IN THE COMPETITION APPEAL TRIBUNAL
New Court,
Carey Street,
London WC2A.2JT

Case No. 1016/1/1/03

26 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 TWO

MR. VAUGHAN: I have just been handed a third witness statement of Dr. Gareth Jones, which we had not seen, despite having been here for about ten minutes, until being handed it this very second, which is not very polite, apart from anything else. We will reserve our position on that, if we may. You have not seen it, I imagine.

THE PRESIDENT: We do not have it.

MR. VAUGHAN: So it is not before the Tribunal.

THE PRESIDENT: It is not in the proceedings at the moment. Yes, Mr. Thompson.

MR. THOMPSON: Perhaps I could just deal with that point straight away. I think it was a point that Mr. Vaughan raised on a number of occasions yesterday and he was awaiting a response from us on this issue.

THE PRESIDENT: On which issue?

MR. THOMPSON: On the issue of the question asked about paragraph 240 of the Fresenius/Caremark report.

We have made a number of enquiries, culminating in some enquiries with Heathcare at Home on the basis of which we have a statement from Dr. Jones which was faxed to the Tribunal at 10 o'clock, which I appreciate is not ideal - and to the other side.

THE PRESIDENT: I do not think it has got through the system. At least, it has got to the Registry but it has not got physically to the members of the Tribunal.

MR. THOMPSON: I apologise for that. Can I hand up copies? (Same handed)

THE PRESIDENT: Give them to the Registrar for the time being and we will look at them later; we will not look at them now.

MR. THOMPSON: I think it is probably best in that case to go straight into the witness evidence and, as I understand it, Mr. Brownlee intended to come first.

THE PRESIDENT: Yes, I think that is the idea.

MR. THOMPSON: So if I can call Mr. Brownlee. I do not know how formally you wish me to call him, but I was proposing to take him to his statement in the conventional way, but if that is not necessary ----

THE PRESIDENT: Well, first of all, I do not think it is necessary on this occasion for these witnesses to be sworn, unless anybody thinks they should be.

MR. VAUGHAN: No, not at all.

THE PRESIDENT: If you would be kind enough to ask Mr. Brownlee to come forward and ask him who he is, we will go on from there.

MR. THOMPSON: Certainly, and the only other question, of course, is whether there is anything which the Tribunal wants to raise in the light of the discussions overnight or whether you are happy just to proceed and see how we get on.

THE PRESIDENT: I am proceeding on the basis that the e-mails that were disclosed yesterday are in the proceedings and we have to deal with them on the basis that they

are in the proceedings. I find it very difficult to see how we can really treat as confidential the subject-matter of those e-mails.

MR. THOMPSON: I am going to speak to Mr. Brownlee this morning. I do not know whether that issue can be cleared up at the start.

THE PRESIDENT: I think we ought to clear it up before we have any evidence. That ought to be sorted out first, if we may.

MR. THOMPSON: You will recall that there was a formal position which ----

THE PRESIDENT: Which was a holding operation until you had a chance to get instructions or clearer instructions.

MR. THOMPSON: Indeed, and my formal position is as it was before. So far as I understand it, the formal position of the Tribunal has not changed. I am simply raising it to see what the formal position of the Tribunal will be when Mr. Brownlee takes the stand.

THE PRESIDENT: If you want to invite us to treat the contents of these e-mails in some restrictive way and if that is opposed by Mr. Vaughan - if it is - then I think we ought to rule on it before we go any further.

MR. THOMPSON: Indeed. I think the principal issue is whether, as a representative of the Department of Health, Mr. Brownlee's views should be known and taken into account; that is why I raise it now.

THE PRESIDENT: It should be raised now and if Mr. Brownlee has views on it, I think you should take instructions and tell us whether you maintain the position that you were maintaining yesterday.

MR VAUGHAN: It is as I understood it, Mr Brownlee is not concerned about the content being discussed, it is simply there is an issue of principle here for the Department and he is happy to explain what it is in his own words if that would assist the Tribunal.

THE PRESIDENT: What do you say, Mr Vaughan?

MR VAUGHAN: It is wholly unsatisfactory, my friend has had the whole evening, night, and morning to discuss this, it is up to his solicitor to give him instructions and for him to make a decision and an application. At the moment there is no application for confidentiality. It is a matter for my friend to make an application. If the wants to make an application one can deal with that with everyone here, but otherwise the court has to be cleared, and it looks as if half the Hutton Inquiry has arrived here wanting something to do.

THE PRESIDENT: It is not a suitable analogy I don't think.

MR VAUGHAN: No, no, but very large numbers of people are here.

THE PRESIDENT: Yes.

MR VAUGHAN: And we cannot start Mr Brownlee without you ruling on this matter, and my friend has to make his application. We would certainly oppose anything---

THE PRESIDENT: What Mr Thompson is inviting me to do is to hear what Mr Brownlee has to say about this aspect, before we rule.

MR VAUGHAN: My friend has to take a point of principle. Confidentiality is not a matter for individuals, it is a matter for my friend, he represents the Office of Fair Trading, he has to make an application and rely on evidence if he wants to, but one cannot deal with it on the hoof as on goes along, you rely on submission. It is of fundamental importance, because clearly these documents have some relevance, and otherwise we cannot really question, and you cannot question Mr Brownlee, and we cannot question Mr Brownlee without referring to the documents. It cannot be done in shorthand or code.

THE PRESIDENT: Yes, Mr Thompson?

MR THOMPSON: Can I clarify? I am not making a formal application. On Monday I indicated that this might be a matter of sensitivity, and that there might be aspects of Mr Brownlee's evidence that would be confidential, and since Monday a particular issue has arisen on which the Tribunal made an order. That order was still in force, as I understand it at the end of yesterday and the beginning of today. I simply raise the matter so that we all know where we are when we start. My formal position is that Mr Brownlee is perfectly happy to discuss the content of the emails. He does have reservations about the use that might be made of the content, for example in the Judgment, and I simply raise that and the obvious person to give evidence on what the Department's concerns are is Mr Brownlee himself, rather than me to do it, especially as he is about to appear in the witness box. That is the only point I make, and in my submission that is an entirely reasonable position.

THE PRESIDENT: I think we had better have Mr Brownlee, and he had better explain to us what his concerns are, if he would be kind enough to come along. Have we got Mr Brownlee?

MR JOHN MICHAEL BROWNLEE, Called

THE PRESIDENT: Good morning, Mr Brownlee.

A. Good morning.

MR THOMPSON: Mr Brownlee, you will have heard that exchange. Can I just explain, you have two bundles there. One is a bundle of defence statements which I think is the fatter bundle underneath, and your first statement is in there. The other one is a more recent bundle, bundle 47 and your more recent statement is in there, and the documents appended to your first statement are behind the first statement in that bundle, if that should be necessary, and I am sure you can be provided with a copy of the emails in question as necessary, if you have not got them already.

THE PRESIDENT: Yes, well do you want to ask the witness about the confidentiality issue?

MR THOMPSON: I am sorry, I had understood the Tribunal was going to ask, but the question is what is the position of the Department in relation to these particular emails, both in these proceedings and more widely the issue of confidentiality in such discussions between the Department and the Office of Fair Trading. If you could explain that to the Tribunal I think that would be helpful.

A. In this case, and if I may refer back to the previous case, the Napp case with which I was also involved, we have a position where, on the one hand we talk to the Office of Fair Trading as inter-Government departments and in the other case we make statements or things into the public domain. In the Napp case we found ourselves, we were feeling our way in a sense, we found ourselves in a situation where there were conversations that had taken place and minutes that we had not seen which two years or eighteen months later we then find there is a request to be released and as I recall they were.

So when we got to this place we tried to make a distinction between what I might call informal conversations and discussions and what was going to be possibly released. The three or four emails that are the point of this morning come into the latter, they were not deemed at the time that we understood would be relied on.

There was, if you like a point of principle there rather than actually the content of the emails themselves of which I have no concerns about them---

THE PRESIDENT: No concerns over content?

A. ---being discussed, because I think they are pretty well what subsequently was said, not necessarily the exact words---

THE PRESIDENT: Yes, but you are happy with the content?

A. Yes.

THE PRESIDENT: Well, I think for the purposes of today, all we need do is rule that there is no objection to the contents of those emails being discussed today. The Tribunal is in a difficult position, Mr Brownlee, because we are simply trying to get information about what happened and how the system works and all that sort of thing. In this particular case this decision, rightly or wrongly, has placed a certain amount of weight on your views which is why we have asked you very kindly to come and help us. The emails - both your existing email of 13th and now these further emails of a couple of days before tell us informatively what your views are and it is useful for us just to explore what your views are in the context of this case. I do not think anybody feels, I do not think that you feel particularly that you have any reason to hide what your views are. So I think if it is all right with you we will proceed on that basis, on the basis that the emails will be the subject in this public hearing, and if there is any later issue that arises, of course, or any concern that you have then either directly or through OFT's counsel by all means let us know what your concerns are. We will proceed on that basis

if we may.
A. Fine.
THE PRESIDENT: Thank you very much. Good, are you all right standing or would you prefer to sit down?
A. I would like to sit down eventually but---
THE PRESIDENT: Yes, please sit down if you feel you would like to sit down. Just for the record, I just need to establish if I may for the transcript, that you are John Michael Brownlee. You are a civil servant, and you work for the Department of Health and you have responsibility for the Pharmaceutical Price Regulation Scheme, known as the PPRS?
A. That is all correct.
Q. And you have in fact been doing that for nearly seven years now, since 1996?
A. Yes.
Q. We, in this Tribunal, as you know - if I may say so by way of background, are investigating matters under the Competition Act, 1998. We are not investigating the PPRS or how the DoH administers that scheme. We are only interested in the PPRS in so far as it bears on the competition issues in this case, you will understand me. We are primarily interested in understanding it, and understanding the background with which you are familiar but we are not, so we may well - I in particular - may well ask you questions that seem to you very simple questions that anybody would know, but please bear with me if I seem to ask things that may, at first sight seem to be rather simple. We are very sensitive to the fact that you may have issues that you may have to decide from time to time which may or may not have arisen so far, and you may not particularly want to commit yourself as to what you decide if any case arose, so please do not feel inhibited in telling us that you do not have a firm position or whatever it is, if that is all right. Is that a reasonable basis upon which to proceed from your point of view?
A. Yes, sir.
Q. I think you have had the chance to read the decision. You were to some extent involved in exchanges prior to the decision being taken. We have various items of evidence, particularly from Professor Yarrow and Mr. Williams that has been produced by the appellants in this case, and we have the advantage of two witness statements from you: one of 30th June 2003 and the other of 5th September 2003. So that is the general background.

Could I now just start with a few questions to clarify my mind on the NHS list price? As we have understood it - and I would like you, if you would, when I have asked a question if you could just say yes or no so that the Shorthand Writer gets it, rather than just nod your head because there is a transcript being kept - under the

system, if I can use the word loosely, for a new pharmaceutical product, a new active substance, the company can freely set its own NHS list price. That is as I have understood it; is that right?

A. Yes, it can, sir.

Q. Once that is set, under the PPRS, it cannot actually increase that price without your permission; is that right?

A. That's correct, sir, yes.

Q. From time to time there may be an across the board reduction in that price insisted on by the Department of Health, as happened in 1999; is that right?

A. The last two occasions we have re-negotiated the scheme, as part of the new scheme, the Department has negotiated a price cut.

Q. As I have understood it, the list price, which is also the price that appears in the drug tariff, is the basis or the starting point for the reimbursement of the pharmacist when the drug is dispensed in a community pharmacy; but there are circumstances in which the pharmacist is not actually paying the NHS list price to acquire the drug, so there are arrangements for, as it were, clawing back any discount he may have received under a discount scheme, except in cases of drugs that are known as zero discount drugs. Am I broadly right so far? Would you like to explain it in your own words?

A. The first thing to say is, not all drug prices are in this document. Indeed, the products that we are dealing with today are not in here. The system is that for a new active substance the company concerned will inform the Prescription Pricing Authority what the price is. It will hopefully also tell us.

Q. But they do not necessarily tell you or are they supposed to tell you?

A. They pretty well do, actually, if only because it has become known that sometimes the PPA will take things up with us if they are not clear, so most companies realise that it is quicker to short cut that loop.

Q. But the scheme does not actually say they must tell you first.

A. No, it does not. That price is then the basis upon which, as you correctly say, the pharmacist is reimbursed, less a discount claw back, which is currently slightly less than 10% across the board, except for a classification of drugs, as you correctly say, which is zero discount, which, because of their exceptional circumstances, because of their distribution requirements - cold storage or something like that - the Department, in co-operation with the PSNC, which is the representative body of the community pharmacist, have agreed that there will be no claw back against the list price. So the wholesaler and the pharmacist are allowed the whole margin, which nominally is 12.5%.

Q. So they are allowed that margin irrespective of whether in a particular transaction the actual transaction price is less than the ----

A. We generally do not know what, in terms of branded medicines, the transaction price is between the manufacturer and the wholesale and the wholesaler and the community pharmacist or any other variation of that ----

Q. -- particular chain of supply.

A. Yes.

Q. Perhaps I can come back to zero discount drugs in a moment and just press on for the time being. If we can then look at the standard or typical case. We know this case is perhaps not standard, which may be one of the underlying problems, but if we look at the typical case, as I have understood it, the NHS list price is not normally the ex-manufacturer price, that is to say, the manufacturer will normally be selling to a wholesaler at a discount, conventionally 12.5% but maybe less or more than that figure; is that right?

A. That is the assumption, yes.

Q. That is the conventional assumption.

A. That is the conventional assumption.

Q. In fact, that is in the decision at paragraph 85. Would it be, in general, fair to say that, conventionally speaking, the published list price is "a delivered price", that is to say, within that price is the idea that it will cover the distribution of the product through the chain in the standard conventional case?

A. Yes, that is correct.

Q. Looking at how the PPRS works, as we have understood it, it is a control over the overall profits of the company by reference to a return on capital employed rather than a direct control over individual drugs or the prices of individual drugs; would that be right as a broad description or how would you describe it?

A. I would describe it as, it limits or controls the prices of medicines indirectly through placing a limit on profitability of companies.

Q. In that context, you control the profits of companies that are above a certain size, I think.

A. Yes, 25 million.

Q. Twenty-five million.

Q. And those companies submit to you, I believe, a detailed return of their costs and their profitability. Some items are allowable and other items are not. In the case of this company we are discussing today, Genzyme, I gather they are under the 25 million limit.

A. As far as I am aware, yes, they are.

Q. Do you have any direct knowledge of what kind of returns they submit or is that not something you have got present in your head at the moment?

A. They should submit their annual accounts to us. If I might just add a little bit more

detail.
Q. Yes, please.
A. Below the 25 million, if a company does not apply for a price increase or wants to do something that we think is a bit peculiar or wants investigation, then we need never see them other than them sending in their annual accounts and then that is it. If there is an issue to do with the deliver of, say, the 4.5% price cut or they consider that they are justified a price increase, then they write in and for a price increase one of the things we would say is, "Can we please have a financial return on the same basis as a company above 25 million?"
Q. So for companies in this case, below the limit in the ordinary way, they will simply sail on unless they wish to do something or something alerts you to something that you ought to be looking at.
A. Yes.
MR. GRINYER: How detailed would those accounts be? Would they cover a cost analysis of any sort?
A. The accounts for the 25 million?
Q. Under 25 million.
A. The annual financial return that we would apply ----
Q. -- would just be the normal company accounts.
A. -- would just be the normal - companies submitting their figures - we have got a tailored return that companies have to complete, which tries to extract the costs and the assets related to NHS sales and those figures should be related back to UK published accounts so that we
can ----
Q. So that relates to companies under 25 million too.
A. Where we ask them to submit a return, yes.
THE PRESIDENT: We can look at particular returns actually submitted in this case and that will tell us what they should have included.
A. As far as I know, Genzyme has not been asked to submit - in fact, I am 100% certain that we have not found it necessary to ask Genzyme to submit a return.
Q. So what have they actually been sending in, their statutory accounts?
A. I presume so. I am sorry, I have not checked in detail as to what has been coming in.
Q. That is fine. There is no reason why you should have done.
A. We have provided that that is what they should be doing.
Q. Sending their normal statutory accounts.
A. Yes.
Q. As we have understood it, even in cases where a more detailed return is being submitted in which the companies over 25 million are invited to break down their costs

under various headings - distribution, R&D, marketing and so forth - that is done on a company basis rather than on an individual drug basis; would that be right?

A. Yes, that is correct. Obviously, there are circumstances where you get companies with one main medicine, although that does not typically come with a company with 25 million or more.

Q. In the typical case, it would not be your particular concern to go into the costs of individual drugs: you would get the general figures for a portfolio of products; is that right?

A. Yes. There are two circumstances in which we get involved in the prices of individual medicines. One is where a company comes along and proves to us that it is justified a price increase across the board on its total - we then will obviously want to know which products it want to take those in and have some idea as to comparable products in that class of drug. The other is where a new medicine is introduced which is not a new chemical entity, a medicine that has got some sort of delayed release formula or something that has been added to it, in which case the company comes in and says, "We would like to charge twice the price", or whatever, and we say, "No". There then proceeds a negotiation on what, in the circumstances of that medicine and in the circumstances of what the NHS is paying for comparable products, the price should be.

Q. In those specific circumstances, you might look in more detail at the build up of the price of particular medicines.

A. Yes, and the circumstances and what the company was claiming would determine what we looked at, so it is hard to give a generalised rule.

Q. One of the conundrums we have in this case is what the NHS list price is supposed to cover. The evidence that we have so far is that there is no precise definition of the NHS list price or what exactly it is supposed to cover. What I am wondering - and I would be very grateful for your view - is this. Given that the PPRS scheme is a control over profits and it is looking at the company as a whole, can we really draw any conclusion from the way the PPRS is administered as to what the NHS list price is supposed to cover, if you see what I mean? In other words, since the PPRS is not a cost plus schemes, I think is one of its virtues or is often said to be - features, anyway - is there in your view a read across from the PPRS to the list price? Does it throw light on what the list price covers, or is it somewhat obscure, if I may put it like that? We would be glad of your view.

A. As you will know from my statement, actually part of this was the first time we had actually been asked to try and define---

Q. You had not been asked to define it before?

A. Well not to my knowledge.

Q. Not to your knowledge, no.

A. As the new products' companies are allowed to name their price, as it were, and that is the reimbursement price, and that becomes the NHS list price, we do not then say "Please what are the components of that?" If, on the other hand, a company comes in and puts in for a price increase, and it says "We want a price increase because we want to build worldwide headquarters int he UK", we may or may not say that that is a valid cost reason for that price increase. To that extent we would look at what the actual components of the list price might be, but only in a fairly limited way. I think there is a general recognition between us and the pharmaceutical industry, one of the benefits the pharmaceutical industry see of the PPRS is that we do not ask, and the with globalisation of the industry, it becomes increasingly different realistically to give a cost breakdown, because actually they do not have the data---

Q. Intra-transaction prices, different manufacturing bases, all sorts of things, yes.

A. Yes.

MR MATHER: Could I ask if you have any guidelines on how you take those sort of decisions, going back to your example, perhaps, of the world headquarters, in deciding yes or no to that, how would you be guided?

A. It intentionally has not been written down because one of the things I was throughout the last negotiations of the scheme, and I think I can disclose what we were trying to do was to get greater clarity into the scheme, and it is a difficult balance of getting that clarity, and maintaining flexibility. So we do not have a template into which all companies have got to fit. We have obviously, we look at similar cases and similar companies to find out what we have agreed, and there are clearly some "no-no's" and there are some things that are reasonable cost additions and, as you will appreciate, although it has a statutory backing it is a voluntary scheme, so obviously there is a fair amount of ---

THE PRESIDENT: There is a fair amount of give and take in the negotiations.

A. ---give and take.

Q. I think you are telling us that in order to maintain that give and take and flexibility there is a certain argument for not being too prescriptive in advance as to what is allowed and what is not allowed.

A. It is clearly relevant in terms of us deciding what return on capital employed a particular company has had in a particular year.

Q. Yes, absolutely.

A. But unless they are in a profit repayment situation that is, in a sense, an academic figure, so we do not tend to get too much. We have a discussion but it is not too tough a discussion. It becomes tougher when we are either saying to a company well, "You owe us a million pounds because we are disallowing..." whatever it is, or when they come in for a price increase.

Q. If we now, as it were, come a little bit more to the circumstances of this particular case, we have a situation - would it be fair to describe the present situation as a non-standard situation in the sense we do not seem to have the normal wholesale function and the normal delivery to the community pharmacy that would be the normal conventional operating assumption of the scheme, would that be right?

A. That is certainly correct. Again, one of the points in the operation of the scheme, clearly we do not go out to get, there are 15, 16 people, including myself, operating this and doing other things at the same time.

Q. Of course, absolutely.

A. So we do not set out to go and dig into every company to find out whether there is necessarily a comparable case, so there may well be comparable cases, but they have not come to our attention.

Q. Yes. So it may be rather theoretical to ask how a case like this would be treated under the scheme if, hypothetically the company was over #25 million and it was exceeding its return on capital which would be the circumstance in which you would be interested in what was going on?

A. Yes, that issue we have not had. We have had comparable situations to draw on. Because Genzyme has not had to submit a return, the only information we have had available is what are in its published accounts, and we find it far easier to deal with company situations where we do have returns, because over a period of time and over meetings and discussions we get a knowledge base of the company. That was absent in this case, and was certainly absent in September, 1999 when there was an exchange of correspondence.

Q. Quite, well we will have a glance at that in a moment, if we may.

A. There was also an issue when being asked, and the exchange of emails, and all the rest of it, "What would you do?" The reason for, if you like, hesitation, is saying well, "We probably would not allow it", but not wanting to lay down in the abstract, hypothetical and benchmarks that might make it difficult for us to take a more reasonable position.

Q. No one, I don't think, is levelling any reproaches in your direction, Mr Brownlee. It is very interesting for us to try to get into the detail of it with the man who knows most about it. Do you have that little bundle of emails, the recent emails, to hand?

A. Yes, I do.

Q. I am not sure that I am necessarily going to get them in the right order, but basically what I think happens is that the OFT case officer in this case sends your department an email asking for the definition of the NHS, what the NHS list price is intended to cover, posing a number of questions, and one of those questions - I think it was question 2 - was "Please comment on the following: The NHS list price is intended to cover the cost of the pharmaceutical together with manufacturer's profit which is constrained to a

maximum by the PPRS. The NHS list price also covers de facto the cost of delivering the medicines to the patients", and it was particularly that last sentence, "The NHS list price also covers de facto the cost of delivering the medicine to the patient". I think initially, in your absence a colleague of yours, Mr Kullman on 11th December, 2002, replied to the effect that he was not aware that the NHS list price is defined, but he would not disagree with the statement that was being put to him. That was the first part of the exchange.

The case officer then took it further up with you, and you were clarifying the situation and in a further email of 11th December, 2002 at 15.59, which begins: "Dear Mike", it is from the case officer, you are recorded as having explained that there is no legal definition of what the NHS list price covers. PPRS works on the assumption the medicine is delivered to a pharmacy and is then collected by the patient on presentation of prescription. In this context it would be correct to say the NHS price covers the cost of delivering the medicine to the patient."However", it goes on "the NHS list price does not cover the cost of delivering a medicine to a patient's home", and that is put to you for comment.

Then you reply in an email that seems to be at 4.28 on 11th December, 2002, although for some reason your machine seems to invert the date, and it is that particular email at 4.28 on that day that we are interested in at the moment. Have I followed the sequence of events so far?

A. I think so, yes, Sir.

Q. And you are then discussing the statement: "The NHS list price does not cover the cost of delivering a medicine to a patient's home". You reply, effectively, that we have not had to consider a case where the medicine is delivered to a patient's home, and you go on to say: "I am not prepared to say that in no case would we accept, it would depend upon the case the case that the company put to us. Then you explain about the company being able to decide its own price, but if it was over 25 million it would submit an annual return, "we would look at the position, strip out costs outside the scheme", and you concluded by saying: "In the absence of a specific example I am not prepared to say there are no circumstances in which we would allow some, at least, of home delivery of costs. Does that email still reflect broadly your view of the question that is being put to you?

A. Yes, Sir, for the reasons I was explaining just now, that one could envisage hypothetical situations where clearly it would be outwith because we would not think what the company wanted to do was value for money in some way, in which case it could be stripped out. On the other hand it might be perfectly acceptable.

Q. Yes. Now, I am going to put a hypothetical situation to you and if you decide you would rather not say please put what caveats in you want. In this particular case, we

have a situation where the product, as we understand it, comes from the manufacturer, and goes to dedicated pharmacies that are really part of the manufacturer's or distributer's operations. One of them happens to be in Burton-on-Trent where a company called Healthcare at Home live, and the other is in Oxford, where Genzyme Homecare live. As we understand it the product is then following prescriptions and so forth, instead of going from, say, Burton-on-Trent to a community pharmacy, the product is delivered direct to the patient's home. If we take patients that are up in the North-East of England, for example, as I have understood it (and someone will tell me if I am wrong), as far as the physical delivery of the product is concerned, what happens is the vehicle will leave Burton-on-Trent and go up to Newcastle (or wherever it is) and instead of going to the local pharmacy it will go several streets further along to the patient.

Looking at that sort of analogy with the way things really work and as a matter of first impression, would it seem particularly unreasonable to think that the cost of that delivery exercise would be the sort of cost that would be allowable under the PPRS if an issue arose, or is that not something upon which you could give us a view?

A. A firm view on a hypothetical case is difficult, as you will appreciate.

Q. Yes.

A. If we were saying that the company was concerned with doing a drop, as it were, literally, "Here's your medicine, sir or madam", and that is it - so it was, if you like, a distribution cost in a slightly different way from the normal, I think we would find it difficult to resist that. But I think one would also want to look at the relative efficiency of that compared to a more traditional wholesaling operation.

If I might take an absurd example. Let us suppose one of the big drug companies decided as a marketing ploy that, instead of using the wholesaling operations, it was going to deliver every medicine to every person's home in the country. That is absurd, but we would say, "We are sorry, but that does not represent value for money for the NHS. If you wish to do that, that is your business, but we are not paying for it."

Q. So you would be looking at value for money, which is obviously a highly relevant consideration. Presumably, you would be looking at the clinical justification for doing it in this way.

A. That would obviously be a factor.

Q. The therapeutic arguments that are being advanced for this system rather than the conventional system. If it turned out - I do not know what your view would be - that this intermediate operation, whatever it exactly comprised, as a percentage of the total cost of the product, was actually less than the 12.5% conventionally allowed to a wholesaler in the list price, would that give you particular cause for concern, or would

you still want to scrutinise it relatively carefully?

A. The 12.5% is a nominal figure. In the normal course of events, we would not know because it would only be if the company came in and wanted a price increase on that or some other basis and we started to scrutinise the costs. Then, obviously, it would become apparent to us.

Q. As far as I am concerned, although my colleagues my have one or two supplementary questions, I would just like now, if we could, to glance briefly at the 1999 exchange, which is very helpfully exhibited to your witness statement. We have got various letters from Genzyme, but I think probably the most convenient for present purposes is a letter of 22nd March 2000 from Mr. Foster, financial controller to your colleague Dr. Bratt at that time, which is towards the end of the first exhibit to your first witness statement. Do you have that letter, which begins, "I am writing to outline the basis for the price reduction for Cerezyme that they have made as a response to the PPRS"?

A. Yes, I do.

Q. He says under the heading "Basis. The list price [Genzyme's list price] to the NHS represents two elements. Firstly, the cost of the pharmaceutical drug and, secondly, the cost of providing homecare assistance for patients who have infusions in their home environment. The cost ... depends on the level of service provided, ranging from delivery of the drug and ancillaries and waste disposal ... nursing systems and home visits." I think we need to jog back to one earlier letter, the letter of 28th September from Mr. Cortvriend to your colleague, Dr. Bratt, which in the first paragraph says: "The NHS list price, as I mentioned in my previous letter to you, includes an element of cost which covers nursing care for home infusion, home delivery, provision of ancillary such as water for injection infusion pumps and lines, needles, swabs etc., together with refrigerated storage of the drug."

I do not know if you have any personal recollection of this correspondence at the time or whether you were involved in this exchange at all or perhaps only distantly.

A. I was involved in the September - I have never spoken to Genzyme personally - I recall having conversations with Dr. Bratt in September. I was not involved, as far as I can recall or can find in the subsequent March.

Q. It may be we cannot speculate as to what Dr. Bratt thought, but maybe you can help us as to what impression you got. When in this letter Genzyme say that this price covers home delivery, I wonder what you thought or the Department thought was being said there. It pops up in a general description that covers nursing, ancillaries, refrigerates and what-not.

A. I am not avoiding your question, but if I might answer it in this way, please, sir. If you would allow me, if I might just set the scene very briefly.

Q. Please, yes. It would be very helpful. The deal was done on the PPRS at the end of

June 1999. The Health Act, from memory, also received Royal assent at about the same time. The policy imperative was to deliver the 4.5% price cut. We had introduced a system that was quite different from the previous agreement and also we were asking companies to sign whether they would be prepared to be bound by the scheme or not, which was new. We had something like 30 companies that had been involved in the process in terms of being part of the core ABPI membership, then another 120 who said, "What's all this?" There was an awful lot of explaining and all the rest of it to do.

There was something like 3,000 price changes that had to be looked at, and that had to be done by, effectively, the beginning of September. I know this went on into September. So we were not in a position to give everything that a company said the sort of inquiry that we might.

The other thing that we were aware of at the time was that both the new PPRS agreement and the Health Act gave provision for an arbitration process and an appeal process. We had not had a chance to set those up. So we were, if you like, operating in quite a difficult environment in terms of the decisions that we made. If we were too hard, we were going to be unfair in the sense that, apart from going to judicial review, a company did not have a ----

Q. It did not have a mechanism.

A. No, and we were conscious of that at the time. As I recall, the key paragraph in all of this is the paragraph at the top of the second page of the 7th September, which is where it goes into "provide extensive nursing support" etc. It was on that basis that we made the decision in principle - and it was made very quickly - that we were prepared to accept a price cut on a lower figure. At that time, we were not quite sure what that figure would be. I remember being party to that decision.

Q. One can understand that entirely. As has been said many times in other contexts recently, hindsight is a wonderful thing. One has 20:20 vision in hindsight, as they say. I do not want to put words into your mouth, but hypothetically speaking if one had focused on the fact that what is described here as "home delivery" in some senses replicated the normal wholesale function that is notionally included in the idea of the list price, might one perhaps have challenged the price reduction sought on the basis that home delivery was being included here?

A. If the emphasis had been on home delivery, but, as I recall, it was not.

Q. As presented, as you rightly point out, it starts with nursing services and all the rest of it. I follow that. Again hindsight is a wonderful thing and no-one is going to try to criticise the Department of Health in the situation it was in. If you flick through the bundle to the left of the 22nd March 2000 to the very last page, which is under the heading "The calculation", at the end of that paragraph there is an average health care

cost quoted of 33p and then it is explained what the average is. It goes on, "As the average is nearer the lower end of the scale, the Genzyme management have thought it appropriate to build in a contingency of 20p to cover likely increased service levels for new patients", so they have added on 20p for contingencies, which is not formally certified by their auditors, Pricewaterhouse. I just wonder if I could put the same question to you with the benefit of 20:20 vision in hindsight and if one had had perhaps more time and was not in the situation in which you were. Would one perhaps have put a question mark over a contingency of that kind being included in what was being asked of you?

A. Obviously in preparation for today I have given this quite a lot of thought. I think in retrospect we should have done two things: we should have challenged that 20p and we should have also somewhere have said, "We want you to provide a further analysis in 12 months' time or some such similar date so that we can see the extent to which what you are saying now does in fact come about or whether there is a change in that."

Of course, in a sense, it could have gone the other way as well. The analysis that has been done since indicates that the costs were less and I have got no reasonable basis to challenge that. It could, of course, have gone the other way and we were not to know that at the time.

Q. No, absolutely.

A. It could have been that they were greater than that and it would have been a bargain for the Department.

Q. As far as I am concerned - my colleagues may have one or two questions in a moment - those are my main questions. I do not know whether you have got anything you are burning to say to the Tribunal on the basis of what we have had so far, or do you feel you have more or less been able to express yourself?

A. No, I think you have allowed me to say what I wanted to say to you.

THE PRESIDENT: You have explained what you want to say, yes. Professor Grinyer, do you have any follow-up questions you would like to put to Mr. Brownlee?

MR. GRINYER: Let us have Graham's first.

MR. MATHER (To the witness): I am interested in an area of your witness statement, the first one, at paragraph 38, when you said that the Department "... cannot compel a company such as Genzyme to unbundle its prices to promote competition on behalf of the National Health Service, except to the extent that the profit limits are exceeded."

To help me understand that, can you tell me a little bit more about the structure of dealing with the supply of drugs to the NHS? Is your area of medicine pricing and supply the sole area which deals with that or are there other parts of the health service which have a function there?

A. The PPRS deals primarily with medicines dispensed in the community, in primary care

through community pharmacies. The hospital sector has arrangements in many cases where it deals directly with the manufacturer where it may or may not be able to negotiate a discount below the maximum price set by the PPRS. In many cases, these will be medicines that actually are either not used at all or are not used very much in the community because of the nature of the drug. That goes on, if you like, in parallel with the PPRS. Obviously, we have communication and quite close relations with the NHS Purchasing Supplies Authority, but actually the process is very often delegated to individual hospital trusts and, given the general movement to delegate out to the front line, we do not get detailed returns of what is going on.

Q. Does the Purchasing and Supply Authority have any co-ordinating or policy role for those hospital purchases?

A. In the main, it will, as I understand it - and I am not an expert in this - focus on medicines that are fairly commonly used, possibly those that are either out of patent or nearly out of patent. Where it is a specialist medicine, along the lines of what we are talking about, very often it will leave it up to the trust or maybe even a consortium of trusts to deal directly with the supplier.

Q. Thank you for that. I must say, when I first read your witness statement I was a little surprised at the idea that the Department, with all its powers and its enormous purchasing clout, could not compel a company to do something in the nature of its supply.

A. In theory, we could. What was behind that statement was two things. First of all, the PPRS agreement as negotiated does not allow us to; we have not sought to either, I have to admit. Secondly, we cannot use our statutory powers against a company that is a member of the PPRS and is complying with the scheme: we would have to have a reason to seek to throw the company ----

Q. First of all, you have got to chuck them out of the scheme.

A. Yes.

Q. And then do something else.

A. Yes, and, although we have had companies in and told them what might happen to them if they do not stop doing whatever they are doing, we have not yet gone as far as trying to remove somebody from the scheme.

Q. That is exactly my point or the point towards which I was heading: your mentioning that you have had companies in to tell them that they are doing something you do not like and asking them to stop. It did not occur in the Genzyme case: to call them in and say, "This bundling is something we do not like; will you stop doing it?"

A. Under the powers of the PPRS as currently drafted, it does not give us the right to do that. Before this whole investigation by the OFT, you could say we were aware of it in the terms of the exchange of correspondence in September, but for reasons which are

apparent from what I have just said we did not look at it.

Q. As I say, it was not in force at that time, the Competition Act?

A. No.

Q. 2000, was not yet in force.

A. And I think, although we have informally said something I think we regard looking at that sort of area to be OFT business in a sense, rather than us trying to get into the case in terms of competition regulation.

PROF GRINYER: What sort of circumstances do lead you to call people in....

A. Usually it has to do with trying to put prices up without or agreement, or to do something that effectively means that. A case for instance, and this is just an example, a company decided that it would genericise the medicine, which meant it took it outside the PPRS, and wanted to put the price up by three or four times so we called them in ---

THE PRESIDENT: Slight of hand.

A. ---and said "No, we are not having that." Most of the times, actually, I think it is innocent that companies, they are new, start-up companies, normally small companies not really aware of the ways of the world, in this respect, and so there might be a bit of chancing going on, but they normally go away quite happily, but they go away without much fuss, and do whatever we ask.

MR MATHER: I just have two more points, if I might. So if a general problem appeared, let's say, sticking with bundling, it was decided that this bundling of homecare services was a problem, would that come up in the context of the renegotiation of the PPRS or could the Secretary of State use the reserve powers, and general power to direct people to solve it. How would the NHS overall, this may not just be your part of it, address that if it was seen as a general problem?

A. I think there are possibly a number of ways open to us. One is yes, clearly we could, in extremis, if it became obvious that as a result of this the NHS was getting a reduce value for money, significant from this, he could I think give six months' notice of the ending of the scheme and we could renegotiate it or we could put in statutory arrangements.

He could also, I think, issue directions in terms of what - again, sorry this is not my area, but I think he would also be able to issue directions in terms of what was and was not permissible in terms of pricing within a hospital and services provided. I think there is probably scope there. I have to say I am not sure on that last point.

THE PRESIDENT: No, well we have lots of legal advice in the room that can help us on that.

MR MATHER: Finally, the philosophy of dealing with orphan drugs, and the specialised drugs, are we right in assuming that the principle that is adopted of the company setting its own price, at least at the outset, is that that is designed to provide an inducement to

research and development, and innovation of drugs, and on the whole it is int he public interest to allow them to set that price, and that is the overall philosophy behind your approach?

A. Probably but I think actual it is probably a bit more pragmatic than that. You will be aware that the pharmaceutical industry is important to the UK economy, and successive Governments have wanted to maintain that position. Therefore, we in this country have, all be it it is statutorily backed now, but a voluntary arrangement, rather than the sort of statutory product by product pricing that they have in most other EU countries. When you move into a voluntary negotiation there are certain "givens" if you see what I mean, probably not negotiable, and because the UK price is very often used as a benchmark for these pricing regimes in the rest of Europe, I think I am right in saying - I have never said it as directly as this - but I do not think it would be possible to negotiate a voluntary agreement with the branded pharmaceutical industry that did not have this freedom of pricing. That has been the philosophy in the past. In the same way that we would not have a price regime that said after that you can continue to do what you like as well.

THE PRESIDENT: Would you just say again what you have just said, for the benefit of---

MR VAUGHAN: Sorry, you could not negotiate with the industry without the benefit of - sorry, my voice is worse than yours----

A. ---without the benefit of freedom of pricing, and I just do not think you would be able to do a deal on that basis.

MR MATHER: Thank you very much.

PROF GRINYER: The first point relates to the PPRS and the transfer prices, in the case of an imported product like Cerezyme, quite clearly the transfer price at which the American Parent transfers the product to the UK subsidiary is critically important in determining profits, and therefore any potential influence you have over price ultimately which is indirect as you say, have you any ability to challenge or question in any way, or influence transfer price?

A. There are two bases for declaring the basis of the transfer price. One is would be for companies to give us the basis, the build up of transfer price, and a small number do, and we then are in a position to challenge it. The agreement has, for many years and as far as I have gone back, included in it what is called a "default option" which is an assumption that the company applies, which we negotiate every time we negotiate with the PPRS. There are, as I understand it, in terms of American companies, there are reasons in American Law that make it difficult for them, even if they wished to, to divulge the breakdown of their transfer cost price. Added to which, to be fair, it comes back to an earlier question that given the global nature of the industry it would be

difficult for them to build up a cost element.

PROF GRINYER: Thank you. The second point is, in a way, to ask you to interpret or at least give some sort of initial reaction. Clearly we are in a situation where there is a new product like Cerezyme has come in, the manufacturer has set the price, and now it has arrived to Mr Bratt, and he is looking at it. Was he in a position to question the bundling, and ask whether there could be a reduction in price, or was he in fact required under the scheme, as I believe probably to be the case, to accept that price, in which case he could well see the bundled element as a valuable additional element for the NHS.

A. Because it was a new chemical entity when it was introduced---

Q. And it was the same price?

A. And it had not sought to increase the price since then, we had to accept under the terms of the previous scheme, the 93 scheme and this scheme, the price that the company set. So threw as no question of Dr Bratt, in September, 1999 saying "We would like it at 10 per cent. less".

Q. He had no power to question the bundling, basically, because the price was set by the manufacturer?

A. Under the PPRS, no, we have no power to question it, literally. The reason for my hesitation is because sometimes we do try and interpret the terms of the PPRS as broadly as we reasonably can because we see something we do not like, and depending upon the circumstance, we might, if we thought there was a case, there are words in there about representing value for money for the NHS, and that sort of thing, so we might well, if we think we have a case---

THE PRESIDENT: Yes.

PROF GRINYER: Might it therefore be regarded as an active acquiesence at the very least that this inclusion of the additional services, the homecare services were in the price at that point?

A. I do not think so, but we looked at it anyway in terms of either OFT and indeed, now yourself, have looked at it quite frankly.

Q. You just accepted and it was not a matter which was questioned or even thought about?

A. I certainly did not. As my witness statement says, I have spoken to Dr Bratt on the phone.

Q. Yes, surely.

Q. Be he has left us now for some three years, and when you move on to another job you will appreciate that his memory is---

THE PRESIDENT: Quite, we understand that.

PROF GRINYER: We understand. Thank you very much.

THE PRESIDENT: I just have one question I forgot to ask before. We touched briefly at the

beginning on zero discount drugs, and I understand you to say that that was a list arrived at by a sort of negotiation with pharmacists, on the basis that the clawback arrangements would not apply to a group of drugs. Is that right?

A. Yes, we have to be satisfied that there has to be a reason for it being on there, and it is currently being reviewed, actually, but over the years there is a sort of exchange of correspondence between somebody else in the Department - not my area - and the Committee and us agreeing or disagreeing, and normally it is the community pharmacies that put forward the case for it being a zero discount on this medicine, and we say "yes" or "no" depending up on the circumstance.

THE PRESIDENT: That would mean presumably, or it is supposed to mean that the community pharmacist is normally buying from the wholesalers, shall we say, at list price?

A. Yes.

Q. Does it follow, if it is a zero discount drug at the pharmacist end that the manufacturer is not giving a discount to the wholesaler, i.e. can we have a zero discount drug that is being sold to the manufacturer in the normal way to a wholesaler, and then being sold to a pharmacist, all be it at list price, or what?

A. I am afraid that we do not have detailed knowledge of that. Again it comes down to what we call "light touch" regulation. We try to allow, although the PPRS clearly distorts the market, beneath the reimbursement price we try and let the market operate. We have everybody coming in saying that they are being "done" by the other party, but that is another matter.

THE PRESIDENT: Right, thank you very much, Mr Brownlee. Mr Vaughan, I do not know whether you have any supplementary questions for Mr Brownlee?

Further questioned by MR VAUGHAN:

Q. There is very, very little. (To the witness): You explained, and I think we entirely agree, the inter-relationship between the PPRS and the Drug Tariff price, and you gave very clear explanation. So when, in your witness statement, you say they are inextricably linked, you mean it in that context of your explanation, as it were?

A. Yes, and int he sense that they are pretty well always the same, the headline price, by which I mean before the clawback, is always the same.

Q. But they are linked in the context you have explained, they have different purposes but there is a linkage between the two. It is a question of the "inextricably linked" which I find difficult?

A. Well we can debate the meaning of the word, and indeed Professor Yarrow, in his witness statement, but in saying that I meant that the company, in whatever way, either through the drug tariff or directly if it is not in the drug tariff advises the PPA of the price, it is the price we take into account for PPRS purposes, both positively and

negatively in terms of we don't jump up and down about it in terms of it being increase. And it is the price which is the starting point for the money that the community pharmacist is reimbursed for that medicine.

Q. You said in looking at the overall profitability on the PPRS system of the company, there is a thing called "modulation". Is modulation, as it were, in my understanding modulation - providing overall they keep the same return on capital they can move around the prices, up and down to some extent if they want, providing they maintain overall the same total. Is that right?

A. It is not quite right. We sought a higher price increase in the negotiations in 1999 than 4.5 per cent. we ended up with 4.5 per cent.

Q. Yes.

A. The pharmaceutical industry has said for a number of years that it wishes to be able to decide where that 4.5 per cent. is applied, so it might want to take 9 per cent. on one medicine and nothing on another, volumes and values being the same. So what modulation does is to allow companies to choose where they are able, and I mean that in terms of having enough products, where they wish to take their 4.5 per cent. and what we check is that they are delivering the 4.5 per cent. price cut overall. It does not say it has to be the same return on capital employed.

Q. Yes, so modulation only applies on the reduction, not on the PPRS system?

A. Well, subsequently, after the first 15 months of the scheme, companies are allowed to modulate, but it has to be at nil cost to the NHS. In other words, they have to come in and say "Well, we want to put this price up and that price down, and by the time you take the different volumes into account the NHS will continue to pay overall the same for those two medicines.

Q. So they can move some up and some down?

A. Within parameters, yes.

Q. Providing they achieve the same overall result?

A. Yes, but it is expressed in terms of the price that the NHS pays value dated at list price rather than return on capital employed.

Q. I know you said you do not know much about this zero discounting, but in order to get into this zero discounting scheme, presumably the pharmacists have to show that they do not get discounts. Is that right? The obligation seems to be upon them, is it?

A. Yes, I don't know, I have not been involved in the detailed discussions on this myself.

THE PRESIDENT: The zero discount side of things is not really your area, is that right?

A. Yes.

MR VAUGHAN: I will leave it. Was the EL95 part of your world?

A. I am afraid it wasn't, no.

Q. Thank you very much, that saves another question, thank you.

THE PRESIDENT: Mr Thompson?

Questioned by MR THOMPSON:

Q. The first question I had was that the President asked you a question about whether you could infer anything from the PPRS across to what the NHS list price was intended to cover. Can I ask you, as it were, the converse question as to whether anything can be inferred from the nature of the Drug Tariff and the reimbursement process as to what it is intended to cover. If I put it like this: the Drug Tariff is directed towards the reimbursement of the pharmacist. Is that correct?

A. Yes.

Q. I believe in this case, and I do not know how familiar you are with Part 2 of the Drug Tariff, I believe it is clause 8(C) of Part 2 which has a provision whereby the manufacturer's list price is reimbursed to the pharmacist unless otherwise directed. I think that is the gist of it.

A. Yes.

Q. There are different rules for the reimbursement of pharmacists relating to issues such as clawback, etc. and in relation to supplementary serviced and expensive drugs, and indeed, dispensing fees, is that right?

A. I believe so but I am not familiar with the details.

Q. Can you infer that the list price is not directed to costs incurred by pharmacists which are reimbursed separately but towards the costs of manufacturers and in conventional terms, wholesale distributors, who supply to pharmacists. Is that what the list price is directed at?

A. Yes, because I mean the other things that you mention, they end up by being reflected in what the pharmacist is actually reimbursed, but is a subset of the calculation as I understand it.

Q. Are you aware of any element of the NHS list price that would relate to reimbursement of the pharmacy for its own costs?

A. Well, not directly to the list price, yes. When the pharmacist is reimbursed, they will get the price of the medicine, there will then be a dispensing fee and all the rest of it added onto it, so what the pharmacist gets is probably one payment.

Q. Indeed.

A. But it will the dispensing fee would not be part of the cost of the drug, shall I say?

Q. So even the dispensing fee, which is a little cost ----

A. It is 90p something per item.

Q. If somebody put that into the NHS list price, that would be disallowed.

A. Yes.

Q. Even though you might think that was rather close to the retail. That would be disallowed.

A. Yes.
THE PRESIDENT: Forgive me for interrupting, but as I have understood it, in the conventional case the community pharmacist is not really intended to take a turn on the drug itself: the idea is that that should be minimised and they are remunerated for this service, the service that they give by a dispensing fee, sometimes an expensive drug dispensing fee ----
A. Yes.
Q. -- sometimes a rural area supplement and all the rest of it.
MR. THOMPSON: There is no provision for the pharmacist to be reimbursed for things after dispensing under the NHS list price.
A. No.
Q. The Chairman put a point to you on the basis that if the pharmacy was not a community pharmacy, would that be a relevant consideration. Could I put the converse point to you? If the pharmacy was a community pharmacy, as indeed I believe it is required to be for the purpose of reimbursement by Part 2 of the NHS Act, would that be a relevant consideration to take into account in assessing the matter?
A. I am sorry, I am not quite sure what you are saying.
Q. I think it was put to you ----
A. I remember. I am not quite sure exactly what you are asking.
Q. Would it be more of a normal case where the normal rules would apply if one was dealing with a community pharmacy rather than some sort of special pharmacy that formed part of a business.
A. On the basis that there are something like 10,000 community pharmacies in England and I do not know how many exceptional cases one can find if one trawls the dispensing of medicines, then, yes, the community pharmacy by definition must be the norm.
Q. Can I ask you another question? The question arises from the Chairman's question about if the wholesaling was of a traditional kind but simply went to the patient's home instead of to the community pharmacy which was, as it were, next door, would that make it relatively likely that the cost would be allowed. Could I ask you a variation on that?

If the elements of wholesaling described by the Chairman formed an integrated part of a service containing wider non-standard elements, would that influence your assessment of the situation? I mean the overall situation.
A. Where there is a wider scheme - without wanting to go into commercial details about individual companies - there is the odd example where companies do not operate - although their medicines go to community pharmacies, they operate the standard - either in terms of the time at which the title of the goods - takes place or in terms of the

way in which they use the wholesaler and we have had discussions with those companies to make sure that overall the NHS is not disadvantaged as a result of those schemes.

Q. If I could make it a bit more concrete, although there was still delivery of a drug but the delivery was regulated and only took place in a managed way involving further elements - and in particular involving nursing - and the costs were all tangled up, would that be a relevant factor in assessing whether or not the drop off, as it were, would be treated as part of the NHS list price or would you seek to disentangle them? If I am going too far into the detail, say so, but it is obviously highly material to this case, as I am sure you will be aware.

A. Because our involvement with this case has been has largely been as a result of this process and not in terms of detailed negotiations with this company or, indeed, any other company, it is difficult for me to say precisely; but I think, as I have said in one of the exchanges of
e-mails that we started the proceedings with, I would err on saying that we would disallow it, for instance, if they came and asked for a price increase; on the other hand, our process does not enable us to go out and track it down.

Q. I fully understand that; I am grateful.

THE PRESIDENT: That is in the context of asking for a price increase.

A. That is the only ----

Q. That is the only context in which the question would arise.

A. It is the only context in which it is likely to arise. Or the other one would be if there was a new product that was not a new chemical entity, that could hypothetically be another one.

MR. THOMPSON: Then I had one more question which arose out of the Chairman's question about whether, viewed overall, was it less or more than 12.5%. I think you may have answered it already. If the costs were not regarded as part of traditional wholesaling. I think we have discussed the 90p dispensing fee. Would you concern yourself with whether those costs were less or more than traditional wholesaling costs, so whether they were more or less than the 12.5% allowed for wholesaling? Is that relevant in discussing whether or not, for example, the dispensing fee should be allowed?

A. We do not take the 12.5% as a given. Apart from the stated allowances in the scheme, which have been documented elsewhere, the other references to 12.5 - I have referred to it as a nominal amount rather than a specified amount. There are other allowances - there are other costs in the scheme and we look at the circumstances of the case, rather than saying, "Because we believe nominally it is 12.5%, you can have 12.5% regardless."

Q. Perhaps I can make it a little clearer. If something clearly is not wholesaling, for example, dispensing by pharmacies, then you disallow it, as I understand it.

A. If something is included in a heading that clearly is not that heading, we disallow it.

Q. It does not matter whether it is more or less than 12.5%?

A. No.

Q. Likewise, in deciding whether to allow the dispensing fee, for example, would you concern yourself with whether the actual wholesaling costs were high or low and would that be a relevant consideration in deciding whether or not, for example, the dispensing fee should be allowed if it were included in a hypothetical case?

A. Put in those stark terms, no.

Q. You have said that you would have looked at certain things in the context of a price increase. Can I ask that you should be shown four documents which are material to this case? They arise in bundles 31 and 37, if you could be given them. (Same handed) The first one is the Office of Fair Trading's core bundle, page 7.

THE PRESIDENT: A letter written to the Gaucher Association in 1993.

MR. THOMPSON: It is just the first paragraph. You will see that there is a reference to a meeting and then, two lines from the bottom, they say: "We will charge a sterling price which is currently 2.63 per unit." Do you see that?

A. Yes.

Q. Then if you turn on two pages to page 9, you will see another letter to Mr. Manuel dated 2nd February 1994. I do not think we need to read the detail, but the penultimate paragraph says, "I am acutely aware that Ceredase is already a very expensive drug. In an effort to limit the impact of these events on the cost of Ceredase treatment, we have decided to pass on only one-third or a 20 cent per unit as a price increase." It does not add up, but I have done the work on the exchange rates and it does make sense, given the movements in the exchange rates etc. "In the case of the UK, this will mean a new price of 273, which will take effect from 7th February 1994."

On the face of it, that is a 10p price increase and would you have expected in a normal case this to have been brought to your attention?

A. Well, it should have been brought to our attention, but it was not, as far as I have been able to find on our files.

THE PRESIDENT: This is Ceredase.

MR. THOMPSON: Indeed. (To the witness): If it had been brought to your attention, is this the sort of event that might have led to a more intensive scrutiny of Genzyme's cost?

A. I can only answer yes. I was not around doing this job in 1994, so I cannot talk for them, but if this happened now then we would ask them to justify it and we would call for a return, as I was describing earlier.

MR. GRINYER: Does that depend on whether the company is a member of the scheme or not?

A. The situation in 1994 was that we did not have the Health Act powers that came in in 1999, quite clearly. Therefore, if companies decided to ignore us it was difficult. There was little we could do, other than protest. Why this was not seen by the Department at the time, I cannot explain because I was not here. I do not think it was.

Since 1999, the company either has to join the PPRS or we have the power to put in place some statutory scheme and all companies selling branded medicines have either signed up or a few very, very small ones are acquiescing and we have not chased them to sign the document. So the situation now is very different from what it was in 1994.

Q. There seems to be some question as to whether Genzyme was a member of the earlier scheme, as I understand it, and it seems to have applied for the first time in 1999.

A. The way the Department was operating its agreement with the APPI was that the 1993 scheme applied to all branded medicines sold to the NHS in the UK. Because there was no statutory power and because - the agreement was formalised by a shake of hands, effectively, between the Department and the APPI. We never actually went out in 1993, I understand, to say to companies, "Sign here or not sign here."

Q. So they were automatically a member of the scheme, but they might not have been in any dealings with you at all.

A. And if we had not - as we appear not to have done in 1994 - found out about this increase - and I can understand why - because it was a relatively smaller used medicine - then we would have had no cause to write to them and they had no cause to contact us. I guess that was the situation.

MR. THOMPSON: Could I now just ask you to turn to bundle 37? There are two more documents. It is tab CB28 in that and within that it is page 291 of the numbering at the top and it is 3237 at the bottom. This is a short letter to the PPA saying, "This is to confirm that our NHS trade prices for Ceredase remain at 154.50", which by an elementary calculation is #3.09, "and these are the prices we have charged throughout 1995.

Then if you turn over the page, you will see a letter to a Mr. Jenkins of the PPA of 16th May 1997. I do not know if you want to read that briefly. It is an explanation that Cerezyme is replacing Ceredase or is being introduced at the same price as Ceredase at 3.09 per unit.

A. Yes.

Q. If these documents had been brought to your attention, bearing in mind that in 1994 the price was #2.73, would you have expected an explanation of why they now were 3.09 and, again, when Cerezyme was introduced would that have been the sort of event that

would have occasioned an explanation of why it was the same price as Ceredase?

A. As I understand it, Cerezyme was a new chemical entity, a new active substance, so the company had freedom of pricing for that. I do not think we would have questioned why it was the same price as its predecessor. We would have liked to have been informed of it; we were not. We would then, I think, if we had have received a copy of that letter, have tracked back to try and find out what had gone on.

MR. THOMPSON: I am grateful. Those are my questions.

Questioned by MR. VAUGHAN

Q. Could I ask one or two questions about the 1994 situation? It is bundle 31, page 9. You looked at this before.

Mr. Manuel and Mr. Termeer from America. My instructions are at that stage there were four patients in the United Kingdom receiving Ceredase. Do you know anything about that? Presumably not.

A. I know there was a time when it was being - I think I am right in saying that it might be at a time when it was on a named patient basis. I do not know when.

Q. I think at this stage they were moving over from a named patient basis, which was the previous situation, to a more conventional system. There were about four patients at that time; do you know that?

A. No, I do not.

Q. You were told in 1995 about the price.

A. No, as far as I ----

Q. So be it. PPA was told about that.

A. Yes.

MR. VAUGHAN: Thank you very much.

THE PRESIDENT: Mr. Brownlee, thank you very much indeed. I think this witness can be released, unless there is any reason not to.

(The witness withdrew)

THE PRESIDENT: Yes, Mr. Thompson?

MR. THOMPSON: I believe that the bundles that Mr. Farrell will need are probably the same or include the same as

Mr. Brownlee, so I would simply ask for Mr. Farrell to be brought up as well.

THE PRESIDENT: Yes.

MR. JOHN FARRELL, Called

Questioned by THE PRESIDENT

THE PRESIDENT: Mr. Farrell, good morning. We are extremely grateful to you for coming. You have probably been at the back, listening to our questions to Mr. Brownlee.

A. Yes.

Q. So I do not need to say again that we are simply seeking to understand the system here and we are very grateful to you for sparing the time to be here. I just need formally to establish that you are John Farrell, Head of Pharmacy Services for a number of NHS Trusts, including, notably, the Royal Free Hospital NHS Trust.

A. That is correct, sir, yes.

Q. And you have given, in particular, a witness statement in this case that is dated 30th June 2003. I will, if I may, just ask one or two points of clarification that are relevant to his particular case.

Could I start by asking you this? In relation to this witness statement that you have given, who exactly, in your view, do you speak for? Do you speak for yourself or do you speak for the trust that you represent or for whom exactly? What is the basis of this evidence?

A. The basis of the evidence is on behalf of the trust which I represent.

Q. I think they are mentioned in the second paragraph of your witness statement.

A. That is correct, yes.

Q. We have had, as you will appreciate, a lot of discussion in this case about what are called homecare services. Could you help us on what you understand homecare services - the phrase "homecare services" - to cover? It crops up in a number of contexts: there is a tender document in which it crops up. You have given us an explanation at different parts of your witness statement, but we would be very interested in your telling us in your own words as to how you see this idea of homecare services.

A. Homecare can range from a variety of inclusive and integrated services.

Q. You need to speak up a little because the Shorthand Writer has got to hear you and others are taking notes.

A. In particular, homecare services are provided to patients who may in the past have been either in-patients in hospital or have long-term chronic conditions which can be managed now within the community, within the primary care setting. The context of homecare has evolved in order to enable these patients to be managed within that care setting.

In that context, it ranges from the dispensing, supply and management of medicines to those patients and it may be more than one drug - it may be a number of different drugs - to the full provision of nursing care within the context of homecare. That will largely depend upon the extent of the patient's condition.

In that there may be a population of patients who are eligible for homecare, they may not all at any one time require full nursing care. It is a dynamic situation, because these patients' condition can vary and they may need to be stabilised. Therefore, nursing care may be requited. When patients are stabilised, then a

dispensing, delivery and drug management service will be a more appropriate level of service. But there has to be that level of integration within the homecare provider in order to be able to move between different elements of homecare.

The other point to identify is this. I have already said that the patient may be in receipt of more than one drug and, indeed, some of these enzyme disorders from which patients suffer run in families, so there may be more than one sibling in receipt of the medicine also. It is, we think, sensible to try and have the same homecare provider providing a service to a particular family or a patient group. That is what I understand by that.

Q. That is very clear. As you were talking, you used the word "integrated" more than once.

A. Yes.

Q. I think I understood you to refer to dispensing, delivery, what you described as drug management and in many but not necessarily all cases or at all times a nursing service as well, or at least the ability to provide it if it became necessary; are those elements what a home care service provider will be typically providing in your experience?

A. Yes, sir, that is correct.

Q. We have come to understand that there are a number of companies active in the provision of homecare; is that right? Are there many companies that do this or a few or what?

A. There is a handful of companies. I think it is correct to say, sir, that it is an emerging market. It really started some years ago in the United States, where I understand it is a considerably large business. I suppose it has been slow to develop in the UK, but I think now it is finding its feet and is beginning to emerge reasonably rapidly.

Q. You have, in various circumstances, quite a wide range of patients who need homecare of one kind or another who are suffering from different diseases. Could you paint the picture for us in general terms? How do you go about seeking, negotiating, agreeing with companies to provide you with homecare services? What is the typical case or the possibilities?

A. The normal arrangements are, we would look at what is in the best interests of the patient primarily. That would be the main driver. We would then look at how stable the patient may be on homecare. For example, an element of homecare may mean that the patient is required to attend hospital on a less frequent basis, so that could be an element also.

We would discuss it with the patient and the clinician involved and then would seek to identify a homecare provider in order to deliver that service.

Our greatest experience with the arrangements and what I think was the best way forward was to tender for the homecare service, which we have undertaken as part

of our haemophilia service. That was done with the full co-operation of the patients, the clinicians and the hospital nurses as well. We ran a pilot for some time just to identify what the patients' needs were in this respect before we went to tender.

I would see that as being the most appropriate way to advance homecare services and for the NHS to secure best value for money.

Q. Why do you say that as being the most appropriate way; what is your reasoning?

A. I think as it is an emerging market we clearly need to ensure that there is competition within that market and we need to be fair to homecare companies who would wish to provide a service and maybe to develop these services.

Q. In a tendering procedure, for what length of time of contract do you normally tender?

A. We normally tender for a year, but we have added a caveat that we may wish to have a roll-over period of a further year. The reason for that is that we want to cause minimal disruption to the patient groups.

Q. At the end of that period or the extended roll-over period would there be another tender?

A. Yes. I think the other issue, sir, is that events may change within that timeframe, so it is a balance between getting a reasonable period from our point of view in having a stable service to enable the homecare provider to work up their services, so that they would have to invest clearly and also to take account of events which may change, both in products, because new products may come on to the market or indeed developments in homecare services themselves. So it was a balance between identifying what was a reasonable period of time, and for that reason we put in the roll over caveat of one year.

Q. Is the haemophilia example a typical example, or are there some cases where you do not go to tender, or you have a negotiation or---

A. Haemophilia is the only tender which we have let for homecare, but we would wish to have the same process in place for other elements of homecare as well.

Q. And what have you done for other homecare, let us not talk specifically about Genzyme yet, there are presumably other patients who have homecare, who have other diseases?

A. That is correct, yes.

Q. What happens in those cases?

A. Well we have taken the view that to date we have contracted with one homecare provider, but more are emerging and we would eventually wish to test the market with regard to their services also. The reason we have gone for one company to date is that from our point of view it is a considerable paper work burden in managing - there is a considerable paper work issue in managing this process, and we are looking to automate that in terms of putting it on to an IT system. So we are looking to the best

way internally. To date also it has been a situation where we have identified a homecare provider with appropriate standards which meet their needs, and we would h ave to look to do the same kind of investigations to other homecare providers to ensure that they would also meet those standards as well. So it is quite a large undertaking and we would not want to see a huge number of homecare providers, but we would certainly like to see more than one to deal with, maybe a handful.

Q. Yes, I follow that, but your basic idea, or the concept developing in your head is that you would be dealing with one at any one time, is that right? But from time to time, there would be a tender process or a negotiation process, or what?

A. I think we would probably like to deal with more than one?

Q. Yes, I see.

A. At any one time.

Q. At any one time?

A. Yes, indeed.

Q. And for what reason? It may sound a silly question.

A. As I said earlier, we need to ensure that we are getting best value for money, and we need to, as it were, develop the competition in terms of other companies that can provide the service as well, and maybe that will result in lower prices.

Q. Yes, but I think you also were suggesting that there is probably a natural limit to the number of homecare providers you would want to be dealing with, or could survive in this market perhaps?

A. I think that is correct, yes.

Q. I do not know if you have any impression as to how many providers we could economically support, as it were?

A. I don't know. I think I would certainly like to deal with more than one, possibly two or three, as a manageable event.

Q. In relation to homecare services - we will come on to this in more detail in moment - how do you see the pricing side of this? Do you see homecare being provided at an identified cost, or provided within the drug cost, or provided by a manufacturer who also does homecare, or provided by independent homecare companies, or what? Is there any pattern that so far emerged?

A. Our view has been that we would wish to see transparency in the pricing arrangements, so that we would know exactly what we are paying for the medicine, and for the homecare, and that in turn would make future negotiations or contracts for the drug, and the homecare service, it would be easier to undertake those as separate events, so we would look to have a separate pricing structure.

In terms of whether we would look for an independent company that is an interesting question, and I think to date we have looked to an independent company for

the reasons that if we want to change the product, then we do not necessarily h ave to change the homecare provider as well, which can be quite disruptive for patients. The converse is true also.

Q. Changing the---

A. Changing the homecare provider but keep the product, as it were. I think there is the issue that if we use a homecare provider who is also the manufacturer, then it may be difficult for that homecare provider to deliver a product by a competitor, and that was of concern to us.

Q. If I may just look at one or two now more detailed points that come up from your statement. You mention first of all that sometimes patients need nursing. Sometimes they do not need nursing. I think you tell us in the specific case of Gaucher's disease, your Gaucher patients who are treated at home are not cared for by NHS nurses, b ut are cared for by the homecare provider in question.

A. Yes.

Q. There is some evidence in this case that in some other cases it is the NHS nurse who looks after the patient in other areas. What determines whether it is an NHS nurse who does the nursing, or whether it is the homecare providing who does the nursing? Where in the decision process is that decision taken and why?

A. I think one of the reasons why is our hospital is a tertiary referral centre for Gaucher's and in that context can see patients from virtually within the UK. It would be difficult to enable our nurses to travel large distances in order to manage these patients on a homecare environment, and that is quite a major issue. I think also we would not look to a homecare option unless the patients had been stabilised in the hospital environment before entering into homecare. I think those are the two main reasons. In terms of the patients who do need a level of nursing care, an example of that would be a patient recently who came to hospital just seems to have lost all confidence in being able to insert the cannulas himself, and in that context h as needed a level of nursing care to provide support until his confidence may return.

Q. And that example is then provided by the homecare providers?

A. That is correct, yes.

Q. And what happens in physical terms? Does somebody say to the homecare provider "let's send a nurse"?

A. That is correct, yes.

Q. I see. You mentioned a little earlier on the possibility of what you call "block", or are called "block" contracts That is to say the homecare provider services a number of different diseases under one contract. Is Gaucher's disease suitable for being included in such block contracts?

A. Yes.

Q. Could you include it with haemophilia and some other disease?
A. You could do.
Q. Is there anything specific to Gaucher's disease that would mean it is so specialised or so separate that you could not really "lump" it in - if I may use the expression - with other kinds of patients needing homecare?
A. No, I do not feel that there are any reasons for that. We would clearly want the homecare company and nurses to maybe come to the hospital and have some additional level of training, but there is nothing that would exclude it from being part of a block contract.
Q. In relation to the funding, the financial side of all this, I think we have gathered from the papers, although I cannot put my finger on it, that you have got about 70 Gaucher patients under your wing, if I may put it like that?
A. Yes.
Q. And I believe there are about 180 altogether in the Country and others are looked after by other specialist centres. Our understanding is that the tab, as it were, is picked up at the end of the day by the local PCT where the patient is living, how does the PCT, where the patient is living regard your sort of negotiation of the contract, as it were, because they have to pay for it, but you are negotiating the price, how does that work out in practice?
A. To my knowledge, the process would be if a Gaucher's patient presented to the hospital and then required treatment is that it would be outside what we are currently calling in financial terms the "block contract" i.e. the sum of money given through the Trust to manage its services. In that context we would have separate discussions with the individual PCT from where the patient came. We would discuss with them various treatment options, one of which may be a level of homecare service, and in that context we would then make certain arrangements regarding treatment, because treatment is also part of the discussion process, because these are quite expensive treatment cases, and we would identify a separate homecare cost as part of that, which is why it is quite useful if we can have in place a tendering arrangement, whereby we can identify to the individual PCT that we are truly getting value for money on behalf of the NHS for the services that we are providing.

We would have complete transparency with the PCT in terms of the cost of the drug or any discounts which we may or may not have negotiated,and the cost of the homecare service as well. Those patients are normally put into their group in that they area outside the block contract. They are normally referred to in our Trust as "programmed" patients, and those are patients who fall into a cost bracket that we identify as "high cost" drugs, or "high cost" patients, and that means that our contracts and finance department will have these discussions with individual PCTs.

We do that for a number of different conditions, because tertiary teaching hospitals do tend to get quite expensive patients, and the number of PCTs we will be working with in any one year can be over 140 PCTs. So we will have to have a of detailed discussions with many of them about high cost medicines, so this is not exceptional for a teaching Trust.

Q. There are other patients looked after by other centres who are in other parts of the Country who would presumably need to have the same kind of discussions with their local PCTs as well.

A. That is correct, I suppose the main driver from our perspective is we retain the clinical responsibility for the patient, and therefore it is a requirement on us, a duty of care on us to ensure that the appropriate level of treatment is provided, in terms of drug treatment, but also that the arrangements for homecare are appropriate as well.

Q. Can I ask you this, we are considering a case at the moment - this case - in which at the moment there is no separate price for the homecare. It is, as it were, included in the drug price, in technical terms "bundled" is a phrase that is sometimes used. One of the suggestions of the Office of Fair Trading is that this price should be split, or unbundled into homecare for the one hand, and drug for the other which, if I have understood it, would therefore free up or allow a process of negotiation to take place as to the price of the homecare on the one hand, and the price of the drug on the other. How do you see that working out? Is that going to work out along the lines you have already described?

A. That would be my preferred option, yes.

Q. I see. Now, I do not know whether you have thought whether there is any balance here. They are high cost, but it is a very small number of patients, suffering from Gaucher's disease at least. If you have to go into negotiation on Gaucher's and other referral centres or PCTs have to do that, and your contracts' department has to make telephone calls to many Trusts and all the rest of it, just to do that there is a certain transaction cost, as it is called - a certain cost of changing the system and going over to a more competitive situation - or there might be. Do you see that as an extra element in the system? Is that a disadvantage, as it were, of what you are suggesting, and if it is or might be, how would you balance that against what you see as the advantages of the system that you are advocating?

A. If I can use the haemophilia example, until fairly recently Trusts would negotiate for haemophilia products individually with the drug companies. We now have an arrangement which is headed up by PCT - Primary Care Trust - whereby we have a consortia, so that the consortia is in the process of agreeing the price for all of the hospitals in that consortia with the drug companies, and indeed, going out to tender, and that is a very satisfactory arrangement. On top of that, they are also working with us to look at drawing up the next round of tendering for homecare, and I would see that

where small groups of patients exist in small numbers of hospitals that might indeed be the way forward, and that would reduce the administrative burden considerably.

Q. So you see a system developing in which PCTs would really co-operate---

A. Yes, indeed.

Q. ---to arrive at an efficient---

A. Yes, it has worked very satisfactorily with Haemophilia in that they are part of the discussion process now. One of the advantages in involving the PCTs at this level of negotiation is that, not to put too fine a point on it, they are more willing to fund the drug which is sometimes a difficulty, so we seek to involve them with all high cost drug discussions?

A. Yes, I see.

Q. Could I just ask you, you have your statement there, I think, somewhere, annexed to it are various documents in something called exhibit JF1 an at page 1 of that there is a note of a meeting that you had at the Royal Free with various representatives of the OFT on 17th December, 2001.

A. Yes.

Q. If you have the second page of that, you see a headline "Issues raised by Genzyme's actions" - are you with me?

A. Yes.

Q. On the second page, there is a sub-heading half way down that says "Issues raised by Genzyme's actions", and there is a list of considerations: "Hospitals should have a choice of homecare provider". "If a hospital wishes to use its own homecare provider that company should.." I think it is "not" "...face differential pricing. There should be equal access to products for all homecare companies. Genzyme say they are not prepared to deliver someone else's products".

Can you recall at this distance, and I do not know whether you can or not, whether those are issues that you raised, or were matters that were put to you, or what?

A. These are probably issues which I have raised.

Q. And those are issues that you still regard as issues that should be raised?

A. Yes, I do.

Q. Then we have a heading "Advantages of an independent homecare provider". "Safeguards patient confidentiality, ease of switching between treatments prevents patients being locked in, this makes it easier for new drugs to enter the market. The Trust can make their own decision about best homecare provider and remove them if they are not performing well. Convenience for patients on combination treatments, eg HIV, who can receive all the different manufactured products by one delivery." Is that still a summary of your views on this issue?

A. Yes, it is.

Q. Could I now just explore a general topic, which is whether the situation we have int his case concerning Genzyme is a typical situation or an atypical situation, i.e. what picture can we build up of other pharmaceutical companies who themselves supply homecare services and who may, perhaps, include those homecare services in the price of the drug, as distinct from charging separately. I am going to look at some details in a moment, but I do not know if you are able to give us a general answer to that question, whether it is a typical or untypical situation that we have in this case?

Q. I think in that this treatment was the only treatment for this condition at that time it was not a typical situation, and indeed at that time there was only one other company in a similar position.

Q. Yes. Which company, I think you are able to mention the name?

A. Novo Nordisk, who provided a treatment called "recombinant Factor VIIA" for haemophilia patients, and had a homecare provider of their choice which they wished us to use, so subsequently---

Q. I.e. they did not do it themselves but they employed somebody and they said to you "Use this person"?

A. That is correct.

Q. We gather there is a product, I do not know if you are familiar with it, that for Fabry's disease there seems to be a situation in which there is a company called "TKT" that provides a drug called Replagal, that apparently competes with a Genzyme product called Fabrazyme. Do you have any general knowledge of that situation?

A. Yes, I do

Q. We gathered that Replagal, if that is how you pronounce it, is in fact distributed by Healthcare at Home, I gather?

A. That is correct.

Q. Is that a situation where you are expected to use the homecare provider that the drug company has identified?

A. Not to my knowledge, no. If they had come to us with a homecare provider of their choice we would have taken a view on that. It may be fortuitous that Healthcare at Home was the company of their choice. Nevertheless, we would have required a homecare company of our choice to have been used.

Q. Yes. And how would you have gone about doing that? How can you do that?

A. We would have negotiated the price with TKT, the company concerned and we would have added a caveat to our contract prices which we do now for all our contract prices to the effect that the medicines, if required, should be made available to a homecare company of our choice, so that the homecare company can access the drugs at our contract prices, and we would have requested them to have supplied Healthcare at Home, should we have patients who may have benefitted from a homecare service.

Q. I do not know if you know the details, and we may have to go a bit cautiously here for business confidentiality reasons. We are led to understand that Replagal is provided a the drug price and that the homecare service element is wrapped up in the drug price. Is that a correct understanding?

A. Yes, it is.

Q. How do you distinguish that situation from the present situation?

A. We are not happy with it. We would rather know exactly what the drug price, and the homecare costs are, and we have made that position known.

Q. But you have not so far at least been able to achieve the split?

A. No.

Q. I think you would probably like to get this over with this morning, rather than break for lunch, Mr Farrell?

A. At your convenience, Sir.

MR VAUGHAN: I think I will have quite a few questions to ask him.

THE PRESIDENT: What I think is the easiest thing, if you could bear with us, what I wanted you to do now, is to look at a particular paragraph in a report prepared by the Monopolies Commission some years ago in relation to a merger between Caremark and Fresenius, which identified various companies that are said to be providing their own homecare services, and another list more recently provided by Genzyme, of other companies whom they say do something similar to what they are doing, just to explore with you to some extent how far those cases have come to your attention and whether they are similar or not to the present case.

I think what is convenient for us, if it is convenient to you, we are coming up to 1 o'clock when we normally break for lunch. If, over the luncheon break somebody, perhaps you, Mr Thompson, could help us on this, would be kind enough to refer Mr Farrell to paragraph 240 of the Fresenius report, and to Mr Morland's third witness statement, so he has a chance to see what is being said, that is time well spent, and we will come back to that issue after lunch, if we may, if you could spare us more time this afternoon, that would be very good.

A. Yes.

Q. We will resume at five past two if that is all right with you.

A. Yes.

Q. Could I ask you, apart from receiving from Mr Thompson the documents I have asked you to look at, could I ask you please, not to discuss your evidence that you have given so far with anybody else until the evidence is complete.

A. Indeed.

MR TURNER: There is just one issue on that, the statement that was served on my learned friends from Dr Jones of Healthcare at Home, as Mr Thompson mentioned also deals

with the issue of these companies. It has not been formally read into the record, I understand my friends have not seen it, but they will have an opportunity to consider it. Perhaps, after the lunch adjournment we might consider whether Mr Farrell might want to consider that as well.

MR VAUGHAN: He may as well see it now.

THE PRESIDENT: I think everybody ought to see the statement, and then we will see where we are at 2 o'clock. So there is another document to look at. Thank you very much, Mr Farrell.

(Adjourned for a short time)

THE PRESIDENT: Would you like to come back, Mr. Farrell? Thank you very much. I do not know if you have had a chance to have a look at some of these things over lunch. What we are trying to get a picture of is how far this case is typical or, as I said earlier, atypical of the situation that exists.

Could I ask you first to look at a report that was made by the then Monopolies & Mergers Commission concerning a proposed merger between Fresenius and Caremark in 1998, paragraph 240. There is a list of companies who provided various kinds of care as well as being drug companies. Have you got a copy of the Fresenius Report?

A. Yes.

Q. Have you have a chance to look at this list?

A. Yes.

Q. We have got Abbott, Alpha, Baxter, Novatis, Nutritia and Pharmacia. Do you have any knowledge of what sort of activities these companies were doing at the time and whether they are still doing it? If we could start with Abbott, for example; is that a company you have ever come across?

A. We use Abbott, but I have no knowledge of their work in enteral feeds, pumps or related equipment. That is outside my field.

Q. It is outside your knowledge.

A. Yes. Alpha we have used. I think they have been subsequently taken over by a company called Grifols. We have purchased from them immunoglobulin, IG treatment. Where any of our patients need that for homecare, we supply the product directly to our homecare provider.

Q. So you provide the drug.

A. Yes.

Q. In other words, they do not do the homecare: your homecare provider does the homecare as far as you know.

A. With immunoglobulin, there are three different companies which we use for the purchase of immunoglobulin. There are three different brands of immunoglobulin.

The reason that we have to use three if that once a patient starts on a course of immunoglobulin it is generally considered good policy to retain them on that treatment, the reason being that these patients may develop antibodies and the more times you switch between products, the more likelihood that the antibodies - not only that but the patients become stabilised on immunoglobulin anyway, so it is generally considered good policy. That is why we have a number of different immunoglobulin suppliers, but we use one homecare company should we need to.

Baxter. We use Baxter primarily in terms of intravenous feeding solutions but they also make a recombinant factor 8 product, which I have referred to in my statement.

Q. They crop up in haemophilia.

A. That is correct, yes. Other than that, we have not used them. Novatis ----

Q. Before we leave Baxter, I think your evidence was that in the tender for haemophilia about which you were telling us they had tendered on the basis that they would supply the homecare and they did not get the contract, but apparently later said words to the effect, "We would have split it if that is what we had thought you wanted to do"; is that right?

A. That is correct, yes. They would have been prepared to either allow their product to have been delivered by an alternative homecare company or their homecare company would have delivered another product. That is the way I saw it. They were prepared to be flexible.

MR. MATHER: Would the unbundle the price?

A. They did, yes. As part of the tendering arrangements, there was a separate tendering for the homecare service and the cost of the drug. It was explicit in the tendering arrangement.

THE PRESIDENT: If we go over the page, Novatis - I do not know if they are related to the other company which began with Novo to which you were referring to earlier.

A. No, they are a different company. Novatis, if I may just refer to my notes ----

Q. This looks like IG.

A. Immunoglobulin again.

Q. Immunoglobulin and also enteral products.

A. Yes. As I say, enteral products are outside my area. Again, we have used Novatis immunoglobulin and the same arrangements would apply there.

Q. You mean that there is a separate homecare provider?

A. No, we would use our homecare provider. We would purchase their immunoglobulin product and then supply it to our homecare provider. We do not have a great number of immunoglobulin patients treated at home.

Q. Would you forgive my ignorance? What exactly are enteral products?

A. Enteral products are products which can either be taken by mouth, by naso-gastric tube, which is a tube which goes up the nose and right down into the stomach, or through what is called a peg device, which is a peg which is effectively a direct insert from the abdomen into the stomach. The latter two would be used for patients who have problems in swallowing or particularly, maybe, cancer patients who may not be able to get food into their stomach easily. So they are called enteral feeds.

There is another group of solutions called parenteral feeds and parenteral feeds - referred to in these documents as "PNs" - are feeds which are given through a central intravenous line. These are products which require to be manufactured. Normally they are bespoke products for the individual patients to feel there kilocalorie and nitrogen requirements. These are for patients who cannot tolerate any food at all orally. Many patients rely on these feeds. They are provided in quite large, 3 litre, bags and that bag is normally run in over a 12 or a 24 hour process into a central line. The central line is an intravenous line which is inserted as part of a surgical procedure which goes into the central vein. These solutions are too concentrated in order to be delivered into a peripheral line. They do require a level of nursing care because the risk is with all of these parenteral feeds that the central line may become infected. If it does, it can have very serious consequences for the patient.

Q. Is that an example where there would be clinical reasons for the manufacturer providing the product and supporting service?

A. There are two ways of approaching it: normally the patient cannot connect themself up but sometimes they can or we can train a carer, but if the carer's aseptic technique is not good, as it were, or the environment in which the patient is living is possibly not good, then it is safer to provide it with an element of home nursing care attached.

Nutrica is enteral feeding and I have no knowledge of that.

Pharmacia and Upjohn. In fact, most of our parenteral solutions we buy from Pharmacia and manufacture them both for our in-patients and for patients who will be receiving a homecare service as well.

Q. Who provides the homecare service for your patients?

A. We would use Healthcare at Home for that service.

Q. You do not use Pharmacia.

A. No. Indeed, Healthcare at Home sometimes bring patients to us from other trusts who do not have in-house manufacturing facilities and ask us to make the solutions for them, which we do. It is part of the NHS working together arrangement. Hospitals that do not have resources go to hospitals that do - large teaching trusts - in order that we can prepare products for their patients.

Q. We have got a witness statement from Mr. Moreland, his third witness statement. I do not know whether you have had a chance to look at that. There is an annex to that

called annex 1, which has got a first page that starts, "Situation as per MMC report in April 1998 ..." Turn through the text until you get to annex 1. The top part of the page, "Situation as per the MMC report in April 1998" we have just discussed because we have just been looking at that report.

He then has "(b) Current situation." Have you had a chance to glance at this?

A. Yes, I have, sir.

Q. Could we just go down this list quite quickly and see whether this now adds anything? You have told us that as far as Abbott is concerned that is really outside your immediate knowledge; is that right?

A. For enteral solutions.

Q. For enteral solutions, yes. Do they do parenteral solutions, do you know?

A. No, not that we use.

Q. Alpha you have mentioned.

A. Alpha has also now merged with Grifols, who are further down.

Q. Just remind me of this. The position as regards that is that they use Healthcare at Home.

A. That is correct.

Q. Then I think Baxter you have told us about. I notice they seem to have some parenteral products as well as other products.

A. Yes, they make peritoneal dialysis, which is a renal solution, which I am not involved with. Parenteral ... yes. They also have a recombinant Factor VIII product, which is a haemophilia product that we have discussed. I am not sure about their rheumatoid arthritis involvement. I have no knowledge of that.

Q. Do you know whether they typically use homecare providers or do it themselves?

A. I do not know.

Q. Or what the pricing is?

A. No.

Q. Novatis and Nutritia I think we have discussed. Pharmacia we have discussed. TKT with Replagal cropped up this morning and I think you explained to me this morning that, although they use Healthcare at Home and although it is, as it were, a bundled price, you are not very happy with that situation.

A. I think it is fortuitous they have used Healthcare at Home and I am not happy with the bundled price arrangement.

Q. Then we have got Genzyme and we know about Cerezyme; do you deal with them on Fabrazyme as well?

A. Yes.

Q. Are you concerned about the situation regarding Fabrazyme?

A. With Fabry we use a Genzyme product. We have only got one patient on a Genzyme

product, so we purchase the Fabrazyme. No, I beg your pardon. It is provided on a compassionate use basis until March 2004, so Genzyme provide it to us on a compassionate basis.

Regarding the Replagal, the TKT, we have about 30 patients on that and that is again a bundled price, which I am not happy with.

Q. Would it be fair to say that with Fabrys you do at least have a choice of supplier?

A. Yes.

Q. You have two competing drug companies.

A. Yes.

Q. Then we have got Roche, apparently. It is somewhat obscure. They seem to have some kind of in-house homecare presence but it might be suggested that it is actually HH under a different ----

A. I think it is a marketing or an agency arrangement. I am not entirely sure of it. To all intents and purposes, they use Healthcare at Home.

Q. Then the next one is all information taken of HH's website. Have you come across Ortho ----

A. Orthobiotech. Again, it is a drug called Etheropoetin, for which there are a number of suppliers. We do not use any homecare for that. In fact, our arrangements pre-date homecare and we issue these patients generally with a prescription called an FP10 HP prescription, which is a prescription those patients can have dispensed in their community pharmacy.

Q. Then somebody called Ferring.

A. That is a growth hormone and, again, that is by Healthcare at home and, as far as I know, that again is a - all of our growth hormone is provided in-house, so we do not use homecare for that. But that is going to become a big issue now because adults will be receiving growth hormone in the future. I think there was a NICE guidance issued on that - National Institute for Clinical Excellence.

Q. Is it Biogen that is next?

A. Biogen, yes. That is a new drug for the treatment of multiple sclerosis. It is not new - there are three companies that provide different products. One is Shearing Health Care, which provides betainterferon; another one is Biogen, which provided Adanex; and another company Serono, which provides a drug called Rebis. They are a bundled price, but we are allowed to use either Healthcare at Home or Clinovia as a healthcare provider. So once the price is bundled we do have a choice in the homecare provider currently. There is also a new drug for the treatment of multiple sclerosis made by a company called Tiva, which is called Copropazone. We have yet to identify whether that is a suitable drug for homecare, but is an immunomodulating drug, so it is a new kind of drug for this treatment. So we have a choice of drugs here and we have a

choice of homecare providers as well, but we have a bundled price which we are unhappy with.

MR. GRINYER: To all intents and purposes, it is similar to the Cerezyme situation where you have a bundled price and you have a choice between HH and Genzyme Homecare.

A. Not necessarily, because we currently purchase the drug into the hospital and supply it to Healthcare at Home.

THE PRESIDENT: I do not want to put words into your mouth, but is this what you are saying? There are various different situations. If we have a choice of competing drug suppliers, there is at least an element of competing choice there. If we have a choice of homecare provider, then there is choice there, even if the price is a bundled price, and there is even more choice if you have more than one drug manufacturer.

A. That is correct.

Q. In this particular case of Genzyme I think you are saying that we do not have a choice of drug provider, we do not have a choice of homecare provider either, and your evidence is that that is a situation that is almost unique - there is one other situation to your knowledge that exists?

A. That is correct.

Q. That is your evidence?

A. Yes.

Q. Let us just quickly finish the list. We have Merck, an oncology drug, I do not know if that comes into your----

A. No, we do not use---

Q. We have Wyeth, looks like an Enteral drug of some sort. There is a little bit of evidence about Wyeth, but I can't put my finger on it.

A. Sorry, the Merck drug, Sir, is a new drug Topatecan and we do not have a homecare arrangement for that at the moment.

Q. I see

A. The Wyeth drug is Etanaset, it is an immunomodulating drug. We do not have homecare provision for that at the moment.

Q. Fresenius, these seem to be "PN" type products.

A. That is correct, and they also do peretoneal dialysis, which is a renal - which is outside my control.

Q. Then there is Gambro who are also doing peretoneal dialysis, and then we have a group of haemophilia drugs, suppliers who we have already discussed, and then we have finally got Angen, with Aronicept?

A. Aronicept, it is an Etheropoetin - epo - drug, again for treatment of anaemia, and we would issue an FP10 HP prescription for that.

Q. So there is no homecare?

A. No, not from us.
Q. Right, that is very helpful.
A. There is also, we have just had before lunch a witness statement from Dr Jones, of Healthcare at Home. I don't know if you were given that and had a chance to read that?
A. Yes.
Q. Is there anything in that statement that you would like to query or express a view about or a point of disagreement?
A. No,I am quite happy with that.
Q. I think it may be that there are some questions for you from counsel for the parties.
MR VAUGHAN: Yes, please, thank you very much.

Questioned by MR VAUGHAN:

Q. I think it is clear from your evidence that as regards the homecare market you regard that as not being disease specific from what you have been saying, it is just general?
A. Yes.
Q. And basically it is a service that a homecare could provide across the wide range of products, and types of service?
A. Generally speaking, yes.
Q. One has seen, for example with Healthcare at Home it provides enteral, perenteral, the whole range of these type of services when they are needed by nursing?
A. Yes.
Q. Perenteral and enteral neither have to be done by the manufacturer, but can be done by the manufacturer, that is right, isn't it?
A. That is correct, yes.
Q. Mr Jones mentions the fact that there are also delivery only services, that is right, isn't it?
A. Yes.
Q. So if you wanted a delivery only service without any nursing you could get that?
A. That is correct, yes.
Q. And you would go out and get a price for that?
A. That is correct.
Q. And apart from the haemophilia which I will come on to in a moment, are there any other delivery only services that the Royal Free deal with?
A. Thalassaemia would probably fall into that.
Q. You will have to tell me what that is?
A. It is a condition where patients require an infusion and the patients are generally trained up to self-administer. The infusion is made up within the hospital and delivered by a homecare company under cold storage conditions.
THE PRESIDENT: From the hospital to the patient?

A. That is correct, yes.
MR VAUGHAN: But that will never need nursing, or is it ----
A. It is possible that it sometimes will need nursing, and it is, I think, important to have the nursing element there, should it be required, because for a variety of reasons patients may, at some stage, need an element of nursing care.
Q. But we are talking about these type of things but there must be other products where - are there any other situations where the hospital delivers to the patient's home, other than the ones we are talking about?
A. Yes, we have a large number of HIV patients who are on a wide variety of medications. Once they have stabilised, we will offer them an option for homecare delivery.
Q. How do you do that?
A. Prescriptions are sent to the homecare provider once the patient has been seen in the outpatient clinic. They are dispensed by the homecare provider, and delivered to the patient's place of work by the homecare provider.
Q. But that is just delivery only service?
A. More often than not, just delivery.
THE PRESIDENT: When you say the homecare provider, what sort of company are you talking about?
A. We use Healthcare at Home for that. They have a registered pharmacy and they can dispense prescriptions which we send to them.
MR VAUGHAN: But a company of such a Polar Speed using another pharmacy could have easily have tendered for that type of contract.
A. I have no knowledge of Polar Speed, but I would imagine the principle would apply, yes.
Q. Yes. Because I think Mr Evans, in his statement, said he did not know about the contract, he does not read the official journal, I suppose? Do you actually put them in the official journal?
A. Yes. Well, we have tendered in the official journals, open tender, for haemophilia.
Q. Yes.
A. We have not yet tendered for other elements, but our intention is to do so.
Q. But if you do you have to through the European system?
A. That is correct, yes.
Q. And a Greek company or a Spanish company might well get the contract.
A. If they were interested.
Q. And tendered for the contract?
A. That is a possibility, yes.
Q. On haemophilia it is nursing only, the contract?
THE PRESIDENT: The opposite.

MR VAUGHAN: Sorry, it is the opposite. It was product plus delivery in that?
A. Yes.
Q. Sorry. That was because nursing was not needed, was it?
A. It was because the patients are very well stabilised before we would transfer them on to homecare. The difficulty with haemophilia patients is in managing their medicines, because if a child has a bleed, they will need a lot of medicine very quickly in order to prevent the haemorrhage.
Q. Yes.
A. In that context they always have to maintain an emergency stop or supply of medication in their own home for that purpose.
Q. The parents---
A. Well we have found the best arrangement is for the homecare company to take responsibility for the management and rotation of the patient's stock.
Q. But the tender they put in included the drug price bundled with the delivery price, does it?
A. We were conscious when we were going to tender that the companies who would provide the product and may also want to provide the service and we felt that to be fair to everybody we had to give them an umber of different options, and so we asked them to tender for product alone, for delivery alone, and if they wished for product and delivery. So we tried to cover all the eventualities to be fair to all of the companies.
Q. So you might well have ended with a split situation where Roche, or whoever, got the product and Healthcare at Home or Polar Speed got the delivery?
A. That is exactly what happened, but not Polar Speed, it was Healthcare at Home.
Q. Healthcare at Home, yes.
A. Yes, that is exactly what did happen, yes.
Q. So under that system, Roche provide a product, deliver the product to you, do they or to whom, under the haemophilia system?
A. We negotiate the price, now that is done through a consortia. The consortia will fix a price.
Q. Well, "fix" - negotiate?
A. Negotiate the price, yes. Then the healthcare at home company of our choice has access to the drug at that price, which is convenient because they can then keep it in their cold store rather than ours.
Q. So you do not have to physically hold the drug at all?
A. Yes, that is a considerable benefit because the cold storage of these products and the continual monitoring of them is a major concern, because a refrigerator may have a million pounds of drug in it at any one time, and that is the responsibility of the homecare provider.

Q. Yes, absolutely. Indeed, some of the figures we have seen in this case, at any one time, there were massive amounts of product being held.
A. Yes.
Q. Presumably if something goes wrong with the refrigerator the whole lot goes?
A. And it is their problem, not mine!
Q. Yes, I can see that. But it is a problem?
A. Yes, a very big problem, yes.
Q. If I can ask a little bit particularly in relation to Gaucher's disease, I think it is 70 under the Royal Free's supervision?
A. Between 50 and 70, yes.
Q. What was the other figure you said?
A. Between 50 and 70. They say 70.
Q. How many of those need nursing?
A. It is a variable number. I would say at any one time it is probably 25 to 30 per cent.
Q. Per cent?
A. Yes, of the total, but it is a fairly dynamic, the same 30 per cent. will not be nursing care all the time. As they get better and become stabilised somebody else may require a level of nursing support.
Q. And the people requiring nursing may be all over the Country?
A. That is correct.
Q. Cornwall, or Newcastle, or wherever?
A. In fact we have two of our Gaucher's patients have just started at university so we deliver to their university and that enables them to carry on as normal a life as possible.
Q. That is fantastic, yes.
Q. But how do you fix a price, as it were, because everyone gets delivery, that is easy, isn't it? So under the arrangement for homecare for Gaucher, every one gets delivery in the nature of homecare, and 20 per cent. of your people get nursing?
A. Not everyone, they would have to be stable patients.
Q. Sorry, then I ought to have asked more specific - you have 70 Gaucher patients?
A. Yes.
Q. How many of them are at home?
A. The majority would be treated at home.
Q. So let's take 50 for the moment, then, at home. Is it something like 50?
A. Probably 50 to 60.
Q. And about a quarter of those will be getting nursing on a fairly regular basis, but they may change, the people?
A. That is correct.
Q. How does the tender work for nursing when you have to do somebody in Cornwall,

somebody in Newcastle, how do you fix the price of a tender for a nursing visit in that situation?

A. We have a fixed cost. In the early days it was worked on a percentage of the drug, but we felt that was not the right way forward so now, as with the haemophilia we fix the cost to a certain value.

Q. Per visit?

A. Per visit, and that visit would be if they were in Billericay or Berkhampsted---

Q. Or Cornwall?

A. Or Cornwall, and that we find is the best arrangement.

Q. So they bear the cost of the variable transportation?

A. That is correct.

Q. Supposing you have the Cornish person, and the Truro PCT or whatever it is called down there, says "It is much cheaper if we provide our district nurse who is very good at cannulation, why doesn't she do it?"

A. We would be quite happy to look at that, but that situation has not arisen as far as I am concerned. In fact, if I were to be perfectly frank with you that would be my preferred option. It means that the District Nursing Service would have to take a level of responsibility for this additional work, and the refunding implications for it as well

THE PRESIDENT: Why would you prefer that, Mr Farrell?

A. I feel the District Nursing Service, years ago these patients probably would not have been treated, and then they were treated in hospitals and it was sort of high tech care. My feeling is that the District Nursing Service could provide an element of homecare, which would incorporate management of these conditions. The difficulty is that these particularly highly, in some respects, specialised patients there may only be one in Cornwall, or one in Billericay and it is a question of expertise then, and is it worth the PCT or the Community Care Trust setting up the arrangements for that. But if it could be done then I think it would have certain advantages for the NHS, because we may not need homecare companies. But there is a cost.

The other issue is in transporting these products if they are all coming from, for example, a major teaching hospital then there is the issue of how do we get the product to the patient.

THE PRESIDENT: If you were doing it entirely yourselves you would have to arrange the delivery as well as the nursing.

A. Yes. We even looked at the notion of employing our own nurses, but it is just not economically viable for us to do that, they would all need cars, and there is cover for annual leave, and they would all need training, and we would probably need about ten nurses, and the sums just do no work out.

Q. So it is more efficient to have a homecare provider?

A. Yes, indeed. However, as the numbers of patients requiring homecare increases in the future it may be an option that we could look at in partnership with PCTs, and GPs and Community Pharmacists.

Q. This is probably outside the remit of this case, but I suppose speculating more generally, to some extent, if there could be more homecare that relieves hospitals in another direction?

A. One of the big pressures on hospitals at the moment is hospital beds, and hospital targets and the throughput, and this has no doubt enabled us to make more efficient use of hospital facilities by having a homecare element.I think you are right, if it was to develop, which I think it will do, into a larger sector,then we may engage with PCTs and develop our own NHS Homecare.

Q. I see. I am sorry, Mr Vaughan.

MR VAUGHAN: If one is looking at the longer term, the more homecare grows as a factor, the more it becomes interesting for the NHS service to get into that market itself, if you call it a market?

A. Yes.

Q. Because you can save the cost?

A. Yes. But there is a cost in providing the resources to do that.

Q. Of course, there is a cost in everything.

A. Yes.

Q. But on the delivery, if you went down that line then the delivery, providing it was cold chain delivery would be a fairly standard delivery?

A. Yes, as we have with HIV patients, it is a fairly standard contract price per patient, per delivery episode.

Q. Yes.

A. And the patient's drugs are dispensed and delivered on a two monthly basis, so they get a two months' supply of drugs. We had a standard set charge for that.

Q. And that is what happens with Cerezyme, something like two-monthly ----

A. Something like that.

Q. And the nurse coming in very two weeks when nurses are required.

A. Yes.

Q. Or, sorry, infusion every two weeks, sometimes by the person themselves and sometimes the nurse.

A. That is correct.

Q. In your statement I think you say that the act of cannulation by itself is not very difficult because an individual can do it and almost every nurse at a certain standard with an element of training can do it.

A. Yes and no. I think nurses these days have to be particularly trained and have a

competency level in terms of IV cannulation.

Q. All nurses.

A. No, not necessarily all. Certainly the administration of drugs by IV cannula is something which does require specialist nurse training.

Q. The person can do it themselves.

A. Yes, they can.

Q. You can train the person to do it.

A. Yes.

Q. It is not like a tube down your stomach.

A. No, no.

Q. Even with a great deal of training, you could not do it.

A. No. I think the difficulty with IV drugs is the risk of hypersensitivity reactions and clearly there is a need for a very rapid action if a patient goes into anaphalactic shock.

Q. But that might happen when the patient is by themselves.

A. Indeed, yes, which is why we stabilize them. Normally it will happen if a patient is changed from one drug to another. That is why the stabilization process is important, because we will ensure that - probably you will know the patient who is showing an allergic reaction between the first two or three doses, if not the first dose, so the basis of the stabilization is to ensure the patient is safe in terms of receiving that drug, but it can happen.

Q. That is one of the reasons, in the evidence, why Genzyme were very keen that their nurses do it: that people with the skills in Gaucher disease and Fabry can monitor these things.

A. I go back to your original point. I would say that it is an element of core nursing training and I would imagine most acute unit nurses, nurses working in hospital would be able to do this and nurses working in community care would clearly need top up skills because they would not be doing it so frequently. I would expect most nurses who are practised in hospital to be able to do this.

Q. Mr. Moreland's evidence is that some of the at home people go along to their local community health centre and the cannulation - the insertion of the needle - takes place there. Do you know about that?

A. I do not know about that, no.

Q. There is a mixture between the two.

A. I can see that being a perfectly reasonable way.

Q. So it is moving towards the NHS end of this particular field. But basically Healthcare at Home nurse, by the look at it, sets off in the morning and goes around, seeing all sorts of different conditions.

A. Quite possibly, yes.

Q. And a Gaucher parenteral or - I am assuming it is a lady, which is an old-fashioned view of these things. She will go from patient to patient, doing what she has to do. I am not trying to minimize it.

A. I do not know how they work. My understanding is that they will see anything up to three patients in a day and I have to say I do not know whether they are the same patients or whether they would be a mixture of patients.

Q. You may or may not know this. When the EL(95) letter came out, were you about the place then?

A. I think I remember it.

Q. My impression is - I have not got the reference at the moment - is that what that did was to strip out the nursing from the other bits. All the EL(95) things included the ones that were made into contractive services. There were two groups. One is a prescription service, one contractive. Prescription services remained as before the prescription covered the service down to the nursing that was applicable. The contracted ones cut off after delivery but before nursing. Do you know that or not?

A. I am not familiar with that.

Q. We will come back to that argument at a later stage. The President asked you questions about the transaction costs of these things. Presumably, if you went down a system of individual negotiation, individual tendering, there would clearly be an element of cost about that. Presumably there will come a time when the benefit you gain is not worth the candle: the transaction costs will be bigger than the savings you make; is that right?

A. I am not with you, sorry.

Q. When you are looking to see what the advantages of your system are, of going down the tendering system, there is an element of cost in the tendering.

A. Yes.

Q. But it will not be much benefit if the result of the tendered cost was more than the pre-existing cost.

A. Yes.

Q. So you decide not to go down that route, if it looks as though that might be the situation.

A. It may be, or we may decide that this patient's needs require homecare and that would be an additional cost for the trust. That could happen, I can see, with a number of cases.

Q. But what situation do you mean by that, the additional cost to the trust?

A. It would be where the trust would negotiate with the PCT regarding any additional homecare costs, but if it was still felt that homecare was necessary - an example might be if a child moves away from their carers and into university - then homecare might

suit them better, whereas with the nursing level of support, whereas a delivery service has sufficed to date. So we would look to discuss those one-off cases with PCT.

Q. So it is not a one size fits all.

A. No.

Q. It is all very much individually done.

A. Yes. We have tried to make it fairly robust in standardising the service where we can, particularly for HIV drugs. That is a fairly straightforward dispensing process, but even then the dispensing is quite complicated. These patients are on regimes of drugs which are hugely important to managing their condition, so we have taken steps to ensure that is done properly, but we have standardised it and therefore have standardised the delivery price. It is much more difficult when one is dealing with a chronic condition that can change. We then may have to alter our arrangements to suit the patient.

Q. Would that second group include Gaucher?

A. It may well do, yes.

Q. You might have to change things.

A. Yes, and it is important to keep a level of flexibility.

Q. The dosage might change.

A. Indeed, or the patient might need more of the drug or less or whatever, yes.

Q. That would be the decision of Dr. Mehta in your case.

A. Indeed it would, yes.

Q. The cannulation is not too difficult: it is everything else that is quite difficult.

A. Some patients cannot cannulate at all and some can. We cannot factor whether they can or cannot cannulate be the determining factor if they require homecare, if you see what I mean. Some patients feel very vulnerable at times and they lose confidence very quickly.

Q. This is the point I was wanting to make. In many ways, there are 180 different examples of patient: they are all slightly different.

A. Not necessarily all different. A large proportion for a reasonable period of time will be OK, and some will need additional care. As I have said before, that can be a slightly moving target in terms of population.

Q. There are some who seem stable on self-cannulation who then develop a phobia or whatever the expression might be.

A. Possibly, yes.

Q. And then might either have to have nursing or even come back to hospital in that situation.

A. Indeed.

Q. The whole thing moving into a tendering system, all the homecare, is a long-term

ambition, by the sound of it.

A. Yes, whether we would move in one leap to homecare is probably debatable. We would probably look to do it by disease groups where we could find a cluster of conditions which may be suitable. That is what we did for haemophilia: we took a view that we were sufficiently mature in what we understood to be homecare to enable us to do that.

Q. But haemophilia, this was Factor 8, was it?

A. Factor 8, yes.

Q. Is that a rare one?

A. We have currently anything up to 80 to 100 patients.

Q. On Factor 8?

A. Yes, and it is clearly a very important drug for these patients, otherwise they would have a lot of bleeding episodes. The difficulties are that they are mostly children and they can fall over and get injured. If they do get injured, they can have inter-articular bleeds if not dealt with quickly. But when they are stable they are quite stable.

Q. But that is very different from the Gaucher patient who, once a fortnight, regular as clockwork, receives the treatment and not more often and not less.

A. No, no, the haemophilia patients will require treatment on a weekly basis.

Q. They require it on a weekly basis.

A. Even sometimes more frequently than that.

Q. Is that self-administered?

A. Self or carer given, yes.

Q. By "carer" you mean not a nurse but the relative.

A. The relative, possibly, yes.

Q. Or wife or whatever - son, husband. But the situation might arise when there was a sudden need, which is unlikely to happen in Gaucher.

A. Less likely to happen in Gaucher's, yes.

Q. On TKT and Replagal, there we have got a situation of the two orphan drug rivals, twin orphans, as it were, competing on the basis - we know that Healthcare at Home has an exclusive arrangement with TKT to distribute and supply the services and the price is the drug tariff price.

A. That is correct. I do not think it is the drug tariff price. Is it featured in the drug tariff? It is a set price.

Q. The published price or whatever you like to call it. You do not like that either.

A. I think, as I have said to the Chairman, it is fortuitous that TKT have used Healthcare at Home, but be that as it may that would have been our preferred company. However, I am unhappy with the bundled price.

Q. That is the thing that concerns you most.

A. I like to know what I am paying for in terms of the drug and the cost of homecare.
Q. Just one or two little points in addition. Have you seen the interview with Dr. Wraith at Manchester, the note of the interview?
A. No.
Q. Perhaps you can be shown that. It is in CB3, which is 39, tab CH78.
THE PRESIDENT: It is page 5715, if we are looking at the numbers at the bottom of the page or 1071 at the top of the page. If you go over the page ----
MR. VAUGHAN: You get to a completely different number - 283 for some reason.
THE PRESIDENT: Separated by 5000 pages!
MR. VAUGHAN (To the witness): This is a meeting that Anne Pope and somebody else had with Dr. Wraith and various others from the Royal Manchester Children's Hospital. This is July 2001. Do you know Dr. Wraith?
A. No, I do not.
Q. He is one of the four consultants in this field, specialising in children. He provides treatment for about 30 patients with Gaucher's disease. Two-thirds are children. In theory, the children would transfer to the adult centres at 19. The remaining third is adult patients, who are also seen by Professor Cox. So, say, 20 children under him and a third jointly under him and Professor Cox. He thought that Vivesca - we do not want to go into that - was unsuitable for children because of side effects. That was 2001 and before it was on the market, I think.

"The opinion was expressed that entry by another competitor would not be difficult." Do you have a view about that or not - into this field? Cerezyme.
A. In the context of - it was currently a single company providing the drug with its own home delivery system attached - is it in that context?
Q. Just dealing with production at the moment.
A. It could result in difficulties, yes.
Q. Sorry, he said it would not be difficult.
A. I think it would be difficult.
Q. TKT had no difficulties of setting up a trial for their treatment of Fabry. Do you know about that? Probably not.
A. No, I do not know about that.
THE PRESIDENT: What are the difficulties that you had in mind, Mr. Farrell?
A. If a new drug became available and we had an arrangement with a supplier using their homecare company and a new product became available, it would be fine if that supplier was prepared to continue using their homecare company to supply a competitor's drug. But I think that is what would cause the difficulty, that particular issue. I do not think it would affect anything other than that in terms of clinical trials or us evaluating the drug or in any other respect.

MR. VAUGHAN: That is the real point. "6. The view was expressed - unlikely that health authorities realise the price they are currently paying is other than the cost of the drug." That is probably your point, is it not?

A. Yes.

Q. Then 7, over the page, "The treatment, Cerezyme, is bought as a package; the services of Healthcare at Home are included, whether needed or not." So this is in the days when Healthcare at Home was the exclusive distributor.

A. Yes.

Q. "Healthcare at Home appear to be independent and Dr. Wraith indicated he had little control over supporting activities. They will visit patients without him asking and subsequently provide a report." Have you had experience of that?

A. No.

Q. "Dr. Wraith used the role of the Healthcare at Home more as delivery and support rather than provision of a nursing service. The patients and their families are trained to give infusions in their local hospital rather than HH alone." Is that your experience at all?

A. No.

Q. Have you had no experience?

A. It clearly will be up to Dr. Wraith how he chooses to manage his patients. In our arrangements we have engaged the use of Healthcare at Home nurses, and we have used them to monitor drug supply to patients' homes.

Q. Of course, all his are children or young people?

A. Yes, indeed, and some of ours are children. I think it is absolutely crucial with homecare provision that it is set up appropriately.

Q. Yes.

A. And it is not something that one can simply undertake, it takes a lot of planning. For example, with the haemophilia, although there was no direct nursing support, the Director of Nursing from the company visited each of the haemophilia patients and one has to make sure that if the Homecare company is providing a service on our behalf to our patients, then it is of the correct standard, and that is why we attach such a lot of detail to the selection and the monitoring of the company. I do not know what arrangements this doctor has for his patients, but it seems to me that some of the infrastructure was not there in order to facilitate good arrangements. That is all I can conclude.

Q. But if a drug company is having its drug distributed by a third party it is pretty important to it to know that everything is perfect, in this sort of field?

A. Well, drug companies supply drugs to hospitals and GPs every day of the week, and

sometimes they take very much interest in what we do with the drugs. I think it is up to the persons who have clinical responsibility for the patients to ensure, not for the drug company. It is for the clinicians, pharmacists and nurses who are responsible for the patients to ensure that the care is being delivered correctly and the drugs have been used appropriately.

Q. But a rather different feel because there is a very strong Gaucher Association, the company, Genzyme has very close links with the Association and regular meetings, and you could not criticise a company for having a very careful look, and wishing to have a control over the application of its treatments?

A. No, and we would probably like to work with them in that respect.

Q. Indeed, in your witness statement you refer to the problems like Genzyme had with Caremark, you had problems with Caremark?

A. Yes.

Q. And Genzyme had problems with Caremark?

A. Yes, I don't know---

Q. They were quality control problems were they?

A. No, my concerns were complaints from patients, drugs not being delivered on time, drugs being expired, a lot of wasted drugs, a variety of concerns.

Q. Pretty much the same complaints as Genzyme had, if we look at the evidence?

A. I don't know, I mean how can I say, it was sufficiently important for me to stop that service.

Q. Indeed, and Genzyme themselves terminated it. If problems occurred with a patient, a blocked catheter, the patient would usually have to come to hospital, be treated and this is - 9 - sorry, going on down the---

A. I am following on what you are saying.

Q. A blocked cannula, the patient would usually have to come to hospital to be treated. Without Healthcare at Home the patients would have to come to a hospital to have their infusion, there would be no mechanism for delivering the drug. That is obviously right?

A. Yes, but I think if there was a blocked cannula we would particularly look to Healthcare at Home to resolve that issue. I would not see the patient having to come to the hospital for that, that would be part of the nursing role.

Q. Dr Wraith obviously thought it was, but it may be because they were children. 10 is a different point. It is probably easier if you do look at the note, because you can see it is a different point he is making. "Without Healthcare at Home the patients would have to come to hospital have their infusion. There would be no mechanism for delivering the drug, that is physical delivering the drug, it is not the nursing point.

A. That is an important point, because part of the homecare service is delivery of the drug,

and if patients are all over the country we need to find a mechanism for doing that. It is not the kind of drug that I would at this stage look towards being dispensed by a community pharmacist.

Q. Can I ask you why?

A. For a start there is the cold chain, and most community pharmacists do not have large refrigerated units, so that is a particular issue. However, there is a change coming, I think in the future, to the local pharmaceutical contract where additional fees may be payable for a medicines' management approach, and there may be some community pharmacies who are interested in engaging with this.

Q. So they would become the product holder for the hospital?

A. Yes, that is a possibility in the future. It does not happen at the moment, but I could certainly see that evolving.

Q. Then the dosage required by children would be higher than that required for adults. Dr Wraith thought he could change the dosage on the basis of what Genzyme suggested. There was an allegation going around the place that Genzyme was trying to boost up the dosage at the time, and he found it inconceivable that clinicians were changed. Presumably that is on your basis too, you would agree with that?

A. I would be surprised if Genzyme would do that. In that respect they are very ethical.

Q. Yes. Thankyou very much, thank you, it is nice of you to say that. Local doctors never altered the dosage without consulting a specialist, and then there is the patient register, there is no issue in this case. The treatment is bought as a package and no discounts have been obtained from the list price, and presented with the hypothetical situation where the price of the drug could be separated from the cost, some interest was expressed in the merits of such a proposal. That is rather like you on that?

A. Absolutely.

Q. The hospital would usually prefer one provider of home healthcare for each type of treatment. So he wants a different one for each type of treatment?

A. A different homecare provider for each kind of treatment.

THE PRESIDENT: Paragraph 15 of this document - if you have the document there, just glance down to paragraph 15. It is a note of the discussion with Dr Wraith. He says that "the hospital would usually prefer one provider of home healthcare for each type of treatment". It is slightly ambiguous in the note, isn't it, Mr Vaughan, we are not quite sure whether he means one provider per treatment, or one provider overall?

A. Yes, that is my understanding, yes.

MR VAUGHAN: I thought he was saying each type of treatment, one for IV, one for EN.

THE PRESIDENT: That is a possible interpretation, but I think the other interpretation is not completely excluded.

MR VAUGHAN: No, well we will leave that one as it is.

A. It would be very impractical to go for the former.
Q. Then 17, he felt it was logical for Genzyme to take the homecare service in-house. Do you see it as being logical to do that?
A. No more logical than using an independent homecare provider.
Q. Yes. Thank you very much.
THE PRESIDENT: Just a moment, Mr Farrell, I would like to ask my colleagues if you have any questions before you come in.
MR MATHER: Briefly, Mr Farrell, I was interested in your point about additional fees for medicines' management about to be introduced, a change in the culture. Could you explain who would establish that new arrangement?
A. There was a document out called "A vision for pharmacy practice", and that is out for consultation now by the Department of Health, and the notion is that community pharmacists are engaged more within a medicines' management approach, and indeed, we are running a pilot ourselves where the community pharmacist is currently providing anti-coagulation services for patients who previously would have had to go to the hospital, clinic, in order to have their anti-coagulation monitored and it is that kind of service that community pharmacists are now looking to extend their roles into. They are a huge resource,there are something like 10,000 of them out there and they are very accessible to patients, and I think the view is currently that they are a huge resource that is under utilised. One of the purposes of this document has been to see what additional elements of management, or even medicines they could be employed to undertake. The funding of that would inevitably be part of the new contract arrangements that they would have, and I suppose that would come down to some kind of central funding which would be distributed through primary care trusts who hold their contracts. So this could be moving in that sort of direction, possibly.
Q. In terms of your role as a key buyer, you cover several hospitals, how many other buyers are there in the Health Service in your sort of position? How many peers do you have who are group pharmacy purchasers?
A. In the London area there are probably three colleagues who have the same area of activity and spend that we do. It normally clusters at around something like #100 million of drug spend, and that is a sort of volume you need to be talking about in order to get consortia contracts directly with drug companies. For example, we are talking of X-ray contrast media. We will link up our usage of drug at three hospitals, and do a tender on that basis. It is volume driven.
Q. Across the country how many?
A. As you go out of London the pattern changes. There is more of a cluster of hospitals in London. As you move back into Essex, it becomes almost down to individual hospitals, but as you go to maybe Manchester or Leeds - Leeds hospitals have just merged, so the

two large teaching hospitals there are now under one management organisation, so they would be about the same size as my arrangement. I think there are rumours of mergers in Manchester between hospitals as well. I think pharmacy is quite interesting because it works better on a management arrangement which is bigger than current Trusts. So the plan has been to network - I think that is the common term. An example of that is I have manufacturing facilities and quality control facilities which are hugely expensive to set up, but I have them in one Trust and they service four or five other Trusts as well, both within my control, and other Trusts who just do not have those facilities themselves. So we will make products for those other Trusts. I sort of regard myself as working for the NHS rather than four particular Trusts.

THE PRESIDENT: The scale gives you those advantages.

A. Yes, the scale does, particularly when one is looking at capital bids. There is no point in me putting in a bid for several million pounds to build a septic unit that is going to stand idle for, "a part of the day". I may as well say to my colleagues "You build it", or we will provide it and we will then service another Trust", and that tends to be the way that it works. That is not just me, that has been driven by the strategic health authorities and before that, regional health authorities, and there are regional specialists in areas like drug information, quality control, manufacturing, who take an overview on all of these issues. Even in terms of procurement, there is a national and a regional specialist who we feed into in terms of procurement decisions.

MR MATHER: That is exactly where I am heading, because there if there is a national or regional procurement arrangement, would that to some degree be capable of redressing a position where a manufacturer does not do what you want. Let's take, for example, bundling homecare, could not the regional network or procurement system, perhaps prompted by you, say "Mr Farrell is having a spot of trouble, he can't get them to unbundle this, they have said 'no', but if we all pile in, that will increase the power versus the manufacturer"?

A. Yes, we have had exactly that discussion last week with the regional pharmacists. I think that the homecare issue generally is going to be taken up on a regional basis, because it has become not a mature market, but certainly a rapidly evolving one, and I think it is going to require a regional overview at some stage. But you are correct. Whether or not we have the - well we certainly do not have the power locally to force people to unbundle prices, but it is something we can aspire to.

THE PRESIDENT: What power has the Region got that you do not have local?

A. The regional pharmacist is responsible for overseeing procurement within the region, and he also has regular meetings with officials from the Department of Health, and then these matters can then be brought up through those channels.

PROF GRINYER: In your written statement in paragraph 58, you seem to be

implying that you do not, at your operating level, see yourself as having countervailing buying or monopsony power as a big buyer against a monopoly like Genzyme, where you have a uniquely efficacious treatment, just one, and you are unable to persuade them to unbundle and so on.

A. Yes.

Q. This is a correct interpretation?

A. That is correct.

Q. Do you think that moving to a more networking and more reasonable procurement sort of collaboration, consortia, will actually change that or not?

A. It is something we would be asking for, and if we went to tender it is something we would be putting in the tender document.

Q. But if you are tendering just for one product----

A. That is a difficulty, and that is the difficulty we find ourselves in in this particular case. If there is only one product there is no point in tendering.

Q. Thank you. On another unrelated point in a way, but one that is significant, it has been proposed that one advantage of an exclusive distribution system, as with HH in the past, or a tied vertically integrated company like Genzyme Homecare, there is a major advantage to the manufacturer in terms of feedback of information relating to the patients, and the problems they have, so records are kept relating to each patient. Could you see this as important at an early stage of the launch and development of an orphan drug, where you have got only a few patients? If so, is that a reason for having such an arrangement or would you see that your systems themselves would allow this passage of information rapidly to go to a manufacturer, even if you had a multi-disease delivery, as with HH?

A. I think for such cases we would be looking at the database that would be required and the information that would need to be collected and probably putting the systems in place ourselves, if it was an orphan drug, but it depends on the status of the orphan drug, because it is orphan because it has been used in relatively few numbers of patients and possibly the long-term side effects are unknown, then we would want to be monitoring that quite carefully ourselves.

Q. The condition.

A. Yes, the condition, absolutely.

Q. Would you normally collaborate closely with the manufacturer on this?

A. We may do, but we would see that as a clinical role that we would wish to take on, because the patient remains our responsibility, not the responsibility of the drug company or indeed the homecare company: it is our responsibility.

For orphan drugs, whichever company is providing the homecare, we would set the parameters for the data we required and how it would need to be collected, so it

would not matter to me.

THE PRESIDENT: Would you be accommodating for a manufacturer who wanted to have as much feedback as possible?

A. Yes, indeed. I think it is important. We rely on the pharmaceutical industry to develop new drugs. It is important that we have a mature and sensible dialogue with them. I have always felt that. They need to know how we use their products. We can then make suggestions to them in terms of further product developments. In fact, that is very much the case. We began using a drug which was used for renal patients at the Royal Free for a condition called atopic psoriasis and, following several talks with companies, that clinical problem has now become a new product. So we like talking to drug companies that are willing and looking at developing new products, because that is their expertise.

THE PRESIDENT: Yes, Mr. Turner.

<u>Questioned by MR. TURNER</u>

Q. Mr. Farrell, first of all, I would like to go back to a question from the Chairman about how you go about agreeing with companies to provide homecare services and whether you would discuss it with the patient and, I think you said, the clinician also and then look for a provider.

Just to clarify, to what extent are the views of clinicians taken into account in deciding, in the context of a tender, who actually does get the business?

A. Our experience with tendering was with haemophilia and we did discuss the tender proposals with the clinicians involved and took their views into account as part of the overall tendering arrangements.

Q. My second question is really a point of clarification: it relates to the haemophilia tender and an issue in relation to the number of patients for whom it makes sense to engage in a tender. Can you just clarify again how many patients were subject to care under the tender: how many haemophilia patients you have at the Royal Free Hospital?

A. Overall, I think we have probably about 200 receiving treatment. I cannot tell you the exact number we have got with homecare, but it may be 50% of that.

Q. About 100.

A. About 100, yes.

Q. Mr. Vaughan at one stage may have suggested that a company called Polar Speed might have tendered for the home delivery element for the haemophilia tender; I understood you to say that you were not familiar with that company. May I therefore put the question in a slightly different way? If you imagine a company which is a cold chain delivery company and whose function it is to deliver the product to the patient's door at a set time, whether or not Polar Speed itself conforms to those parameters, but that is what it does - that and no more - could you please explain whether that would be

sufficient for the home delivery service that you require for haemophilia or, indeed, for the Gaucher service?

A. No, I think our requirements would be considerably more than that.

Q. Could you explain, please?

A. I think one has to look at the full range of what home delivery is. We have arrived at an arrangement with the haemophilia where the driver is responsible for not only delivering the drug but rotating the drug, because these are hugely expensive medicines. They provide patients with a refrigerator and on occasion some patients have felt a level of confidence in the driver that they give them their front door key so that the patients can then have the drugs delivered whilst they are not there.

I think the other issue is that these are children mostly and we put in the specification that the drivers should have police checks for obvious reasons.

Q. This is the haemophilia.

A. The haemophilia. I think, again, with Gaucher's we would want to ensure that drivers were of an appropriate standard. So those are just some of the reasons why it goes beyond a straightforward delivery to the door system.

Q. I do not know about the haemophilia drugs specifically, but Cerezyme is, of course, a very high value drug. Is that an issue at all in relation to the home delivery service that you are looking for or not at all?

A. Hugely. Hugely. There is also the issue of compliance. Patients do not always turn up at clinics when they are meant to, and that is a considerable - even for acutely ill patients or even chronically ill patients - this ensures that we get the drug to the patient and their compliance is improved in that respect.

THE PRESIDENT: By "compliance", you mean the patient's compliance.

A. The patient taking the drug, yes.

Q. The patient actually taking it.

A. Yes, that is quite an issue sometimes. The cost of a drug is of concern to us and we have to ensure that it is not left with a neighbour or left in the garden shed or something like that. It has to be looked after and managed as part of the total homecare package.

In some respects, I have to say I prefer a homecare delivery company delivering the drug rather than the patient collecting it from our pharmacy for security reasons.

MR. TURNER: Just to pick up on something that you said in the course of discussion earlier, you mentioned an issue of wastage; is that connected with that?

A. Yes, it is. Wastage of these products was a considerable problem before we had the haemophilia arrangements in place and, in fact, I have not got the exact figures but our usage of haemophilia products reduced by about 10% once we put in place a homecare managed arrangement. I have not got similar before and after effects with Gaucher's

because we have always had a homecare arrangement for these patients. But there is no doubt that, left to their own devices, patients can waste a considerable amount of drug.

Q. After lunch, you were asked to look at a paragraph from the MMC report and part of the statement of Mr. Moreland of Genzyme. I would like to just stand back outside the parameters of those two documents and ask you the general question, how common is it in the pharmaceutical industry for a drug company to offer you a price which includes the cost of homecare and not to offer an alternative drug only price?

A. Rare, very rare.

Q. The next is a point of clarification as a result of something that you said. It relates to the relationship that you have with the PCTs who ultimately bear the cost for this service, the cost of the drug. At the moment, there is a rolled up price. There may have been an issue as to whether, if you were to contract for homecare services, that means that they will contract with the homecare provider or yourself. Just pausing there for a moment, do you have a view about that, about the extent to which contracts for such services would be centralized or PCTs would do that, enter into contracts for themselves for this particular service?

A. I think it is important to identify in the context of this who has clinical responsibility for the patients. That is not the PCT, that is the clinicians who look after the patients. In that context, I cannot see how it could be reasonable for the PCTs to contract for a homecare service. My view is that that should be done as part of the clinical programme of care for the patient.

We would clearly discuss with the PCTs, as I have discussed in terms of programming these patients through the system, what the extent of the arrangements and the financial implications would be, but the responsibility resides with the care providers. So therefore, to answer your question, the contracting responsibility has to rest also with the care providers.

Q. By that you mean largely yourself in this case.

A. Yes, and the clinicians involved, yes.

Q. May I then move to a second stage of that question? That is this. If you were to engage in such contracting, would it involve a significant additional burden for you in terms of having to liaise with these PCTs? If I may just explain that. At the moment, as I understand it, you already need to negotiate with these PCTs in relation to the cost of the drug which involves the rolled up homecare.

A. Yes.

Q. My question is, would there be a significant additional burden that you foresee or would there not?

A. No, there would not. In fact, the PCTs that we have discussed it with have all been

very happy for us to undertake this contracting process, but they wish to be informed of it. They are happy for us to do it and to lead on it.

Q. My next question really picks up on something on which the Chairman touched and it related to parenteral nutrition (PN). You were mentioning the possibility of infection through the injection, using the central vein, as a reason - or it may have been suggested that that risk of infection might be a reason for the manufacturer of the parenteral nutrition product to provide a homecare service.

Could you just clarify this, please? In parenteral nutrition, so far as you know, does the manufacturer of the product supply it to you together with homecare services, or have I misunderstood?

A. I think so. The point I was trying to make there is that parenteral nutrition in the trust that I am responsible for - we manufacture the drug. We buy in the raw material from the company in terms of solutions, we undertake a compounding process, so we make up the three litre infusion fluid bag, if it is to be three litres, and then we contract with the homecare company to collect it and deliver it to the patient's home and any nursing care that will be necessary as well.

Q. And the company with whom you contract - which company is that?

A. That will be Healthcare at Home that we would contract with, but the supplier of the raw material (if I can call them that) in my case has no involvement beyond supplying us with raw materials.

Q. Moving onto one or two questions that Mr. Vaughan raised with you, he mentioned in passing that if you were to tender using the official journal it is a possibility that a Greek or Spanish homecare company might win the tender. Would you please say whether, in your mind, that is a theoretical possibility or whether you are aware of any?

A. No, I think it is theoretical, although I am aware that Healthcare at Home did employ a Greek driver to talk to the thalassaemia patients who were of Greek extraction, so that was quite useful.

THE PRESIDENT: That tends to run in Greek families, does it not?

A. Yes, it does. So that was quite a useful thing to do. I think it is theoretical, but I could not say that it would never happen.

MR. TURNER: District nurse usage. I think you said that the administration of drugs by intravenous cannula is a specialist technique. You canvassed with Mr. Vaughan the possibility of district nurses becoming involved in homecare.

A. Yes.

Q. Again, my question here is this. First of all, take it in stages. The present situation, the availability of district nurses for this sort of function, for homecare. Could you just summarise how you see that at the moment?

A. There are currently insufficient district nurses to provide this service. That is partly

one of the difficulties. I am sure they would be willing to do it, if there were sufficient numbers.

Q. Is it a foreseeable development, therefore, that district nurses become involved to any significant extent in this service? Is it something under consideration or, as you were canvassing it, is it more an ideal wish on your part?

A. If there were clusters of patients within particular areas, I could see this working reasonably well.

Q. To clarify, my question is not whether you can see it working well but whether, looking forwards, this is a real possibility on the cards at the moment or it is something which you imagine could work well.

A. It is something I think for the future. I cannot see it operating, certainly within the foreseeable future. It is an aspiration that we will work towards.

Q. My last question, subject to anything from my right, is a question of clarification. Mr. Vaughan, in one of his questions, described Healthcare at Home as an exclusive distributor for - I think it was - TKT and you said earlier on - perhaps you have forgotten this - that you had read Mr. Jones' latest statement. He said at the end in relation to that issue: "I can confirm that Healthcare at Home is not the exclusive homecare provider for TKT in relation to Replagal." Really on a point of information it may be that that went a little bit too quickly for you to pick it up. Do you have any reason to doubt that?

A. I do not, no.

Q. Finally in relation to the last sentence of Mr. Jones: "There is nothing unusual about homecare companies dealing with competing products, for example in the multiple sclerosis market."

A. That is correct.

MR. TURNER: Mr. Thompson may have a question.

MR. THOMPSON: There is just one short question. This is something for the future. If the district nurses became available, for example, in relation to the Gaucher patients, would that eliminate the concerns that you have over Genzyme's pricing strategies at the moment?

A. If that were to become an option, we would have no need of homecare companies or services and therefore we would be simply buying the product and the price would be clearly the purchase price for the product, so would it eliminate my concerns? In part it - sorry?

Q. In relation to the price you are currently paying for Cerezyme.

A. Yes, it would.

MR THOMPSON: Thank you. Sir, unless the Tribunal has any further questions---

MR MATHER: I just wonder how much business you do with Healthcare at Home?

A. It is an emerging market. We do a substantial element of business now, sufficient that I would be looking to want to tender elements of it.

Q. Is it #20,000 a year, or #100,000?

A. No, no, it is several million pounds a year.

Q. Several million pounds a year you pay to Healthcare at Home?

A. No, that is the drug content of it, oh no, we do not pay them that much.

THE PRESIDENT: They are homecare providers in relation to several million pounds of drugs?

A. Yes. And the reason that it is several million is because it is the high cost end of the treatment market, if you see what I mean. These are all high cost patients.

THE PRESIDENT: Thank you very much indeed, Mr Farrell. I am afraid it has been a long day for you. It has been immensely helpful for the Tribunal and we are very grateful to you for coming. Thank you very much.

PROF GRINYER: Sorry about your lunch.

THE PRESIDENT: The Tribunal is just going to rise for five minutes, Mr Thompson.

(Short break)

THE PRESIDENT: Yes, Mr Thompson?

MR THOMPSON: Chairman, gentlemen, inevitably I have had to slightly rethink, because I thought I would be starting rather earlier in the day than I am. If I could tell you the structure of our presentation as we originally planned, which we will obviously think about over the weekend, and see whether it can be shortened or not. We were intending to break up our submissions into six parts. I was going to do the first three. Mr Turner was going to do the fourth and the fifth, and then I was going to do the last one.

The first one was by way of introduction, which I think we will get through today, I hope so. The second and third was intended to take the Tribunal through a number of documents under the headings of two propositions. Those propositions being since at least 1995, and thus since 1st March, 2000, the NHS list price for Cerezyme has been a bundled price, i.e. it has included not only the cost of supplying to the dispensing pharmacist, but also the supply of homecare services. That was our proposition one. There is quite a number of documents which have not yet been opened.

THE PRESIDENT: I am not sure that is disputed, is it?

MR THOMPSON: Well, I do not know whether it is or not.

THE PRESIDENT: Right. We do not need to look at things which are not disputed, we just assume that it has been a bundled price all the way through until today.

MR THOMPSON: A lot of it is either free, or I think in the words of Mr Yarrow---

THE PRESIDENT: Well, it depends what you mean by "bundled", if you say "not separately charged for", that leaves open whether it is free or not.

MR THOMPSON: It is also a question of whether or not it is legitimately above the NHS list price. Anyway, it may be that the drafting could be improved on, but I think the gist of the point is one that was worth making, and quite a number of documents bear on it.

The second one, in respect of NHS patients who are treated at home with Cerezyme, supply and demand is for in addition to supplies of the drug to community pharmacies, and conventional dispensing services, i.e. a bespoke, flexible, integrated homecare service for Cerezyme---

THE PRESIDENT: Wait a minute, you are going a bit too fast. It is for a bespoke----

MR THOMPSON: ---and flexible integrated homecare service for Cerezyme, that is to say homecare services.

THE PRESIDENT: Yes.

MR THOMPSON: Then Mr Turner was going to deal with the adverse effects of the bundling and margin squeeze abuses that the OFT has found in relation to the provision of homecare for Gaucher patients, and also the justifications advanced for Genzyme's pricing behaviour. Then I was going to deal with the Tribunal's questions including the issue of how the direction should be framed, if there is to be a direction, and any other remedies.

THE PRESIDENT: Yes.

MR THOMPSON: If I may start with some introductory remarks under five heads. I will just give them briefly. First, the nature of the OFT's case. Secondly, the obligations of a dominant supplier. Thirdly, the economic significance of the case. Fourthly, the issues of refusal to supply, exclusive distribution, and vertical integration. Fifthly, what I have called the "Tom, Dick or Harry" point, Mr Vaughan's point that it was implicit in our remedy that they would have to supply every Tom, Dick or Harry, with Cerezyme.

By way of preliminary remarks, as we say at paragraph 4 of the skeleton argument, the reference is at bundle 45 page 2.

THE PRESIDENT: Do we need it?

MR THOMPSON: I do not think so, I am simply giving the reference for the transcript in due course. This is a case about abusive pricing. However, what it is about could also be expressed by the use of a homely expressed, redolent of the more rugged competition policy regime of Victorian England, it is a case about "cornering the market" through bundled pricing, and then exploiting that situation by vertical integration accompanied by a simultaneous margin squeeze on all actual, or potential, competitors.

The second point is, although this aspect of their case did not feature prominently in Mr Vaughan's remarks yesterday, the theoretical foundation of Genzyme's case on this appeal, is that the bulk of homecare services is a standard form of wholesale delivery, readily undertaken----

THE PRESIDENT: You will have to go a bit slower, Mr Thompson, we are trying to write it down. Yes - standard form of wholesale delivery?

MR THOMPSON: Undertaken by many competent delivery companies, and in particular by Polar Speed. It is only in this way that it can argue that homecare services are essentially within the NHS list price and that any free provision, i.e. bundling, is de minimis and comparable to a supermarket providing help at the checkout in packing the groceries. That is an image of Professor Yarrow, bundle 37, tab 22, page 196.

The OFT rejects this approach completely, and invites the Tribunal to do the same. This is a point that is made at paragraph 4 of the defence, bundle 28, page 2. Gaucher patients are chronically ill people being treated in the community. They are not convenience purchasers of milk, or take-away pizza. Convenience purchasers, as a group, can perfectly well go and make or buy other food and drink if they are not happy with their local milkman, or their local pizza store. Gaucher patients at home are entirely dependent on their homecare services supplier for their good health and thus for their quality of life. They have no alternatives readily open to them if that supplier lets them down in any way. Their specialist care centre may be many miles away, their local surgery or pharmacist is unlikely to have expertise in Gaucher disease and will not, in any event, stock Cerezyme.

Their specialist care centre equally relies on homecare service providers to discharge their functions skilfully and to monitor the patients' well being and to cater for their special and varying needs. For example, Dr Mehta and Professor Cox make this very clearly and in a form that is completely unchallenged.

The NHS rightly, and we now have the evidence of Mr Farrell directly, insists on very substantial safeguards in such circumstances as reflected in the detailed specifications drawn up by NHS purchasers such as the Royal Free Hospital and the Birmingham Children's Hospital, and in the detailed plans that went into the transfer of functions that to Healthcare at Home in 1998 and into the creation of Genzyme Homecare in 2000.

This is the basic fault line between the primary evidence of NHS purchasers such as Mr Farrell and Professor Cox, and of NHS suppliers such as Dr Jones, and to be fair, Mr Johnson and Miss Kelly in her original evidence, and the somewhat flippant tone of the secondary and theoretical evidence of Professor Yarrow with his talk of milk, bundle 37, tab 22, page 194 - pizza, groceries---

THE PRESIDENT: I think we have got that point about the pizza, Mr Thompson.

MR THOMPSON: ---picnic boxes and cool bags. Well, I am sorry, Chairman, but Professor Yarrow---

THE PRESIDENT: What we want is hard argument at this stage, and not flights of oratory.

MR THOMPSON: It is fundamental to this case. We are being told that the delivery in this

case is essentially a straightforward matter. This will not go on for a long time, I can assure you, but I do wish to make the point.

Of course, another important difference is the deliveries of milk and pizza tend to be worth only a few pounds, and are paid for directly by the customer at the time. Deliveries of Cerezyme are worth over #10,000 per delivery and are paid for by the NHS on the basis of secondary documentary evidence, from the service provider. There is an obvious and very serious risk of fraud, or theft in such circumstances.

MR VAUGHAN: I am afraid there are certain limits to oratory.

THE PRESIDENT: Well it is a high value product.

MR THOMPSON: I am not suggesting any employee in Genzyme, I would have thought they would be as concerned as anybody else about the risk.

THE PRESIDENT: Well the argument about security because of the high value product I do not think is one that figures in the decision, does it?

MR VAUGHAN: Except it is one of the objective justifications that we give in these matters.

THE PRESIDENT: Yes, well let Mr Thompson go on.

MR THOMPSON: In all these circumstances NHS buyers and prescribers rightly and properly want to specify and monitor the services they receive carefully, to choose the service provider carefully on the basis of a competitive tender and to control the potentially high costs of this highly specialised and sensitive service. The move to homecare is a recent but important development in NHS care. It has obvious potential benefits to consumers and to overstretched NHS hospitals and surgeries if it can be made to work well. It also has substantial but incidental cost savings arising from the fact that at least for expensive drugs such as Cerezyme the additional costs of homecare services are more than offset by the 17.5 per cent. saving on VAT that results from home supply.

THE PRESIDENT: Sorry, the cost savings are more than offset by the 17.5 per cent. saving on VAT.

MR THOMPSON: The additional cost---

THE PRESIDENT: Where is the evidence on that? I am sorry, I may have misunderstood the point, but the cost savings to the NHS, by having independent homecare suppliers, are more than offset by the ----

MR THOMPSON: It is a point that is made both by Genzyme and accepted in the decision that the costs of homecare services which are, of course, material---

THE PRESIDENT: Oh I see, because they save the VAT?

MR THOMPSON: Yes. As I understand it that is a material consideration which both Genzyme and the Director and the Office accept, it is a significant feature of the service.

THE PRESIDENT: It is, but it is a saving you make either way, isn't it, whoever is the homecare provider, you still make that saving? It doesn't matter whether it is Genzyme Homecare who is doing it, or Healthcare at Home who is doing it, you are still saving 17.5 per cent.?

PROF GRINYER: In a sense it is a move to homecare provision,k rather than hospital?

MR THOMPSON: Indeed.

PROF GRINYER: Just one.

MR THOMPSON: Indeed.

THE PRESIDENT: So what you are saying is one of the reasons why it is a good thing to move to homecare generally is because the VAT is saved.

MR THOMPSON: Indeed, it saves both resources in hospitals and it can have financial benefits to the NHS.

THE PRESIDENT: Yes.

MR THOMPSON: These benefits are jeopardised if NHS suppliers are unable to specify and choose their suppliers or to control the costs of the services they need. That is the problem that has arisen here. Genzyme's bundling and margin squeezing abuses have arrogated the choice of supplier and the specification of the service to the drug company excluding all competition and all consumer choice. This has culminated in the current extraordinary situation where Genzyme is continuing to receive full remuneration from the NHS for a service that is, in fact, in general being provided by somebody else, Healthcare at Home, at its own cost. This commercially perverse situation has arisen because Genzyme's competitors and customers refuse to be driven into accepting this situation by Genzyme, unless this Tribunal grants its endorsement to such conduct.

As the Tribunal noted at the interim relief stage, the reaction of NHS customers to Genzyme's transparent attempt to force them to transfer to Genzyme Homecare in May 2001, for example, bundle 31, tab 1, pages 42 to 56, is eloquent testimony to the fact that end consumers whom Advocate-General Jacobs and Advocate-General Warner have both correctly identified as the primary focus of Article 82 in a passage from Oscar Bronner cited by Mr. Vaughan yesterday - as it is of the Chapter 2 prohibition - consider themselves prejudiced by Genzyme's conduct.

It is not enough for Genzyme to assert that they have nothing to fear. In addition, Mr. Williams' latest statement, revealingly but apparently unwittingly, confirms the benefit to Genzyme, given that the company is receiving no incremental revenue for performing its services, any savings that Genzyme makes by bringing services in-house will fall directly to the bottom line and enhance its profitability (bundle 37, tab 25, page 25, paragraph 25). That by way of general introduction.

Turning to the specific topics, the obligations of the dominant undertaking, the economic significance of the case, refusal to supply exclusivity and vertical integration and the Tom, Dick and Harry point.

First of all, the obligations of a dominant supplier. It is a basic principle of competition law that a dominant supplier bears a special responsibility to safeguard competition. I am sure that is a point that is very familiar to the Tribunal. I have brought the introduction to the Full & Nickpai chapter on abuse of a dominant position, but the point is a familiar one and appears, for example, in the Knapp judgment.

The fact that a dominant supplier is what I might call a benefactor of mankind or someone given a degree of statutory monopoly protection to reflect a particular benefit conferred on society is no defence to an action for downstream market abuse. One finds that in cases such as Volvo v. Veng or, indeed, Tetrapack and there is the familiar distinction between the existence of such a right and its exercise, i.e. extending its legitimate scope by abusive conduct.

It follows from these two elementary points that it is no defence for a dominant supplier to provide evidence of similar conduct on parallel markets unless it can establish that its conduct is truly common commercial practice. Where, as here, an entrenched monopolist excludes downstream competitors and exploits its upstream dominance, the OFT is clearly entitled to act.

The Competition Commission's general powers of investigation are not the appropriate recourse in such a situation. This is an investigation into the market conduct of a single dominant company in a market that forms a discrete part of a wider market sector.

THE PRESIDENT: So we are looking at this case on its own facts basically.

MR. THOMPSON: Yes. It is an entirely appropriate use of the OFT's resources, given the particular facts that have arisen in relation to this individual company.

MR. MATHER: Is it not a general issue, as Mr. Farrell explained, which was being considered by the purchaser of a number of different drugs across the country?

MR. THOMPSON: Yes, it is, but the treatments and the market situations from case to case are, quite plainly, discrete and different and it is entirely appropriate to investigate this particular situation, given the rather unusual facts, in fact, possibly unique facts or virtually unique facts that prevail on this part of the market.

Turning to economic significance, Genzyme here adopts a somewhat inconsistent approach. At some points, it derides the OFT's interest as trivial; at others, it suggests that Genzyme's world will fall apart if Mr. Farrell or Mr. Walsh is permitted a margin from which to find a way to competitive tendering for homecare services; and that is also of intense concern to others.

The OFT's position is that this is indeed an important case in the nature of the

issues that I have already addressed, the nature of the abusive conduct and the implications for other markets. That is not a reason for the OFT not to act, but rather the reverse.

If I can now make some general remarks in relation to refusal to supply exclusive distribution and vertical integration. The OFT's position, which, in my submission, is particularly rigorously argued in this case, is that this is not fundamentally a case about refusal to supply or exclusive distribution; nor is it a case about vertical integration as a form of market abuse; though it is a classic instance of an abuse made possible by vertical integration.

In respect of refusal to supply, I should just add that, contrary to Mr. Vaughan's assertion yesterday that this is a very late introduction, the nature of the OFT's basic concern has been clear at least since the Section 26 notice, which it may be worth just turning up. It is bundle 31, tab 1 ----

THE PRESIDENT: I think you can just give us the reference.

MR. THOMPSON: -- pages 57 to 58. I will read out the relevant part. "The suspected abuse consists of charging a single price for Cerezyme, which includes the provision of ancillary services, thus reserving to itself or an undertaking acting under contract for it the provision of those ancillary services", that is the 11th October 2001.

MR. VAUGHAN: So that we are clear, the point I made was that the margin squeeze was very late.

THE PRESIDENT: I think what is at the back of one's mind to some extent is that the allegation that the abuse consists of charging a single price for Cerezyme seems to contain the suggestion that one ought to charge a separate price for the drug and a separate price for the homecare services and one should make the drug available to third parties at a different price from the price that would be charged for the drug and the homecare services separately, if you see what I mean.

MR. THOMPSON: Yes.

THE PRESIDENT: So, in a sense, within the concept of bundling comes the idea that the product is not being made available on economic terms to somebody else and from there you can say it is a sort of refusal to supply, even though the product is in fact being supplied, if you see what I mean. It is all the same sort of area.

MR. THOMPSON: Indeed.

THE PRESIDENT: Every tying case - it is the other side of the coin, if you see what I mean.

MR. THOMPSON: It might also be said that margin squeezing can always be said to be a form of discrimatory pricing because giving somebody no margin whereas your own person has a margin is a form of price discrimination, but, in my submission, the way that this has been put is the logical and correct one.

If I could just make my point in relation to refusal to supply, even were the

treatment of Healthcare at Home since May 2001 to be treated as a constructive refusal, that is not in itself fatal to market competition. Genzyme is entirely willing, first of all, to provide end users such as Mr. Farrell with Cerezyme at the NHS list price and, secondly, to arrange for homecare services through a third party and/or itself, albeit that since May 2001 it has varied its pricing on that.

What it is not prepared to do is to supply either intermediate buyers such as Healthcare at Home, Clinovia or the other suppliers who were written to in virtually identical terms (bundle 31, tab 1, page 49 and bundle 38, tab 49, pages 736, 740 and 741) or to provide end users such as Mr. Farrell at an unbundled price.

THE PRESIDENT: So it is not to supply at an unbundled price. That is what you have just said. That is a sort of refusal to supply. I think we all know what we are talking about and we should not quibble about the particular wording that is being used, but when Mr. Vaughan submits that this case is essentially a refusal to supply case it could be said that this case has significant elements of refusal to supply, even though it is not a refusal to supply case perhaps in a classic sense; would that be fair?

MR. THOMPSON: It is true that the words "refusal to supply" appear in Telemarketing, which I think is not always regarded as a refusal to supply case, but there are clearly issues of principle which are common to both.

THE PRESIDENT: I do not think it particularly matters which pigeon hole we try to put it in: it is fairly clear what the allegation is.

MR. THOMPSON: If Genzyme supplied intermediate buyers at an unbundled NHS list price, for example, #2.73 being the price that they have charged to hospitals since 1994, then the intermediate buyers could offer their services to end users at a commercially realistic price. Alternatively, if it supplied end users with such a price, then the end users could make their own arrangements for tendering etc. It is not in itself necessary that Cerezyme should be supplied to any particular purchaser: it is merely the fact that whoever does get it should have the margin with which to operate.

Similarly, in respect of exclusivity, even if the exclusivity granted to Healthcare at Home or now sought by Genzyme Homecare aggravates this situation, the underlying impediment to the competitive process is that neither end users nor intermediate purchasers can obtain supplies of Cerezyme at a price that allows them to contract separately for Cerezyme or for homecare services for Cerezyme. It is only because of the bundled price that Genzyme is in a position to contract at all for the supply of homecare services, as it were, on behalf of the NHS and its patients.

If intermediaries or end users could get a drug only price, they would not have to involve Genzyme in the specification or pricing of homecare services, though they might well chose to consult, as Mr. Farrell described, given the close working relationship between Genzyme and the principal UK consultants and pharmacists.

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.

Finally, the position in relation to vertical integration is, of course, clear. Vertical integration is, in itself, entirely compatible with effective competition; indeed, it offers customers an alternative suppliers and is thus in principle pro-competitive.

The difficulty is that where an upstream monopolist with the obvious market power of Genzyme decides to integrate vertically there are a number of risks that can arise. Of these, the present case is perhaps the grosses and most obvious: where an entrenched monopolist uses its market power to drive out all competition, thereby increasing its profitability and further reinforcing its upstream market power.

Finally by way of introduction, the Tom, Dick or Harry point (day 1, page 48, lines 7 to 11). Genzyme asserts that it wishes to protect its customers, revealingly described by Genzyme as "our patients", rather than those of the NHS, from homecare services provided by "any Tom, Dick or Harry". However, there is nothing in the decision to support this entirely unrealistic scenario. The OFT has never required Genzyme to supply all-comers, let alone required the NHS to authorise these ill-defined and incompetent suppliers of homecare services to be reimbursed for supplies of Cerezyme.

It is obvious that even at an unbundled price very few suppliers would wish to buy it as they would not do so unless they were assured of reimbursement, either under the PPA as a registered pharmacist or from a hospital or a PCT. In either case, that would require approval by the NHS. In reality, by both the relevant PCT and the National Referral Centre as the Tribunal has heard this afternoon and this morning from Mr. Farrell.

In any event, were Genzyme to impose selective criteria on homecare service providers and to supply only approved suppliers but at an unbundled price, that would raise entirely different considerations from those considered in the decision. In the event, the primary, if not the sole, criterion for supply seems to be a willingness on the part of the buyer to buy it at the same price as Genzyme charges end users who receive Genzyme homecare services, that is to say, a bundled price.

Those are the points that I wanted to make by way of introduction. I do not know if that is a convenient time to stop.

THE PRESIDENT: I think it probably is a convenient time to stop, yes.

MR. THOMPSON: Can I hand in the note of what I was going to say now? (Document handed)

(The President gave indications as to timing)

MR. THOMPSON: It may be worth looking at the note. First of all, I should give due

credit to
Mr. Turner as the literary consultant to this side, who has already contributed Weichgenstein and now adds Tolstoy to his list of credits. More importantly, the pages 2 to - really the bulk of it sets out quite a large number of factual references which I had anticipated having time to go through, at least the main ones, this afternoon.

It may be that the Tribunal will want to consider whether they think that will be a complete waste of time and that they are sufficiently familiar with the documents that they do not wish me to do that, which will obviously save quite a lot of time.

THE PRESIDENT: I would have thought that if you are able to tell us why you rely on these particular documents or what conclusion you are inviting us to draw form them, I would not have thought you needed particularly to take us through them document by document. Most of them we are roughly familiar with if not familiar with in detail.

MR. THOMPSON: Indeed, and there are one or two points which are spelt out slightly more fully. I should perhaps point out that Mrs. Pope, the expert on this case, has pointed out the very obvious typo in that in proposition 1 I have put "prescribing pharmacists" but it should be "dispensing pharmacists" where it appears further down.

I do have one or two points by way of submission and it may be we will consider over the weekend whether I should make those points fairly briefly and then let
Mr. Turner deal with the questions of abuse and then I come back on the question of the Tribunal's questions and the direction at the end.

(Discussion as to timing)

THE PRESIDENT: We for our part have certainly been considering, in any event, the possibility of some sweep-up hearing of some kind. There is quite a large number of issues and lines of thought now floating around that may need to be brought together before we finally give judgment. Let us say we will not sit beyond Monday in any event and we will either take your reply in writing with references and so forth or we will fix another, later date.

MR. VAUGHAN: There will be more than just in writing. There will be a bit of colour, I suspect.

THE PRESIDENT: Thank you very much. I look forward to that.

MR. VAUGHAN: It will be basically in writing.

MR. THOMPSON: I think there is a slight concern on this side that we might suffer a submission squeeze, given that the original oral submissions delivered yesterday essentially consisted of nothing more than headings and if Mr. Vaughan is going to tell us what his case is in writing at 4 o'clock on Monday, then I would respectfully ----

THE PRESIDENT: I do not think we are going to get the writing on Monday, are we?

MR. VAUGHAN: I think you will, yes. That is our intention.

THE PRESIDENT: Mr. Thompson is extremely sensitive to concerns that people have not had a chance to deal with things and if at the stage of the reply there are still new things that have cropped up or things that you feel you want to come back to us on, you will have to indicate and we will be sympathetic.

(Adjourned to the following Monday at 10.30 a.m.)