IN THE COMPETITION APPEAL TRIBUNAL

Case No. 1016/1/1/03

New Court,
Chair Street,
London WC2A.2JT

6th October, 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 appeared for the respondent.

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PROCEEDINGS
DAY FOUR

THE PRESIDENT: Good morning everyone. Yes, Mr Vaughan?

MR VAUGHAN: Good morning, gentlemen. As we intimated in writing we do not object to the supplemental submissions in reply, and we will deal with them today.

THE PRESIDENT: Yes, thank you.

MR VAUGHAN: Basically what we have done and, Sir, you have, is a long reply skeleton, some nearly 50 pages. It is long so we can be short - or shorter - today.

THE PRESIDENT: Thank you very much.

MR VAUGHAN: What we will do, so as you can see, as it were, the outline, is in paragraph 8. The first point is that homecare is a matter for Department of Health and NHS policy, not for competition law.

Then if that is wrong we then deal with the other matters, because if we are right on that then one does not have to go any further. If one has to go further then we deal with the various points we set out below in that paragraph, namely, an investigation, the List Price, downstream market definition, alleged abuses, alleged effects, objective justification and relief. We do not deal with matters which have really played no part in these oral hearings, such as orphan drugs and upstream market. The OFT have not advanced any argument in oral hearing on those.

Paragraph 7 - we do not deal with the question of penalty because even counsel for the OFT conceded it is a "novel case", and we give the reference. We make the point that the Department of Health have never objected to what we are doing, and NSCAG never has done. Indeed, the first reaction of the OFT was to try and force us back into the exclusive distribution agreement which, in fact, would have run to the date of the decision, which is March, I think, of last year.

At the beginning we complained yet again about the tone of the way in which the OFT are presenting this case. We set out at paragraphs 1, 2, and 3 - I do not ask you to read it now - some of the things we point out, that Genzyme is not a wicked ogre rampaging around the World. Genzyme is a thoughtful, careful company which engages in thoughtful conduct in these matters. It does not do things off the cuff, it took advice in these sorts of matters.

The reason we make this point is that at the beginning of the submissions, which were obviously designed to be the keynote for the submissions made by the OFT, they include this rather objectionable quotation from Tolstoy:

> "*I sit on a man's back, choking him, and making him carry me, and yet assure myself and others that I am very sorry for him and wish to ease his lot by all possible means - except by getting off his back.*"

Whether that is a reference to the Tsar, or something, I just do not know. We object violently to that. We think it is thoroughly offensive, would never have been said orally by counsel, and should not be put in any part of the OFT's case. It is a very offensive

remark and deeply resented by us. In a way it mirrors the whole way in which the OFT have approached this case, which we think is far from the objective way in which they should have done it.

Sir, if I can take the first issue, which is on page 4, namely it is a matter for Department of Health policy and not competition law.

We set out that essentially that neither the Department of Health nor the NHS has worked out a policy to deal with these things. There are lots of different views, a lot of different ways in which the matter can be approached. Is it to be approached globally with regard to all homecare treatments? Is it to be dealt with specifically in relation to Gaucher, and each of the other diseases, which might be relevant - haemophilia and that sort of thing.

Nobody has sat down to work out the right way to do it as a matter of policy. So it is impossible, in our submission, to say we are doing it in the wrong way according to Competition law until that has been worked out.

Of course, one must not forget (paragraph 10) now we have devolution it is not just a matter for London deciding these things. In Scotland it is the Scottish Executive, in Wales it is the Welsh Assembly and so on. So the Department of Health does not speak with one voice now it has to speak together with other voices which need to be taken into consideration in these matters.

Paragraph 11 - we say basically that the Department of Health has been kept informed throughout the whole time of what we were doing. A long time before the OFT came on the scene we were telling the Department of Health and NSCAG what we were doing, what we were intending to do, and nobody took any objection.

Paragraph 12 - the reason we say that it is a matter for health policy is because a good test is what would a direction be if it were a breach of competition law? Essentially we say that the two original ones contained in the Decision have now basically been abandoned and now at 13th hour the OFT have produced yet another possibility. We say the original ones were unworkable, and this one is unworkable, and we will develop the arguments about that. It is strange, in fact, it took them until after they finished their reply to alight on this new possible direction, and they did not deal with it in their submissions, and there was no real debate with them, on what they would say this one would be because of that.

Secondly, the policy, as I have already said, has not been worked out. The EL(95)5 clearly was a policy decision, dividing up the contracted and the prescribed services, which the OFT had never heard about, although we told them about it frequently, and they thought it was a dead letter at the time of the interim measures. Clearly that, as it were, was the first element of the policy developing in this matter. So you could not prescribe treatment for certain diseases under the prescription. It had to

be done under special, contracted arrangements. That was the first and only bit of policy that has ever come forward on this whole matter.

As we will develop, the Department is moving towards a policy. Mr Farrell told you that there were various papers, there were various meetings as to how they should proceed in this matter.

The third point is that the direction they are now proposing goes totally against the general policy of the United Kingdom Government, that is the benign policy towards pharmaceutical companies, that is to say that they can fix their own prices and that is the price under the National Health Service, subject only to the PPRS and obviously to effects of other people coming into the market and competing for the particular product. There is no point in having a price which is way out of line with competition and other competing products in that way.

So nobody has had a problem and, indeed, nobody has a problem with the price that we charge under the PPRS system. There has never been an argument that the price is excessive at all. We have never had to meet that case, and we still do not meet that case, and it is still not suggested. Obviously it is a very expensive product but that is not the question in these matters.

Paragraph 13 - we set out what they now say it should be. But that leaves a lot of questions outstanding, even if it were an appropriate direction to make.

"*Where Genzyme offers to supply Cerezyme to the NHS or to third party providers, for use by the NHS* ..."

THE PRESIDENT: Yes, we have read it.

MR VAUGHAN: "*...in conjunction with the supply of Homecare Services to patients, Genzyme must, where requested, make the drug available...*"

Well, on "available", it asks to whom? And at what point is it to be made available? It cannot be to the NHS, because the NHS is to the hospitals, first of all, they get a concessionary price; and secondly, this case is about pricing to the NHS as the OFT have accepted. At what point has it got to be at the factory gate, or the real community pharmacy or where at that time?

Then it goes on:

"*...at a price set at a sufficiently low level..."*

well that obviously begs an awful lot of questions -

"*...that would enable a reasonably efficient provider...*"

again, a lot of questions there -

"*..to make a reasonable on the supply of Homecare Services..*"

and obviously, what is "Homecare Services" is a highly contentious point anyhow. It is defined in the direction but we do not accept that at all. It assumes that you accept that definition of Homecare Services. So all those sort of points are still wholly unmet as

regard to direction, and we come on later to compare this with what, in fact, was said in the direction in *Napp* which was obviously a perfectly workable and enforceable direction. We come on later to make the point that a direction has to be sufficiently clear that the High Court can take action if there is a failure to comply and it does not take a great imagination to see that the High Court could not possibly enforce that. It has to have the same specificity as a mandatory injunction, and this certainly does not.

Paragraph 15 - they do not even begin to think of the problems that would arise. Who is to make those assessments? Is it the OFT? Is it you? - it cannot be the High Court - and on what criteria? What is the reasonableness? Who is the person who has to be looked at as the hypothetical, reasonable, supplier in that? What is to be included? Delivery or nursing and all those sorts of points. It is completely different now to what it was at the time of the interim relief that was granted at the time.

THE PRESIDENT: Why is it completely different now?

MR VAUGHAN: Because you have to make a finding on the facts, rather than make holding the ring, and we have no complaints about the holding of the ring exercise, but now there has to be a definitive position which is binding on everyone.

What evidence is there to be in this assessment, because certainly we have virtually no evidence, except for the evidence of Professor Yarrow in that respect, and of Mr Williams. Nobody has settled down, least of all the OFT, to look at what is the level, the price level, the efficient provider, the reasonable profit, nobody has ever thought about that. Who would be involved in those procedures? Healthcare at Home is by no means the only provider at this time. Healthcare at home we have very little evidence at all as to what its current position is. In fact, we have no evidence as to current position, and we make the point that their accounts still have not been produced, even though they are late for this year. There are other producers, there is Fresenius, there is Caremark still, and there are others in the ring, and all those have to be equated to see what they are. We know, for example, that Healthcare at Home have a minimum number of hours - the hours are confidential I think - as being the basis upon which they charge, but it is more than the average time that is taken. That cannot be the basis of a reasonable assumption to take.

Paragraph 16 - they seem to envisage a new, "across the board" pricing thesis which would take into account all the things they assume are included in homecare, that is, dispensing, delivery, nursing and so on, of Cerezyme only. That creates enormous problems as to how to work out what is the across the board solution in that.

Paragraph 17 - it has no mechanism for determining the separate costs of nursing and delivery, but we all know now that I think only a quarter of the people who get delivery, leaving out the hospitals, get treatment from an independent provider. A lot of people get nursing treatment from the National Health. At home a lot of people

get treatment from the National Health from hospitals in that situation. So somehow one has to arrive at some figure which takes into account those differences and takes out those other services.

We have no evidence about the actual costs or profit expectations of this industry. At the Healthcare at Home interim measures' stage, the Healthcare at Home said that without this they would go out of business. So it would suggest that all their other services are run either at a very low profit margin, or a nil profit margin. So one has to look at what are the differences? Should they be done on different profit expectations or what? Basically it has to be something like a civil trial as between us and Healthcare at Home, with all the other people intervening and a great deal of other evidence in order to decide that from other producers.

Paragraph 18 - this does not take into account where the nursing is to take place, or the delivery is to take place. It seems to assume that they will always be bundled, that is the delivery and the nursing will be bundled. Indeed,if the price paid by people such as Healthcare at Home was a lower price, it seems to assume that the NHS would still then accept that as being the Drug Tariff price at £2.975, and there would be no claw back in that situation. That is far from clear given that the NHS price is designed on the basis that there should be no profit on the price for the product. We do not know what the position would be and indeed, nor do the OFT, and indeed, nor do you.

Paragraph 19 - it is clear that the cost of delivery by itself is obviously less than the cost of delivery and supplying nurses. So it is almost impossible to give a direction which would be applicable to all providers. There may be some providers who just do delivery. Homecare might decide to do delivery only, for example, and leave nursing to the National Health, where that was appropriate, or to some other person who was prepared to do nursing only.

We go on to say that basically a single discount across the board would create greater anomalies, create too high prices for some and too low for others.

Paragraph 20 - obviously delivery costs vary as to where you are going to deliver the product, and from where the delivery starts. Obviously in London there will be more people requiring this service, or would tend to be more, and therefore the costs will be less in London than in other places. The question then is would there be some left outside the whole system, where the costs were just too high, for the service provider to do it, so they would cherry-pick what they wanted to do.

Paragraph 21 - Nursing is very much an individual matter depending upon the needs of the individual patient. Some patients require longer visits than others, some need regular visits, while some merely need some "respite visits" they tend to be known as. The dosage changes between the different types of patient, depending upon the

weight and the age of the person involved.

So if you took an average discount that would not take **that** into account, so if you had more children, or more adults, or more heavy ones, or more light ones, the reimbursement, if it were done on a percentage of the price, would differ.

Paragraph 23 - really they have taken none of these factors into account in advancing this new direction which we think is again totally unworkable, and it seems to assume that you can fairly have some generalised system which is far from clear that it would be ever possible to arrive at a fair, generalised fashion.

Paragraph 24 - we say the Competition Act itself does not give them power to make the proposed alternative direction. The scheme of the Act contemplates that a direction will be clear and precise - this is the point I have already made - so the addressee can comply with it, it is like a mandatory injunction, and I have made that point already.

Then we contrast the position with the *Napp* direction which was clear and precise and everyone knew what they had to do in order to comply with it.

Paragraph 26 - The point Professor Yarrow makes, and we make too, was that the OFT repeatedly said throughout the whole procedure that they were not wanting to make this sort of direction. [para. 330 of the Decision] You have only the power to make the directions they could have done, and once they have said they are not going to make it, and therefore no argument has been addressed in the administrative stage to that, in our submission you could not make that direction at all and, anyhow, there is not the ammunition to make that direction or any equivalent direction in this case.

We make the point that this would be a moving target, it has always been a moving target, but the last target to be shown to us in snap shooting, as it were, was introduced last Thursday, late in the evening, after they had closed their case. But we contend we have shot that one down too.

We have explained why that direction would be unworkable and I am not going to go back to that. In our submission, it would also be particularly unfair because we alone of all producers would be forced into selling our product to users at a price that was not the NHS price. Nobody else would be forced to do that nobody in the LSD market and nobody at all otherwise. As we know there have been a large number of companies doing exactly the same thing. We come on to that complaint at a later stage. [para. 2.40 Fresenius Companies]

Paragraph 29 - there is no evidence that a requirement to supply at an ex-manufacturer price is workable. There was a lot of debate with Mr Farrell, a certain amount of debate, about the system that he favoured, but that was only for the drug and the delivery, it did not include the nursing at all, because the nursing he said was not really required in that situation.

It is also very unclear what would happen when Mr Farrell's preferred option, that is all of it being done by District Nurses, or Community Nurses I expect they are now called, doing most of the work. If you had **this** system, this would very much discourage, in fact prevent that happening, if people were going to be subsidised for doing that sort of work.

Paragraph 30 - there has been no consideration at all of the terms of supply in that situation. One saw from our exclusive distribution agreement that included quite a number of specific covenants by the distributor, Healthcare at Home, on regulatory compliance, adverse event recall, warranties, liabilities. That is something of great significance to us, and what is going to happen to those sort of obligations in some future where everyone can take this product if they wanted.

The analogy was made by Mr Thompson with the distribution of shoes, where he said that well, with the distribution of shoes you would well understand why you needed an exclusive distributor, but he couldn't, for the life of him, think why you need an exclusive distributor for something as important as Cerezyme. We have explained that in considerable detail and if he can't see it then I hope that the Tribunal can see the difference between shoes and Cerezyme, there is cold chain distribution which I do not think usually happens in shoes. The products are vastly valuable in that respect.

Paragraph 31 - we deal with the point of the pharmacovigilance importance and develop it. It is a point we have always been making throughout the whole matter, the whole time, you will find it in the Notice of Appeal, paragraph 616D, and we point out the great significance, importance of that. In fact, if we have failed to do that we are liable for criminal prosecution under the UK Regulations if we do not report adverse effects. Indeed, as we made clear, adverse effects are very widely defined. The person who broke their leg while they are under this treatment is an adverse effect, because although it may not be related at all it could be. So you have to report those sort of incidents in that matter. That was one that wasn't reported to us and we were very concerned about that.

Paragraph 34 - nobody has looked at the costs and benefits of this sort of requirement to supply, which they now think might be the way forward in this particular matter. As we have said before the nursing requirements vary, and there is no one size fits all for the patients in this matter. Basically, we go back to the point that in this area this is a matter for the Department of Health, the National Health Service and the various responsible Bodies in Scotland and Wales and Northern Ireland, to decide what is the proper way forward. The transaction costs, or the administrative costs of their preferred system need to be examined. The Department of Health clearly will think about whether EL95 should be extended in any particular way as to what happens in this case. Then no doubt they will take into account what the consequence of that

decision would be on the pricing.

It is by no means clear that their system is cheaper, more efficient, or more cost effective from the system that exists at the moment. Certainly, the Department of Health has not seen fit to intervene in that matter in that way.

Paragraph 38 - we also say there would be some anti-competitive effects of what they are planning to do, which they have not thought about at all. One of the merits of competition is that it is conducive to diversity and experimentation, and at the moment people can take action and decide what they want to do in that particular way - the prescribed and contracted, there are a pros and cons for each one you do. These need to be looked at carefully and not merely decided on the hoof as the OFT seem to have done, having sat down.

The point we make is that all this is particularly important in an emerging market - or a potentially emerging market. If the price is forcibly dropped what effect is that going to have on the TKT and its GCB generic product. Clearly we do not have to read very far, or imagine very far to see that the high price is a factor that is encouraging them to produce their product. If the price drops what are they going to do? Whereas we were going to have competition in 2006 from their product coming on the trials at the beginning of next year, then what will happen to them, nobody knows about that. What is going to happen about their existing system of distribution and their future system of distribution, because at the moment they compete extremely effectively in Fabry and with the existing system which is decried now of having distributors, and whether they are exclusive, or sole, we know not. But it is pretty strange, and we dealt with this in our oral submission, that after years of us saying they were exclusive, and TKT not disputing that, for the very first time during the course of this hearing Dr Jones has said they are not exclusive. They may or may not be exclusive, but certainly they are the only one who is doing it as far as we know, and as far as it seems Mr Farrell knows.

So all there are all these other factors that have to be looked at and taken into account, and leaping in on the hoof, as I said, is not the way to deal with these particular sort of matters - these are policy matters for them.

The OFT suggests in their supplementary submissions that the tenders may not be subject to the full tendering requirements under the EU public law. Once again, we say the OFT has failed to investigate the legal position properly and its suggestion is wrong, and we set out why in fact Mr Farrell was right when he said it needed to be dealt with under the EU procedures, and we explain why that is and refer you to a case, *Felix Swoboda* [2002] ECR 1-10567, 53, in the European court on that matter.

THE PRESIDENT: Do you know off hand - we can no doubt check it - at what turnover level the EC's Rules kick in? There is presumably some threshold?

MR VAUGHAN: 250,000 Euros, I think it is that. So we would be way above that in the ordinary way. Mr Farrell certainly did not suggest that it did not apply to a fairly limited number, his haemophilia contract - I do not know what the value of the contract was in that respect.

We make the point, as it were, Professor Yarrow mentioned the "Options for the Future Supply and Reimbursement of Generic Medicines, and then published a further consultation document at the beginning of last month which is on the Department of Health's website in which it rejected "central purchasing through tendering" which had been thought of as a possibility, and they expressed the reasons why that is not appropriate. It is not easy or straight forward to develop a system, or obviously right to develop a system such as the OFT suggests which, if right for us, presumably would be right for a certain number of other people in this field, who are providing nursing care together with the product.

MR MATHER: Are you saying that the Department's latest thinking is at odds with Mr Farrell's thinking, as they express it?

MR VAUGHAN: Well, it is not directly at odds, but it does not like the idea of central purchasing for one particular drug, and Mr Farrell is moving towards the idea, which he does not do at the moment, of central purchasing for these sort of things - whether it is central by one Body or central by regions in that particular way.

We will come on to it, but the clear evidence is that Mr Farrell's views are not necessarily shared by everyone in his world, and they are continuing to discuss this question and how to move forward, even amongst the London based hospitals, let alone the United Kingdom based hospitals.

Paragraph 42 - We go on to deal with imposed unbundling via differential price would, in effect, eliminate one form of supply arrangement that has evolved in the market over time in response to the needs of patients, that is, as it were, us providing the service and competing in that way. Obviously we would have to be able to compete, if it was on a named product, with them and everyone else in this respect.

THE PRESIDENT: I think that the proposal is that basically there should be a choice. They can either sell at the list price to those that wish to buy at the list price and save the transaction costs, etc., or make available to either yourselves or to third parties some price that is a bit less than the list price to enable other people to supply services only. That is the concern.

MR VAUGHAN: Yes, but then of course, what is that price---

THE PRESIDENT: Yes, well that might be a matter of considerable debate. It might be possible to arrive at some solution to that eventually.

MR VAUGHAN: Unlike at interim measures, where one takes a view to hold the ring----

THE PRESIDENT: One would have thought provisionally it has to be a properly defined

price and it has to be fully argued and it has to be justified and backed up and all the rest of it.

MR VAUGHAN: Absolutely, yes. Our basic case is that there is no evidence, and certainly no OFT evidence, to provide anything like that in that way. That would be a different case which we would be having to meet to the one we have been fighting over for the last two or so years.

Paragraph 43 - the OFT make the point that their submissions on the legal powers are uncontroverted but, in fact, it is exactly the opposite. It is our response to them which remains uncontroverted. Quite clearly, Department of Health have either statutory powers, other legal powers, powers under the PPRS as Mr Brownlee accepted, or powers to adapt the EL(95) in order to deal with these particular matters.

THE PRESIDENT: Do those statutory powers apply also as far as Scotland, Wales, and Northern Ireland are concerned?

MR VAUGHAN: I suspect they do. I suspect you will have to go to the Devolution Acts in order to see that.

THE PRESIDENT: There is a limit to the degree ----

MR VAUGHAN: I know the Welsh one quite well, but not all the schedules, I must admit. But one assumes that they got it right in the Devolution Acts. Even if they are not now, they certainly would be made right.

THE PRESIDENT: Anyway, you say there are back up powers---

MR VAUGHAN: There are back up powers.

THE PRESIDENT: ----to deal with all this if necessary.

MR VAUGHAN: The suggestion that the EL(95)5 was only designed for GPs we have made clear in our submissions on that that is just not right, and yet they still maintained that position in their oral submissions today.

Paragraph 44 - A Direction requiring a discount cannot be supported by the reasoning of the Decision. A Direction would do no more than simply require unbundling, since it would fix the level of prices as well as establish differential prices. It would only be justified if we concluded the current price was excessive when viewed simply as a charge for the delivered drug. There is no evidence to support that. The OFT appear to consider that if their NHS price were lower the remedy would be a separate and positive charge for additional services. This makes clear the dependence of these sorts of directions on an assessment of the level of price for the delivered drug. Basically, one has to look at what is the unbundled price for the delivered drug because everyone accepts now that the price is appropriately a delivered price. So one has to work out what would be the appropriate price for that in order to strip out the nursing element of that - the fact that some people might want to deliver, some might want to nurse, still requires one to go back to look at these fundamental matters. Nothing about

that was what we had to meet.

Paragraph 46 - and I am not going to go through it in detail - we ask a large number of questions which one would have to answer clearly in order to be able to provide an answer to what the alternative price should be, or what the discount or the reduction should be. I am not going to go through these sort of matters, but it is clear that there is a lot of factors which need to be considered before one could leap in, as the OFT have done, in order to provide this alternative pricing basis.

Paragraph 47 - we say that they have not considered any of those issues. It has just asserted that Mr Farrell and two clinicians want more choice. But as Professor Yarrow observed "More choice is generally preferable if it comes at no cost, but to put much weight on that statement is to omit the economics from the economic analysis". That is what the OFT have done, and Professor Yarrow has introduced the economic analysis, and nobody has suggested he is wrong on that, except for the "pizza" smear, which I will come on to later on, which is a little unfair on Professor Yarrow's careful report.

Paragraph 48 - it raises the question about having these alternative prices as to how that can be reconciled with the ability to set your own list price. If you can set your own list price then that, in our submission, is a question - and quite an important question - that has to be retained and the element is the price is determinative subject only to the PPRS system.

THE PRESIDENT: I think, Mr Vaughan, we are under the impression - please correct us if we are wrong - that the normal, or at least a very common situation, in the NHS is that the manufacturer sets the list price, which is the price at which the pharmacist is reimbursed.

MR VAUGHAN: Yes.

THE PRESIDENT: But the price at which the manufacturer actually sells to an intermediary is discounted off that list price?

MR VAUGHAN: Yes, to cover delivery.

THE PRESIDENT: To cover delivery and so forth and so on. This case seems to be a bit unusual---

MR VAUGHAN: Yes.

THE PRESIDENT: ---in that there is no intermediate discounted arrangement.

MR VAUGHAN: Yes.

THE PRESIDENT: That, I think, is where the whole argument centres. At the moment you are saying well it is really too difficult and too costly, not sufficient reason to do it.

MR VAUGHAN: Yes.

THE PRESIDENT: The OFT is saying "Well, if you don't do it, that is an anti-competitive effect according to them, and we should make an effort to do it, and you should do it",

and that is probably where the debate really centres.

MR VAUGHAN: In one way it is. I do not want to accept it is the only basis, but I can see it is one basis. Also, the other basis is the point Professor Yarrow pointed out, that a lot of the difficulties arise because of the pharmacist being in-house in this case, or virtually in- house.

THE PRESIDENT: That complicates or on one view slightly confuses the analysis.

MR VAUGHAN: Yes, so that they are getting, as it were, the NHS price at the factory gate almost, as opposed to further downstream.

Also, of course, one has the zero discount prices, and that seems to be where there may or may not be a discount given in those cases, but there are certainly some drugs for which no discount is given at all to the pharmacist and presumably that is where the delivery takes place by the producer himself. I think Mr Brownlee accepted, or Mr Farrell, they tended to be things like whole chain deliveries were required in that case.

THE PRESIDENT: I think we are a bit short of information on exactly how it works.

MR VAUGHAN: Yes, but Mr Morland's latest witness statement said that and I think that was the last word - whether it is the right word, although we have tried to make sure it is the right word---

THE PRESIDENT: Yes.

MR VAUGHAN: --- on that particular point.

THE PRESIDENT: Yes. Incidentally, if I just say "yes", it just means we are thinking and trying to follow what you have said rather than agreeing with you!

MR VAUGHAN: Well there are three of you anyhow! I think I will have to get three "yes-es" to be sure that is right. I entirely accept that "yes" means "Let's get on to the next point", which is not unknown in forensic fields.

Paragraph 49 - we make the point "What is the Government policy". Mr Brownlee really set out what it is, about the importance to the economy of having---

THE PRESIDENT: The voluntary policy.

MR VAUGHAN: ---what I call the "benign" policy to pharmaceutical companies. Indeed, it was the benign attitude which brought a massive investment by us in something completely different, in Renagel in Haverhill, and it is a successful policy and has brought the pharmaceutical industry into the United Kingdom in a way that does not necessarily apply throughout the Community in that way.

Then we go on to say that Mr Farrell obviously has his own preferences for what he wants. Again, we say his views are not Government policy and are not necessarily the right policies, or the policies that will be adapted, and we develop that point.

Paragraph 53 - he accepted that it was a matter for the Department of Health

and the NHS to deal with this particular sort of problem. A lot of people are receiving their nursing at home through the NHS, which he regards as the preferred option, and that is an important fact for him it was the preferred option but for others it may not be, because the distant community nurses may be an expensive way of doing it, if one had to cost out the cost of district nurses or community nurses. It may or may not be a good thing to do in that case, but it is just yet another uncertainty.

Paragraph 54 - The Department of Health issued a Discussion Paper at the beginning of last month (available on the Department of Health's website) on the 1999 PPRS and Mr Brownlee said they are just about to start renegotiations on the PPRS with the industry, and this may be a factor which may be taken into account in the course of negotiations. So this is another factor which is, as it were, within the policy area, whether the Government will try and force through some changes in this respect or not. It depends whether it is benign policy or not, in its respect.

MR MATHER: Mr Vaughan, I read that consultation paper with some interest. It concerns generic drugs.

MR VAUGHAN: Yes.

MR MATHER: Are you saying that the issues we are looking at now could be brought into that discussion in some way?

MR VAUGHAN: This is not generics. The original one was generics. This new one is not, I think. The Professor Yarrow one was generics, as you quite correctly say. This development is wider, and this is the new PPRS system.

MR MATHER: I see, thank you for that.

MR VAUGHAN: But you are certainly right. But equally, if they are thinking that for generics, well there may be a read over, there may not be a read over, but it is just an element of uncertainty.

MR THOMPSON: I do not want to interrupt Mr Vaughan, but---

THE PRESIDENT: You are going to anyway, Mr Thompson. [Laughter]

MR THOMPSON: I do not want to do it regularly, I am not going to do it regularly, but I am sure he is well aware that this is supposed to be a reply submission, and this appears to be a completely new point.

THE PRESIDENT: Well we all know that the present PPRS expires in 2004, that is in the record.

MR THOMPSON: I am not going to bob up and down all the time, but I am sure the Tribunal has it well in mind.

MR VAUGHAN: Mr Brownlee referred to this and we know about it from that. In a way this really makes my point for me, this is an evolving situation where things are evolving the whole time, and somehow we are having to put ourselves artificially back into the date of the Rule 14 Notice to see where it is. But in a matter of reality and the

new directions which are being sought, have to be as of now, and to work for a reasonable time for the future. There is no point in making one that is only going to apply until 2004 in that situation. So that basically is our first point. I have missed out page 18, I am sorry.

THE PRESIDENT: Yes, we had glanced at it.

MR VAUGHAN: Yes, you will not be surprised to find *Bronner* coming back in again at that stage, and Mr Advocate General Jacobs saying that getting involved in the regulatory field is really anti-competitive in its own way, but obviously you will read the whole of the submissions.

In point C we complain yet again about the conduct of the investigation and of this appeal. But it becomes important now, in the light of the new direction, that is being sought.

Our case was then and remains that if this is a competition case they have failed to carry out any detailed investigation of what they should have been doing. It is not as though we did not tell them, because our response to the Rule 14 Notice, our response to the interim measures, our evidence we adduced in the oral hearing is full of these particular matters.

On objective justification they have not really considered at all our case on objective justification. Indeed all they do is to say it is for us to prove, and not for them. If it were right, which we say it is not, we have abundantly proved these matters and there is no evidence at all to suggest that our view is not right. We ask you to accept Laddie J's interpretation of the Decisions of the European Court in that respect and we develop that in our skeletons and in our Notice of Appeal - I am not going to go into that.

Paragraph 59 - the OFT's investigations concentrate almost entirely on Professor Cox and Dr Mehta. They said they were speaking for the NHS, and repeatedly they equate Professor Cox and Dr Mehta as being the "NHS" (in quotes), but that is not right, they are just two very distinguished consultants in this particular field.

THE PRESIDENT: I am sorry to interrupt you. It is a bit difficult in a case like this to identify who exactly is the NHS.

MR VAUGHAN: Absolutely.

THE PRESIDENT: The NHS seems to be a multi-headed Body.

MR VAUGHAN: Absolutely, yes.

THE PRESIDENT: In relation to which this kind of issue does not seem to slot in anywhere obvious.

MR VAUGHAN: Except there is the MPI and the NSCAG, and those sort of bodies. There is the PPRSs, which can deal with it, and those were the bodies which were the

potential bodies to look at these things, and they did look at these things.

Then there is the body, who ever it was, that issued EL(95) in there. I am told that was the NHS Executive which issued that---

THE PRESIDENT: Do we still have the NHS Executive - I am a bit hazy about that?

MR VAUGHAN: Yes.

THE PRESIDENT: We do?

MR VAUGHAN: Yes.

MR MATHER: There is also a body called "The Purchasing Supplies Authority" which made a brief appearance, we don't know much about that?

MR VAUGHAN: Mr Farrell referred to it, I think.

THE PRESIDENT: They figured in *Napp* quite prominently.

MR VAUGHAN: Yes. They do not seem to have played very much part in this---

THE PRESIDENT: No, well everyone seems to think this is the sort of thing the OFT should be looking after.

MR VAUGHAN: Yes, but obviously we differ on that, and you cant abrogate a policy meeting by just allowing ad hoc decisions to be taken in this situation.

But in order to get to the views of clinicians, they do not fairly represent what the views of clinicians now, what they seem to do in the decision is that if they do not like them they either forget about them, or misquote them, or quote bits out of context, and we have dealt with that substantially in our Notice of Appeal, paragraphs 551 to 562 and I am not going to go through that.

Paragraph 61 - we looked at Dr Waldek's evidence, and one could see from that, first of all, that Dr Waldek was somebody of great experience, not only medically but also administratively in his own hospital, and he gave a clear preference for specialist homecare as opposed to generalist homecare, for example, and Mr Farrell would prefer generalist homecare. I am not quite sure where Professor Cox comes down on that, but it just shows that the position is by no means all one-sided, as it were, on any of these things.

Indeed, in order to establish an abuse, my friend has effectively to show that we were acting, flagrantly, deliberately and intentionally contrary to the Competition Act, and he has to prove it to the high standard that he has to prove - well, it may not be quite right to say that he has to prove that matter, but he has to prove it to a very high standard. If there are very respected clinicians and administrators saying something different it would be virtually impossible ever to establish the OFT's case on that. What they do is they blinker them and distort their views throughout their decision. We quote again the Notice of Appeal 282-284, 552-561.

They justify taking only two views by saying that Professor Cox and Dr Mehta treat adult patients. But that, with great respect, is a difference but is not a justifiable

difference in any way, and it is not by counting heads that one goes to that situation. Others treat more children, and children are just as important as adults in this respect. But nobody has looked at this question in this way.

We then go on to say Healthcare at Home is not restricted to Gaucher or to Fabry. It is a wide matter. But they do not look at the wide matter. They adopt what Professor Yarrow referred to "zero one fallacy", that is having defined what they think is the market and then stopped there, and do not look outside at all at anything else that might be relevant. That, in our submission, is a wholly inappropriate way of going about this matter.

Paragraphs 66 - 71 we set out all the bits about the Department of Health's awareness of all these things. Paragraph 67 - the PPRS knew about this in 1999/2000 correspondence. The Department of Health knew that we were planning to move in-house, and that was before we actually did so and nobody raised any objections. It was said "Oh well, it was only a one hour meeting", therefore it cannot have been a very significant meeting. As Mr Robertson points out the length of the meeting is not indicative of the importance, and he gives an example about a one minute meeting about the Greeks intervention in the Second World War. The question obviously is "Was it an important meeting", and it really was. There was preparatory correspondence before the meeting, there were documents produced for that meeting, there were letters written after the meeting, and we know that they had had quite a lot of dealings with Dr Doyle, who was a previous medical Secretary to NSCAG, about these matters. I think Mr Johnson deals with that. So NSCAG clearly was an important factor in all this.

They then said it is not the relevant body to deal with these matters. Well, first of all, who is the relevant body because everyone thought that NSCAG was. Miss Stallibrass does not suggest who the relevant body was. Clearly, it is a pretty good body to be dealing with these things.

Mr Johnson dealt with this in his written witness statement, and we have dealt with it in our reply in the skeletons. We point out the fact that the other consultants took the view that it was the appropriate body. There was Dr Vellodi's memorandum to Dr Doyle, and the other three Gaucher disease consultants about the replacement for Caremark with Healthcare.

> "*It is our responsibility to ensure that the service provided by Health Care at Home is satisfactory. I also feel that something like this should be built into the patients charter that NSCAG have proposed.....Perhaps these are issues that we could discuss this issue [sic] the next time we meet with NSCAG.*"

So clearly he and all the others thought it was the appropriate body to deal with these things, and nobody objected to that suggestion. But whatever its precise role

it knew very well what was happening and we told them that.

Paragraph 73 - As well as NSCAG there was the MPI Division and, as is pointed out, it was to them that Mr Cox originally wrote his complaint about Genzyme's decision to bring homecare in-house. I think it is worth pointing out that Professor Cox has never had a problem with exclusive distribution in that field. He never had a problem beforehand with us dealing through Healthcare at Home in that way, as far as I am aware.

In the minutes they have disclosed item 7, NSCAG, which refers to the OFT's investigation and noted:

"*[NSCAG's] involvement is relevant on the implications for commissioning: equally, there are important policy issues for the Medicines, Pharmacy and Industry (MPI) Division of the Department of Health. The OFT plan to meet MPI and specialist services.*"

First of all, that accepted that NSCAG was relevant, and secondly, the planned meeting with MPI in fact never took place. They didn't ever have a meeting with MPI, and the only one we know about is the 17th December, 2002 meeting, which was unminuted.

THE PRESIDENT: 17th December, 2002?

MR VAUGHAN: Yes, that was after the oral hearing and before the decision was taken, and it was a meeting which obviously was unminuted, so although we were given some details - we were sent some information after the oral hearing about the Department of Health but not **this** one, because obviously it was unminuted. That was the only meeting, it seems to be that Junior Counsel at the first interim measures hearing said that "At that meeting Mr Brownlee had seen no problem with the solution set out at 2.53 of Fresenius, but that indeed was the wrong question because that was dealing with the difference between contracted and prescribed services.

THE PRESIDENT: Mr Brownlee is in MPI, isn't he?

MR VAUGHAN: He is in MPI, yes.

MR THOMPSON: Just on a point of information, the minutes referred to there, refers to Mr Brownlee as a member of MPI and likewise, Mr Kullman as a member of MPI. That is the minute at page 355.9 referred to there by Mr Vaughan. So I think my understanding is that that was the meeting.

MR VAUGHAN: No, well, we can see this, but there was a meeting on 17th December, and we have seen the minuted meeting, and it did not deal with any of those sort of things. The meeting I am talking about is a year and a half after the first meeting.

THE PRESIDENT: You say there is no meeting?

MR VAUGHAN: We accept there was a meeting but it was unminuted, which we say is surprising, because they minuted much less significant meetings.

THE PRESIDENT: Not until much later. There is no meeting according to you shortly after, or within a reasonable time of 27th June, 2001?

MR VAUGHAN: That is right, yes, because the meeting, in fact, with Mr Brown and Mr Kullman, had taken place beforehand, before that.

THE PRESIDENT: I see.

MR VAUGHAN: So they did not go back again to talk to them.

THE PRESIDENT: Well, we can sort it out.

MR VAUGHAN: They did not go back to talk to them until after the oral hearing in that matter.

Paragraph 78---

THE PRESIDENT: I see, they had met them on 18th June, 2001.

MR VAUGHAN: That is right, yes, and then they had the NSCAG meeting was 27th June, and so there was nothing between that one, as far as we have seen, and the December meeting, 2002.

THE PRESIDENT: Yes, we can sort that out.

MR VAUGHAN: But there was the exchange of emails which we will be coming on to in a moment or two.

THE PRESIDENT: Yes.

MR VAUGHAN: We now turn to the question of the Fresenius companies, as it were in 2.40 of the report. Throughout the whole time, we have been making this point, hopefully, very forcibly about these companies. They were relevant in the interim measures, they were certainly relevant in our response to the Rule 14 notice, and they were relevant in our appeal in that matter. Indeed, they were relevant in our oral submissions.I think I can remember Mr Johnson saying "Well, if they can do it why can't we?" - or words to that effect. We give a lot of references there which I am not going to read out where we have really developed this point throughout this whole thing. It is not a "Johnnie come lately" or anything like that.

We make the point that the OFT accept in paragraph 9.2 of its skeleton that the report was essentially correct. But they explain it by saying "Well, it is not a Monopoly Commission investigation". But that is not the point. The point is it is not either a Competition Act investigation, if you do not look at the relevant things, and merely just to shut your eyes because it is outside is an extraordinary way to conduct an investigation which led to a company being fined nearly £7 million in that way.

They now seek to play down this whole question in supplementary submissions of last Thursday. But, as we say, we have always been making this point against them. They have never disputed these particular matters, particularly as regards Nutricia, the company that took it back in-house, having given it away, and one would have expected, if proper investigation was made, they would have written, either emails

or whatever, they would have served section 26 notices on people, they would have found out what was happening with these particular companies. But one has to proceed on the basis these companies were doing this sort of thing, and were taking it in-house, were providing treatment in the price for the NHS price at the time, and that they were, as it were, prescribed services in that way. We make the point that they should have investigated this whole thing.

Paragraph 79 - We then turn to Genzyme had also explained that Mr Brownlee's evidence is that we interpreted Mr Brownlee's evidence as in fact agreeing with Professor Yarrow, that is to say that the price included delivering drug to the patient's home, and basically thanks to those instructing us pushing this point we have now discovered that is exactly what Mr Brownlee said. His wording of his witness statement was extremely carefully worded. But if one looks back at it one sees it was capable of having the interpretation we said it had.

In fact, one does not have to indulge in that sort of exercise because we know that in fact he does agree with us, and Mr Kullman's email, unconditional email at the beginning, 11th December, totally agreed with us. He then went away and that is why Mr Brownlee became involved, but Mr Kullman, one assumes is equal seniority or very senior in his division.

Mr Brownlee also agreed with us about this matter, and that even from a PPRS point of view is not prepared to say that the delivery would be excluded as being an excessive charge, even if it were a matter for the PPRS in that situation. Basically they tried to defend their non-disclosure of email correspondence, this is paragraph 80.

They continue to say: "...that, in the present case, this non-disclosure cannot materially have prejudiced the fairness of the administration procedure." They are saying "There is no solid basis for an argument that Genzyme's right to a fair trail in these proceedings has been infringed!" But they have because effectively the whole case has changed, because the disclosure of those emails has shown that Mr Brownlee and Professor Yarrow, and Mr Williams, are in total agreement, and Mr Kullman about these matters.

Clearly, if it had not been for that we would have had to cross-examine Mr Brownlee in these matters, but these were disclosed and these showed that, in fact, he did agree with us in that respect. Basically it places the whole case in a completely different light, because the whole question of making the NHS pay, and the NHS price does not include the price of delivery to the patients home is shown to be completely baseless, and an enormous amount of the case, if not all the case, depends upon them proving those particular matters.

Indeed, as the Tribunal pointed out the whole case depended upon the OFT's evaluation that Mr Brownlee's evidence should be preferred to Professor Yarrow and

Mr Williams. But in fact they are all in total agreement as to what the correct position is. There is no question of preferring them. The evidence is really, effectively what we say it is.

No explanation at all has been produced still as to why we did not get these things earlier. They have not suggested that it was an oversight or a slip, or anything like that. It looks now as though it were a deliberate decision, that it was not discloseable and therefore was not to be disclosed.

One does not have to go back through much law, *Soda Ash v ICI* in the Solbay cases are pretty good ammunition to show that a body has to disclose things eve if it is unpalatable to it to do. The suggestion that these have made no difference to the case just beggars belief in our submission, and they have made that statement several times, certainly once in the Treasury Solicitor's letter saying: "We are not going to disclose it because it does not alter the things at all". It alters the case dramatically and if they thought it did not alter the case it shows they did not understand what the case was about, and that probably is part of the explanation. It just shows that it is wrong to leave the prosecuting authority with the task of deciding what is helpful and what is not.

Again, we had all those arguments in *Soda Ash, ICI v Solbay* in the European Court, or the Court of First instance in these matters, which obviously you are familiar with.

Paragraph 83 - We then go on to say that they have sought to shore up their case by producing a vast amount of new evidence in their defence and that, of course, begs the question: "If it had been a competent investigation these should have been produced in the course of the investigation, or at least the effect of them should have been stated at that time but they were not.

We refer you to the whole way in which they have done this is contrary to what Tribunal said in *Napp*, and we give the relevant quotations.

Indeed, it is not as though the Decision was an end of it, the thing still goes on in this matter.

Paragraph 86 - a great deal of reliance was placed for the very first time, not in its defence but during oral submissions, upon the Caremark documents, and a small clutch of documents was given to you. What they didn't explain was in fact those were a very few documents, out of about 100 on the OFT's files, and we include at the annex page 49 onwards a list of the relevant documents which either us or the Gaucher's Association has disclosed under the disclosure provisions. You will see that what they have discussed are letters between 8 and 16, and then 19 and then 24 out of a vast amount of documentation dealing with this particular issue. There is a file available but we suspect you have seen enough of new documents, and I can make the point generally without taking you to these---

THE PRESIDENT: So that is picking - it has been a bit picked out of context?

MR VAUGHAN: It is "picky" in the extreme and it just should not have been done in that sort of way, particularly when there was a new point that had not been developed at all in the defence, and was never really a point in the whole case because Caremark was gone a long time, two or three years before even the interim measures' hearing took place.

But if one looked at the whole file one would see effectively that we were behaving thoroughly responsibly, as no doubt my friend has looked at the whole file, and we have given all the document references that he can look at in the OFT's file - or he may not have been given the full files in this matter, I know not.

Basically there were a lot of complaints by Caremark, and from all sources, and we then had to go back to Caremark, including us - we had a lot of complaints about Caremark. We went back to Caremark to give them an opportunity to improve their situation and they did not. We then had to look around to find an alternative because you could not just abandon Caremark without finding an alternative.

We undertook a considerable search of, I think, five companies to see who the appropriate person was, and eventually Healthcare at Home won through in that matter. Then we had major problems resolving claims brought by Caremark for termination of the agreement which were settled on favourable terms to ourselves - it does not really matter. As one would expect, it was dealt with thoroughly, and just picking out a few choice letters which give a wholly unrepresentative view of these matters seems to us to be not the right way to conduct litigation, particularly when it is a new point at all. Indeed, there is a lot of evidence about Caremark, paragraph 88, and we give references to that during the course of the oral submissions and the response to the Rule 14 Notice.

Paragraph 91 - one of the letters they did refer to (it is in their core bundle) was a letter from Mr van Heek who explained that one of the reasons they had gone to Caremark originally was, if it went to community pharmacies for dispensing, then they charged 10 per cent. on that whole exercise, so effectively the price was being pushed up by the community pharmacies and in going to a distributor in fact ended up with a reduced price than was otherwise available. That was a situation which enabled us to keep our price when we introduced Cerezyme, the new product.

Paragraph 92 - we say the OFT placed great weight on Miss Kelly's fax to Rachel Mackintosh, but again we explained that that really is taken completely out of context and if it is read in context it is a perfectly proper position to adopt.

Basically what the Caremark and HH correspondence shows is that we were really keen to ensure that the patients got the best level of homecare service, that is the driving force for its patients, and indeed we do regard them as our patients. They are a

very limited number of people who are very often in direct correspondence with the company, either here or in Boston about these matters. I have seen letters where the people are saying "Please get on with research into these Pompe, and these other things, because our children are dying", it is heart rending some of it in that respect, and that is one of the reasons driving us forward. Obviously economics is another, but that is a considerable factor in these cases. There are many people where that is the only hope. That is basically the second major point, as it were.

We then go on, and I think I can deal with these much shorter.

The List Price. Effectively, the first point they seemed to make a lot about the price of Ceredase. Ceredase existed between 1991 and 1994 and for that period it was supplied to a small number of patients, on a named patient basis. It then continued from that period on an imported basis under the full marketing authorisation scheme.

Cerezyme, as you will have seen from the witness statements was developed because people were worried about using human based ingredients in the making of Ceredase, and wanted to move to a recombinant version and so we developed that in order to allay that fear in these matters, and that is the basis on which it is still produced.

We received marketing authorisation on 18th November, and the list price was then immediately notified to the PPA which is the appropriate body to be told. We then go through, as it were, what happened to the price in that. At that stage it was £3.09p a unit, and Mr Brownlee accepted it was a new chemical entity and was therefore entitled to have a new price and that was the price at that stage.

That continued to be the price until we entered into the PPRS system, and then there were the negotiations to reduce the price to take into account the 4.5 per cent. reduction that was required.

As we say in paragraph 98, it is quite clear that Professor Yarrow and Mr Brownlee both agree that there was effectively a "horse-trading" negotiation that happened at that stage, it was not a formal decision that was taken by any one in a formal decision sort of way. It was just a solution that had to be reached in a hurry in order to arrive at the position.

Paragraph 99 - The OFT asserted unequivocally in paragraph 93 of the Decision that the NHS List Price:

> "*...is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home*".

Well, we now know that that is wrong, and we know from the position that that is wrong. In paragraph 101 the OFT sheepishly concedes for the first time:

> "*this particular conclusion by the OFT can be criticised as too definitively expressed*."

It was just wrong. It is the whole basis of the Decision that that is so, and repeatedly throughout the decision, the sort of mantra that the NHS price does not include delivery. If it does include delivery that changes a lot in the whole case, and makes the reasons for the decision completely unsupportable. Then we know from those bits fresh in your mind - Mr Kullman, Mr Brownlee, and those sort of points.

Paragraph 108 - Mr Brownlee also accepted that his statement that the PPRS and the NHS list price "are inextricably linked" had to be read in the context of the explanation he gave, that is, that the delivery price could be included in the List Price, and that the PPRS is linked to the extent that it provides cap on profitability for the company and is nothing to do with drug related prices at all in that respect. Obviously it has some effect because he can disallow certain costs in the evaluation of what the profit should be in a particular case, so that if a drug company spends all its money on golf competitions for doctors then that no doubt will be disallowed under his system.

Paragraph 109 - we go on to make the point that they have misrepresented what Mr Brownlee said in the course of his submissions.

Dealing with costs we say they have never sought to look at what the costs are, the distribution of costs in making home deliveries. The only evidence there is at all is effectively Professor Yarrow and Mr Williams in that respect. The snearing remark about "pizzas" and "milk deliveries" we deal with in paragraph 111. Professor Yarrow cannot be rejected on that basis. He is far too distinguished merely to be thrown aside on that cheap point.

In fact, what he was doing was saying that there was nothing particularly special about this delivery. Obviously it had to be accurate and good and sensible, and well organised, but it was not a delivery service that required any vast amount of detailed expertise.

THE PRESIDENT: We have a lot of evidence now, including Mr Morland's latest statement about that.

MR VAUGHAN: Yes indeed, and it all supports Professor Yarrow's views of what it is in that way. It may not be "a pizza" but it is certainly not anything of vast complication requiring particular great skills. Police approvals and things like that everyone accepts are right, and co-delivery needs to be done, and elements of trust have to be there, but that happens in many fields - no doubt probably in my friend's field of shoes as well.

Paragraph 115 - the challenge to Mr Williams' figures. Again we are a little upset about that, he was accused of gross errors in the oral submissions he made. But at the Tribunal's suggestion Mr Williams was here on day 2, and in our submission it is not appropriate to attack somebody for making gross errors if you do not even put the point to him when he is here to be dealt with, and allow him to explain why these things happened, it is just not right, it is not fair play. There is no evidence to support

the gross errors in evaluation.

Paragraph 116 - we deal with the argument based on the Dixon Wilson Report and explaining that it was done on a different basis.

Paragraph 117 - making the NHS pay which is where the second sort of mantra under which the whole thing is supported, and the other sort of leg, as it were, of our argument. The first of their arguments was that delivery is not included; and secondly, it is making the NHS pay.

Again, if one looks at that - even if one assumes that is right - we have attempted to quantify what, in fact, they have to pay extra for the nursing service, and it is a very small amount indeed. There are 42 visits - that is assuming Healthcare at Home do all of them - lasting two hours every other week which works out at just over 2000 nurse hours a year, assuming the nursing costs are £50 an hour which is Professor Yarrow's figure, which is not very different from the figure that you had in the interim measures, that is the sort of level of amount that one is talking about.

There are no alternative costings put forward by anyone in this case, still less the OFT and we would say that is the costing one would have to take in this case. Taking that as a proportion of the total value of the sales is de minimis if anything is.

We point out the fact that we have higher costs than other people do. We have introduced the internet device, which is the ambulatory device which enables people to walk around whilst they are infusing, which is obviously a great boon to some people, and it costs us about £800 a year for each patient, and we bear that cost. As far as we know nobody else does that, providing for their people.

So one has to look very carefully at some of these costs in the system. There is no evidence that the just the NHS cost would be lower if alternative arrangements were adopted. If there is £100,000 in it, as it were, if they had all the patients, then one has to look at what is the cost of the NHS doing that sort of thing, and indeed is it, in fact, going to lead to greater efficiency in the provision of the service, or better quality in the provision of the service? We say there is no evidence about that, but we think that our service is second to none on that way.

We then go to deal with the downstream market, and we then raise the question about what is the market they are talking about. They describe it, in capital letters "HOMECARE SERVICES" and then define it in a way that does not seem to have any reality at all. They see it as including distribution and nursing, being restricted to Cerezyme for Gaucher patients, thereby excluding, as it were, Zavesca, which are provided on an oral basis.

We point out the correct approach to market definition set up by Professor Yarrow. They then seem to accept to some extent that we are right, except what they say that our particular behaviour distorts the market, and creates a wholly new market

in that way. First of all, that is wrong in law, and secondly it is wrong in fact.

It is clear from Mr Farrell, if one took him as an example, he regards all homecare service providers as being capable of providing all treatments. As it were, he is a journalist in that way and not, as it were, a specialist provider which others would be, and clearly prefer to have a specialist provider. Dr Waldek I think was one who supported the specialist provider rather than the generalist. There is no, as it were, one answer to this whole question. We obviously support the specialist provider, and we advance reasons in the objective justification why that is so, but it is something about which other people think differently. So when one is applying the *Aberdeen Journals'* test, namely, "what does the market think?" there is nobody in the market who thinks the same way as the OFT, that everything should be Cerezyme, everything should be bundled together in that particular way because there will inevitably be, if things developed at some future stage, there will be people who are keen to produce the drug and the delivery only, as has been done with haemophilia. There may be some who want to provide just the nursing service because they have particular nurses, such as the NHS does where it can do so. So the idea that you can narrow a market because of somebody's particular conduct, from what it normally would be thought to be, in our submission is without any basis at all, and we have developed that.

Paragraph 127 - the possible temporary foreclosure by taking treatment in-house one just does not know what is going to happen, because we may then decide that we want to push it outside and have an exclusive distributor again as we did in the past if it does not prove to be as successful as we expect.

THE PRESIDENT: Are you saying that this is a temporary arrangement?

MR VAUGHAN: No, but obviously depending on what happens here we may have to think again about what we do, so you will be providing a situation which may not be there at the time. Obviously Genzyme has to look very carefully at what it is doing in these particular elements, but it may decide that it does not want to continue with Homecare in a particular situation. The present intention is that we will continue with it. But of course, things are going to change because in 2006 or thereabouts or even before then, because first of all the GCB is going to come on the market in 2006 if the tests go well - it is going to be subject to trials in 2004 - and so it is going to come on the market. One cannot assume that Zavesca will remain in its present position as really being of rather limited competitive strength - no doubt people will try and improve Zavesca in order to provide real competition. That is one of the attractions of competition law, they have such a big margin to aim for in this way to undercut us. Then, of course, if they undercut us then we would be entitled to react and then the NHS price would then change.

One has the situation then with GCB and TKT using Healthcare at Home as

their distributors, or GCB in the same way - whether exclusive or the only one - as they do in Fabry in that particular situation.

We go on to say that the NHS are not deprived of choice, and they can use and do use their own nurses in something like a quarter of the cases, and Mr Farrell hopes that this will extend as and when the community nursing service can provide this sort of service.

Indeed, the OFT solution would inhibit this, because it would mean that effectively the commercial providers were being subsidised in that way, and the NHS was not in that situation because no allegations are made about the prices we sell to the NHS.

We then go on to deal with the alleged abuses and the expert reports. We come back to the question of refusal to supply and whether in fact it is a refusal to supply case as we have always contended it is. In fact, if you look to see what has happened after the alleged abuse started, Healthcare at Home have rapidly expanded. They now have something like 5000 patients up from 2000 in 2001. it is quite clear that this whole treatment area is an emerging market and we are here talking about 42 maximum who require treatment in this particular area.

We go back to our old friend, *Bronner*, and Advocate General Jacobs, and Laddie J. in that respect, and I am not going to spend time on that, you have the point.

THE PRESIDENT: We have gone round that track, yes.

MR VAUGHAN: A lot of this I think we have probably gone round before, and just I would probably just invite you to read this.

THE PRESIDENT: Yes.

MR VAUGHAN: The point we make is that there are very considerable benefits of doing it either in-house, or in doing it through an exclusive distributor in this case, rather than just having to supply anyone who comes along wanting to buy the product in that sense.

We deal with the history of the early days of Ceredase and the changes to that, and then go on to the change to Healthcare at Home, and the problems we have had with Healthcare at Home - much fewer than with Caremark.

Paragraph 142 - we deal with Fresenius. The OFT's proposal proceeds on the basis that it would be better for patients if each Trust included homecare treatments for Gaucher within individual block contracts, hence its reliance on the hospital in the North of England and its deal with Fresenius. That again is an assumption that that is a better system. It is not a better system, according to Dr Waldek, of block contracts. It does not seem to be much favoured even when dealing with generic producers of centralised matter. There are no block contracts operating in London or anything like that, it is just the Royal Free adopting their own commercial policy as they are entitled

to do.

One needs also to ensure that the patients are receiving the proper treatment in any particular way. We found when Healthcare at Home were our exclusive distributor they were pushing up nursing visits because they got more money for nursing visits, and we changed the system so there was no in-built incentive to that. But it needs careful control and one cannot assume that everything is going right in this respect. Mr Farrell says he monitors the whole thing but of course he has a lot to do and he could not really remember very much about whether they were generalist or specialists or anything like that.

THE PRESIDENT: I think I, at least, have got down to the end of page 41, Mr Vaughan.

MR VAUGHAN: Yes, I have got there too! On alleged effects, to some extent we have covered this before and obviously again it has to be read together with what we have said previously, but they seemed to accept, as we say at 147, that the downstream market is for homecare services generally and that people can provide these services in a general way. We say, apart from that, it is not surprising that they did not deal with this at all in their oral submissions, and certainly not in their supplementary submissions.

We say there is really no substantial foreclosure at all, unless you define this market in this extraordinary way that they have done so. We are talking here about these very limited number of people receiving this sort of treatment, a maximum of 171 receiving deliveries out of some 5000 patients which they say they now have on their website.

They refer to the Royal Berkshire Hospital in their defence, about the concern they have and, in fact, the Royal Berkshire Hospital has ended up receiving homecare for their patients from us and there is no indication that they are unhappy with that, or felt forced into that situation at all.

On the upstream effect, they are saying it stops people coming into the market and seem to be suggesting that originally it stopped innovation. Clearly that has not happened, indeed, we have encouraged innovation simply by being there, and the only one, and one for which because we are not technically an orphan drug, we do not have that monopoly protection which we would have done if we had, in fact, been an orphan drug under the EU legislation.

The fact that there are two for Fabry is coincidence, we both developed our own at the same time, but it is very unlikely that would ever happen again, and certainly in the future whoever gets there first will become a monopoly. So TKT will get Hunter, for example, and we will get Pompe, and I think we are just about to be declared an orphan drug for Pompe. TKT clearly expect to become an orphan drug for Hunter, and express great concern in the last email that they would then be expected, if

the OFT were right, to distribute it to everyone who wanted to have it in that way.

They now seem to suggest a sort of "attachment" point, that people get very "attached" to their nurses, and a sort of "Carry on Nursing" theory about the whole thing. But nobody ever seems to suggest that this is a genuine thing that might happen. Of course, people liked to have treatment from the person they know, but effectively things change, and we know that people moved over from one product to another sort of product in that respect, and some people do not want to move - it is very much a matter for individual choice at the time. But the idea that, in fact, you become so attached to one particular nurse that you will not allow your clinician to change your prescription, even though he thinks it is more suitable is something which nobody, I think, could really believe. There cannot be an attraction, presumably, to the driver who happens to come along in that sense, and if that were so then if a clinician decided to move his patient in Fabry from Fabrozyme to Replagel then it would be impossible to do that. But nobody has raised that question at all.

Basically we say the "attachment" theory, which is the only upstream effect that is now being suggested, is without any foundation at all when properly looked at in the full context of all the evidence available. We say in paragraph 159 if that were right nobody would move to GCB because they would be so attached to the previous drug, and nobody suggests that GCB is not going to come on the market because of the attachment factor to the individual nurse, and obviously the nurse has no role to play in the clinician's decision as to what is the most suitable product. It was intimated that of course doctors now have to take into account the views of patients, but if you are told "This is going to be better for you" very few would say "I don't want to lose my nurse". Indeed, it does not follow that they would lose their nurse at all if that is the situation. Basically we develop that point through to the end of that passage.

Objective justification is a matter of great importance because it helps to answer the question of whether it should be specialist or non-specialist nursing, and this is a thing the OFT did not investigate at all. Throughout our submissions we give lots of references to it, both in the response to the Rule 14, in our evidence to the Rule 14, and in our Notice of Appeal, to rely upon five basic points and those are set out at 616 of our Notice of Appeal. We think in-house provides:

* a higher quality standard, and one that we can control;
* a more cost effective service without having to compromise higher quality standards;
* it removes dependence on third parties. You will remember that was one of the factors which Nutricia put forward to Fresenius.
* ensuring compliance with pharmacovigilance obligations; and
* ensuring a service which will specialise in other LSD treatments, and

obviously there is to some extent a connection with these particular LSD diseases, although they may affect the patients differently.

What they did in answer to that was, as we say, "studiously to ignore" that part of the case. Basically they joined issue on burden of proof, and said it was for us to prove. We do not agree with that, and anyhow that is one of the matters for the Tribunal to decide. But, even if it is a matter for us, all the evidence goes one way. There is nobody who suggests these are not better things to do in any detailed rebuttal of these particular matters, and certainly the Decision does not, in any way, deal with that.

Paragraph 168 - we quote the Decision:

"*There is no need for the Director to address Genzyme's representations in this respect*."

The only thing they have dealt with here is the Caremark point. So as we say in 170, wherever the burden of proof lies, we say first of all we have shown we were objectively justified and, anyhow, if Laddie J. is right - and we say he is - the OFT is not sufficient merely to show that we are wrong, but they would have to show that no reasonable person could hold those views, and they clearly do not come within a mile of that when they do not produce any alternative view, except for every now and again when somebody would like to have a generalised service, and not a specialist service.

The last point deals with relief, which may well mirror the feeling the Tribunal has got at the end of nearly two hours. We deal with the point, could you remit back to the matter? We have already made the point that you cannot and should not, as it were, issue a Direction which, on the facts of this case, because we say the OFT could not, on the evidence, have done anything like that. If they had run a completely different case, and had completely different evidence, then we would be facing a completely different case. But here we are facing the case we fought and the case they presented against us and now, for the very first time, they present on Thursday a new direction in that case.

We say "Could you remit back to the OFT in order to do that?" We say that would be wholly inappropriate in this case after two years of fighting on case A, and when they specifically rejected the idea they were raising case B, then to be pushed back into the OFT's tender arms in order to fight case B right from the beginning again, because effectively one would have to go right back to the very beginning and fight it in the context we say it should be, that is, that the NHS List Price does include delivery and we are not making the NHS pay.

So basically we say that although, obviously, we accept there is a power to remit, that does not mean it is unrestricted. It has to be appropriate to the situation that exists. Obviously it was appropriate in *Argos v Littlewoods*, but not appropriate in this case after this long battle of two, two and a half years almost now, I suspect, fighting

these things and then for them to be given the chance to have a completely new battle.

In our submission the only solution is to annul the Decision in this case, and make the consequential orders on costs, and we will come back to that, and then if the OFT wants to fight again they can but that is up to them and they then have to take into account the fact of whether it is appropriate or reasonable to battle with public law to start again at that stage.

Sir, those are my submissions. We can give you a list of the evidence on zero discount, but you probably know where most of it is. There is some in Mr Williams, some in Mr Morland as to where it is.

Can I quote the list? Mr Brownlee, the reference to him - Day 2, page 7, particularly lines 30 to 35; page 21 particularly line 36 and then over to page 22 line 20. Page 23 lines 28 to 33, and then the other evidence was Mr Derodra dealt with it at 37 CB1/27 pages 282 and that was not challenged. Professor Yarrow 37 CB1/22 page 185. Then Mr Morland, as translucency 38 CB2/38, particularly paragraph 6.36, but also paragraphs 5.19 to 5.13. Then the Drug Tariff itself - there is List A and List B, so 180 in List A, and 70 in List B in the Drug Tariff and pages 10 to 13.

THE PRESIDENT: Thank you.

MR VAUGHAN: Well you had better thank somebody else, I think. Thank you very much.

THE PRESIDENT: Thank you very much indeed.

MR MATHER: Mr Vaughan, at paragraph 26 you address the Tribunal's powers.

MR VAUGHAN: Yes.

MR MATHER: You say that we only have power:

"*...to give such directions ...as the OFT could itself have given*."

MR VAUGHAN: Yes.

MR MATHER: Then you say:

"*It would therefore be outside the Tribunal's powers for the Tribunal to impose a direction which the OFT had denied seeking to impose*."

MR VAUGHAN: Yes.

MR MATHER: Your position therefore is that if the OFT had a power, but had denied seeking to impose it we were not able to exercise that power.

MR VAUGHAN: Yes, because the whole case would have been fought on a different basis.

MR MATHER: I see.

MR VAUGHAN: It is not so much jurisdiction as whether you can, as it were. We entirely accept you have a jurisdiction to take decisions which they could have done, but as a matter of exercising your jurisdiction we say you couldn't and shouldn't, because they have denied it and the whole case has been fought on a different basis.

MR MATHER: Thank you. Thank you for clarifying that.

THE PRESIDENT: Thank you very much indeed. Well, ladies and gentlemen that brings us to the end of this hearing.

Formally speaking, I think there is no need to make any further order about the interim measures direction because that is in force until further order.

MR VAUGHAN: Yes.

THE PRESIDENT: As far as the timing of a Judgment is concerned we shall obviously do our best. It would obviously be desirable to have this Judgment out by Christmas. I do not think we are in a position to guarantee that because the issues have certainly deepened considerably in the course of this hearing, in a useful way I may add, but it gives us quite a job to do now to sort everything out, but we will do our best.

Probably the only other thing we need to say at this stage is that we are very conscious indeed of the lost weekends, the midnight oil, the enormous background and back room effort that has been necessary in a case like this. We are immensely grateful to all concerned for the help that we have had during these hearings, and I would like the principal participants to pass that message particularly back to all those who have been helping in this case, whether they are photocopiers, witnesses or experts, or whatever, because it has been of enormous help to the Tribunal to have such a detailed and comprehensive presentation.

MR VAUGHAN: Thank you very much. I know it will be greatly appreciated by those, most of whom are here - I know who one of them is!

THE PRESIDENT: Yes, well we do very much appreciate it, whether it is junior counsel, leading counsel, or instructing solicitors---

MR VAUGHAN: Yes, it was a major team effort from both sides.

THE PRESIDENT: ---people from the Company, from the Office, the case officers and others, we are conscious of all the effort.

MR THOMPSON: I do not want to end on mundane note after that, but there was one error which emerged during my submissions, that we had handed up the wrong Napier Brown case. I do not know whether it would assist the Tribunal to remedy that by handing up the correct Decision.

THE PRESIDENT: Just hand it across to the Registrar, thank you, Mr Thompson. Very well, thank you all very much indeed.
