch on the point at issue, and you can see that quite clearly, if the Tribunal would not mind picking up bundle 39, and turning to tab CB 74 at page 1054. You have there the first statement of Dr Walldek, and at the top right you will see that this is dated 18th October, 2002. There are two parts of it to which I draw the Tribunal's attention. In paragraph 2 he makes it clear that we do not yet have any Fabry's patients being treated at home, although at that stage he anticipates that this will happen quite soon. Then the key passage is paragraph 4.2----

MR VAUGHAN: Can you read to the end of paragraph 2?

MR TURNER: I will read to the end of paragraph 2. "By virtue of my role as Chairman of the Hospital's Medicine Management Group for the Hope NHS Trust Hospital, Manchester, and as consultant Nephologist I am well aware of the issues surrounding homecare services generally, particularly as they affect renal care and the use of Erythropoietin."

4.2, beginning on page 1056 concerns the issue as to the identity of the homecare service provider likely to influence the choice of drug and the prescription level, and what is said is we have taken out of context one part of that where Dr Walldek says that he is aware from discussions with patients how much they value consistency in the nursing visits. Without wishing to read aloud the whole passage, perhaps the Tribunal would care to read for yourselves 4.2 on page 3, and going over to

page 4. [Pause for reading]

THE PRESIDENT: So if I have understood him, he is expressing a reservation about the idea of a block contract for Gaucher because he says "If the Gaucher sufferer is dealing with someone who is also handling a number of other diseases the patient may get someone who is not as knowledgeable in Gaucher as they would be if it was just the Gaucher service that has been provided". That is what he is saying, isn't it?

MR TURNER: The gist of his evidence is that it is very important that the homecare service provider should be alive to the particular condition for which they are involved, and whether or not that can be addressed in the block contract situation, perhaps is another matter, but certainly that is the key point he is making in that context.

What he is not doing is grappling with the point which Professor Cox and Dr Mehta are exercised by, and that is the key point for present purposes, that is the issue to which I wanted o draw attention. He returns to it in his reply evidence at the next tab.

THE PRESIDENT: Sorry, the key point is what?

MR TURNER: The key point is the heading of 4.2, suggests whether the identity of the homecare service provider is likely to influence the choice of drug and prescription level. That should properly be put, whether a switch in the identity of the homecare service provider might be a factor which would affect the clinician in deciding whether or not to switch the drug treatment for the patient, but he has not addressed the particular concern that the other physicians have been dealing with.

THE PRESIDENT: No, but he has raised another concern?

MR TURNER: Yes, he has raised another concern, but he is not dealing with that particular point. The concern he is dealing with moreover, in my submission, although important, is not contrary, in any way, to the Office's case, he is merely pointing out that from his perspective he would need to be satisfied that anyone who provides homecare services for his patients had a sufficient level of expertise in relation to the condition at hand.

THE PRESIDENT: Should we look at 4.3 where he goes on to look at the question of a single homecare provider.

MR TURNER: Yes.

THE PRESIDENT: They would have to go out to compulsive competitive tendering, across a range of services - he thinks that is going to be wide for the service to be adequate - if the contract was awarded to a single provider, the nurses would change and be extremely unlikely to have the specialist knowledge which is beneficial in homecare.

MR TURNER: At that stage, the level of his knowledge, certainly in relation to Fabry's disease was hypothetical, because he had not yet begun to provide homecare services for those. But in any event, in my submission if you take the Birmingham Children's Hospital---

THE PRESIDENT: Well, he is Chairman of the Hospital's Medicine Management Group of the relevant Trust in Manchester. This is an experienced clinician expressing a doubt about the desirability of compulsory competitive tendering which is along the sort of lines that Professor Cox was also expressing a doubt.

MR TURNER: Yes, at all events, whether this particular physician says that he does not want a block contract for this group of patients or not, does not touch on the main concern that the Office is advancing in these proceedings which is, as a result of Genzyme's grip, over the provision of homecare to patients, no choice, no possibilities are available to the NHS.

THE PRESIDENT: You can't put it to the test even?

MR TURNER: You can't even put it to the test. Whether or not the doubts that are expressed here may turn out to be justified is a matter that could be put to the test and certainly other hospitals have dealt with that. The Birmingham tender which, Sir, you were looking at earlier, covered a range of conditions, and had specifications in relation to each, as you will have seen.

Turning to the reply evidence, which is in the following tab. The paragraph in which Dr Walldek deals with the point at hand is at paragraph 9, on page 1061. He says "I am quite clear that if an alternative product to Cerezyme were to become available, the clinicians prescribing enzyme replacement therapy for patients with Gaucher disease would look at the product first and foremost and, having made the choice of drug, would then ensure that the home delivery homecare services were of a standard which met their requirements, and those of their patients. I do not think that it would be the other way round, in that clinicians would look first to the homecare service provision and use that as the primary basis for selecting a preparation."

In relation to that I make two points only. First, he is of course describing how essentially Professor Cox and Dr Mehta would behave. He was not shown their statements before he prepared this and, therefore, this is to that extent hypothetical.

The second point is that in any event he is not quite addressing their concern yet again. He is simply asking himself the question "which would be the primary basis for selecting a preparation?" which was not the gist of their concern.

The other statement that has been put in----

MR VAUGHAN: You will see by then he had experience, at paragraph 6 of homecare for Fabrazyme.

THE PRESIDENT: Yes, he has 12 patients by then on home therapy. I had noticed that, Mr Vaughan, thank you.

MR TURNER: The other statement that has been put in is one from Dr Velodi, which is at tab 77, and I do not ask the Tribunal to read this in detail, certainly not now, as opposed to after the hearing, but the point we have made about this is that his essential concern

in this statement is to explain that he has to date been satisfied with the high quality of homecare services provided for his patients by Genzyme Homecare.

In assessing the strength of this evidence, however, there is one point that will not be apparent to the Tribunal. He says, at paragraph 6 of his evidence, that approximately 20 to 25 of his patients are treated with Cerezyme at home. Of these, approximately 15 to 20 have their homecare provided by Genzyme Homecare, and the rest by Healthcare at Home, with only one to two cases where this service is provided by the NHS Community Nurses. It would be immediately apparent that the figure of 15 to 20 patients, for whom homecare is provided by Genzyme Homecare is inconsistent with the general figure of which we know, that a total of 15 or 16 altogether, patients are provided with homecare services by Genzyme Homecare. We have therefore asked Taylor Vinters to clarify the matter, and if I may hand up a very short clip of correspondence on the point. [Documents handed to the Tribunal]

The Treasury Solicitor writing to point out that difficulty, and asking whether the statement contains an over estimate.

THE PRESIDENT: He has 8 according to this, is that right?

MR TURNER: At first sight he has 8. If you look a little more closely, you also see that of those 8, two of them, and two only, number 6 and number 8, are patients where there is Genzyme nursing involvement.

THE PRESIDENT: Yes.

MR TURNER: Then if you turn the page again, Mr Perrett has properly recorded a further comment from Mr Velodi, who himself comments on the figures that he has seen and says "These figures look more accurate than mine, which is why I was only approximating, but you must also check with Healthcare at Home because I think some of the patients alluded to by Dominic as 'no nursing' probably receive their home infusions from Healthcare at Home. Without that your info. will not be complete".

So that in assessing the weight to be given to that statement in any event, one sees that there are a considerably smaller number of patients at issue than at first sight one might gather from the statement itself.

The final point that I desire to make on the subject of effect on upstream competition is that this is not a revolutionary or difficult concept to grasp. Indeed, it is something that Genzyme itself had well in mind, as is clear from its own business proposal for Genzyme Homecare, to which we went a few moments ago when Mr Thompson was addressing you, in bundle 31, the OFT's core bundle, at tab 2, beginning at page 77, and the relevant passage being on page 78.

The relevant passage is the third paragraph down.

THE PRESIDENT: Just a moment.

MR TURNER: Yes. "Genzyme UK propose to develop an in-house homecare team

dedicated to providing homecare services that will enable the management of appropriate dosing---"

MR VAUGHAN: Can you start a bit before.

THE PRESIDENT: Where are you, Mr Turner?

MR TURNER: This is the third paragraph down.

THE PRESIDENT: On what page?

MR TURNER: This is page 78.

MR VAUGHAN: Can you start at the top?

MR TURNER: Mr Vaughan would wish us to start at the top.

THE PRESIDENT: Well, let's read quickly down to where you are going to start. We have already looked at the "Executive summary."

MR TURNER: Yes, the heading "Executive Summary".

THE PRESIDENT: We have already looked at the first paragraph.

MR TURNER: The second paragraph which Mr Vaughan wishes me to read says "Genzyme currently pays approximately 11.7 per cent. of revenue to Healthcare at Home by bringing homecare in-house we aim to reduce homecare costs to 6 to 7 per cent. after five years and then Genzyme UK propose to develop an in-house homecare team dedicated to providing homecare services that will enable the management of appropriate dosing, and protect our current business from potential competition. " We have drawn that to their attention, clearly in the defence, and relied upon that as evidence that Genzyme was itself aware of the strategic benefit of controlling homecare services for the patient population for Gaucher's disease. Genzyme could have dealt with this in its reply with which it served a battery of further witness statements but this point, although clear and manifest has not been dealt with. Therefore, in those circumstances I invite the Tribunal to attribute the significance to it that we say it has, that it shows Genzyme's awareness of the benefit of this strategy.

Sir, those are the only comments hat I wish to address you on in relation to the principle elements of the abuse, and with that I would propose to turn to the issue of justification, and to deal with four topics in headline form, for the most part.

To summarise again, this is common practice within the industry.

THE PRESIDENT: I am sorry, Mr Turner, I should have said it a moment ago,I am just on page 86 of the document you were on a moment ago. Just under "11. Summary". There are various advantages for homecare generally, then there is a list of advantages for homecare by Genzyme - reduces cost whilst maintaining service. I think that is argued. "Puts Genzyme in control", that's argued. "Connects the company with the service", that is argued. The next one is "pushing out competition by providing a shopping basket of tailor made services". I am not quite sure what that refers to. Perhaps Mr Vaughan will deal with that when we get to him. "Raising the standard of care to

superior levels" that is argued. So there are a number of arguments there that figure one way or another in the case, but then there is this "pushes out competition".

MR. TURNER: Yes. There is also the third bullet point down under the heading "Homecare generally": "It provides tremendous added value and would be a selling benefit in the face of competition."

THE PRESIDENT: What is wrong with having a selling benefit in the face of competition?

MR. TURNER: It is perhaps ambiguous and will require interpretation, but one interpretation to be given to that is that it again prevents the advent of potential competition. But, at all events, the clearest expression of that, in addition to the passage to which you have drawn attention, is within the executive summary, which appears to be in clear and wholly unambiguous terms: that at no stage has Genzyme sought to address that. Although I hear what you say - that Mr. Vaughan may seek to come back on that in his submissions - it is at this stage rather late.

The four heads of justification with which I hope to deal are: first, that Genzyme's pricing practices reflect the common cost and common practice within the industry; secondly, that they ensure a high quality of service for the patients concerned; third, that it is a more cost-effective form of homecare provision that any that would result from competition; finally, that the Department of Health has tacitly at least approved of Genzyme's pricing practices. That itself breaks down into three heads: the meeting with NSCAG (if I may use the rather unattractive acronym) on 13th February 2001; that the Department has tacitly approved its behaviour by not exercising powers similar to those manifested in EL(95)5 of the NHS Executive letter; thirdly, by no exercising certain powers under the PPRS and Sections 33 and 34 of the Health Act, the reserve powers.

Address first the first issue, common practice within the industry, the point that I wish to make is that in Genzyme's submissions three distinct positions become confused when it is crucial to keep them separate. The first is to examine drug companies which have an in-house homecare service operation of some kind. That is the contention that was at the forefront of the administrative procedure, at least as the OFT understood it: that other companies have an in-house homecare service operation and this is no different from that.

We say that is not a matter of complaint, nor is it the issue. Insofar as one has in-house service operations, there is an additional option being put into the market place, but it is not the true source of complaint in this case.

The second position is drug companies that, as part of their offering to the NHS, offer a rolled up price for a product, a bundled price, and associated homecare services, but companies which are also prepared to and do offer a drug only price. Yet again, in my submission, companies that fall into that category are different from the

situation with which we are faced in the present case.

The third situation, which is the pertinent situation for this head, are drug companies which only offer their product at a price which also includes the provision of homecare services. It is our submission that only in that third situation does one have a situation that might be capable of establishing at least the starting point for a defence. But the evidence has shown that this sort of practice is very rare indeed.

THE PRESIDENT: These are the paragraph 2.40 companies, are they not, effectively?

MR. TURNER: No, because in the case of the paragraph 2.40 companies some of those, even at the time, had an in-house service operation but may have been prepared to offer the product separately to the NHS.

MR. GRINYER: Do we include in this situation those who have an exclusive distributorship, i.e. that there is just one channel of homecare provision? I am talking about a known subsidiary here. Earlier you said you saw no difference in principle between this vertical integration and having an exclusive distribution arrangement.

MR. TURNER: I am sorry, I certainly did not mean to say that. What I meant to say was that where companies have an in-house homecare operation of some kind that in itself is inoffensive so far as the Office is concerned and is not to the point. The point is whether that is exclusive or not; and what we are interested in is whether it is common practice in this industry for there to be an exclusive provision, through some tied provider, to offer a price and only a price which includes the drug and the homecare element together.

MR. GRINYER: And that tied provider might be a matter of a vertical agreement rather than vertical ownership.

MR. TURNER: It might well indeed. Indeed, Healthcare at Home and Caremark before that, when they were at the saddle, fell precisely into that category because Genzyme did not make the drug available to the NHS other than through that route.

MR. GRINYER: Thank you.

MR. TURNER: The issue here is as to what extent that practice is common or not. That is all I desire to say. There has been a lot of confusion in the papers and when one comes to consider this list of companies in Mr. Morland's third witness statement or in paragraph 2.40 of the MMC report, it is important to bear that in mind as to what one is really looking for on this issue.

MR. MATHER: Did the office make any enquiries as to that in the course of their preparation of the case?

MR. TURNER: Whether there are other companies which also offer ----

MR. MATHER: Exactly.

MR. TURNER: I will just check. No, they did not do that. The reason they did not do that is because it was not raised itself as a compelling issue.

MR. VAUGHAN: That is monstrous. That is a monstrous suggestion.
THE PRESIDENT: You will be able to tell us, Mr. Vaughan. You have established that no enquiries were made.
MR. TURNER: We can go to the written representations and the issue can be looked at for the purpose of dealing with what happens at the administrative stage, but, having looked at the written representations, it is my submission that what you will see there is that what was raised was more a confusion of points and that the in-house operation was what was said to be a common practice within the industry. That was what was reflected in the decision in the parts that Mr. Vaughan took you to when he was making submissions, because the Office was saying, "It's not our case that having an in-house homecare services provider is unlawful in any way." That is a confusion that they at least perceived that Genzyme had fallen into. Their position was simply, "This is not part of our case."
THE PRESIDENT: I think we ought to go to paragraph 2.40 of the Caremark/Fresenius report because what is in my head at the moment - you may well be able to sort it out for me - is that the MMC identified a relatively small number of companies who were supplying prescribed services that were effectively being supplied by the company or the company's tied provider, with the result that nobody else had a choice of provider. That was the main point about which the MMC was apparently worried. That would perhaps have tipped somebody off to think how far this practice was common in the industry or not, since there are about six examples in that report.
MR. TURNER: Perhaps it would be a good idea to turn up that report now and to look at that.
THE PRESIDENT: Yes, I think it probably would be a good idea.
MR. TURNER: Perhaps we can do that before we make any further submissions.
THE PRESIDENT: If someone can tell me where I find it.
MR. TURNER: The MMC report is in bundle 38, tab CB39. The relevant page is page 429. Sir, your correction is well taken, that in relation to this report at least we are dealing with a small number of companies where that may be said to be true.
THE PRESIDENT: I just want to remind myself of what is being said here. (After a pause for reading): Yes. There is something about this on market definition that is relevant later on, but we will come to that. You just run through them for me.
MR. TURNER: Abbott, as Mr. Farrell was telling us on Friday, was a company involved in enteral feeds, essentially a food product rather than a pharmaceutical product and not within his area of knowledge. Abbott was a supplier of those feeds and also involved in home healthcare related to it. Alpha provided home healthcare services in relation to patients on immunoglobin treatment, for which it also supplied drugs. In relation to that, Mr. Farrell on Friday clarified that that has now merged with a company called

Grifols and today supplies the drug or is prepared to supply the drug separately from the healthcare services. Baxter one knows about from Mr. Farrell's statement insofar as it deals with haemophilia products. Insofar as it deals with dialysis products, that again was outside Mr. Farrell's area. In relation to PN treatments, Mr. Farrell made the point that, there again, his hospital at least purchases services associated with PN separately from the product and it makes up the product in the hospital. Novartis was a supplier of immunoglobin and also of PN products and what is said there is that its major presence was in IG, for which it supplies drugs and services. I do not recall off-hand what Mr. Farrell's answer was in relation to that. Nutricia was dealt with primarily in Mr. Morland's third witness statement and canvassed between yourself and Mr. Vaughan. There we see at least now that there appears to be a considerable element of tendering that occurs, possibly for the product and also for nursing services. Pharmacia and Upjohn, supply nutritional products used in the PN sector. I am not sure that Mr. Farrell was able to throw any light in relation to that particular company.

The position that obtained at the time of the administrative stage is that the Office proceeded on the basis of the case that was made before it by the company concerned and we can discuss that and Mr. Vaughan will no doubt take us to the relevant references.

It is fair to say that the Office did not pick up the MMC report and, by reference to paragraph 2.40, investigate the question whether the bundling practices that it was faced with were common practice within the industry.

In my submission, in any event, when one reads 2.40 in the cold light of day there is not really sufficient meat there to have caused the Office responsibly to have gone down that path. In any event, the Office was entitled to address the case that was made to it in the administrative procedure. In that procedure - I do not have the relevant references to hand - certain companies were referred to; in particular, Aventis and Baxter and possibly a company called Wyeth.

MR. VAUGHAN: Do you want the reference in our response?

MR. TURNER: Sir, you have the point, which is that the Office took the case that was made to it and addressed that and that, in any event, paragraph 2.40 does not provide in itself a basis upon which the Office should have realised, certainly off its own bat, that there might be an issue as to whether the bundling of which it complained could be said to be a common practice within the industry. The evidence has shown quite conclusively to date that it is not and there is no further issue there.

MR. GRINYER: Do you see any distinction in principle between bundling in the case of a company like Genzyme with Cerezyme, where there is a uniquely efficacious product, and something like Nutricia, where they are dealing with foods and where there is a number of alternative substitute products which could be used?

MR. TURNER: Yes.
MR. GRINYER: That is a distinction you have not made.
MR. TURNER: To pick up on that point, where one has a company which is the sole supplier of a product able to treat a particular condition, then the customer has no choice and no bargaining power; whereas in an are where there are various competing suppliers then there is a higher degree of choice introduced into the process.
MR. GRINYER: So your argument is not necessarily against bundling per se, it is against bundling in certain circumstances.
MR. TURNER: Bundling in certain circumstances by a dominant supplier, which can constitute an abuse precisely because of the lack of choice that the customer has. I have to introduce an authority on my feet, but it is trite law and my friends will be well aware of it. If one takes, for example, the ITT Pro Media case at paragraph 139 of the court at first instance judgment, one finds there are well-known ----
MR. VAUGHAN: I had forgotten that one.
MR. TURNER: Mr. Vaughan was in it.
MR. VAUGHAN: No, I was not. I would not have forgotten it.
MR. TURNER: The court there makes the trite point in relation to Article 82, abuse of a dominant position, that for a dominant company it can be an abuse to engage in a practice which is not abusive when the same practice is carried out by a company which is not dominant. That follows from the special responsibility that a dominant company has not to abuse its market power.
MR. MATHER: Going back to the office not enquiring into the way in which other companies might or might not operate in the market, two questions. Even if the Office's attention was not focused round the MMC report at all, would not one have expect it to examine such matters just to get a sense of whether there was an abuse or not or how widely spread the abuse might be? Secondly, if the Office did look at the MMC report in detail, is there not an element of a dynamic and fast changing market here in which the facts set out in 2.40 might have changed, therefore requiring some investigation?
MR TURNER: If I may take those points in this way, Sir? The first issue - to pick up on what Professor Grinyer was saying - one is dealing here with a particular condition for which you have a company in a dominant position providing the only treatment, and to all intents and purposes effectively upon the National Health Service, and without wishing to go any further, to examine the position of other companies which are not in that sort of position, and where there is not therefore that sort of problem, because the customer has a realistic choice, may not bear on the difficulty at hand.

Secondly, and I return to this point, in the administrative procedure, the Office is entitled to rely upon the facts and argument that are presented to it by the company

under investigation. Of course, there may be an issue as to the significance of the matters that were placed before the Office. But, first and foremost, that must be the focus of the Office's investigation. This is a company involved directly in the industry. It will know if the practice is common or not, and it will advance the argument, and if it does not do so one asks is it incumbent upon the Office to go out and look for something which has not been identified, at least clearly, by the company concerned.

THE PRESIDENT: In the decision itself, I am looking at paragraph 179, reliance is placed on the MMC's own analysis in the Caremark Fresenius Report to support the conclusion that there is a separate market for Genzyme Homecare services, because in relation to the five prescribed services discussed by the MMC those were situations in which the supplier of the drugs and feeds was able to determine who would supply the services associated with each treatment. So one could perhaps imagine that it was already clear that the Genzyme situation was not entirely unique from which could begin to ask oneself, perhaps in some slightly more wider way, "Well, what is going on here?" "What is normal in the supply of these sorts of products, and what is not?" Because if you have five other examples, even if you are on the question such as intentionally or negligently - quite apart from the question of abuse - one would have thought some sort of background self-informing of what the situation was would've been helpful for the Office to complete its analysis, perhaps.

MR TURNER: So you mean of the up to date situatioN?

THE PRESIDENT: Well, you have a situation where the MMC has already identified very close to the alleged period of abuse, this is in 1998, but the abuse in this case is alleged to begin only a couple of years later, five situations apparently similar to the abusive situation.

If it is then said "Well, this abusive situation is not so different from other things that go on in the industry, you would have thought, perhaps, that one should inform oneself a bit about what other things do go on in the industry, in order to have a full analysis of this particular case.

MR TURNER: The way that the Office approached the issue, I think it is far to say, was from a more focused direction. They took the view that we had here a very narrow area as the Monopolies & Mergers Commission had found, and it is reflected in paragraph 176 of the decision, in the area of what were then called "prescribed services" there is what on one view is a potential difficulty from the point of view of competition law, and having found that that was the case, that confirms the Office's course of action in the decision, because it enabled them to go on and find that in this particular situation there was such a difficulty. But in relation to what was common practice within the industry, again I cannot improve on the point that it is ultimately what the company itself is going to tell you what is common practice in the industry must be your primary

guide. One has to appreciate that the Office is in a different position from the Monopolies & Mergers' Commission, it is not conducting any form of industry analysis, it is concerned with the situation of alleged abuse in one particular case, and whether that is made out.

THE PRESIDENT: Well if it has to concern itself with whether what is going on is different from normal conditions of competition, it might need to inform itself of what normal conditions of competition are for the supply of these sorts of services.

MR TURNER: That is a point well taken, but again in relation to the MMC report what one has, when one returns to it, is a very small number of treatments that are dealt with at all, so that even on the highest view, in my submission, that could hardly be said to amount to common practice within the industry. On further inspection a number of those deal with quite different products and situations as well, in terms of enteral feeds, nutritional products. So that when one is dealing with Gaucher's disease, a specialist pharmaceutical product, and one asks oneself the question, even without representations from the company clearly on point, should the Office have thought from that "This might be a common practice within the industry", in my submission the answer is "no".

THE PRESIDENT: Anyway, I think we have a clear picture of where we are.

MR TURNER: Sir, I think in the course of that exchange I have pretty well covered what I was going to say under that head of "Justification." I will move on to the second head, which is the defence that "Genzyme's exclusionary practices ensure a high quality of homecare service for the patient." This I shall deal with very briefly, but by making one point which is fundamental for the case, so far as the Office is concerned. We say it is an impossible submission to claim that the combination of bundling and margin squeeze together are justified because they ensure a high quality of homecare for the patient,and it is to be borne in mind at all times that homecare is properly to be understood as an extension of the hospital care for patients, buy the NHS and not as a vertical distribution function, by which a manufacturer is getting products to market. As it were, the distribution ends when the product is in the hands of the NHS, and then what one has is an extension of the hospital care. Mr Farrell dealt with this in his oral evidence on Friday. I give the reference for the transcript, Day 2, page 30, lines 24 to 28.

The point is that the drug company has no business in dictating the provision of care to patients who receive Cerezyme in the hospital setting and likewise it has no business dictating the provision of care to patients who are able to receive their therapy in their home setting.

Again, Mr Farrell addressed that point at page 57 of the transcript, lines 33 to 38 where he pointed out the drug companies supply their product to hospitals every day

of the week, but they do not seek to impose themselves on the care that is given to patients in that setting.

Secondly, and following on from that, the Gaucher patients are not, contrary to Mr Vaughan's submission, Genzyme's patients. They are the NHS's patients, and if there were any doubt the proposition can be simply tested by asking what would happen if a new ERT therapy were to emerge in the fullness of time, marketed by a new drug company. At that stage it would be quite apparent that one is not dealing with Genzyme's patients at all.

The third justification that is proposed, is that Genzyme's exclusionary practices lead to a more cost effective form of homecare provision than any which would result from competition. Genzyme has claimed that it is essentially cheaper to use its own operation to provide homecare than to allow the NHS to seek best value. In relation to that, three points fall to be made.

First, Sir, as you noted on Thursday, to the extent that the costs of homecare provision are cheaper when provided by Genzyme Homecare, the financial benefits currently accrue to Genzyme, and not to the NHS, because the NHS must pay the invariant list price.

Secondly, I was going to address certain points in relation to Mr Williams' second report, in so far as that seeks to demonstrate that it is significantly cheaper for Genzyme to use Genzyme Homecare than to use, for example, Healthcare at Home's services. Mr Thompson has traversed a lot of that ground. There is, however, one remaining point which, with your leave, I will ask the tribunal to look at. If I could ask the Tribunal to look at copies of the Dixon Wilson report, because, Sir, if you remember, you expressed the view that at first sight the message did not seem to be too different, as between Mr Williams and the Dixon Wilson report.

I have some loose copies here, if I can hand them up.

MR VAUGHAN: Can we have their reference to this, read it out.

THE PRESIDENT: It is in the bundles, but I can't say where, without----

MR TURNER: I am sorry, Sir, I couldn't find it in the bundle. 16 at page 4260.

THE PRESIDENT: Be careful if you are going to take us to specific figures, Mr Turner?

MR TURNER: Yes. I am aware of the sensitivity. Perhaps one ought to begin actually, by having open for comparison, Mr Williams' second report which is in bundle 37, at tab 25. At page 28 of Mr Williams' report, in a paragraph to which Mr Thompson drew your attention, there is an analysis which Mr Williams has conducted of the supposed actual cost incurred by Genzyme in 2002 in relation to the provision of homecare services, and the physical distribution of product, and we know that that was prepared as a result of work on the management accounts in conjunction with an employee of Genzyme.

If one just drops to the bottom line---

THE PRESIDENT: Paragraph?

MR TURNER: Paragraph 28, and looks at the total figure on the right, that is said to be the total allocated cost subject to certain qualifications made at the beginning of the following paragraph: "For the provision of the service by Genzyme Homecare".

THE PRESIDENT: Yes.

MR TURNER: What I should like is if the Tribunal could compare that with what Dixon Wilson found in relation to the same issue and that is at paragraph 8 of the report - by the internal numbering that is page 10. At paragraph 8.4 you have **here** here again a similar analysis conducted in October, 2002, by reference to the 2002 budget. The column on the right, in paragraph 8.4 shows the allocation to Cerezyme of certain costs and you see the figure at the bottom line there, "Total costs treated as direct costs of Homecare".

THE PRESIDENT: Yes.

MR TURNER: Then at paragraph 8.5 they also add on the overheads that they say should also be allocated to the provision of homecare for Cerezyme. You will see the figure at the bottom of page 10, bottom right.

Then if you turn over the page, the figures are added up in paragraph 8.8 where a costing is given for the comprehensive support operation as budgeted for 2002. When you add the direct costs and the allocated overheads, you get the total figure in the bottom right hand corner.

THE PRESIDENT: Yes.

MR TURNER: Now it is immediately apparent that that figure is greatly in excess of the figure that Mr Williams gives in relation to what is apparently precisely the same activity.

THE PRESIDENT: Yes, can I just say that what I think I meant, when I said "From memory" that the figures were similar to the interim measures' figures was this, that the figures one sees at the end of paragraph 28, that total figure I said to myself from memory looks quite close to another figure that I remembered which is the figure for total homecare costs. In paragraph 8.4 the left hand figure at the bottom of that first column, there---

MR TURNER: Oh I see.

THE PRESIDENT: Those are the two comparisons that I was mentally making, but may say that I was barking completely up the wrong tree because that is not a correct comparison to make.

MR TURNER: I certainly would not say that, but one does see that----

THE PRESIDENT: That was my mental process in case anybody wonders what on earth I was thinking at the time.

MR TURNER: Because in paragraph 8.4 one is dealing there with certain direct costs. The overheads are then dealt with subsequently, whereas if you look at Mr Williams----

THE PRESIDENT: He has the overheads in there.

MR TURNER: He has got it all int there.

THE PRESIDENT: He has got a figure for management.

MR TURNER: He has got warehousing.

THE PRESIDENT: He has not got finance, and he has not got group - I do not know that he has got group overheads?

MR TURNER: No, so for those reasons the two are not---

THE PRESIDENT: They are not directly comparable.

MR MATHER: But what one does see nevertheless, is that in Dixon Wilson there was an attempt by Genzyme to cost the provision of the homecare service and they arrived at a particular figure. The figure that is used in Mr Williams' report is very different from that.

That is all I wanted to go into on the detail.

THE PRESIDENT: Can I just ask one question on this area of costs? One could put it very, very crudely indeed in these terms, there are a limited number of patients suffering from Gaucher's disease. Unlike most markets, a change in price is not going to change the size of the market: there is going to be the same number of patients, however many carers there are. A lot of the figures presumably, in particular the Healthcare at Home figures we had at an earlier stage, are calculated on the basis that, broadly speaking, one company is supplying all the sufferers. In other words, one is spreading the unit costs over the whole population of patients.

If one says one is going to have two suppliers, one serving half the patients and the other serving the other half of the patients, on a unit cost basis, do the unit costs double in those circumstances or are there economies to be made in only serving a smaller population of patients? In other words, there must come a time when it is not efficient for this market to be served by 25 suppliers before they are all going to incur huge overhead costs that no one of them is going to be able to recover. So how many supplier can this market support?

MR. TURNER: There may be an issue with the premise of the question, the market which can support these providers. As I was saying in opening, if and when the bundling practice comes to an end, one is then faced with a situation where you have a small number of specialist homecare providers which cater for quite a large number of conditions. If one takes, for example, Healthcare at Home. They cover a fairly wide range of specialist conditions from oncology through to osteoporosis and thalassaemia and a number of other things. They have nurses who are trained to deal with particular conditions and a market has opened for their services. So that if the pricing practices at

issue in these proceedings are brought to an end you may not be looking at a small, insulated group of Gaucher's patients for whom one provider will be tilting for business.

THE PRESIDENT: So you spread the costs over the other diseases.

MR. TURNER: Yes. It opens out quite dramatically.

Mr. Thompson reminds me that Central Homecare, as we know, under arrangements that are obscure to us, currently provide services for one Gaucher patient only in the Birmingham children's tender. There were, in some cases, a small number of patients with particular conditions who were covered, but in total the business there was sufficient to make it worthwhile.

THE PRESIDENT: Do we happen to know whether Healthcare at Home's existing Gaucher nurses also deal with other patients suffering from other diseases?

MR. VAUGHAN: Yes.

THE PRESIDENT: They do?

MR. VAUGHAN: Yes.

MR. TURNER: We have Mr. Walsh in the room and he nods yes.

THE PRESIDENT: Mr. Vaughan is already nodding. That is an authoritative answer. Would the same be true of the process of delivering Cerezyme to Gaucher patients? Are the drivers who are doing that delivering other kinds of drugs to other kinds of sufferers?

MR. TURNER: Mr. Walsh nods yes. It is working there in the market and one can only assume, therefore, that this is something which is acceptable to the NHS, which is purchasing the services.

Sir, finally on this point, I would make a general remark, which is that, in truth, it is unclear why one should expect it to be cheaper for Genzyme Homecare to provide homecare for the Gaucher's patients than, for example, Healthcare at Home precisely because of the point that you were just mentioning: that Healthcare at Home has a greater, more expansive infrastructure and is therefore far better placed to spread this sort of cost. It would be a surprising proposition if it was inherently more cost-effective to do it through a dedicated in-house operation.

Finally, it is, of course, for the NHS to decide what is best value: it is not for the drug supplier to pre-empt that decision.

The final issue which I shall canter through briefly is the claim that the Department of Health has tacitly approved Genzyme's behaviour. There are three routes through which Genzyme has suggested that such approval has been given for its pricing practices. Those are: the meeting with NSCAG on 13th ----

THE PRESIDENT: You gave them to us a minute ago, did you not?

MR. TURNER: Turning to the NSCAG meeting, I deal with this only to the extent that the

Tribunal wishes me to do so. It is an issue upon which Genzyme places considerable weight and has done so since the case management conference at the end of July.

THE PRESIDENT: Possibly prompted by the Tribunal's questions.

MR. TURNER: That would have been my suggestion, sir. At that time, you noted that there had been a meeting between Genzyme and the Department in February 2001 and asked whether more details could be obtained. Genzyme seeks to rely on this strongly as establishing a kind of acquiescence on the part of the Department for their pricing policy and, in particular, the margin squeeze which it began in May 2001.

Our submission is that the meeting was in fact wholly and unquestionable inconsequential. I would make three points. As Mrs. Stallibrass of NSCAG - she is the specialist services team leader within NSCAG - has pointed out in her witness statement, NSCAG's responsibilities for this condition are limited. They are published on its website, they are generally known and they relate to the funding of diagnosis of the disease, the initial diagnosis, and management advice by which the specialists at the four referral centres can help with shared care with outlying hospital consultants. That is their direct role and their responsibilities do not include funding for homecare nor approval of homecare arrangements.

Secondly, I think it is common ground that the meeting lasted only one hour, which itself should be proof enough that no serious weight can be placed on it conferring any form of regulatory approval.

Thirdly, the only contemporaneous note of that meeting, which is a manuscript note from one of the participants, Dr. Carroll, devotes only a couple of lines to the issue of homecare. At the start of oral submissions, Mr. Vaughan pointed out that there was rather a lot in that note to do with Gaucher's disease. That is, of course, accepted; but the issue with which we were concerned was how far they had gone into the question of homecare and, as to that, you will find only two lines in the copy of the note. I do not propose, unless the Tribunal wants it, to turn that up.

THE PRESIDENT: No.

MR. TURNER: So far as the issue of Dr. Carroll's letter written before that meeting in January 2001 is concerned, that also aroused a certain amount of heat on Genzyme's side; but, in my submission, that was without justification. If I may be permitted to explain that point briefly, the letter concerned - does the Tribunal wish to see it?

THE PRESIDENT: No, we do not need to look at it. Just tell us what your point is.

MR. TURNER: I will give the Tribunal the references. It was raised as significant for the very first time in Genzyme's skeleton at paragraphs 158 and 159 from the final hearing. That is where the significance of the letter was first discussed by anybody. Genzyme said that what this letter did was to make clear that NSCAG wished to assess the introduction of a new homecare service from Genzyme Homecare and that this was a

focus of the subsequent meeting in February 2001.

We responded in our skeleton shortly before the hearing at paragraph 104.3 on page 38 of the skeleton. We recorded our understanding, having been able only to check it orally, that the letter related to a clinical trial for Fabryzyme. That was the new specialist service in NSCAG terms that Dr. Carroll was talking about.

Genzyme made the point again in its reply skeleton shortly before the hearing at paragraph 69. It was in response to that that the Treasury solicitors put in a short letter, merely intended to confirm on the part of the author what it actually meant. It was in response to an issue that Genzyme had raised in its skeleton argument about what the letter meant: we felt that we needed to be able to respond.

One document that the Tribunal, however, may wish to look at, if I may trouble the Tribunal, is at file 47, tab 3, page 5. There is this famous agenda item 7. To clear up a point that may have caused confusion earlier on, this does not relate to the meeting in February 2001 at all. This is an agenda item relating to a subsequent meeting.

THE PRESIDENT: Where are we?

MR. TURNER: This is in tab 3 on page 5. This is an agenda item not for the meeting in question at all. It related to a subsequent meeting that NSCAG held at which the issue of Gaucher's disease came up. It is an internal NSCAG meeting. The purpose of this is that it shows the consideration that actually was given by NSCAG to the question of Genzyme's new innovation in launching Genzyme Homecare and the effect that that had upon Healthcare at Home.

THE PRESIDENT: This is the 27th June.

MR. TURNER: This is the 27th June. The agenda item essentially records information that had come up from prescribers and from hospital staff and that is what it covers. If you go down the page, about half-way, to the passage beginning, "There was speculation among some of the clinicians ..."

Two paragraphs below that: "The letter raises concerns" - this is a letter sent by Genzyme to a wide range of people from whom NSCAG then hear back. "The letter raises concerns that undue pressure is being applied by Genzyme to use their homecare service, the incentive offered being a lower drug cost. There is also a reference, negative in tone, to the involvement of the Office of Fair Trading."

MR. GRINYER: Reading this initially, I was disappointed not to see what came before "... a decision was therefore taken", because there was a statement before that which set a context for this section.

MR. TURNER: I am sorry, yes. Should I set the context for this?

MR. GRINYER: There was a discussion at that meeting and it says, "... a decision was therefore taken by Genzyme to develop an autonomous homecare division as part of the

company."
MR. TURNER: Yes.
MR. GRINYER: What was that discussion? There must have been some explanation of what was happening. It would set a context for what followed on there.
MR. TURNER: I am sorry, perhaps I should have read the preceding text.
THE PRESIDENT: Tab 3, page 5. This is the document of which the earlier one is an extract.
MR. GRINYER: I have the information.
THE PRESIDENT: Yes, I think we are there, Mr. Turner.
MR. TURNER: The short point that I wish to make from this - I do not seek to place any great significance on these events, other than to say that one does not see acquiescence by NSCAG on behalf of the Department of Health resulting from any of this in the pricing practices of Genzyme. That certainly cannot be said.
MR. MATHER: Does the NHS have procedures to assess, to your knowledge, whether its purchasing practices are resulting in an anti-competitive effect of any kind?
MR. TURNER: If I may just take instructions from that, I can give an immediate answer perhaps. (After a pause to take instructions): Insofar as we are aware, sir, there is no-one within the NHS whose antennae are out to look for that sort of behaviour. Sir, you asked a question when Mr. Thompson was on his feet in relation to the letter of 29th March 2001 that Professor Cox had written. You will have seen the fate of that: that was transmitted directly to the Office of Fair Trading. Presumably they are viewed as the appropriate body within Government for dealing with competition concerns. Similarly, Mr. Brownlee, when giving evidence, told us that he views this sort of issue as essentially a matter for the Office of Fair Trading. That was at page 21 on day 2, so far as the transcript is concerned.

My overall submission in relation to the Department of Health is that, for all of its huge and undoubted bargaining power generally, one has to face the issue at hand and there is no mechanism by which the Department of Health is set up to deal with this particular sort of problem. It is regarded as the responsibility of the competition authorities.

MR. GRINYER: So your point is essentially, however many notifications, submissions, meetings a company were to make in respect of a change of this nature, the NHS has itself no machinery to validate or accept that change.
MR. TURNER: Certainly not from a competition perspective, because nobody is looking for that. So, for example, if I may move to the PPRS, we have the basis upon which Genzyme was admitted to the scheme in 1999 and 2000 eloquently described by Mr. Brownlee. Mr. Bratt: "I wasn't on this particular ball at all." It was not his concern, apart from the fact that the Department was over-stretched and so on. It was not an

issue which they regarded as within their domain.

THE PRESIDENT: If you look at it from the company's point of view and you are asking yourself, in particular, whether any alleged abuse was committed intentionally or negligently - if we ever get that far - I am not suggesting we will, but if we did - is it relevant to the issue of intention or negligence that one told one's only customer what one was doing, first of all, in 1999 and against in 2001 and the customer knew what one was doing and apparently raised no objection?

MR. TURNER: By 1999 you mean, sir ----

THE PRESIDENT: The negotiations in the PPRS.

MR. TURNER: In my submission, no and precisely for the reason that they were not saying to their customer, the Department of Health, "This is the way we propose to engage in pricing practices" and looking for any form of confirmation or approval in relation to the matter at hand. The target then was something totally different upon which nobody was focusing their minds.

THE PRESIDENT: They had given them a breakdown of the price, and you rely on that as evidence that the price was actually covering services which it was not supposed to cover.

MR. TURNER: That is true.

THE PRESIDENT: If the customer is getting a price for services that it is not proposed to cover and the customer makes no objection, is that relevant if we ever get as far as assessing the penalty?

MR. TURNER: Sir, in principle it might be, but not in the circumstances of this case, in my submission, because, for a start, the NHS is not a unitary body, so when one talks of the customer one is talking about a creature with many heads. The particular head to which Genzyme was speaking at that time, as Genzyme would have known, was concerned with an altogether different issue. Genzyme itself would not have taken that as being a basis for alleging some objective justification or some defence for its pricing practice. Indeed, I am not even sure whether that is even raised in their case, which, Heaven knows, is large enough. They have not made that case.

When one turns to 2001 - I have covered the point in relation to NSCAG - there again, I say there is simply no basis on which they could say that there is some approval, not from a one hour meeting of that kind.

MR. MATHER: You are saying there is not, amongst its many heads, a head near to validating or approving or acquiescing in such changes. I find, I must say, that it is very difficult to imagine that an enormous monopolistic purchaser can have no means by which it can take a view on whether a pricing policy is acceptable.

MR. TURNER: It is perhaps difficult to take this much further. I must, of course, accept that when one comes to this case one feels that with a large institutional purchaser such

as the National Health Service one imagines that there must be some body that can be looking out for this sort of problem; but the problem is that no-one has been able to find it on either side; no-one has been looking for it. When a complaint is made such as that by the lead clinician concerned, Professor Cox, it is referred on to the Office of Fair Trading.

So perhaps if one likes one might regard the Office of Fair Trading as the appropriate emanation of the state for this purpose. Mr. Thompson reminds me that this is also a novel case and perhaps Mr. Brownlee next time around will be looking out for different things.

MR. MATHER: Mr. Brownlee is the head nearest to the most appropriate to ask.

MR. TURNER: Mr. Brownlee perhaps, because, when asked, I think by yourself, sir, "Is there power under the PPRS to deal with this sort of thing?", he said, "Literally, no." Then he speculated that the Department might, as a result of the pressure it is able to bear, exert some form of influence, but that that situation has not arisen and certainly did not arise in this case.

MR. GRINYER: Dr. Bratt could have suggested that such costs should not be included in the PPRS in 1999; he did not. To that extent, coming back to the President's point, why would you think it was unreasonable for a company to feel at least this was some kind of acquiescence in the way it was actually presented to Dr. Bratt?

MR. TURNER: They presented the figures to Dr. Bratt not in the expectation that he would form a view on whether costs should or should not be included in the list price. As Mr. Brownlee said, that was a matter that was regarded as within the domain of the company, but simply in an effort to persuade Dr. Bratt and the NHS to ameliorate the 4.5% price cut to which they were to be subjected.

MR. GRINYER: I had not mentioned including costs in the National Health Service price because this is a grey area, I think we will all agree, after listening to Mr. Brownlee. But in the AFR, the PPRS people could have said, "Look, we don't regard these costs as legitimate within the PPRS scheme. We will not allow for it when calculating your profits." That would have signalled to the company that, in fact, this would not seem fully legitimate. However, it may be that I am wrong.

MR. TURNER: The first point to which one comes there is, of course, as again we established with Mr. Brownlee, this is not a company that submitted annual financial returns with a sufficient level of detail at all, nor according to Mr Brownlee to his knowledge, had Genzyme been called on to submit any form of returns, it had simply submitted annual statutory accounts. Certainly it cannot be said, and I think is not said, that through the submission of the annual statutory accounts the Department was in a position to validate the pricing practices of the company.

PROF GRINYER: I agree with all of that. My concern was that just at this point in

time cost figures were presented, information was there for Dr Bratt, and indeed, Mr Brownlee, and nothing was said at that point which could have discouraged the company from taking that line, in which case how do they interpret this, and this was, in fact, the President's point?

MR TURNER: I think only two points can be made in response to that. The first is that it is important to recall the purpose for which one is having a conversation and the context in which it takes place, and in this particular context neither Dr Bratt, nor Mr Brownlee, nor anyone had this point in mind.

Secondly, that that is so is demonstrated conclusively by the fact that Genzyme itself has not alleged that that forms a base for it to have been misled as to there having been some form of regulatory approval for its practices, which it might've been expected to have done.

PROF GRINYER: Yes, I am not talking about regulatory approval which is different. Yes, thank you.

THE PRESIDENT: Yes, Mr Turner, we need to press on a little bit, I think. We cannot sit beyond about 25 past 4 today.

MR TURNER: Sir, I think in that case I will make one concluding remark. I think we have fairly covered the PPRS and the Health Act, 1999. I will make only on remark about EL 95(5) which was the remaining category, because Genzyme persists in their arguing that the Department could always correct its pricing practices through issuing a similar sort of letter to EL95(5) and in relation to that I have two points to make. First, our own submission on the point which the Tribunal has at tab 4 of bundle 47 was made after full consultation on the point. The position stated there is at least the most authoritative that we have been able to put together and in my submission nothing in Genzyme's response to it dents it one jot.

EL95(5) was addressing essentially GP prescriptions which also cover the costs of homecare services, as is plainly shown from its language and the letter accompanying it, both of which are copied in the MMC report. But the general point is that even if the Department were to issue a further sort of direction, and one is hypothesising here requiring hospital trusts to contract separately for homecare services, that would not solve the problem of unbundling in this case.

It would lead to hospitals paying twice over if they contracted with anyone but Genzyme homecare. But the irreducible fact in this case is that we have a drug company supplying a product for which there is no alternative, and in that context one asks what is the particular bargaining power of the Department? It has none. Therefore any form of internal arrangements that it makes will not address that particular problem.

MR MATHER: Did not Mr Brownlee, in the passage that you mentioned a few moments

ago, say the Department had got potential bargaining power?

MR TURNER: Well, I would need to go back to the passage concerned to see precisely what he did say, but I certainly did not understand him to say that the Department could, as it were, achieve any result it wanted.

MR MATHER: No, I think a general sense of what he said was although the formal limits of the PPRS scheme imposed some borders, in practice, in h is discussions with the drug companies he could indicate if the Department did not like a particular form of behaviour in the expectation they might reconsider it. I feel his remarks were of that sense.

MR TURNER: That was conditioned by the particular experiences that he has had and he was very particular to point out that he deals with companies in the context of them approaching him for price increases and the like, in the context of the scheme.

The situation that we have here, in my submission, is a rather different and novel situation, and in relation to that issue, as Mr Brownlee did say, he rather takes the view that it is for the Office of Fair Trading, their territory, rather than his.

MR MATHER: Accepting that point, is it not possible to envisage a situation in which Mr Brownlee's, shall we call it "arm twisting", could complement the issue of the circular so that your objection to the issue of a circular is that it, of itself, did not change the bargaining power of the NHS vis a vis the company. On Mr Brownlee's comments, were they to be added to the issue of a circular, would that not significantly alter in practice the bargaining power of the NHS with the company?

MR TURNER: Sir, it is very difficult for me to go into that issue any further. All I can say is that that must remain within the issue of speculation. What is clear is that there are no specific legal powers to address this issue, and Mr Brownlee has made his own position clear as to the appropriate body to deal with them, but beyond that I feel it is difficult to go. Mr Thompson reminds me also that we have a situation where the Patients' Association are extremely vocal and the Leeds clinicians in this area were raising concerns repeatedly and they found no recourse.

Sir, unless I can assist you further, those are my submissions.

THE PRESIDENT: Thank you, Mr Turner.

MR THOMPSON: Well, I do not know whether it is exactly light relief, but I am afraid you have got me again for the closing part.In order to try and expedite matters, over the weekend Mr Turner and I, with a number of able assistants put together written answers to the questions that you put to us last week.

THE PRESIDENT: Has Mr Vaughan got copies of these?

MR THOMPSON: Certainly, it is a speaking note to help everyone to go through. As I understand it we are going to come back on another occasion, so I do not think there is any....

THE PRESIDENT: Yes.

MR THOMPSON: I was intending to go through this as a speaking note with some comments as we go. I should perhaps say that I was not proposing to deal with the issue of the penalty, the matter is fully fairly set out in our defence at paragraphs 254 to 297 by reference to the decision at 397 to 444. So this address is straightforwardly the ten questions that the Tribunal put to the parties almost exactly a week ago.

The first one was "What determines whether nursing in a particular case is provided by NHS nurses or by Healthcare at Home or Genzyme Homecare"? I think Mr Morland's fourth statement represents a degree of convergence on this issue. Our position is set out here based on the statements of Professor Cox, Dr Mehta, Mr Farrell and Dr Jones. Our understanding is that the current situation in relation to new Gaucher patients is that they will undergo initial diagnosis and treatment at one of the four national referral centres. If and when it is considered that home treatment is a practical option there will be a detailed discussion between the clinicians, pharmacists and designated homecare services provider, currently either Genzyme Homecare or in the great majority of cases Healthcare at Home, as to the appropriate arrangements for that patient.

Initial home training in the administration and storage, etc. of the treatment, will then be undertaken by Genzyme Homecare or Healthcare at Home and, if the patient becomes capable of self-administration thereafter, the situation will be continuously monitored by the referral centre and homecare services provider to ensure that an appropriate level of care is maintained. If a patient is unable to self-cannulate the homecare company will continue to provide the necessary nursing assistance.

In relation to the NHS, we understand that it is not in general considered a first port of call, or a practical alternative for such services. The existing involvement of NHS nurses is primarily a historical matter. Prior to the appointment of Healthcare at Home in 1998 a number of patients were already receiving an element of nursing care from NHS nurses, nine of whom are now receiving homecare services from Healthcare at Home but also continue to receive infusion assistance from NHS nurses.

Although Mr Farrell indicated that in principle he would be happy to see a greater involvement of the NHS in homecare in the future, he explained that this was an aspiration and he did not consider it to be a practical alternative to the provision of homecare services from independent providers, given the demands placed on such nurses and the particular requirements of treatment considered appropriate for homecare, and the costs to the NHS of setting up its own internal service. That is what we understand in summary to be where we get to in the light of the evidence we have.

Point 2 I think I can take very shortly. I think the short answer is "yes". We set out two points of concern that are raised in the decision and in the pleadings, and

they relate to the fact that the effect of the pricing policy has been to drive everybody out of the wholesaling market because you can only get supplied at the price above the price charged to hospitals.

THE PRESIDENT: But that is not considered abusive.

MR THOMPSON: The way I put it is in the second paragraph on page 3, the second point is given the way Genzyme explains the price it appears that there may be an element of payment for homecare services, even in relation to hospital supplies, but we did not identify either of those as an abuse on the decision, as they were not taken into account in either the direction or the penalty. The reason for this was that the exclusion of independent companies from the supply of homecare services was of central concern to the OFT. We also took into account that the remedy of the stand alone price, imposed by the decision would result in hospitals no longer paying for service they did not receive as they would pay no more than the new unbundled list price for the drug.

THE PRESIDENT: On the homecare side?

MR THOMPSON: At all. The stand alone price---

THE PRESIDENT: What is the price to hospitals, under your direction, what change if any is there in the price of supply to hospitals for consumption in hospitals?

MR THOMPSON: There may be a negotiated price below the list price, but the list price---

THE PRESIDENT: In relation to hospitals why should the price change at all? I thought you were just telling me that there is no abuse alleged in relation to hospitals?

MR THOMPSON: There was no abuse, but the remedy that is imposed relates to the stand alone price for the drug.

THE PRESIDENT: How can the remedy relate to a part of the case in which there is no abuse alleged?

MR THOMPSON: Well in order to remedy the problem in relation to homecare services, in our submission it is necessary to have an unbundled price for the drug. An incidental feature of that will be that if that unbundled price is lower than the current hospital price---

THE PRESIDENT: You can unbundle a price without necessarily lowering it.

MR THOMPSON: Indeed, if it comes out as higher than 273 obviously this will be a complete non-point.

THE PRESIDENT: I cannot at the moment see how the direction can possible affect the hospital price if there is no abuse alleged in relation to hospital price.

MR THOMPSON: It is simply that if there is a stand alone price which is hypothetically lower than 273 that will be the---

THE PRESIDENT: Why should that apply to hospitals? The idea is to take out the homecare services element. At the moment, in relation to hospitals there is a list price and for the list price you get delivery of the drug to the hospital, included in the list

price. There is no challenge to that so why does that not stay the same?

MR THOMPSON: Well, if it turns out that the NHS list price is actually lower than the "concessionary" price to the hospitals, my understanding is that it is universal practice that the NHS list price is treated as a cap for all purposes by NHS purposes. The second limb of the direction does in fact require Genzyme to supply all third parties at a maximum of the NHS list price, and therefore makes the normal practice, as it were, enshrines it in the decision to safeguard the position.

THE PRESIDENT: Well, is that not, as it were, getting at the hospital price by the back door?

MR THOMPSON: That may well said to be so, yes.

THE PRESIDENT: Is tart legitimate, I wonder? Does it even throw doubt on whether the direction is really focusing on the abuse which it is concerned with, because if there is no criticism of the NHS list price, in so far as it is the price charged to hospitals, it may be rather difficult to have an across the board direction that affects that part of that sector? Anyway, let's go on for the moment.

MR THOMPSON: Yes,I am not sure it would matter in practice. I know, on our case at least, Genzyme has a considerable amount of market power but it might blush to charge for wholesale deliveries to hospitals more than its stand alone price.

THE PRESIDENT: That is assuming that either the present direction, or any direction the Tribunal might substitute, involves reducing the NHS list price. It is also making an assumption about how much the reduction might be. Another perfectly feasible alternative is to leave the NHS list price where it is, and simply introduce the option of some discounted price for anybody who wants to provide homecare services. It does not change the NHS list price at all, i.e. a continuation of the situation we have had since the interim measures' Judgment.

MR THOMPSON: I have some points on that further down.

THE PRESIDENT: Anyway, your case at the moment is that this, one way or another, gets the price to the hospitals?

MR THOMPSON: Well the direction addresses the NHS list price. It is true that one could have a negotiation whereby the NHS list price plus whatever the wholesale cost is, is at 273, so that the end result will be the same.

THE PRESIDENT: OK, well thank you for clarifying that.

MR THOMPSON: That would be a matter for negotiation and it may be that the hospital deliveries would remain at 273.

THE PRESIDENT: Yes.

MR THOMPSON: The third question is about what Genzyme should have done for the 1st March? We say the answer is implicit in a particular part of the decision, and in particular paragraph 307 which I set out at the top of page 4. The answer is Genzyme's

tying policy ultimately leaves the NHS with no real choice of homecare services provider, and as such abusively exploits the NHS, and through it the patients. The fact that the homecare services are provided by Genzyme itself through Genzyme Homecare, or through a third party acting under contract for Genzyme, for example, Caremark, or Healthcare at Home until 5th May, 2001, is irrelevant. In either case, the customer and the consumer are deprived of choice over the source of supply from other parties, because the NHS is effectively tied through Genzyme's pricing policy to receive the homecare services from Genzyme, or an undertaking acting under contract for Genzyme. We refer to paragraph 69 of the Napier Brown decision.

It might be just worth taking you to that. I think Napier Brown is only in our bundle of authorities. It is tab 25 which is bundle 49.

THE PRESIDENT: I think you said 22, which is Tetrapack.

MR. THOMPSON: Twenty-five.

THE PRESIDENT: I am sorry. I have got 25. That is the core. I think you want the Commission decision, do you not?

MR. THOMPSON: I do. I can only apologise.

THE PRESIDENT: Never mind, Mr. Thompson. I think we know roughly what Napier Brown ----

MR. THOMPSON: The relevant passage was cited in the defence.

THE PRESIDENT: I think what is behind this question from the Tribunal - in fact, we get to it in number 4, as you say, is this. If we go back to March 2000, we have a situation where Genzyme at that stage has no distribution arrangements of its own in this country. It is launching or has only very recently launched an entirely new product, which is not yet very far established on the market. It is very often conventionally assumed that some kind of exclusive distribution agreement in those circumstances is an orthodox way of proceedings, in particular because if you are asking a distributor such as HH in this case to take on the business of developing the market and making investments in training and in promotion and so forth, you grant them exclusivity as the quid pro quo for asking them to do that. If you do not give a distributor exclusivity, it might be a bit difficult to get anybody to take it on. That leads one on to ask whether, even accepting, as is the case, that as a result of the exclusivity there is no choice of supplier, should there not be some balancing exercise to see whether, bearing in mind that disadvantage, there are also not advantages in exclusive distribution at this early stage in the distribution of the product?

MR. THOMPSON: Yes. I certainly intended to come back to the issue of exclusive distribution in a moment. If I may just show you the point in Napier Brown, because it is highly material. It is probably the closest case on the facts to the present one. It is in the defence. It is quoted verbatim. It is bundle 28. Having so many authorities, the

only one we have turned up turns out not to be in the bundle.

THE PRESIDENT: Can we not find this? Which tab?

MR. THOMPSON: It is pages 52 and 53 of the defence. The principal conclusion is at paragraph 71, which is cited in paragraph 158. "BS has abused its dominant position on the sugar market by refusing to grant to its customers an option between purchasing sugar on an ex-factory or delivered price basis, thereby reserving for itself the ancillary activity of delivery of that sugar."

The lead up is paragraph 69, which is cited below. "British Sugar has accepted that before the end of 1986 it refused to supply sugar to its customers unless the customer also accepted that BS itself - whether BS delivered the sugar itself or did so through third parties acting under contract for BS being irrelevant - supplied the service of delivery of the sugar. It was thus reserving for itself the separate but ancillary activity of delivering the sugar which could under normal circumstances be undertaken by an individual contractor acting alone." So that is the principle that we are relying on.

THE PRESIDENT: That is a very mature, well-established market in which distribution arrangements have existed for years. This is an entirely new market with no established distribution.

MR. THOMPSON: Indeed, the point of distinction that you,
Mr. President, have put to me is in one distinction, the distinction that we rely on, that this is not in truth a distribution agreement at all: it is an agreement which relates to a necessary element of a services product which is separate from traditional distribution.

THE PRESIDENT: An exclusive arrangement for services, but the principle is the same: you need a degree of exclusivity to persuade anyone to make the investment to take it on in conventional competition law theory anyway.

MR. THOMPSON: I understand the point that is being made in relation to a new product, as it were - somebody wants to launch a new brand of shoes in the United Kingdom and wants someone in the UK to take on the shoes. The customer could not care less how the shoes get to the shop: they go in and buy the shoes and if they thought about it they would know that in the cost of the shoe they were paying for the shoes to get to the shop, but they could not care less how they get there. In relation to traditional competition law theory, it is thought that there is a degree of benefit in exclusivity being conferred in such circumstances or if it can be justified because it gingers up the distribution network to conduct themselves in an efficient way and may, indeed, be necessary if this is a risky product.

Here, we have purchasers such as Professor Cox,
Mr. Farrell and the Gaucher's Association who care deeply about the circumstances in which the service is delivered. Cerezyme is a necessary element in that service

provision, but the position, in my submission, is very different from a supplier of shoes who decides to appoint an exclusive distributor to get the shoes efficiently to the shops and where the customer could not care less how they get there as long as they are still in one piece when they open the box. In my submission, this is an entirely different situation where the effect of the distribution arrangements, and in particular the pricing arrangements, is to foreclose competition between independent service providers in circumstances where the customer wishes to specify the service in considerable detail and also cares considerably about what they pay for that element of the service. That is the essential reason why we say that the exclusive distribution analogy is an imperfect one.

THE PRESIDENT: What evidence do we have of the customer's concern about specifying the service and the price he was being charged in the period up to May 2001 and the period from March 2000 to May 2001?

MR. THOMPSON: I think the primary evidence Mr. Turner took you to in relation to the concerns expressed by Professor Cox and Mr. Manuel in 1996 and 1997.

THE PRESIDENT: They were concerned certainly about Caremark at that time, but have we got any complaints about Healthcare at Home between 1998 and 2001?

MR. THOMPSON: Complaints about Healthcare at Home? No. There was some from Genzyme itself, partial justifications in the background of the termination, but none from customers.

THE PRESIDENT: It is true that people were complaining about Caremark, but - correct me if I am wrong, but I have the general impression that most of the clinicians at least were satisfied with Healthcare at Home between 1999 and 2001.

MR. THOMPSON: Indeed. I cannot argue against that, because of course one part of our case later on is that, despite the fact that Healthcare at Home is doing it for nothing and it involved quite a bit of effort on the part of the primary customers, Healthcare at Home has in fact stayed in the market and people have been loyal to Healthcare at Home, despite the general aggravation of continuing to deal with them in the circumstances that have prevailed since May 2001. So I cannot say that there are any complaints about Healthcare at Home, but, equally, I cannot accept that that is anything against my case because the fact is that the customers generally are happy with Healthcare at Home.

THE PRESIDENT: Your case is that Healthcare at Home would have been obliged to accept a non-exclusive contract as from March 2000.

MR. THOMPSON: I do not really accept it in those terms. In fact, it may be worth just read the next paragraph. We say: "Genzyme should have offered NHS purchasers such as Mr. Farrell the option of purchasing Cerezyme without the price oh homecare services included, at the latest by 1st March 2000. Healthcare at Home could, of

course, have remained Genzyme's nominated or preferred supplier, so that the option for continuing to use Healthcare at Home at a bundled price might have remained. Such arrangements are common place in a variety of economic sectors, but the NHS should have been free to make alternative arrangements at its choice or, indeed, to negotiate directly with Healthcare at Home if that was its preferred option. This was clearly explained by Mr. Farrell in his statement and oral evidence in relation to the tendering process recently undertaken for haemophilia products." So that is the core of what we say should have happened in March 2000.

"After May 2001, the anti-competitive situation was aggravated but not fundamentally altered by Genzyme supplying Healthcare at Home as an independent home care provider, rather than one under contract, at a price which allowed no margin out of which Healthcare at Home could fund its service. Again, the situation could have been remedied by Genzyme supplying Cerezyme at an unbundled price, allowing NHS purchasers to arrange with independent providers for appropriate provision of homecare services." That is what we say are the two elements.

Then as to the state of mind which I think you have put both to myself and to Mr. Turner, we do rely on the fact that the negotiation with the PPRS over the 4.5% price reduction took place at the end of 1999 and the beginning of 2000. Genzyme was fully aware of its pricing policy in the period immediately prior to the Competition Act 1998 coming into force from 1st March 2000. Indeed, there is a further document showing they had been considering their pricing position back to the previous July, because they had known that the 1999 Act was coming into force, which was likely to involve a price cut. So they had been considering this whole question.

Genzyme also re-negotiated its contract with Healthcare at Home at around the same time, culminating in the agreement of a new contract on 1st February 2000 and it could and should have taken the opportunity to establish a stand alone price for the drug.

Then question 4. We come expressly to the question of distribution. The decision does not directly address the question of the exclusive arrangement between Genzyme and Healthcare at Home. The source of the abuse was and remains the fact that the NHS was unable to purchase Cerezyme without incurring the costs of homecare services.

We say that this is not a perfect analogy to an exclusive distribution by any means. At its lowest, this service includes - and we say it is - a service about which the NHS customer has very strong views and which is certainly not just a distribution function. It is not like an ordinary retail purchase of shoes etc. That is the point I have just been making.

If one looks then at the efficiency gains, the limited number of Gaucher

patients is clearly something that the NHS purchasers would have taken into account in deciding what homecare services provision was appropriate. One of the major advantages of using a specialist services provider such as HH being that it has a national network of service teams which are capable of meeting the requirements of the NHS for a flexible service for a small number of patients scattered throughout the country and whose needs vary over time. Again, this was explained by Mr. Farrell.

Insofar as there may be efficiency gains from a sole or exclusive arrangement, that is a matter for the NHS purchaser. They can take that into account in appointing a homecare services provider.

Incidentally, we would not accept that by 2000 Genzyme, which had been dominant on this market, a monopoly supplier, since 1994, could be said to be in the position of a new entrant.

THE PRESIDENT: We have to take it to be 1998, do we not? Cerezyme is a new and quite different product from Ceredase. It is still treating Gaucher's disease, but its chemical composition is different and the ability to self-infuse at home is quite an important innovation, is it not?

MR. THOMPSON: In economic terms, the homecare services element has been involved since 1993. We have seen that in the original appointment of Caremark, going right back to 1993. So I would not accept that this was an immature market in that sense.

THE PRESIDENT: We should treat them as the same product, should we?

MR. THOMPSON: In terms of the economic point that is being made to me, in my submission, this is a company which has had a monopoly position, an unchallenged monopoly, for five years in the United Kingdom and is therefore not in the position of a new entrant requiring an exclusive distributor to enable it to compete on this market. After all, it was a monopolist.

THE PRESIDENT: This is standing on its head a lot of conventional theory about the advantages to the public interest of research in drugs and bringing new products to market and all that sort of thing, which places a considerable weight on encouraging innovation through temporary monopolies at the beginning of the period.

MR. THOMPSON: We are in no way challenging the orphan drugs legislation or the monopoly that Cerezyme has had or that Genzyme has had as a result of its innovation. That is no part of our case at all. The only point is to object to the pricing arrangements and the inability of the NHS to choose who provides homecare services. That is the limited scope. We would not accept that we were standing on its head anything about intellectual property or orphan drug legislation.

We say that insofar as there may be efficiency gains from a sole or exclusive arrangement, that is a matter the NHS purchaser can take into account in appointing a homecare services provider. There is no advantage in Genzyme having control of this

issue. Genzyme could continue to offer NHS buyers such an arrangements or its vertically integrated service if it is of the view that this is the optimal way to deliver homecare services. There is, indeed, no reason why Genzyme Homecare should not be appointed by any or indeed all of the NHS purchasers on an exclusive basis if they think this is the most efficient option. The events since May 2001 do not suggest that NHS buyers generally consider that to be the case.

Then one looks at the other side of the coin and what would have happened if there had been a tender. We say there would have remained an abuse if Genzyme had done this and had continued to supply Cerezyme at a bundled price.

As state above, Genzyme is free to enter into arrangements for in-house provision for approved or exclusive supply. However, the decision is directed towards releasing the NHS buyer from the obligation to use Genzyme's chosen supplier resulting from the bundling of the price of homecare services with the cost of Cerezyme. In any event, the course of conduct that Genzyme actually undertook to drive out competition via a margin squeeze of course renders this question academic on the facts of the facts.

Then we were asked how many players we thought there could be on the market and obviously Mr. Farrell's oral evidence is what we primarily allow in here, which was in the earlier evidence.

Our understanding is that it is implicit in that evidence that he considers a single homecare services provider for a single treatment such as Gaucher's disease is likely to be the most efficient arrangement for an individual hospital such as the Royal Free. However, the precise arrangements entered into by any particular hospital were a matter for the four specialist referral centres in consultation with the various local and regional bodies involved. Whether each of the four referral centres would agree on the choice of service provider is a matter for them, and it is possible that an NHS purchaser may consider it appropriate to enter into arrangements with more than one provider to provide homecare services for the Gaucher patients under its care. Mr. Turner has given one or two examples of special circumstances: the case in Berkshire and, indeed, Central Homecare.

If the price of Cerezyme is unbundled, then it will become possible for homecare providers to compete for business in the supply of homecare services as part of competition in the wider homecare market. Its wider market currently supports four specialist homecare companies and it seems likely that these four companies, along with Genzyme Homecare, would compete to supply services to Gaucher patients.

We then come to the two questions about refusal to supply. The first one is addressed to the OFT and whether or not we accept that there are important elements of refusal to supply. We reply shortly to that.

Characterisation of the abuse as a refusal to supply to the NHS at an unbundled price is possible but does not alter the nature of the analysis. The fact remains that the NHS continues at all times to purchase supplies of Cerezyme - so it is not actually prevented from obtaining it - albeit at a bundled price. The essence of the abuse relates to the anti-competitive terms as to the price upon which it does so.

If one looks at the position of individual providers such as Healthcare at Home, Clinovia, Central and Callea, one might seek to characterise the abuse as a constructive refusal to supply Cerezyme to them since no reasonable commercial terms are offered. Again, however, this does not affect the nature of the analysis. The focus remains on the detriment that is occasioned owing to the exclusionary - and, I should add, pricing strategy - to the interests of the NHS and the patients on whose behalf the NHS deals.

As regards Oscar Bronner, we maintain our position as in the skeleton. The decision does not proceed on the basis of a refusal to supply but rather on the basis of a bundled price to purchasers of Cerezyme. You might say that our focus is on the NHS buyer rather than on the intermediate purchaser, because we regard that as the key to unlock the door.

Nonetheless, were Genzyme to refuse to supply a competing homecare provider, the OFT by no means concedes that the Chapter 2 prohibition would be inapplicable, applying the principles laid down by the ECJ and Oscar Bronner.

The OFT respectfully submits that the exchange between the Tribunal and Genzyme's counsel on day 1 supports the view that there would have been at least a strong argument that such conduct constituted a further abuse. We say that, with respect to Mr. Vaughan, he offered no real answer to the question put to him by the President. We say that it is not necessary to show that a purchaser would be put out of the homecare services market altogether. One might draw an analogy to the port cases, where, although some of them have been criticised, we say it is clearly not necessary to show, in order to found a port type case, that a shipping company would be driven out of all ports in Europe for it to bring a case about a single port and the conduct of the port operator in that case.

If I then go on to paragraph 2.40 of the MMC report, that is a matter that has obviously been discussed with Mr. Turner already, so I can be brief on that. Our general position is that the matter was well summarised, with respect, by the President in his questions to

Mr. Farrell and it has already been rehearsed that we rely on the acceptance of the second question. "Mr. Farrell, I think you are saying that we do not have a choice of provider ----"

THE PRESIDENT: We have read it, thank you, Mr. Thompson.

MR. THOMPSON: Indeed. Then there is specific reference to Nutricia and we make the point that that is a market where there are three competing suppliers. In relation to the exchange with Mr. Turner, I was perhaps slightly in a better position to check the documents than he was at the time. I would summarise the position as follows.

We would accept that it is a good point that the further evidence now available puts the Tribunal in a better position than the OFT was when it took its decision to assess the question of whether this is or is not common commercial practice. However, we say that that is a bad point insofar as it is put forward as a valid ground of complaint of the decision. The reason why I say that - which may seem surprising on its face - requires me just briefly to show you first of all the response to the Rule 14, then the decision and then the notice of appeal.

First of all, Rule 14. It is at bundle 4, page 851, paragraph 13.1, "Summary of the objector justification." Then in the third line it says: "It is plain that Genzyme is a objectively justified in not using wholesalers and distributing Cerezyme directly to patients, as it has to do under the Drug Tariff, and providing homecare where that is wanted. A number of other pharmaceutical companies with products where there may be a need for homecare ..." and then it names Aventis, Baxter and Wyeth "... already do so and it has never been suggested that they are doing so illegitimately."

Then in the next paragraph there is a reference to paragraph 2.60 in Nutricia and it says: "The MMC described how Nutricia decided in 1997 to bring its distribution arrangements with Caremark to an end and to bring distribution and homecare in-house. No objection was taken by the MMC to Nutricia's decision to do so."

Then there are more specific points on bundling at pages 853 and 854 and, in particular, at 13.12, where there is, what you might call, the end strike point about its plans for in-house homecare.

MR. VAUGHAN: Can you deal with page 774, 5.1, where we develop this point?

MR. THOMPSON: That is a different point. That is a general complaint about the Fresenius/Caremark document, which is not really on this point. It is certainly dealt with at some length in the decision and, indeed, great passages of the Fresenius/Caremark report are referred to in the decision.

THE PRESIDENT: What they are saying - forgive me, Mr. Vaughan - if you go down from 5.1 and get down to 5.6 in particular - whether rightly or wrongly this is what they are saying - there are a number of other prescribed services - five - in which there were treatments and the only NHS payment was for the prescription, that is to say, the treatment is included in the NHS list price. I think they are saying - or at least it is fairly clear from the Fresenius/Caremark report - that for some of these companies like Nutricia they are de facto the only source of the homecare concern. That is fairly clear

from just a glance at the Fresenius report. So they are referring the Office across to that report and saying, "This is quite similar to what the MMC was considering in that report", are they not?

MR. THOMPSON: That general point certainly was addressed in the decision. There is a long section quoting parts of the MMC report.

THE PRESIDENT: It was not directly being considered by the MMC, because the MMC was looking at the merger, but by way of background the MMC could see that there were a number of companies who were doing something quite similar to what Genzyme was doing. Is that not fair? The point they are making here is, "There are a number of companies who are doing something quite similar to what we are doing, including having a bundled price." That comes from 5.6. Am I right so far, Mr. Vaughan?

MR. VAUGHAN: It is rather better than I would have done it.

THE PRESIDENT: There is no need to suck up, Mr. Vaughan!

MR. THOMPSON: What is certainly true is, under the heading "Homecare Services Market", there is definitely a reference to the Fresenius/Caremark merger. That is certainly something that is taken into account in the decision at length. The specific point I was dealing with was the question of objective justification by reference to common commercial practice.

There the point seems to be in-house provision was recognised and noted without apparent objection by the MMC. We say they were not investigating that but that was the issue that was ----

THE PRESIDENT: That is how you put it; that is your case.

MR. THOMPSON: If you then look at the decision, that was dealt with at paragraph 363, where the OFT makes it plain that that was not what the abuse identified was, and so the fact that that was objectively justified was neither here nor there.

Nothing daunted, Genzyme came back with the point in the notice of appeal - I am not sure where you have got the notice of appeal - at page 108. Almost verbatim, paragraphs 609/611 set out the same points about direct supply. That was the point that was put on objective justification in the notice of appeal as well as it had been in Rule 14.

THE PRESIDENT: They are specifically relying on Nutricia.

MR. THOMPSON: Indeed.

THE PRESIDENT: As a parallel example.

MR. THOMPSON: As they did in the Rule 14.

THE PRESIDENT: What is the distinction that you make between this case and the Nutricia case? Why could they not say, "That is the same sort of case and no-one has objected to it. It is a bundled price and it is an exclusive arrangement."

MR. THOMPSON: I do not think we accept that that was. The only point that was made was that this is a vertical integration.

THE PRESIDENT: If you read the MMC report a little bit more carefully, it is clear that it was a taking in-house in an exclusive way. Or, at least, that is the inference we draw from the fact that the MMC treated it as a - I was going to say that is the inference we draw from the way the MMC was treating is as a prescribed service, i.e. a service in which the service was paid for out of the cost of the drug. I think you have recently pointed out that there may have been other suppliers of the products that Nutricia was supplying, so that may be a difference in the Nutricia case. But Nutricia seems to have had a policy of including in the NHS list price the services it was giving.

MR. THOMPSON: Yes. But that is not the point that was put either in Rule 14 or in this part of the notice of appeal. It was simply put on the basis of vertical integration.

THE PRESIDENT: We understand what your position is on this aspect.

MR. VAUGHAN: In the notice of appeal, Mr. President, 141-151 deal with this whole question about paragraph 2.40 and everything like that. So it is not just one reference.

THE PRESIDENT: Thank you.

MR. THOMPSON: Just to complete the picture, the Office in the light of the complaints that were generally made about this aspect of the investigation then got specific evidence from Mr. Farrell which did deal with the specific companies that were identified in the notice of appeal and you recall he deals with that in his statement.

THE PRESIDENT: Yes.

MR. THOMPSON: We now come to a rather critical point, which is question 10 and the two possible remedies if indeed we get so far.

Our basic position is - if I can put that in summary and then we will see how far we get on the detail - that our proposed remedy, the setting of a stand alone NHS list price, is the correct remedy to address this form of abuse. It requires two things to be priced separately: first of all, the drug; secondly, the ancillary service. We submit that that is conceptually and practically the best way forward.

In terms of practicalities, the Tribunal will recall that the point was put very straight to Mr. Farrell and got a very straight answer. The OFT's option was described by the President and was then said - it appears at the top of page 12 in the note - there is the question and then the Tribunal asked, "How do you see that working out? Is that going to work out along the lines you have already described?" Mr. Farrell said, "That would be my preferred option, yes."

So, in terms of practicality and reality, we obviously rely on that as a way forward. In terms of, as it were, the rational or conceptual position, I think that the clearest way to look at it is by reference to the drug tariff. We set out clauses 6A and 8C of Part 2 of the Drug Tariff at the top of page 11. You will see a heading,

"Calculation of Payments to Pharmacy Contractors": "Payment for services provided by pharmacy contractors in respect of the supply of drugs shall comprise the total of the prices of the drugs less clawback and the appropriate professional fee as set out in Part 3A", that is clause 6. And then clause 8C: "The basic price for a drug which is not listed in Part 8 of the Tariff shall be the list price for supplying to contractors, that is, pharmacists, of the pack size to be used for that quantity published by the manufacturer, wholesaler or supplier. In default of any such list price, the price shall be determined by the Secretary of State for Health and/or the National Assembly for Wales."

We say that it is coherent with that approach that the additional costs incurred by homecare service companies such as HH or Clinovia will be charged separately to the NHS under contract, as is generally the case where a service is not provided for in the drug tariff.

So the position we put forward is that this would be a coherent and rational way to achieve what is required and that it would cohere with the general approach under the drug tariff that pharmacists, albeit rather exceptional pharmacists in that case, receive separate payment for the separate services that they provide. So that is our positive case.

I should perhaps add that in the question the Tribunal adds a gloss - it is on page 9, the seventh line - that Genzyme would presumably be prohibited from providing homecare services without extra charge at reduced list price, which is effectively dealing with a possible predatory pricing case.

We say on page 12 in the middle that that is not actually part of the decision. The OFT made no finding that there had been predatory pricing, although of course there could be on different facts such a finding. Given the bundled price, Genzyme has to date been remunerated for the provision of homecare services out of the NHS list price, so we say there is no basis for a predatory pricing case at the moment and that was not part of the directions.

THE PRESIDENT: Supposing the price is reduced to a new price, completely hypothetically. The new price is some figure. The drug is available to all-comers at that figure. This reduced figure. Healthcare at Home, Clinovia and all the rest of them buy the drug at this new price and they offer to supply the services to the NHS at so much per visit or so much per delivery or so much a year or whatever it is. Are you saying there would be nothing to stop Genzyme from saying to the NHS, "Here is the new list price and I will provide you with the drug at the new list price and I will include in that new list price the services that you want without extra charge to you"?

MR. THOMPSON: No, I am not saying there is nothing in the Competition Act that would address such a question. In my submission, that would be as clear a case of predatory

pricing as this is of margin squeezing.

THE PRESIDENT: Supposing it is still above cost, it is above average variable cost, it is above total cost etc.

MR. THOMPSON: We are envisaging a situation where the costs, as it were, up to the pharmacy dispensing are separated out and the costs after that to the homecare services provider are allocated separately. If Genzyme could only show zero as its charges after the dispensing moment, in my submission that would be a very clear case of predatory pricing.

THE PRESIDENT: Would they be all right if they changed their procedures and delivered to the local community pharmacist instead of delivering to the patient's home?

MR. THOMPSON: I am not sure what is being put to me.

THE PRESIDENT: This is the NHS list price, but this is the delivered price to the local pharmacy. The patient goes to the local pharmacy and collects it. Would that be problematical? Let us say they charge exactly the same price as they have got now, but instead of the distribution system you have got at the moment it is an orthodox delivery to a local pharmacist.

MR THOMPSON: I am sorry, at exactly the same price as now or at the unbundled price?

THE PRESIDENT: Yes. In what way would the argument change, or what criticism could be made of Genzyme if, instead of delivering to the patient at home they delivered to a community pharmacy?

MR THOMPSON: And would they, at the same time---

THE PRESIDENT: At the same price.

MR THOMPSON: And would they at the same time by supplying to Healthcare at Home at the lower NHS list price, and then Healthcare at Home would be bearing all its own costs in competition?

THE PRESIDENT: There are several alternatives. What you are seeking is what you call a stand alone drug price?

MR THOMPSON: A drug price, yes.

THE PRESIDENT: For services that are supplied post-pharmacy. How does your analysis work if the distribution system used by Genzyme is modified and what they do is supply to the local community pharmacy, instead of supplying to the dedicated pharmacies in Burton-on-Trent and Oxford, and it is from the local community pharmacy that the patient collects the drug.

MR THOMPSON: It is difficult to deal with all the hypotheticals.

THE PRESIDENT: Yes, I am just trying to test---

MR THOMPSON: Well, indeed.

THE PRESIDENT: ---this reliance on the pharmacy, which is not for many reasons a typical case, but seems to be very prominent in the OFT theory, the accident that there happens

to be a pharmacy in Burton-on-Trent, the whole thing seems to turn on that, that the delivery is there, the prescription is dispensed there rather than where it normally is.

MR THOMPSON: In my submission, it is not just a trick of the light, as it were, the fact is from that point on the costs are down to Healthcare at Home. The ordinary pharmacist on your case is simply doling out the drug. In the present case Genzyme at home is bearing large costs.

THE PRESIDENT: Supposing Genzyme assumed the cost that most manufacturers assume, which is the cost of getting the drug to the community pharmacist, would that be open to criticism?

MR THOMPSON: Well that would be a conventional model, but there would be no homecare services. It would simply be on sale to a community pharmacist, but for the reasons I think Professor Yarrow explains quite eloquently, that would not be a good system for Cerezyme, that would be a completely different situation. I do not think it has been proposed by anyone that that would be a workable, practical way to distribute Cerezyme.

MR MATHER: Would the model you are suggesting, the stand alone drug price and the extra charge separately for the homecare service require the Health Service to change all other similar arrangements, or would this apply uniquely to Cerezyme?

MR THOMPSON: Well I think you there touch back on to 240 and also Mr Farrell's various issues that he found unsatisfactory, and I do not doubt that the outcome of this case will be scrutinised by a number of suppliers with a number of different arrangements, but we have made this decision on the basis that this is an exceptionally powerful supplier, with an exceptionally restrictive pricing policy.

It may well be that other pricing policies would come under scrutiny on the basis of this decision, but I do not think that apart from the question of whether this is common commercial practice, which we have already addressed, that that really takes the matter any further. The fact is this is a very unusual situation, where in Mr Farrell's experience there is only really one comparison. I think that is probably confirmed by Mr Williams in his second statement. Apart from that the arrangements vary but I think are universally less restrictive in this one.

MR MATHER: You suggest they should discuss it with the Department of Health in accordance with the principles underlying the PPRS, penultimate paragraph, last line, page 12, which part of the Department would they discuss it with?

MR THOMPSON: Well they would come back in front of Mr Brownlee if they wanted to put the price up, because I think it was clear from his evidence that in the event that Genzyme wants a price rise the right thing to do is to go to Mr Brownlee, and of course, there are various issues that arise in relation to the 1999 correspondence which, in the light of what has now emerged, may be appropriate for discussion between

Genzyme and the Department in any event.

PROF GRINYER: You are assuming that the profits of Genzyme will fall so markedly that they have reached the bottom limit and be able to go to Mr Brownlee with a request for a price increase?

MR THOMPSON: Well, they can always ask for a price increase.

PROF GRINYER: Under PPRS my understanding was only when they had reached a bottom floor. There is a floor.

MR THOMPSON: There is that, or they might argue that the NHS list price as set - there are various possibilities - is not in fact 243 at all. They might argue, for example, that they should be allowed to use the hospital price, or they might argue that one of the prices set in 1993 or 1994 should be used. There are various possibilities, but I do not think it is going to be helpful now to try and work out what might happen if they want a higher price than 243.

THE PRESIDENT: Which bit of the DoH do you chuck this back to? The evidence so far is this is basically for the PCTs to sort out by their own tendering procedures or their own contracts, or whatever?

MR THOMPSON: There are two aspects to this, there is the PPA and the Drug Tariff, and I have shown you the relevant part, and effectively there is automatic reimbursement of the NHS list price, but that is a matter that is regulated by Mr Brownlee and his team under the PPRS.

THE PRESIDENT: Well the manufacturer is free to set the list price, or at least in these cases.

MR THOMPSON: Indeed, but that is a regulation, a regulatory regime which we have looked at which to some extent controls the NHS list price. It automatically gets reimbursed under the Drug Tariff.

THE PRESIDENT: You see the evidence we have from Mr Brownlee - very helpful evidence - is that he was not prepared to say, for example, that home delivery would not be included in the NHS list price, or he would disallow home delivery costs and in PPRS terms. In other words, he had not really met this situation wearing his PPRS hat. So where does that put the PPRS branch when it comes to negotiating what the list price should cover?

MR THOMPSON: Well, he was categorical that a cost to pharmacist would be excluded.

MR VAUGHAN: No, not cost to a pharmacist.

THE PRESIDENT: The dispensing fee is not covered, but we are not talking about the dispensing fee. The dispensing fees are a quite separate thing.

MR THOMPSON: No, I said anything, I put it to him expressly - it was the first question I asked him - if the matter was a cost to the pharmacist, would it be permitted as part of the manufacturer's list price, the NHS list price, and he straight forwardly said "No".

THE PRESIDENT: Well, I may have misunderstood you, but I understood the question to mean that is the cost of running the cost of running the chemist's shop b y the pharmacist, including his cost of dispensing, reimburseable to the manufacturer, to which the answer is self-evidently not. But again you are placing all this weight on **the pharmacist**, whereas in Mr Brownlee's world, the pharmacist is a different sort of pharmacist from the pharmacist we have got here, is he not?

MR THOMPSON: Well in terms of the payment mechanism I am not sure that he is.

THE PRESIDENT: In terms of how to get the drug to the patient, the pharmacists we are talking about here are several hundred miles away from the patient. It is not the typical case. prohibition

MR THOMPSON: No, but I am simply making a point in relation to reimbursement, and there it does not really matter where they are.

THE PRESIDENT: Well, it does, because there are costs of getting the drug to the patient.

MR THOMPSON: Indeed, there are and they are borne by the pharmacist not by Genzyme.

THE PRESIDENT: Well, I don't think we can take this much further. The typical pharmacist does not normally bear the cost of getting a drug several hundred miles from the pharmacist's premises to where the patient is. He bears the cost of physically handing the patient the little packet having dispensed the prescription which was handed to him by the patient over the counter earlier in the day or whatever it is.

MR THOMPSON: Indeed, that is certainly true.

THE PRESIDENT: This is a different operation altogether.

MR THOMPSON: Indeed.

THE PRESIDENT: Not only is it a different operation but it is integrated with whole lot of other operations as your evidence has gone out of its way to tell us.

MR THOMPSON: Yes, the simple point I am making on that point, is that that is a cost that Genzyme is not bearing and so it is consistent with the drug tariff price that that is not a sum that should be---

THE PRESIDENT: But they are not bearing it because they are supplying drivers and so forth to deliver the product.

MR THOMPSON: Through their own in-house service provider.

THE PRESIDENT: Yes.

MR THOMPSON: Which is a pharmacist, exactly.

THE PRESIDENT: He is a pharmacist as well, because he needs to be in order to be able to store the product, but he is, as you keep reminding us, an integrated homecare services provider which includes pharmacy as one of its activities, but those other activities are not the sort of activities generally undertaken by the typical pharmacist to whom the Drug Tariff is directed. I am a bit lost at the moment about the weight being put on the analogy with the Drug Tariff. It does not seem at first sight this really is analogous to

the case normally being considered in the Drug Tariff.

MR THOMPSON: I do not want to dwell on that one because I hoped it was a point of clarification of the case.

THE PRESIDENT: Anyway, at the moment all we are trying to do is to understand what your case is.

MR THOMPSON: Yes, if I could just put it that the other limb of course is not governed directly by the Drug Tariff, it is simply a commercial negotiation between purchasers and Genzyme, and there the Drug Tariff price is essentially a cap on that negotiation, but nonetheless important.

THE PRESIDENT: Yes.

MR THOMPSON: I should say that in relation to the alternative proposal which appeared in the question and which has appeared in the Tribunal's questioning from time to time, our point on that is at pages 12 to 13 and we accept that this proposal might in principle achieve the same beneficial objective but we see it as having certain disadvantages. The first point is that in so far as it was simply a discount it would not create a stand alone price which essentially takes us back to the point that we were discussing earlier, in relation to a direct negotiation between the hospital, either for supplies to the hospital or for home care services, reimbursed by the hospital a discount would not be the appropriate situation because the hospital itself needs a stand alone price of some sort, so it would have to be expressed in a slightly different way from a traditional wholesale discount, but it would be a price to the hospital, possible for somebody else to provide the service. It may be that that could be got round mechanically, but that is an issue which we perceive.

THE PRESIDENT: It is the interim measures' solution we are basically discussing. If other homecare providers could obtain this product at some price that gave them a margin at which they could compete with Genzyme Homecare, it would not perhaps matter very much whether Genzyme Homecare had a bundled price or not, there would be competition int he market, and either the hospital can buy it at an inclusive price if that is the easiest administratively or it can tender for some separate price. As Mr Farrell points out he is asked to tender on lots of different bases.

MR THOMPSON: It may be that the last part of the question: "Do these alternatives come to the same thing?" may be quite a pertinent one, because if sufficient safeguards are built into the discount remedy it will come very much to the same thing as creating a stand alone price. I think that would then take us back, as it were, full circle to the point I started with, that it is more appropriate in our submission for this to be a stand alone price regulated by the Department of Health in that there is a regime already in place for regulation of drug prices, under the Drug Tariff and the PPRS, than for a, as it were, bespoke regulatory regime to be put in place governed either by the Tribunal or on an

ongoing basis by the OFT. It seems to us that it would accord with the system of regulation and reimbursement under the Drug Tariff, for that to be a matter set by the Department of Health, rather than by the Office of Fair Trading and so partly it is a matter of modesty on the part of the OFT to leave this matter where we say it belongs, with the Department of Health, rather than attempting to regulate the drug price ourselves. I think that is where we come out in the end.

THE PRESIDENT: Well, let's leave it there. There are a number of different regimes in this case, including different regimes within the Department of Health, but the Competition Act is undoubtedly a different regime from the Drug Tariff and the PPRS, and whether one should really use the one to solve the other may be a matter for further reflection.

MR THOMPSON: I can see that and the Office has certainly considered these questions in some detail and we are by no means adamantly opposed to an alternative remedy if it is perceived by the Tribunal to be more administratively straightforward and more appropriate to the---

THE PRESIDENT: There was no difficulty in the Office taking it on in the Napp case, and if you remember that had a sort of self-correcting mechanism in it so that the lower the list price went they still had to maintain a certain differential between - you will remember, Mr Turner - was it the community prices and the hospital prices?

MR TURNER: Yes.

THE PRESIDENT: I think it was, yes, however. I think this is all for later in the case.

MR THOMPSON: I am sure the Office would rise to the occasion and there is one clear advantage in that it would simplify the pricing structure, that is the price we make at the end, in that the PPA would continue to reimburse at the bundled price which would be a somewhat rigid price but it would be administratively even more straight forward, and so we certainly accept that that is one advantage of that approach.

I do not know if there are any other points, I am sorry about the time.

THE PRESIDENT: Thank you, Mr Thompson, I am conscious of the fact that I have pressed you a bit. It is part of the purposes of the hearings to press on these issues. There is a lot at stake for the parties.

MR THOMPSON: I should perhaps just say that in relation to 6th October, I am personally available then, and the Office is keen that this matter should be dealt with expeditiously. I do not know what the position is with my learned friend.

(Discussion as to timetable)

(Adjourned until 10.30 am on Monday, 6th October, 2003)