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MINUTES OF EVIDENCE

TAKEN BEFORE

Health Committee

Pharmaceutical industry

Thursday 16 December 2004

MS MARGOT JAMES, MR MIKE PALING, DR RICHARD HORTON,

MS JENNYHOPE and MS LOIS ROGERS

Evidence heard in Public Questions 516 - 658

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Oral Evidence

Taken before the Health Committee

on Thursday 16 December 2004

Members present

Mr David Hinchliffe, in the Chair

John Austin

Mrs Patsy Calton

Jim Dowd

Mr Jon Owen Jones

Dr Doug Naysmith

Dr Richard Taylor

Memoranda submitted by Ms Margot James, Paling Walters, Mr Richard Horton

Ms Jenny Hope and Ms Lois Rogers

Examination of Witnesses

Witnesses: **Ms Margot James**, European President, Ogilvy Healthworld, **Mr Mike Paling**, Managing Director, Paling Walters, **Mr Richard Horton**, Editor, the Lancet, **Ms Jenny Hope**, Medical Correspondent, Daily Mail and **Ms Lois Rogers**, Medical Editor, Sunday Times, examined.

Q516 Chairman: Good morning. Can I welcome you all to this session of the Committee? Welcome to our witnesses. You must just be able to see us from that distance; we could do with binoculars to see you. It is not the best of rooms to be in I am afraid but I hope you will be able to cope. We are very grateful

to you for being willing to come before the Committee this morning. Could I ask you to briefly introduce yourselves to the Committee, starting with you, Ms James?

Ms James: Good morning. My name is Margot James and I am Regional President for Europe for Ogilvy Healthworld, a company which carries out public relations, medical education and advertising services for the pharmaceutical industry. Formerly I have been a non-executive director of an NHS trust and a mental health manager.

Mr Paling: Good morning. My name is Michael Paling. I am Managing Director of Paling Walters. We are an advertising agency specialising in healthcare. Healthcare from our perspective is prescription medicines controlled by doctors, consumer medicines and any product with an interest in health that is consumer product.

Dr Horton: Richard Horton. I edit *The Lancet*.

Ms Hope: Jenny Hope. I am a medical correspondent with *The Daily Mail*. I write about health and medical matters for the news section.

Ms Rogers: Lois Rogers from *The Sunday Times*. I am the medical editor and I cover the whole area of medicine and health related issues.

Q517 Chairman: Thank you very much. Can I begin by asking Dr Horton a question arising from your evidence - and we are grateful for the evidence which was interesting evidence - where you concluded, if I can quote from your last paragraph: "Modern medicine needs a dynamic, innovative, and robust pharmaceutical industry. But it is also the case that the for-profit motive of the pharmaceutical sector clashes with the public health values of NHS clinical care and independent scientific research." You go on to say: "The compromised integrity of medicine's knowledge base should be a serious concern to politicians and public alike. It is surprising and disappointing that this danger does not seem a serious priority within medicine itself." Could you expand on that?

Dr Horton: Perhaps I should start by saying that it goes without saying that we do need a dynamic, innovative industry and it has been a huge success in the last 20 years or so as we have been able to see medicines delivered that have really transformed the practice of medicine. I know you have had examples of that presented to your Committee. Indeed, it is also true to say that there are many common conditions - such as high blood pressure, high cholesterol, asthma, diabetes - that remain chronically under-treated and we need to do better at getting effective medicines to those patients. However, it is also correct to be critical because industry does not just provide an armamentarium of drugs. It also, because of this armamentarium, contributes significantly to the morbidity and mortality of the population. In a study that was done in the late 1990s looking at American data - a study of adverse drug reactions - adverse drug reactions were found to be the fourth commonest cause of death in the United States after heart disease, cancer and stroke. With progress come huge risks which are often underestimated. In addition, the pharmaceutical industry has been enormously successful at inter-digitating itself in the usual process of health care in the UK. It provides people; it provides

equipment, services, buildings, facilities and, of course, hospitality. At almost every level of NHS care provision the pharmaceutical industry shapes the agenda and the practice of medicine. The question then is: what is the nature of that shaping, that relationship? It hovers somewhere between symbiotic and parasitic. It is possible perhaps to explore some of that. I guess I feel that the relationship has tilted too much towards the parasitic rather than the symbiotic because of the way we have our regulatory structure for drugs still with MHRA despite the proposals for reform. We are seeing the population taking part in a largely unregulated experiment in the way drugs are provided through the NHS and I think that is something we had not had a serious enough debate about in the public domain.

Q518 Chairman: In an editorial in 2002 you wrote: "How tainted has medicine become?" and you concluded: "heavily and damagingly so". You qualified medically in 1986, at what stage in your career did you come to this conclusion? Is it something you believed in all the way through or do you feel that something profound has happened during your time since you have qualified that leads you to this pretty strong conclusion?

Dr Horton: This is not something I have thought for a long time at all. It is only since I have worked at *The Lancet* which is a strange environment to work in. It gives you an insight into many of the practices that we may talk about this morning.

Q519 Chairman: To clarify the point then, your thinking of this has been concentrated by the work you are doing now.

Dr Horton: Exactly.

Q520 Chairman: You talk in your evidence about editorial kick-backs. You have actually had situations where you have been offered substantial sums of money to publish certain research studies. Money from the industry. Tell us about it. Who has offered you money? Be precise because we are interested to know how it works.

Dr Horton: The way it works is that an investigator will give you a call and say they have a paper that they would like to submit to us and ask us if we are interested in it. On the telephone I would ask them to tell me about it. If they describe it I would say we are interested. Then the conversation might go: "It is likely that the company will want to buy several hundred thousand reprints" and of course several hundred thousand reprints might translate into half a million pounds, a million pounds revenue to the journal. There is an implicit connection between the submission of a paper and the revenue that comes into a journal.

Q521 Chairman: To be clear, it is the reprint where the money is offered.

Dr Horton: Absolutely. Then at various stages after a paper has been submitted there may be interventions by either the authors or the sponsors to try to move the peer review process in a direction that is less critical. I could give you some examples of that if you want me to.

Q522 Chairman: Please do.

Dr Horton: All the examples I will give are very recent, within the last six to 12 months. Over the summer we received a paper on a Cox-2 inhibitor which we fast tracked to publication. In the process of peer review there was a substantial level of criticism against this paper: over-interpretive, reducing the impact of the adverse reactions. So we put these questions to the authors and in the middle of the peer review process as we were trying to get the paper right for publication we received a call from the sponsor of the company saying: "Stop. Pull back. Stop being overly critical because if you carry on like this we are going to pull the paper and if we pull the paper that means no re-print income for the journal." We then went back to the authors and said, "You need to pull these guys off the journal because if they continue to put pressure on us we do not want your paper". After a few more days the company backed off; the authors were willing to change the way they had interpreted the paper and report more accurately the data in the paper. That is just one example - and it is not an uncommon example - of how there is this constant continuing conflict (and conflict in the peer review process) between the journal and the sponsor and the authors get caught right in the middle of that.

Q523 Chairman: How do you then determine what you publish? If there are all these influxes how do you come to a decision that you feel it is okay to associate your journal with a particular article?

Dr Horton: We are very lucky because in the last ten years or so we have been able to set out a series of independent guidelines which have provided some force when we go to negotiate with authors about the quality of their work. We are a member of the International Committee for Medical Journal Editors which has a very detailed list of guidelines about the way research should be reported which we can appeal to. The Committee on Publication Ethics, which is a UK Committee, does exactly the same. It is a forum which has a list of guidance about the reporting of research and it is also a place where we can take difficulties that we have encountered as editors and place that before colleagues to work out a way forward. The third set of guidelines about the reporting of clinical trials again enables us to force authors and sponsors to disclose information about the results of the search. These are not statutory; these are all voluntary codes so I am the first to admit that they are not perfect but they at least allow a benchmark that we can appeal to in order to do our best to improve the quality of reporting.

Q524 Chairman: You have learned some lessons from problems that have occurred. The Andrew Wakefield study is an issue; do you want to say a bit about that?

Dr Horton: The Andrew Wakefield study is not related to the pharmaceutical industry as such but I think the lesson that I took from the paper on MMR was the way a story which has the potential to be enormously controversial can get put in a crucible of publicity with a rather maverick investigator and controlling that message in the public domain becomes almost impossible. The issue that eventually came out this year, as you know, was the conflict of interest issue that he had, although that was related to the Legal Services Commission rather than the pharmaceutical industry.

Q525 Chairman: Which of course you were not aware of at the time.

Dr Horton: At the time of submission we were not aware of it and also the recent information that came out on the Channel 4 *Dispatches* programme about the patent, we were not aware of that.

Q526 Chairman: Would your guidelines now perhaps be able to take that into account? Would that ensure that you are aware when you publish of any kind of conflict of interest?

Dr Horton: The evolution of the robustness of our own journal's guidelines has developed very quickly in the last four or five years so that now we are much stricter than we were back in 1998 about disclosure statements; much stricter about insisting on the responsibility of the funding source to disclose its role in the research: was it responsible for writing the paper? Was it responsible for doing the analysis? Was it responsible for limiting access to data for the authors? We take those kinds of issues point by point in the process of peer review. Prior to 2001 we did not so this whole evolution of quality control is on a very rapid conveyor belt of change.

Q527 Chairman: Going back to the point about the initial question I asked you in terms of the quote in your evidence and about your comments on medicine being tainted and its integrity being compromised, from your knowledge of the time you have been around as a doctor obviously you have just become aware of this particularly in your current role, but do you feel that something significant has changed in recent times that has reinforced the concerns that you have expressed? If so, what has happened?

Dr Horton: I think the competitive environment in which industry works now is ever greater. It is almost an asymptotic relationship. Its progress maybe from the mid-1960s to the mid-1980s was really quite rapid in terms of developing new drugs and then as time has gone on it has become ever more difficult. Once you have two or three classes of drugs to treat high blood pressure thinking of the next class and the next class and the next class then becomes very hard. The potential gain for research and development investment is diminishing. The pressure then comes - and we have seen that, the numbers of new drugs that have been licensed have gone down with time - and in that almost intolerable pressured competitive environment the emphasis then switches from research more to market. With the marketing focus such as it is the gain that can be got from even one or two per cent market share, and the great example, of course, is the statin portfolio of drugs and the entry of Crestor for AstraZeneca. Tom McKillop said that this drug is going to be the make or break for AstraZeneca. There was a billion dollars of investment which seems a huge amount of money but when it could be a two, three, four billion dollar a year return it is actually not that huge an investment. That is the kind of environment that has changed. The marketing pressure has been ramped up enormously.

Q528 Chairman: I was interested in what you said because Richard Smith, who used to edit the *BMJ* is quoted as saying that "marketing and promotional activity has increased inversely to innovative drug production in recent years. Since 1995 research staff numbers have fallen by two per cent while marketing staff numbers have increased by 59 per cent." That, in a sense, ties in with what you have just said.

Dr Horton: And the problem we have at journals is that the great tool for

marketing are the papers we publish so that has led to the swathe of ghost-writing, public relations attached to research papers, using the research that we publish as a marketing tool and not as an educational tool. We get caught in that vice.

Q529 Jim Dowd: The main question I want to ask relates directly to what was just mentioned by the chair, but I think I think I missed something. In the case you gave where you came under pressure from the company and went back to the authors, what was the conclusion of that and, if you feel able, could you mention the company?

Dr Horton: It is probably better that I do not mention the company. Do you mind if I do not? The reason being that the negotiations we have with authors are somewhat like doctor/patient relationships; we say that they are confidential. I can give you generic examples but I would prefer not to give it on the record. In that particular instance the authors themselves had come under huge pressure from the sponsor and were very grateful that we were then saying that we would not publish this paper unless they had full disclosure about adverse reactions and considerably toned down the spun message in the research. We were able to be allies with the authors. So often what happens is that the authors are caught between these forces of the sponsors who they need to do the research. Let us be clear, you would not have this research done if it were not for industry. Then industry owns the message as a result and the authors fail to win the argument about how the research gets reported. I give some more examples in my written evidence. In that particular case I think we were able to win although we did publish an editorial to go with that paper that was highly critical of the way the paper had been reported and the way the study had been designed. That is often our only come-back, to run a critical editorial pointing out the weaknesses in the study design.

Q530 Jim Dowd: The pharmaceutical industry generally and individual companies put a great deal of resources into promotional activities, advertising and public relations et cetera which clearly they regard as being in their individual commercial interest. Is the net effect beneficial in promoting public health?

Ms James: I think usually it is beneficial in promoting public health. I think as I said in my evidence most of the programmes that we undertake involving public relations are to meet various objectives: very much to improve awareness of certain conditions and treatment choices, also to improve diagnosis, identification and management of patients with those conditions and also such a way as does provide a commercial return for our clients. Occasionally those goals are difficult to marry but I would say that was the exception rather than the norm. In the vast majority of cases I believe that public health benefits in terms of our reaching the first two of the objectives I outlined in addition to the third. We do not always achieve the third.

Q531 Jim Dowd: Does anybody demur from that point of view?

Dr Horton: I would put a slightly difficult emphasis on it. As we were talking about earlier, I think that the influence of industry on education, for example, one has to conclude if you look at the work that is put out under the

mask of education it is largely marketing dressed up as education. One can understand why; that is perfectly reasonable. This is about getting market share. However, let us be clear: this is not education. Again the regulatory environment - despite the ABPI code of practice - is such that while they are fine words they have absolutely no teeth whatsoever.

Ms Rogers: The only other thing I would say is that in general you could reasonably argue that the whole agenda is skewed by the commercial potential of a particular product so we, the media, and in turn the public are influenced in our perception of the relative importance of different diseases by the commercial possibilities of marketing a treatment for it. If there are a lot of people who suffer from something which you can produce a lucrative treatment for, then the perception of that condition will grow. Sorry, I meant the perception of the seriousness of that condition will become more significant.

Q532 Mr Jones: Going back to Dr Horton's reluctance to reveal the name of the organisation that put him under pressure, you ably describe the difficult position that you are in and your research publication but the reality is that it is increasingly important as a marketing tool. As well as putting you under all sorts of pressure it also provides with you an opportunity - because you are an enormously important marketing tool - and if you should so choose you have power over that company.

Dr Horton: Yes, that is true.

Q533 Mr Jones: It may be that you are unduly reluctant to use the powers you have in order to solve the problems that you are under.

Dr Horton: I think that is a very fair point and it is an issue that is underestimated in not just *The Lancet* but across the whole range of journals. There is a bit of a food chain with journals and you have some of the general journals like the *BMJ* and *The Lancet* that you hear a lot about but there are thousands of others. These journals are often very good places to drop articles which are clearly promotional on behalf of a particular company. A very good example, to be very specific, is this whole story surrounding SSRIs. I know you have had evidence from David Healy about this but it is probably the best example where the companies have been very clever at seeding the literature with ghost-written editorials and review papers that promote off-label use of these drugs. You can dress up in an academic argument about "would this drug X be quite useful for this condition; why?" and have an interesting debate about that. What it does in the mind of the prescriber is to think "Hah, this patient with this condition, perhaps I will try it". It is an off-label use and that is how you had two and a half million scripts a couple of years ago for SSRIs in under-18s with no licensed indication for it. I think you are right; I think journals have an enormous responsibility. We are seen as independent; we are seen as a source of evidence and yet we ourselves can be corrupted by this very perverse set of incentives that we are businesses in our own rights, that we are often owned by publishers which have to make a profit.

Q534 Mr Jones: To get back to the point that you have acknowledged that you are maybe sometimes overly reluctant to use the power that you have been given, do you want to reconsider whether you want to tell the Committee the

name of the company?

Dr Horton: I would say we do use our powers a great deal.

Q535 Mr Jones: That is all right; I was just giving you a second chance.

Dr Horton: Thank you but I will decline it.

Q536 Mrs Calton: Can we move on to the influence of the industry and articles covered by the press. I am directing my questions now to Ms Hope and to Ms Rogers in particular. Can you give us a general picture of the types of articles you like to write or chose to write and the types of articles to do with health stories and reports that your readership wish to read?

Ms Hope: Health and medicine are very important to our readership. We know that from feedback in the surveys, the letters I get and the phone calls I get. We cover the whole gamut and it can be from new drugs through to hospital closures through to patient problems. Drugs and the drug industry form a small part of all of this. We get a tremendous amount of information coming to the office every day; dozens of potential story idea presenting and competing for attention and space in the paper. Priority is given to the stories that are embargoed for the day because they are the stories that will be going all around your competitors; they are the ones that have to be screened and filtered and we have to assess whether or not we think they are worth running. Certainly they are going to be in our competitors' papers or considered for publication there. Then you can work through all the other competing attentions such as exclusive stories that you may be working up, government announcements on the day, that kind of thing. New drugs stories are of great interest to us. The whole point is that they are new; they are news; it is innovation; it is discovery; it is possibility of optimism and hope. Something good is coming out of human endeavour. It has all the ingredients. What is there not to like? The point is that that is the news value of the story not the fact that I have been got at by a drug company to run a story about a new drug. It is the fact that here is a story that will interest our readers. Along the way it may be that we are writing a story that actually does not live up to the initial promise of the original announcement or launch or trial data on which it was based. As we know, science is littered with false storms and we cannot know that at the beginning.

Q537 Mrs Calton: Would you like to add anything to that, Ms Rogers?

Ms Rogers: No, because our agenda is vastly different from that of a daily paper anyway and for obvious reasons we just approach it from a completely different point of view. We are not driven by a news agenda, if you like; we are not driven by embargoed stories, press releases or that sort of thing. It is a different way of working.

Q538 Mrs Calton: The answers you have given indicate that you are very much driven by the needs of the newspaper obviously to sell newspapers and nobody can criticise you for that. What role do you think the lay media has in telling the public about new medicines or warning them about problems? Do you have an educational role besides your need to sell newspapers with stories which are news?

Ms Hope: And with stories which readers want to read. That is a critical part of it. We are not going to sell newspapers unless we actually tap into what readers want to read about. I think the thing about the public health element - the educational element - is that it is a subsidiary element of my work. I am completely conscious of the fact that people are reading these stories and may be alarmed, overly optimistic as a result of reading them; they may be my family and friends. I am a responsible journalist and I am conscious of the impact of these stories on my readers. We are a conduit for messages and quite often we get blamed as the messenger for the message. I am thinking particularly of health scares because when the Government wants to put out a warning about a drug and a set of side effects we are the first port of call. We are the first people to say: "Do not take this drug" or "Go and see your doctor because new problems have been raised about it". Going back to the pill scare in 1995 - and I know this is ancient history but it still rankles - newspapers were actually used to put out this message that you must change your brand of pill instantly. It caused complete panic; it caused 29,000 abortions in the long run and even at the time journalists are saying that this is based on unpublished, unreviewed evidence; we cannot see it and we are having to go on trust. Within months the European drugs agency refused to endorse the Government's advice - the Government of the time - and within four years the Government had changed the advice.

Q539 Chairman: When you get this good news story or the bad news story what do you do to check the other side? Last week we had the predication that we are all going to die of bird flu next winter or something; the reason we are going to die of bird flu is because we do not have enough of this great drug that is going to stop us getting bird flu. I do not think it was your paper I read. It was a paper I read. How do you get the balance in there? We all like to read good news. We are all going to live forever, great, it is really nice to know that, but how do you balance it out? What do you do to get the other side of the story, particularly where that other side may not have been analysed sufficiently to get a balanced picture?

Ms Hope: That is a very good point. It is a constant dilemma in journalism about balancing information. If you have a basic story, a basic working hypothesis based on research evidence you are going to want to run this, but you need to ask questions while you are assessing the information and work out if there is someone you want to contact or some people in order to check out problems that you see arising from this data or from the interpretation that the public is going to put upon it. You just have to use your common sense sometimes about how this is going to play with the public and try to contact sources of information you think are going to put some sort of perspective on the story.

Q540 Chairman: The worry we have with what is called disease mongering is that often the media - and I am not talking about either of your papers in particular, but the media in general - presents it in a very simplistic way. Take the Viagra debate for example. We were looking at sexual health around the time that all this was kicking around. The magic cure for erectile dysfunction is to take this pill not to stop drinking ten pints before you try to make love. It was an imbalanced debate. How can you broaden out the debate in a way that is sensible rather than focus on what seems to be the headline issue?

Ms Hope: It is very hard because what you are dealing with is one single issue - usually in a story rather than in a debate - and you have about 600 words to put all the points in. You have to include background; you have to include the elements of how many people are affected by this, how seriously they are affected by it and what is currently happening. It does not leave you very much space. You have to try to stand back and see how that story fits into the trajectory of a particular disease or drug. If, for example, there is new push on with diabetes you have to assess whether or not you think it is as a result of a big PR campaign to try to get a particular sort of drug into the market place. As I said in my written evidence, I feel very strongly that journalists are quite used to looking for vested interests, the hidden agenda. That does not mean, if we spot it, that it negates the story or distorts the coverage. We are aware of it in all walks of journalistic life, be it transport, be it politics, whatever. We are used to looking for it; we take it into account. That does not mean we do not run the story.

Q541 Jim Dowd: Looking back to what Dr Horton said earlier when the Chairman asked about MMR, I do not know whether it is true of *The Daily Mail* or *The Sunday Times* or anybody else here, and I am not expecting you to answer on behalf of the whole media, but take the MMR, certainly the tabloid end of BBC - *Radio 5 Live* - cannot report MMR without describing it as the controversial MMR. Technically that may be true, but that gives the impression that this is a 51/49 split but the issue on MMR was one rogue - as it is now described - piece of work. Everything else, every other country in the world, every other piece of scientific information said that the MMR vaccine was perfectly safe as it was and there was no link through to irritable bowel or autism or anything else. That is not how the issue continues - continues to this very day - to be reported whenever there is a story around MMR in the media.

Ms Hope: I would defend the use of the word "controversial" because it is a newspaper shorthand word. It sums up a whole history of controversy surrounding the drug and surrounding the vaccine and surrounding the effect it has had in Britain on immunisation.

Q542 Jim Dowd: There was not a whole history; there was one incident.

Ms Hope: But it has run and run.

Q543 Jim Dowd: Yes I know, by you.

Ms Hope: By a lot of papers. May I also add that whenever papers are asked to run stories about how poor immunisation rates are in large areas of Britain - including London - the MMR vaccine is actually attributed as the reason for this fall; the reason that parents have lost confidence is because they have lost confidence in MMR. Whether we like it or not the vaccine remains controversial.

Q544 Jim Dowd: You do not understand what is cause and what is effect here.

Ms Hope: I think I do. I think the story rumbles on whether or not you think it has been put to rest.

Ms Rogers: Although we are getting off the point, do not forget that there was

a huge lobby of parents of allegedly vaccine-damaged children. I suspect a lot of them were not vaccine damaged but statistically some must have been and they are quite a loud lobby group. They pop up all the time. There is an underlying problem of what you do with this minority of kids who are damaged by vaccine because in any vaccine there is a fraction of one per cent that will be damaged. They also leapt onto the Wakefield study and that gave it an extra momentum of its own. It was a very unfortunate series of events I think.

Q545 Dr Naysmith: You said about one per cent; it is a tiny, tiny fraction.

Ms Rogers: I said a fraction of one per cent. I think it is several decimal points.

Q546 Mr Jones: In terms of this study on the pharmaceutical industry the sort of story that needs to be told - whoever tells it - is not the story about the drug that works marvellously (because that is a good story) or the drug that does not work and causes dreadful problems (because that is a good story); one is a good bad story and is a good good story, but in terms of what we are doing we are mostly concerned with the drugs that do not work at all and that is not much of a story, is it? It is particularly not much of a story because people are not paying. If they were paying for the drugs that do not work, that might be a story: you are being ripped of personally.

Ms Rogers: We do report that. We regularly report the fact that the vast majority of drugs work on a fraction of the people they are given to; a minority of the people they are given to. I do not think that that take home message gets through at all. In the same way that we were the paper that demonstrated the MMR thing was a complete con, that message clearly has not got through. It takes a long time to change public opinion and the message from the drugs industry all the time is that here is yet another treatment for cancer which has a response rate of something extraordinary which, when you unravel the statistics, it does not stack up at all. We do report the fact that only one in seven people will actually benefit from this highly toxic drug. We most definitely do, but if you have cancer you want to hear that there is going to be a drug that is going to cure you. You do not want to know that you might not respond to the drug.

Ms Hope: We need a newpoint in order to say that a drug does not work or a class or drug does not work. For example, if you get a report in a journal - I have heard up to now about the journals and the degree of trust we can place in the reports we see - as we did recently about the fact that a blood pressure drug called Atenelol does not work, it just does not have an effect, we run the story. We ran the story but I am not going to be running stories as a matter of course and say that generally speaking drugs do not work because we actually need to have the evidence on which we can base the report.

Q547 Mr Jones: Does Dr Horton or the equivalent of Dr Horton ever phone you up and say, "We have just discovered that this drug does not work at all" or something like that? How do you cover it in your paper?

Ms Hope: That would be undue influence.

Dr Horton: I have never called Jenny.

Q548 Mr Jones: You only get pushed from the commercial side; nobody tells you from the other side?

Ms Rogers: Yes, they do.

Q549 Chairman: Who tells you?

Ms Rogers: It tends to be individuals who I know who have done work.

Q550 Chairman: Not other companies?

Ms Rogers: No, sorry, that is not true. I did get calls about the Vioxx thing from other companies asking why we did not have a look at this. In fact, that is a very good case in point because with Vioxx I had several approaches from competitors saying that we should have a look at this because there was something going on. But unless you have actually got the hard evidence there is not much you can do. You have to say to them, "Unless we have the evidence that it causes heart disease as opposed to you saying what the rumour is, we cannot do anything at all". These are very litigious companies; you do not take them on lightly.

Q551 Mrs Calton: What are the main sources for drug stories? Out of the articles you have published on medicines what proportion would you say come from drug companies or their representatives and publicity agents and what proportion would come, say, from government sources?

Ms Rogers: For me, neither of those. They would come from individuals I know who are academic researchers. I can say reasonably confidently that I have never in the eleven years I have worked at *The Sunday Times* written a story about a drug that has come from a drug company.

Q552 Mrs Calton: They have always come from researchers.

Ms Rogers: Yes. Sometimes patients.

Ms Hope: If I could just add to that point, we are very much more embargo driven so a lot of stories would come from journals and conferences where trial data - usually significant results, that is the reason why we are thinking about reporting on them - are embargoed to a certain point in time and that would affect the daily papers. We are six out of seven days and that is where a lot of our stories come from. It may well be that PR companies are drawing your attention to the fact that this is going to happen at a certain point so you can put it in the diary and it becomes a potential story of note.

Q553 Mrs Calton: Going back to Ms Rogers and your response, with all these researchers do you enquire who is funding the research?

Ms Rogers: Yes, absolutely

Q554 Mrs Calton: Does that go into the story?

Ms Rogers: Yes. Obviously it depends on whether it is relevant. Sometimes

somebody would ring me up who happens to know something which is absolutely irrelevant to what they are doing at that particular point. You would ask what is their relationship with the company whose products they are attacking and because most academic research is funded by the industry in some shape or form it is inevitable that everybody has had contact in financing from commercial sources.

Q555 Mrs Calton: Does it always come from that side, from people who are attacking another product that they are not involved with or sometimes are there people who are involved with research and are being paid by a company?

Ms Rogers: The Viagra story which we got before everyone else - which is many years ago - I actually was told about by the person who was doing the research. In the course of conversation - we were talking about blood pressure - he said, "We have discovered this fantastic compound which is going to make a huge amount of money" - this is almost how the conversation went - "and it is going to work on erectile dysfunction and the market for that is going to be vast". The company - it was Pfizer - were not at all pleased that we were running the story because they did not want their competitors to know at that stage. That is how that one came about. It is serendipity a lot of the time.

Q556 Mrs Calton: Do you ever feel you are being used by a drug company in a promotional sense?

Ms Rogers: Yes.

Q557 Mrs Calton: Could you give us some examples?

Ms Rogers: We regularly receive approaches where people are trying to use us principally as a conduit for getting a mention of a particular drug into a story because they know that we are not going to write a story saying that this new drug is about to be launched on Thursday because Sunday papers do not do that. It would be much more to try to talk me into mentioning something in a favourable way.

Mr Paling: Could I just make a point here? My company is not involved with the lay press in any way, shape or form. I do think we are hearing some incredibly sweeping statements about some treatments: drugs work on a fraction of people, the blood pressure treatment atenelol (which is a beta blocker) just does not work. If that is the case - and atenelol has been genericised for many years but probably available for 25 years - I find it quite remarkable that doctors around the world (hundreds of thousands of doctors) and millions of patients are being treated with a product that does not work when it is actually very easy to measure blood pressure. It does work - I am not saying it is the best treatment and I am not an advocate for it - and I think we have to be a bit careful that we are not making incredibly sweeping statements like that.

Dr Horton: I think it was us who published the paper on this particular drug. You can reduce blood pressure but actually it is not blood pressure you are trying to reduce. What you are trying to do is change the risk that flows from having high blood pressure: the risk of subsequent stroke, heart attacks and so on. It is a question of whether that particular drug is effective at reducing those clinical end points and there is a question about the efficacy

of that drug. I think the point that has just been made is a really interesting one about our drug regulations. A drug gets licensed and there it is; it is there for prescription forever more until the company decides to stop making it. That is crazy. Surely what you should have is a regulatory structure for drugs where you have continuous assessment of the evidence and periodic formal reviews of whether that drug should still have its licence. That is something we do not have right now and I do not think it has been suggested in the oral evidence you have heard so far.

Q558 Chairman: We have certainly had the old yellow card system criticised.

Dr Horton: That is nonsense; that is the worst way of doing epidemiology you could possibly think of.

Q559 Dr Naysmith: To be fair, there have been a number of occasions we have suggested to NICE (when we have had them before us) or government ministers that they should look at some of the existing treatment and see whether the work or not. They are over-loaded with work but that would be another possible way.

Dr Horton: Five yearly periodic reviews of every drug on the market looking at what the evidence is for and against would clear out all the dross - and there is a lot of dross - and it would give up-to-date evidence for prescribers about what works and what does not work.

Q560 Mrs Calton: I was actually in the middle of asking two people a specific question, helpful as the exchanges have just been. Can I come now to Ms Hope and remind you of what the question was. Do you ever feel that you are being used by drugs companies as a promotional conduit or as a vehicle? If this happened what would you do?

Ms Hope: I do not feel that I am being used but I feel I am a target for promotional and marketing activity. I think there is a difference. If there is a story there, if there is some news merit, if I think the news values holds up on something I am being offered which is obviously promotional for the company involved then that takes precedence. If there is a benefit - either direct or indirect - to the drug company involved then so be it but I do not feel used and I can weigh up everything that comes in front of me with those news values in mind: should the public know about it? Is it of interest? Would it be wrong if I kept it a secret?

Q561 Mrs Calton: When you are writing drugs stories how often do you rely on opinion leaders - I think Ms Rogers has already addressed this to some extent - or patients suggested to you by a drugs company? Does it ever work that way round? What procedures would you follow to check whether such a story is reliable?

Ms Rogers: That does not happen.

Q562 Mrs Calton: From what you were saying you actually have some very direct relationships with researchers.

Ms Rogers: I have a very good network of people and I know exactly what

funding they have had from who because, as I said earlier, everybody has and these are people I know well and whose views I would respect.

Ms Hope: I would concur with Lois that I too have what I hope is a good network of contacts to call upon but the PR industry sets great store by opinion leaders which slightly mystifies me. I just see it as doctors they can call upon to back up what has been said about a drug. It may well be because they are an investigator or because they have many years' experience in the area. That is fine, but you know where they are coming from. If you feel the need - and I usually do, I do not rely on single-source stories - to talk to somebody else then I talk to somebody in my bank of contacts about where this information comes in the whole stream of information about a drug, where the drug might have its place in the future. I fear that the influence of these opinion leaders is really rather something that has been got up, to be honest with you, by the PR industry.

Ms Rogers: Can I just add to that, even the expression "opinion leader" to me is a deterrent because if I happen to be talking to someone from a drug company and they say, "Have you spoken to so and so about this?" that would immediately tell me that that person in the pocket of that drug company. That would be exactly how I would interpret it so I would be disinclined to talk to them.

Q563 Mrs Calton: Can I ask each of you something which is probably a little unfair but nevertheless I shall ask it: have either of you written up a story and subsequently thought to yourselves, "I really should not have done that because had I had the time or whatever to look into it more fully I would not necessarily have covered this story"? Have you ever regretted putting a story in because it has caused an adverse set of reactions in the public arena?

Ms Rogers: No, but I can say that I would regret seeing things in the media generally that I think are misleading about the value of particular drugs and products.

Ms Hope: My biggest regret is the Pill story and I had no choice about running that. That was a story out there that had to be run and had to be followed it up. We assiduously followed it up; we assiduously contacted and talked to people and criticised the original decision and the basis on which it was made but all the caveats were lost in the general furore surrounding it. It had dreadful consequences that you could see unfolding from day one.

Q564 Dr Taylor: I am very interested in your comments about opinion leaders and your active disregard of them and I really want to go to Ms James because a quote from your website is: "The effective development of opinion leaders in all your stakeholder groups is essential for your commercial success." How do you set about identifying these opinion leaders and how do you use them? We have heard that two important newspapers - if they get any hint that these were opinion leaders that were selected by you - would shy off.

Ms James: I think the evidence was actually slightly different. I think I am right in saying that Jenny checked with other doctors; she did not disregard opinion leaders supplied by their company. If there is a question in your mind then you will go another doctor as well and I would expect any good journalist

to do that. The way we go about identifying opinion leaders, it depends on the condition and how big a pool of expert doctors exist. Obviously if it is heart disease there are a lot of people; it is a very small, narrow niche in cancer there are not many. There are a lot of variances, but in principle we start off with a conversation with a client and the client already has some doctors that they are working with clearly. A lot of those doctors will be triallists so some of the opinion leaders self-select by participating in trials and leading clinical trials; they will be natural opinion leaders for us to work with. Beyond that we will look at all sorts of databases to identify which doctors have an interest in which fields and we will start targeting a few doctors who have published research in a similar area and are known to have an interest. We might establish some relationships with them. It is a long term process really, over many years.

Q565 Dr Taylor: Can I broaden it out and go back to ghost-writing? I was absolutely horrified to hear Dr Horton say that some - even leading - articles can be ghost-written. In years of practice somebody like me has always regarded *BMJ* leaders and *Lancet* leaders as the gold standard. Are you implying that there are some journals that do accept ghost-written leading articles and how do you check to see if something is ghost-written? Or am I wrong in assuming that something that is ghost-written is somehow second-class?

Dr Horton: To start with *The Lancet* we ask people who write for us whether they have written the article themselves or whether someone else has collaborated. If they have had somebody ghost-write it and they deny that then they will be telling us an active lie if that is the case. I think we have fairly robust - as robust as we possibly could have - procedures for picking that up. However, people do lie and I can give you an example. We received a review earlier this year on a particular subject which had been commissioned. This review was about a particular treatment for a particular neurological disease. As with most things these days it is submitted on a disc as a Word document. The clever thing about Word documents is that you can go into the properties part of a Word document and see various messages that have been written by the person who has been the author. The author of this paper said, "I've written this paper; there was a link with Novatis" and he had had some assistance with the writing of it, but it was his paper and there had been absolutely no substantive input from the company. When we went into the properties field of his Word document it said: "Marketing approval required please" and a little tick box next to it. We were able to go back to the author and say, "Come on, we've caught you out here". The paper was rejected, he went away and we have not heard from him since. I think there are examples of out-and-out lies that come from supposedly independent scientists who are presumably on a substantial retainer fee to get their articles seeded in journals. This is the constant conflict we have in trying to weed these out. It gets worse as you get down the food chain of journals because there the very viability of those journals depends entirely upon the re-print revenue that they get from the editorials, the research articles, reviews and so on. It is critical that if those journals are to survive they are financially successful and then the relationship they have with the sponsoring organisation as an industry becomes much more powerful and influential. There have been examples, for example David Healy's work where he has shown very clearly in his British Journal of Psychiatry paper - which he gave a summary of in an oral session here - how information is commissioned by industry through third party medical communications companies and then gets seeded in

the literature and that information has a systematic bias in favour of a particular drug or issue. That is the thing we are constantly trying to fight against.

Q566 Dr Taylor: Do you think doctors recognise that there is what you call a food chain of these journals and they are sufficiently aware - and I am not asking you to name them but I am sure I know quite a lot of them - of the quality of the ones at the bottom end?

Dr Horton: They are certainly aware of the food chain of journals, but it is the way the articles then get used. If you get what is essentially a promotional piece of work written up and it looks beautiful in print and it is all fantastically typeset and that gets given to a doctor, whether it is in *The Lancet* or the journal of whatever it might be down the food chain then it looks credible. It has the imprint of the journal and the publisher attached to it. There is an authenticity given to what are often completely spurious views not owned by the author him- or herself.

Q567 Chairman: As a non-medic, how aware would the average doctor be of the quality within this food chain of what he or she was reading?

Dr Horton: I would believe - maybe I am naïve - that most doctors would be aware of the fact that the *BMJ* and *The Lancet* are somewhere hopefully near the top and then you would have leading speciality journals in the middle and then there is a whole bunch of third and fourth rate promotional journal that sit somewhere at the bottom. I would hope they would understand that, particularly those in the general practice community. They will not necessarily have the academic background and critical appraisal strengths to be able to discern which are strong and which are weaker articles.

Q568 Chairman: So key prescribers could be fed a load of rubbish by these at the lower end.

Dr Horton: They are, daily. That is what drug representatives are there to do, to feed them rubbish; that is their job.

Q569 Dr Taylor: Going on from that, Ms James in your submission you give us some of the rules you follow to preserve the integrity of articles written by your editorial staff on behalf of doctors, one of them is that some doctors do not have the time or the writing skills necessary for publishing their own work and value this service. I do not want to argue about the writing skills because we are all notoriously bad at writing, but I do argue with the other bit because surely if you have done a piece of work that is worth publishing you will find the time to write that up. Is this not rather stimulating the production of articles that the people doing the research were not that bothered about?

Ms James: I do not think so. It is extraordinary how busy doctors are. They are not just doing research, a lot of them are seeing patients, a lot of them are justifying what they do to budget holders and all of that; they are very, very busy. I know you are a doctor so I shall be careful what I say, but doctors are not necessarily trained in things like time management and organisational skills. I think what we find is that very often if we leave it

to them they know they have to do it but months pass. That really is our experience.

Q570 Dr Taylor: I would not argue with that. We certainly never had time to do the yellow cards.

Ms James: That is very important, too.

Q571 Dr Taylor: But if you have done a bit of work you are desperate to get it out.

Ms James: I accept your point but I think the service really came about partly because of people's desperation to get this work published. It is not just the doctors who are keen it is the companies as well.

Q572 Dr Taylor: Mr Paling and Ms James, how do you actually build up relationships with journalists?

Mr Paling: We do not build relationships with journalists; we do not have contact with journalists. The only time we have material that is appearing in a newspaper or a magazine is paid-for advertising space so that is through a very different channel. My company does not even plan and buy that either but we are really filling the space; that is all, and that is paid for and it is branded.

Q573 Chairman: Would it not help you sometimes to have contact with journalists?

Mr Paling: I cannot honestly say that I have had contact with a journalist in my life apart from a friend who was a sports writer with *The Mirror*.

Ms James: I think in days gone by the word "relationship" might have been more applicable because there was more time to get to know people, take people out for lunch and so on. These days I think the relationship is much more business-like. If we think we have a story we will assess the likely press who are going to be interested and our staff might speak to ten journalists four times a year. It is not that huge a part of our business. We have a media office staffed by two ex-journalists who take the lead whenever we have a media programme to undertake and I think they probably had daily contact with journalists. They used to be journalists; they know them. It is quite a hard question to answer really.

Q574 Dr Taylor: Going on to promotional campaigns - by which we mean really advertising campaigns - do you target patients? Do you target nurses? Do you target doctors? Where do you target your campaign?

Ms James: I am sure Mike will want to come in here because I know that is his area of expertise and we do advertising as well. Advertising is 80 per cent aimed at doctors, increasingly aimed at nurses and to a very limited extent aimed at consumers. There has probably been about five to ten disease areas where the company has decided that it wants to use advertising to reach patients and consumers.

Q575 Dr Taylor: What about over the counter drugs?

Ms James: That is predominantly aimed at consumers, yes.

Mr Paling: We work across a number of audiences, as you say. When it is over the counter medicines we are largely aiming at the end user or sometimes at the pharmacist who has a role in advising a customer or a patient. In terms of prescription work we do, the vast majority - 90 per cent of it - would be aimed directly at the doctor who maybe in a specialist sector more likely to be a general practitioner. The only time we would do anything which was not branded would be when it was a disease awareness campaign. We have been involved in one of those which I mentioned in my submission.

Q576 Dr Taylor: The contract to run this campaign comes from the maker of the drug presumably.

Mr Paling: We would agree with the company concerned depending on the nature of the product who we would be aiming our advertising at, yes, and they would have a budget although we do not actually buy space as I said so we would not be controlling that budget.

Q577 Dr Taylor: Would you have any control over the content of the advertisement, for example?

Mr Paling: We would develop the content of the advertisement in agreement with the client. We would jointly develop a brief. Our role is really to put that into a communication form and have that medically and legally approved through the normal system, which I am sure you will get onto.

Q578 John Austin: I have a question for our two journalists. You talked about the way you are fed information to try to produce stories, but to what extent have you been obstructed by pharmaceutical companies in trying to gather information about stories you want to write? Can you give us some examples of where you have been obstructed in trying to obtain the truth?

Ms Rogers: I will give you a recent example. I did something a few weeks ago about testosterone patches because I thought it was a very interesting example of the way something had been promoted. They are produced by Proctor and Gamble; they are initially trying to get licence approval for their use in post-menopausal women who have had their ovaries removed but they have managed to seed across the whole of the media a huge number of articles about how testosterone patches will be the answer to Viagra for women. There has been quite a lot of data that has emerged suggesting that testosterone does not actually work very well and, not only that, it has never been tested properly as a drug but it might have extremely unpleasant side effects in the formation of male characteristics et cetera. The food and drug administration in America turned down about two or three weeks ago the licence application for this product. I tried to ring Proctor and Gamble and they were very, very difficult. I put in any number of calls to Proctor and Gamble but I kept being put through to answering machines with messages left from last September. Eventually I rang their offices in America and got a call back at about eight o'clock on a Friday night, a day after I had attempted to get a response to the question: what was their reaction to the suggestion that testosterone

patches were potentially harmful? The reason they take so long to come back to you is because they hope that if they do not you might lose interest in pursuing the idea and not write it.

Q579 John Austin: In one sense that is them obstructing you by not giving you information.

Ms Rogers: That is the normal way they would do it.

Q580 John Austin: Do you have examples of where they might have been giving misleading information? For example, on the testosterone patches you said in your evidence that there is also an increased risk of raised cholesterol and heart disease as well which presumably the company - Proctor and Gamble - manufacturing it are aware of. Have they at any time attempted to suppress that information?

Ms Rogers: I cannot recall having asked the direct question when I eventually got through to someone who was put up as the company spokesman; they were too junior to deal with that sort of question anyway so I never went down that track particularly. There have certainly been other occasions at regular intervals where people ring you up and tell you things. As a journalist you do not want to miss anything so if somebody tells me something that sounds phenomenal and plausible then you have to check it out. If it turns out to be completely and utterly untrue then I would make the time to ring back the source and tell them that they have wasted however much of time and also make it clear that any subsequent approach would not be looked on favourably. It is a give and take relationship. If people are helpful and truthful you build up a relationship with them where you respect them. If they say you are wasting your time on this, whatever you have been told is actually not quite how it is, then you know not to pursue it.

Q581 John Austin: You have the luxury of not being a daily driven by embargos and having the time to investigate. I wonder if Ms Hope has a similar experience.

Ms Hope: I am sorry to disappoint you; I cannot think of any specific examples of active obstruction. As Lois says, it is more the case that they might not get back to you or they might be economical with their answers and that could be because you have asked the wrong question. That happens even when I ask some government departments; I might not get the right answer because I have not asked the right question. I just want to add to the testosterone patches story because we published a story saying that testosterone patches offered some relief to symptoms in eligible women based on a paper given at the American Society for Reproductive Medicine. I think it was in October. I was there and saw the paper being given, looked at it, went to the press conference where they presented the details again. I asked about side effects, side effects were included in our story. They had a company spokesman there, very upbeat and, as is to form, I included one quote from him saying, "I hope to get marketing approval" but I did not feel I was a particular target of the marketing campaign but obviously, as Lois suggests, they are getting papers together, presenting them at conferences, putting them into journals and then they become a potential news story.

Q582 Chairman: You went to the States for that.

Ms Hope: Yes.

Q583 Chairman: Your paper paid for that presumably.

Ms Hope: Yes.

Q584 John Austin: Since the other question I was going to ask has already been asked, I want to go back to something that Dr Horton said earlier about the food chain. I am not sure whether you are prepared to name names as to those publications which are lower down the list, but reference was made earlier to general practitioners and general practitioners, by their very nature, are generalists. *The Lancet* publishes very specialised and specialist articles which perhaps general practitioners might not have the time to study in detail. What they do get weekly is a whole range of magazines, presumably sponsored by advertisements and the pharmaceutical industry which gives them easily readable information or mis-information. Would you say that the presence of those magazines was overall helpful or a malign influence?

Dr Horton: Definitely a malign influence.

Q585 John Austin: Would you name the magazines? What are these magazines?

Dr Horton: There are many magazines that get given out to general practitioners and it would almost be invidious to name one because it would put a focus on one rather than another but you are right, I can probably count on the fingers of one hand the number of general practitioners who read *The Lancet* in the UK; you are quite right, nobody is going to read *The Lancet*, it is not written for them.

Q586 John Austin: That is not a criticism.

Dr Horton: No, it is just that that is not who we are; that is not what we do. So you have these intermediaries and the intermediaries may be through a promotional campaign or advertising, a drug representative visiting where the work that is published in general is completely distorted - I have examples if you want me to go into that - so that the general practitioner would see the results of a study and be completely misled as to the efficacy and safety of a particular drug. Or what happens is that with these controlled circulation free newspapers that will come to doctors the reporting of the studies there or the presentation of those studies at meetings again often is filtered through company PR systems. To take an example, if you have a big meeting - a research conference - where work is presented many of the journalists who will be attending - I am not talking about Lois or Jenny here, but journalists on these sorts of free newspapers - will have had their travel and hospitality paid for by industry.

Q587 Chairman: Which is why I asked that question, obviously.

Dr Horton: Exactly. They will go with the express purpose of covering the conference but particularly to cover the conference about the products made by the company which is paying for their travel. It may not be the company that

has taken them; it may be a PR company working on behalf of the pharmaceutical company involved. They will go, they will go to the satellite symposium, they will write up the story and that will then get published in their newspaper. That is what the general practitioner will read. Again, there is no identification that the travel was paid for by the company, no identification that this journalist was there for just 24 hours to go to the sponsored satellite symposium, no indication that the way that study has been reported is misleading. The quality control here is appalling.

Q588 John Austin: Does this also lead to unnecessary prescribing?

Dr Horton: I think you have examples of that. You have examples - whether it is SSRIs, Vioxx or other drugs - where you can see that the prescribing rate has gone up hugely and then you have a public health disaster. Ken Woods, Chief Executive of MHRA, said only the other day - I think last week - that there had been over-prescription of SSRIs. Yes, the way drugs are marketed and the way that information gets seeded in the pseudo literature as well as advertising material has enormous impact on prescribing habits.

Q589 John Austin: Could I raise one which has not had a great deal of publicity and is costing the NHS an enormous amount of money at the money, and that is the prescription of proton pump inhibitors - PPIs - when there are much cheaper remedies which are applicable to most people who might turn up at their general practitioner's surgery. Has that been influenced by marketing campaigns by the pharmaceutical industry?

Dr Horton: Yes, and the classic case example that we talk about a lot is the way AstraZeneca very successfully took omeprazole to Nexium which had a little bit of fiddling with its formulation but was essentially the same drug, got marketing approval for what was a new branded drug - supposedly - and kept the patent life for that supposedly new drug when in fact it had no competitive advantage on now what was a generic medicine. Yes, there are very good examples.

Q590 John Austin: Does Mr Paling share your concerns?

Mr Paling: When you were talking about the issue of PPIs - proton pump inhibitors - unless I am wrong I thought that NICE had recently deliberated on the treatment of oesophageal reflux and said that these were the treatments to use. They did put the caveat in that it should be the cheapest and I do not think that is a negative issue at all; I think that is important. I think that proton pump inhibitors have made a tremendous difference.

Q591 John Austin: In that specialist area?

Mr Paling: In the treatment of all the conditions that they are involved in. Their big impact has been on ulcers, first of all the H2 days of Zantac and so on and these treatments have literally wiped out the need for surgery for the treatment of ulcers. I think they have value; I am not arguing the case for them one way or the other but I think they have value and I think we have to be careful not to make too many sweeping statements as I said before because I think there are drugs which have brought tremendous benefit over the last years where appropriately used and used in the right patients and used in the

right way. I do not want to swing the pendulum too far the other way. I do take issue with something that Dr Horton said when he said that drug representatives are there to feed doctors rubbish. I do not know whether he means the information they are giving them or that the products are rubbish, but given that journals - including *The Lancet* - carry advertising for pharmaceutical products, I do not know whether that is vetted by *The Lancet* before the adverts are allowed to appear, but advertising is an important function of all of these publications. I would also say that when we are talking about what general practitioners read whether this is right or wrong the bulk of the readership to my knowledge seems to be in news-based publications not pseudo-scientific or scientific publications. They are not reporting on clinical trial results; they are giving doctors other information whether it is political or news of whatever. That is where the bulk of the advertising goes in my experience.

Q592 Dr Naysmith: I want to explore the area of voluntary regulation that all of you are under in terms of putting out the information that you put out and so on. I am going to start by asking Mr Paling a question. The kinds of bottom end of the market that Dr Horton was talking about in terms of journals are often described as "the comics" by GPs and I think quite a few of them understand that they may not be fully scientific. What I wanted to ask Mr Paling was, you say you adhere to the ABPI code of practice and guidelines and that you are satisfied with the existing standards relating to the quality of drug promotion. Why do you think there is such concern about the practices of companies such as yours? Why do you think that people do not have a particularly high opinion of the work that companies like yours are performing?

Mr Paling: Just one comment first of all about the journals, in terms of comics they are news based publications, as I say. I think the ones that we have both got in our minds are actually the highest readership amongst general practitioners so it would suggest that it is their choice.

Dr Naysmith: They are given free or they are sent through the post freely.

Q593 Chairman: If nobody else will name names, will you name names? We are in the dark you see.

Mr Paling: Almost all of the publications are free.

Q594 Dr Naysmith: There are so many of them that if you name one or two or three then you are sort of picking them out. Things like the *GP* and *Hospital Practice* and things like that.

Mr Paling: In terms of how materials are regulated for prescription products through the ABPI code of practice - which is what we adhere to and obviously our clients adhere to - the process there is a self-regulating one and you are quite right to point that out. When we are talking about pharmaceutical products it is a vast amount of knowledge base, it is not like regulating advertising in FMCG consumer sector where you may be looking at other things but you are not looking at the same amount of data and I think it is important that a large part of the self-regulation goes on at the company where the highly responsible people - one of whom has to be a doctor - have to regulate all the output. We have worked with client companies on that basis for many

years now and I think it is the most stringent and incredibly accurate place to verify the output of the material. The code of practice is very clear; the products can only promote within their licence and their summary product characteristics. The checks and balances I think are very tight and I think if a company does breach the code - and I am not saying there are not breaches; there are breaches, I think about a hundred a year and about 70 per cent of those are upheld (the ABPI would be able to give you that data) - that is taken very, very seriously. It causes all sorts of problems within companies, not least of which from a commercial point of view is loss of time while advertising is removed, the cost of replacing it, which we obviously feel; it has an impact on us as well. I do not think it is taken at all lightly; it is a very detailed stringent system.

Q595 Dr Naysmith: Do you have any worries about the length of time the advertising complaints procedure takes from the time of a complaint being put in before there is an adjudication?

Mr Paling: I cannot give you an accurate answer on that I am afraid. I would imagine it is a matter of weeks.

Q596 Dr Naysmith: It can take longer than that; sometime six months. That is a disincentive. Why can they not adjudicate much more quickly than that?

Mr Paling: I would have thought they would be able to adjudicate much more quickly than that. As I said, there is not a vast amount of complaints so there are not a thousand complaints sitting waiting. I would imagine that is something you would have to take up with the ABPI. I think if there is a complaint, particularly if it is going to be upheld, it should be adjudicated and sorted out very quickly.

Q597 Dr Naysmith: If one of your adverts was found to be misleading would you be penalised in any way or would this cause any problems for you?

Mr Paling: For our company directly?

Q598 Dr Naysmith: Yes.

Mr Paling: We have had a misleading advertisement through the ABPI and it created a great deal of difficulty between ourselves and the company concerned. Both of us had to be carefully audited and monitored to see how that process had occurred. It is important. Our relationship with our clients is a very important one and we do not want issues like that to get in the way, plus the fact that we do not want to be breaking the code full stop.

Q599 Dr Naysmith: Have you ever withdrawn from negotiations with a drug company because you felt that a campaign they were asking you to undertake might be unethical or misleading?

Mr Paling: No, never.

Q600 Dr Naysmith: Have you ever come across the need to argue or discuss that with a client, or you just accept it?

Mr Paling: Not at all, no. The ultimate responsibility for a campaign rests with the doctor inside the companies and I think they could not be more careful, stringent and totally honest with what they are doing in my experience and in the work we do, which is advertising sales promotion, as you know.

Q601 Dr Naysmith: Ms James, do you have anything you want to add to what Mr Paling has said?

Ms James: I would like to reiterate the seriousness with which the code of practice is taken by our clients and by ourselves. I was amazed to hear Dr Horton say earlier that it has no teeth, it is just words because that really is not the case. I have also noticed that over the time I have been in the business - over 15 years - that the seriousness in which it is taken has significantly increased. When I started in the business the code was a bit over there and although it was taken seriously the top directors would pay lip-service to how important it was and the product managers would just turn the other eye. Now that is most certainly not the case. Even the product managers now go in fear of breaching it.

Q602 Dr Naysmith: Why do you think that has happened?

Ms James: I think it is partly a societal trend overall in business. I think the whole trend of corporate social responsibility is having an effect and that effect is being felt within pharmaceutical companies just as in any other. That would be my first comment. I think also the regulatory situation is becoming tighter around the world and companies that start to get a bad reputation for breaching ethical guidelines are probably going to feel the heat from the regulators.

Q603 Dr Naysmith: Dr Horton, you were talking to the Chairman earlier on and you were talking about the rules that *The Lancet* has for conflicts of interest for authors and editors and reviewers. In general terms do you think your rules are effective? You told us about one example where you discovered that you were being deliberately misled about a paper, but do you think in general that they are effective and you can be sure that you are not publishing anything that you would not really want to be publishing?

Dr Horton: As you rightly point out, the system is voluntary; it depends upon trust; it depends upon good faith between ourselves and the authors who work with us. Clearly there is room for great exploitation in that relationship. I think that over the last four or five years we have made our procedures much more robust. We have changed the conflict of interest disclosure now so that you actually have to actively lie if you are going to deny that you have had a conflict if you have in fact had a conflict. We insist that we have a description of the role of the funding source in the research: did they take part in the design, the conduct, the analysis, the writing up and submission of the paper. We did not used to do that. We insist on the naming of all contributors to the paper including those who might have been ghost authors of the paper. I think within the voluntary nature of this we have done all that we can do. We have tried - that is the editors of journals - have tried to strengthen this and so the Committee on Publication Ethics that was created in 1997 was created largely out of a failure amongst us to persuade those in medicine at the General Medical Council and some of the other colleges and

organisations that run medical research that we need to actually go a step further and to create what we call the Council for Research Integrity. This is a body that is a place where complaints about the way research was done and reported could be taken to that had legal teeth. If you look in some European countries - particularly the Scandinavian countries - they have statutory bodies where these kinds of issues can be referred where there has been a breach of practice and sanctions can be made against individuals, against sponsors and against universities that have taken part in these malpractices. We have been singularly unsuccessful - our failure - to persuade anybody that we need such a body. There is great scepticism within the science community because they feel this would be another layer of bureaucracy and regulation and that is the last thing science needs. However, from where I sit we desperately need it because we do not have the teeth that we need to enforce these voluntary regulations.

Q604 Dr Naysmith: Do you think that similar voluntary regulations apply to other journals of the standard of *The Lancet*?

Dr Horton: : When the code was introduced about 1997 it was the *BMJ*, *The Lancet* and one or two other journals that came together to create this and we tried to draw in many other journals in the last five or six years to make them part of this process. Again, it only goes a small step of the way; this is really just a scratch on the surface.

Q605 Dr Naysmith: The point you made just now was a very good one. The last thing science needs is more bureaucracy and more regulation. Where do you feel the balance lies now, having laid out the case for it and then pointed out why it is not going to happen or is very slow to happen? What would you like to see happen?

Dr Horton: What we do not see is an office of research integrity like they have in the US, a huge superstructure of bureaucracy looking over science and interfering in the conduct of research. We do want something very light. There are models - and I would look to Norway, Sweden and the Netherlands as very good models - of lightweight oversight but which have some sort of legal statutory teeth. I think there are models that we can draw on and that is what I would go for.

Q606 Dr Naysmith: Turning to Ms Hope and Ms Rogers, are there any kind of voluntary regulations that apply to *The Daily Mail* and *The Sunday Times*?

Ms Hope: Speaking for myself I feel I have personal ethics that I abide by in reporting. I have been a reporter for a very long time and I am a trained reporter, but because I knew this question was coming up when I rang yesterday I specifically went and looked at the code of practice for the National Union of Journalists (of which I am a member) and I was delighted to see, for example, point eight: "A journalist shall not accept bribes nor shall he/she allow other inducements to influence performance of his/her professional duties" which I feel is just taken as read by journalists, let alone those who are members of the NUJ. Certainly in this context, talking about the pharmaceutical industry, I feel it is important to highlight and I can confirm that I have never personally felt that I have been unethically lobbied or offered a bribe or inducement to run a story or not run a story. I have to say

that I cannot imagine a drug company or a PR company would have the temerity or the stupidity to approach me with that kind of offer.

Q607 Dr Naysmith: You have never had such an offer?

Ms Hope: No.

Q608 Dr Naysmith: Travel or gifts or hospitality of that sort? Nothing like that?

Ms Hope: Do you think that going out to dinner with somebody is an inducement? I do not.

Q609 Dr Naysmith: I think many MPs would have difficulty answering that question.

Ms Hope: It is likely to go both ways. I take doctors out and I get taken out by doctors or occasionally by PR companies. For example, I had an offer to go to a dinner last month which I leapt at because sometimes PR companies run supper attached to a kind of educational programme - about an hour's worth of press briefing - and it was on heart disease and the Government's heart tsar was speaking. It is not often you get the chance to spend 20 minutes listening to him talking about heart disease and then questioning him. I leapt at it and so did other journalists on national papers and broadcasting organisations. I was also going to make the point about advertising that we should not lend ourselves to the suppression of truth because of advertising considerations. For example, I think I am correct in saying that ours is the only national newspaper that has actually written stories about the potential detrimental consequences of putting statins over the counter, of re-classifying them for pharmacy use. We were a paper that ran stories about how the Royal College of General Practitioners and the Consumer's Association had produced evidence that they were against this on safety grounds and other grounds. We ran stories about this on at least two occasions. It did no good whatsoever; it just went through on the nod as far as I can see. That is another opaque system that I feel you should address because we do not get to see the information on which these decisions have been made. It appears to me that new classification is now a big deal for the health service. It has all sorts of unforeseen consequences that may come from it. The point I am making is that we now run enormous full-page ads for statins that you can buy from your pharmacy. If I had given it one single minute's worth of thought and thought whether this would affect our future advertising if we wrote stories which actually ended up with statins not going over the counter, but it just does not come into your thinking and it would not do at our paper.

Q610 Dr Naysmith: Ms Rogers, do you share the opinions we have just heard from Jenny Hope?

Ms Rogers: Yes, I do but I do think that the issue of hospitality is one that should be looked at not just a propos of journalists but MPs even because the drugs industry does spend an enormous amount on it. As Jenny just said, there are often occasions when there are government advisors or people you cannot normally get to because the Department of Health is very protective about its advisors. All journalists have to go through the press office in a way which

is peculiar to the Department of Health; other government departments are less protective. If you want to speak to an advisor in an informal way often you might have to go to an event which is sponsored by a pharmaceutical company which they are also attending. I think you could argue that that is problematic, that the influence of the industry is so all-pervasive and tight.

Q611 Chairman: Ms Hope would not have gone to that function that she described - the dinner - had it not been for the fact that the heart tsar was going to be there.

Ms Hope: The fact that I am going to get something out of it, that is the point. It really was very interesting, I have to say. He made the point just in passing that you might be interested in, which is that he felt that heart drugs had got to such a state of good effect at bringing down heart disease and heart attacks that now studies were being devised that were aiming to produce non-inferior outcomes but with improved side effect profiles. I think this is a fascinating development, that you cannot now look forward in some areas of medicine to getting black and white answers any more.

Q612 Chairman: Lois Rogers is making the point that in a sense you are in the company of the industry.

Ms Hope: No, I have better things to do with my time.

Q613 Chairman: Let me finish the question. You are in the company of the industry and having the hospitality of the industry on the basis that that is a mechanism for you getting access to these people you would not otherwise have access to.

Ms Hope: I just think it is an added bonus. If I really pushed for it I could probably get to talk to Roger Boyle on the phone at some point but it is more interesting if he is giving a presentation where you actually have the opportunity to question him in company of other journalists which always has an impact on the kind of story you get. Also, it is public; whoever is running it, it is public forum. Other journalists are there and a story is more likely to emerge that you might be able to report on. I thought you were going to ask me I would have gone if it had not been Roger Boyle, if I just thought I was going to get a free supper" and quite frankly I have better things to do with my time.

Q614 Chairman: Of course; I was not going to say that. Lois Rogers was saying that she probably has access to special advisors at some function where the pharmaceutical industry is involved. That is the impression I got.

Ms Rogers: That is correct.

Q615 Chairman: It just struck me that that was rather strange that you could not get access to them without being in the company of the industry.

Ms Rogers: If you go big conferences around the world - the heart disease and cancer conferences in particular - I have often found myself the only person who is not in the thrall of one or other drug company. There will be all the leading specialists from around the world at these functions and every minute

of their time is timetabled by whichever drug company has sponsored them to go so you can hardly get to talk to them because they are going straight from the session on whatever to the drinks party to the white water rafting event the next day or whatever. It is like that. There are all these jolly activities that are bolted on to their whole stay in whichever resort it happens to be; they not necessarily resorts but they tend to ferry them out to nice places around wherever the city is. Every minute of the time they are there can be absolutely timetabled so you hardly get to talk to them.

Ms Hope: To pick up on a point that Lois was saying about access to people via the Department of Health, I can only concur that it is incredibly difficult. You just cannot get to speak to people there; you cannot get any sort of meaningful dialogue going from anybody involved in the drug regulatory system, for example. I am going to see Ken Woods next week and this is quite frankly an earth shattering occasion; I have never had access to the MHRA before. The only other time I have come into contact with the system, as I said in my written evidence, was when I was invited by Jeremy Metters - along with some other journalists - to comment on the yellow card system. A fat lot of good that did, quite frankly. The point is that there is some movement because the MHRA for example, is appointing its own press office, but it all comes back to the point that we have hardly touched on which is the regulatory system: how little access journalists have to the information being discussed there and how we are in an impossible position when it comes to looking at whether or not data has been corrupted by lack of evidence being put forward or it being distorted because we - and anybody else who asks to look at the data - just cannot get to it.

Ms Rogers: That is a very good point.

Q616 Mr Jones: We have heard what you have said about your reluctance to accept hospitality from organisations. We have three professions represented here - doctors, journalists and politicians - and there seems to be an inverse relationship in terms of public trust. Doctors come right up there; the only people below politicians in public trust are journalists but we appear to be the other way round in the way in which we accept hospitality. From the evidence we have had doctors seem to accept hospitality at the drop of a hat.

Ms James: Can I make a point on behalf of the advertising and PR profession which you did not mention.

Q617 Mr Jones: I assumed everyone understood you were below journalists.

Ms James: I like and respect Lois very much but she must have been to different conferences than the ones we run. The code of practice that we abide by now precludes any excessive entertaining of the sort of white water rafting, glossy resort hotels and all of that. I would concede that those kinds of activities were more common place in the past but now we have very strict rules that we abide by: no spouses are paid for; no accommodation is booked in four and five star hotels; no accommodation is booked in any kind of spa or resort type of hotel. The guidelines for entertaining costs are: lunch, no more than £30 a head; dinner, up to a limit of £70 a head. These are very strictly supervised by our clients. I appreciate I am saying something which is in direct contravention to what you have heard, but that is our experience and we are one of the biggest companies laying on this kind of conference and

events. I am quite happy to send you after this meeting typical examples of conference programmes so that you can see for yourselves.

Q618 Jim Dowd: I am sure that is true from your end of the operation but we get too many reports from the way that companies operate themselves for them all to be simply disregarded and I think there is a difference there. If you could send us an outline of the programme it would be very helpful. I want to move on now to direct to consumer advertising particularly of prescription drugs, drugs that can only be obtained through a general practitioner. Certainly we had evidence - very alarming evidence - of how this works in New Zealand and it is also prevalent in other parts of the world. Is it your view that this is opening up information to the lay person and to the man and woman in the street in the face of professional jealousy, the gatekeepers wanting to keep all the information to themselves and this is actually a liberating feature for ordinary citizens, or is this going to lead to disease mongering, to over-subscription, to increased prices and to a perversion of the prescription market.

Ms James: Are you suggesting that that is going to happen in the UK?

Q619 Jim Dowd: I am trying to assess what the effect might be if it were to; it does in the US and there is similar pressure on the EU to accept it. I do not want to argue about it; I just want to know what your assessment of it is.

Ms James: I will give you my assessment of it; it is an individual point of view and the pharmaceutical industry in the most part is actually now against bringing in this form of advertising into the UK. They might have had a more open mind about it a few years ago. I sat on the ABPI's informed patient initiative task force which looked at this issue for four years. There is no appetite among pharmaceutical companies for bringing that kind of advertising to the UK. My own opinion of it is that largely I think it has had a positive health effect in the US. The most recent FDA research was actually published last month and it showed that by and large the public (they interviewed doctors and patients) felt that it did prompt them to seek information. Most of the information that it prompted them to seek was actually about side effects and risks rather than benefits - which questions the competence of the advertisers, possibly - by quite a large margin. On the benefit:risk ratio 60 per cent of the public felt that the advertising did not provide enough information about risk which might explain why they sought the information independently. However, 44 per cent did say also that it did not provide enough information about benefits. In terms of the doctors' viewpoints, slightly under half - 41 per cent - said it was beneficial and only 18 per cent said it caused problems. I think that the main benefits really are that people get more informed about diseases and both professionals and patients are able to enter into a more productive dialogue as a result of the DTC advertising in the States. I think it has also had a positive effect on prescribing. I know that the branded advertising that AstraZeneca did for tamoxifen over there led to doctors getting up to speed on the benefits of that drug as well as patients asking about it.

Mr Paling: I think something else that came out of that research was that the FDA concluded that it had had no noticeable increased effect on prescribing. I know that is very difficult to judge because there is no control on that, but I think that was the biggest worry, that it was having an increased effect.

Whether, in the long run, even in the United States, this will be seen as a good way forward I personally doubt. I am certain that we will not have it in the UK and that was definitely not the intention of the ABPI.

Q620 Jim Dowd: If it is being contended that the US experience is beneficial to the patient why should British patients not benefit similarly? Why is the industry against it? Given the fact that the people who are advertising in the USA and New Zealand are the self-same drug companies who would be advertising here, why do they think it is a good thing there and they will take part in it and something they would not want to see here?

Ms James: I think there are two possible reasons for that. One reason is that they do not see that it is possible for it to happen here. We have a very difficult healthcare system in Britain compared to the US. Some of the disease areas which people have become much more conversant with as a result of DTC advertising and some of the under-treatment that existed in those categories has been removed or certainly improved so that where patients were not getting decent treatment for high cholesterol or schizophrenia, for example, they now are because they are informed. I think that the companies feel that that would obviously have a cost implication because statins are more expensive than doing nothing; atypical anti-psychotics are more expensive than the dreadful old therapy which provides awful side effects. I think the companies accept that there is an issue in this market with what I have just described. The second reason I think that some companies - not all perhaps - are reluctant is because it is costing an awful lot of money in the United States. The cost of consumer advertising is much more costly than representative and professional advertising and I think quite a few of our clients do not want it here.

Q621 Jim Dowd: That has also impacted on driving up prices to the consumer in the US.

Ms James: There is no evidence of that at all.

Q622 Jim Dowd: Where do all these costs go? Do they just disappear into the ether?

Ms James: If a patient was not on medication that he/she needed before and thanks to the advertising and the dialogue with the doctors they now are, that is obviously an add-on cost. That does not mean that the price of the treatment has increased.

Q623 Jim Dowd: Presumably someone has to pay that somewhere.

Ms James: In the States it is a different system. It is based on insurance and co-payment. Obviously the patient is bearing more of a brunt of that cost than the patient is here where most people are on free prescriptions.

Q624 Jim Dowd: Is this not at heart just an attempt by the pharmaceutical companies to recruit the patients into their promotional campaigns by increasing pressure on prescribers?

Ms James: I think from all the transcripts I have read from your debates I think what I detect is an inability to see that an action can have two

consequences. It can improve public health and be to the public good and it can also provide a return to the shareholders of the pharmaceutical companies. The example of patients being better treated in the States is an example of just that point.

Q625 Jim Dowd: Is that a general point on the work of this Committee?

Ms James: No, just some of the transcripts I have read I have felt there was a reluctance to accept that an action can be to the good and be also profitable.

Q626 Jim Dowd: The premise of this whole inquiry is that the pharmaceutical industry in this country at least are a genuine legitimate business. We do not dispute that for a moment; they have shareholders and they have the right to make money. Certainly one of the cases from the New Zealand experience was a completely manufactured condition that nobody was complaining about before: bladder incontinence. They alleged it was incontinence; they said, "Are you going to the lavatory too many times a day? If so, you need this drug."

Ms James: Are you suggesting that does not exist?

Chairman: Of course incontinence exists; I think we need to clarify this.

Q627 Jim Dowd: What I am saying is that they introduced this problem by direct marketing to patients telling them to go to their general practitioners and demand this drug and even giving them a free sample. They showed the rate of consumption of this drug; the rates of consumption went up enormously. The effect it had on the condition was zero. People had not even asked their general practitioner about this being a problem before and it was done entirely to inveigle the patient into the position of marketing on behalf of the drug company. That is the great danger.

Mr Paling: Often patients do not go to a doctor if they do not think there is a treatment available. Erectile dysfunction would be a very good example of that. To me the bigger issue is that if you take a country like the UK and the way we treat and compare it to the United States - even to other European countries like France - there is serious under-treating of very, very important conditions (diabetes would be one very good example) because we do not have such a level of contact between the patient and the doctor. Our treatment is therefore not so early; it is not so aggressive in terms of treating the disease and I think that whoever creates it or whoever does it there is an important need for further information. I am not talking about branded pharmaceuticals, but we need to get more information to the patient to understand conditions (a) that they might have them and (b) that they should seek medical advice. Then the doctor can decide if they have to have treatment. The numbers suggest that there are 300,000 diabetics in this country at large who have never seen a doctor and never been treated. That, to me, is a really worrying concern.

Q628 Jim Dowd: There are many things that are very worrying; what is also worrying is if you try to tell somebody that they are ill without them knowing it because you have a treatment for them.

Mr Paling: If they go to the doctor the doctor will tell them they are well.

Q629 Jim Dowd: These are people who were not presenting with this condition before.

Ms James: I do know about that condition in terms of this country - I do not know about the New Zealand example that you have quoted - and a great many people over the age of 40 do suffer from incontinence and I know one of the pharmaceutical companies did undertake research about four years ago of a population of women over the age of 40 and also general practitioners and they found that a large number of women - I cannot remember the exact numbers - did have this problem, it really did bother them and they were too embarrassed to consult their doctor about it. When the company did the research with the general practitioners they found that 90 per cent of general practitioners were too embarrassed to mention the problem as well. So this is the role for the pharmaceutical company, to bring these things out into the open and give patients hope.

Q630 Chairman: No-one would deny what you have just said as being a problem. Women with childbirth implications obviously understand that. What was a concern in New Zealand - we have not explained it fully because it was quite detailed - was the way in which a problem had been created that did not really exist. It was implying that if you went to the loo so many times a day then that was abnormal when, in view of people objectively, most medics would say it was not abnormal. What Jim was saying was that an apparent abnormality had been created in the interests of a particular company when a problem did not really exist. That was the difficulty.

Ms James: I suppose you are saying that it was exaggerated.

Q631 Mr Jones: If there is a problem and it is medically treatable and that sells X amount of drugs, if you widen the market out so that you include in the range of abnormality a large part of what would then be the normal population you would increase the market for the drug.

Ms James: This is a very bad strategy commercially because all you do is you get a lot of people in, you treat them, they go away, their lives are unchanged and your drug gets a bad name. Most of our clients would not want to do that for that very reason.

Jim Dowd: The point was that they can behave in this fashion because DTCA is available. That is when they said, "Go to your GP and get a free sample" and they used DTCA precisely to generate this. Anyway, I have gone far enough on this point.

Q632 Dr Taylor: Can I just go back to Ms Hope for a moment. I am afraid it highlights a paper that I do not read for which I apologise, but do you say that statins are being advertised with whole page advertisements?

Ms Hope: Yes. This is now appropriate because one statin has been granted approval to go from prescription only to pharmacy and it is just a start, really, of a whole lot of things that are going to be rolled out.

Q633 Dr Taylor: Are these sorts of advertisements appearing widely in other newspapers as well?

Ms Hope: Yes, it is consumer press that we can now run these. There have been some surveys carried out - which I am sure you are aware of - since this happened in July showing that some pharmacists are giving inappropriate advice and also highlighting a conflict of interest between pharmacies offering cholesterol testing with a statin next to it. I think there are real concerns about this and we do not really know what led to this decision to free up the market because we do not have access to the decision-making information that was in front of the authority but against the advice of, for example, the RCGP, but it also coincided - as you will be aware - with the extension of the patent (if you like, in quotes) on the statin concerned from six months to a year when this particular statin cannot be challenged in the market place. A cynic like me might think that this is a very interesting development that you can now move your statin which is out of patent in the prescription market into pharmacy only medicine and get a year's worth of protection.

Q634 Dr Taylor: I think we are aware of that and are looking into it. Can I just go back to Dr Horton? Advertising revenue: does that depend from any companies on the publication of articles or are they completely separate? If you refuse to publish something do they then withdraw some advertising revenue?

Dr Horton: I do not know of any instance of that, but what I do know is where journals have published critical editorials of a particular company or industry and an advertising has been withdrawn from those journals which has precipitated a crisis within the publication where the editors have got sacked or there has had to be some whole scale change in the way the journal is organised. For those journals that depend upon advertising revenue very much advertisers are key constituents for that journal and they wield enormous power in shaping the agenda of that journal. The example I am thinking about is the *Annals of Internal Medicine* which published a few years ago an article very critical of industry and advertisers just withdrew their advertising whole scale and two very well respected editors were sacked.

Q635 Dr Taylor: Do you actually vet the advertisements?

Dr Horton: Yes, we do. I think we are very lucky here because the advertising that gets submitted to *The Lancet* goes through the commercial department of *The Lancet* and then it comes to the editorial department and we apply criteria to adverts as much as one can in the same way that you look at research articles. Actually, *The Lancet* does not have a massively high circulation so we do not publish huge numbers of adverts; it is not such a difficulty for us.

Q636 Dr Taylor: Going back to Ms James, your website produces evidence that campaigns actually work. I think the quote is that your work can "independently increase sales". What is the evidence behind that? What is the evidence that promotional campaigns work?

Ms James: It is difficult to demonstrate a direct link with sales and we do not do so very often. The reason it is difficult is because there is so much going on in any particular market that to pinpoint your own activity and pull it out and demonstrate that patients have had better treatment because of what you have done is difficult. There was a campaign we ran last year for increasing the uptake of flu vaccination and I think that we did demonstrate

an increase; certainly over 200,000 who were not planning to take up the vaccination took it up as a result of a huge publicity campaign that we ran. There was not too much else going on in the market so we were able to demonstrate that that was a success that was driven by our campaign. For the most part, the way we evaluate and monitor our programmes is more to do with benchmarking awareness levels: has our campaign increased the awareness of a particular problem or a range of solutions or have doctors become more aware?

Q637 Dr Taylor: How would you assess that they have become more aware?

Ms James: We sometimes undertake benchmarking before a campaign starts so that we might research medical awareness and views of a particular area of medicine or treatment or a message that we want to get across and then after a series of activities we would undertake the research a second time and we would monitor the difference. Again it is difficult because you are not the only player in the communications mix.

Q638 Dr Taylor: What is the response rate to questionnaires from general practitioners about those sorts of activities?

Ms James: You obviously have to provide a financial incentive and as long as that is appropriate to the time that it takes you can usually get quite a substantial response, probably a good 20 per cent if it is appropriately remunerated.

Q639 Dr Taylor: Ms Rogers, in your memorandum to us you say, "*The British Medical Journal* itself is distributed free to doctors in Britain because it is subsidised by the drugs industry." I remember paying a whacking subscription to the BMA which included the *BMJ* so it is not quite true to say that it is distributed free, is it?

Ms Rogers: I do not know whether the subscription that you pay to the BMA would cover the production costs of the *BMJ*. I do not think it does.

Q640 Dr Taylor: It is a lot more than you have to pay for *The Lancet*.

Ms Rogers: Yes I know, but you are belonging to the BMA and you are supporting the editors of the BMA principally rather than the journal, I think, which is a fairly enormous operation employing a large number of people with regional offices.

Q641 Mrs Calton: Can we move on to contact with patient groups and professionals? Ms James, the Shire Health Policy Unit is involved in - and I quote - "health policy intelligence gathering and lobbying". Could you explain what this lobbying involves? Is this an important part of the work of medical communications companies?

Ms James: Lobbying is a very small part of our business. The example that first leaps to mind is a campaign that we undertook in the late 1990s on behalf of a drug called Taxol which was a new treatment at the time - or relatively new - for cancer. It was not funded by the majority of health authorities at the time so we brought our expertise at a local level to deploy a series of meetings around the country in the areas where we knew women were

being denied the treatment of Taxol and we would get together a local oncologist, some interested general practitioners and a member of a patient group (I cannot recall which one it was, it was probably Backup but I could not be sure about that now). We would then have a meeting and invite the local press to attend a press briefing at the end of it. We would write up the outcome of the meeting and use that in a series of one-to-one meetings with key decision makers with the then local health authorities. That campaign was combined with a lobbying campaign here in Parliament as well. There was a lot of activity trying to make MPs aware of the benefits of better treatment for breast cancer and how this was being denied at the time. That is a typical example of a quite all-embracing lobbying campaign. For the most part our relations with patient groups I would not describe that as lobbying; I would describe that as a meeting of minds about a particular condition, what the patients' needs are. The patient groups are obviously expert and I think they will help companies put across very appropriate and very balanced messages about a particular disease. We will help them with a lot of research and communication skills and so forth. The moment that relationship gets out of kilter it is a disaster; you cannot try to influence the patient groups to think a certain way about a condition. Any patient group worth its salt - and I am talking about quite small ones as well, not just the big ones - will not wear that.

Q642 Mrs Calton: Could we just explore this a little further? I am aware as an MP that I frequently have people coming to my surgery who are my constituents who are, nevertheless, asking questions about specific drugs or whatever. As part of your lobbying package, if you like, of all of the different things, would you encourage members of patient groups to go and see their MP to raise this issue; to raise a particular issue about a particular drug that you were working on?

Ms James: Very rarely. I would not say that it did not happen, but it is certainly not commonplace. I suppose our motivation really is to inform patients such that if they have questions in mind they visit their doctor rather than their MP. There are conditions, I suppose, when it is funding related that I could imagine companies would do that, but I do not myself have personal experience of it.

Q643 Mrs Calton: Could I go back to the original question which I asked about the health policy intelligence gathering. The Shire Health Policy Unit states that it is involved in health policy intelligence gathering. Could you tell us a bit more about that?

Ms James: Yes, it is straightforward monitoring of public health policies so, for instance, when the national service frameworks came out we would make sure that we were very much in touch with the advisors to the Government on those implementation task forces. Where vaccine policies are concerned we would make sure that we are in touch with advisors so that we know where Government priority is going to be and that way we can advise our clients. If any of our clients have an interest in helping the Government reach its targets then we would bring that kind of information to our client's attention and work with them to see how best to capitalise on the opportunities.

Q644 Mrs Calton: How would you go about gathering the health policy intelligence? How does that work?

Ms James: An awful lot of it, to be honest, is available on the internet. The Department has a good website that issues names. A number of these doctors are known to us anyway. We would make contact with them; we would discuss the way things were going, what sort of priorities were going to come out. It is not in any sense to manipulate the agenda, it is more to find out what is going on so that if our clients, for instance on the elderly side, have anything that would be really beneficial in helping the Government attain those targets then obviously there will be a pay off for the company as well. It is a case of getting intelligence and using it appropriately.

Q645 Mrs Calton: Mr Paling, would you say it is fair to say that the core of your business involves promoting clients' brands by stimulating demand through authoritative third parties such as patient organisations or leading healthcare professionals?

Mr Paling: We do not work with patient organisations and have never done except with one exception which was on some disease awareness work which I mentioned in my submission for erectile dysfunction. The bulk of the work we do - which is paid-for advertising or sales promotion - is very clearly branded and it is a branded message that we have developed as part of the process of deciding how to present and offer the product to the doctor which would primarily be a general practitioner in most instances.

Q646 Mrs Calton: So you would not say that you are involved in stimulating demand.

Mr Paling: Advertising and promotion is there to do a number of things. It is there to raise awareness first of all of a drug, particularly if it is a new drug or raise awareness of an issue that might be a new indication or a new piece of information for instance. In that sense we are part of the process of taking the information on the products we work on to the doctor. That could result in him changing his practice from one treatment to another. If it were a treatment that he was not particularly aware of it could start him using that treatment in isolation. The way that all advertising works - the advertising to doctors and the advertising to the general public - has many similarities. The difference is in tone and approach and the content of the information that we give to a doctor is not the way you would sell or the way even we in our work would work with Johnson & Johnson baby products to a mother; it is a very different relationship, a very different tone and a very different dialogue and approach.

Q647 Mrs Calton: What about yourself, Ms James? Would you say that you stimulate demand via the vehicles of patient organisations or leading healthcare professionals?

Ms James: I think what we want to achieve is improved management of the conditions that our client has an interest in. I think, whether it is a happy coincident or what - I do not know - that 90 per cent of our clients I would say have products which are really going to improve opportunities for patients. We seek to inform opinion leaders and get their views as well. Sometimes clients are over-ambitious with their products and the intelligence we gather from opinion leaders reveals something of a gap between the clients'

aspirations and what the opinion leaders feel is an appropriate goal and at that point we will go back to the client and say, "Look, doctors are thinking that this treatment has a place, but it is not perhaps the sort of place in the sun that you were hoping for". A dialogue will take place and very often the brief will change and will moderate. What it is about really is getting more awareness of the potential of treatments and informing patient groups. Patient groups will have their own views because they will have members perhaps who have been on clinical trials and will be reporting anecdotally. They will see the peer review evidence as well. They will have their own views. Similarly they will inform us. It is not really as crude as to say "stimulating demand". I think it is partly because the drug development process is so slow. You might hear news of a product that is a major breakthrough and that kind of news will stimulate demand and quite right too. However, it is the exception, not the rule.

Q648 Mrs Calton: Would you say your work involves any form of relationship that the public might conceive as improper?

Ms James: No, I really do not. I think in any commercial relationship in the healthcare business there is always a potential for something improper, but I think that the checks and balances work in such a way as to preclude that from being a possibility.

Q649 Mrs Calton: Do you believe that drug promotion through disease awareness campaigns is a good thing? Are there any aspects of this type of campaign that concern you or that you think might have negative effects? Could I start with you, Ms James, and then move on to others?

Ms James: I think for the most part they are a very good thing, yes. I think without them patients would be in the dark on so many conditions. I have the benefit of quite a lot of hindsight now and I can remember the introduction of statins for the treatment of cholesterol in this country. They were introduced in 1989 and for the first five years of their life the *BMJ* led a vociferous campaign to undermine them, claiming that cholesterol was not a risk factor for heart disease at all and that drug companies were manipulating and stimulating demand for something that people did not need. Looking back it was quite scandalous. This is not the only example; I do not have time to give you all the examples. A lot of people did die unnecessarily from that misinformation but many more would have done. I think we really do need the pharmaceutical industry appropriately regulated to bring out some of these things with a kind of "not invented here" syndrome that attacks them at every turn. It is the same thing in schizophrenia, in cancer. These public awareness campaigns are a vital source of good public health. They do need to be properly regulated and I accept sometimes the case you outlined from Australia sounds most unfortunate and I am sure they do exist, but in a very small minority of cases.

Q650 Mrs Calton: Does anyone else want to add to that or put a different point of view?

Mr Paling: I do not think anybody would disagree that we need to increase the level of public awareness on general health issues in this country. It is the view of the public - it is certainly the view of the Government - and I think that is very important. Like Margot, I think the industry can have a large

part to play in that partly because to do it would cost money and that perhaps is part of the reason more has not been done before. I think if it is harnessed in the right way there are rules and checks and regulations and they should be adhered to. I think it is very important that we are able to communicate with the public. I would rather - particularly in a condition where somebody has diabetes or whatever - that ten patients went to the doctor who did not need treatment than one missed it who did and subsequently could be in a far more serious situation because they had not received treatment. Having said that, with our limited experience I think it is quite surprising how hard it is through disease awareness to actually get patients to go to doctors. Maybe that is a British thing; maybe it is the condition that we worked in (which was basically middle aged or older men who do not like going to the doctors) but it is not simple to do that. It is a hard task; it takes a lot of time and money.

Q651 Mrs Calton: Dr Horton?

Dr Horton: I think if you are looking at disease awareness campaigns amongst doctors, let us be real: this is about selling drugs. We had a paper submitted to us about a disease awareness issue. It was submitted to one of *The Lancet's* speciality journals, *Lancet Neurology* and in the process of peer review of that paper the company was trying to negotiate a reprint sale and the e-mail from one of the communications companies that the pharmaceutical sponsor had hired read: "As I am sure you can appreciate the more reviewing that is done on the papers" (that is the papers that were submitted to *The Lancet*) "the less value the ultimate publication will have to Sheering as the information on Sheering's products becomes more and more dilute." So let us have a reality check on the purpose of disease awareness campaigns. This is about sales; it is not about disease awareness.

Ms Hope: I recognise that disease awareness campaigns will at least indirectly benefit drug companies. I probably think on balance they are worth while because of the information gap in this country between the way that people get information about drugs from newspapers and doctors and the fact that it is very hard in the middle when you are diagnosed with something to actually get more information easily. It is a fine line with disease awareness campaigns because you cannot advertise prescription medicines directly to the public in this country and this is a way, if you like, of - in quotes - getting round it. You could argue the same with celebrity endorsements that are carried out of a disease whereby somebody who has got a disease talk about it because they want to raise awareness which is all well and good, but they may well be being paid to raise that awareness so I take that into account when I am actually looking at something that is being offered like that, but I think on balance people would like to read about a famous person who has a disease.

Ms Rogers: I would say it is highly arguable whether they have any benefit at all. It is an almost daily irritant. A PR person rings me to tell me about a disease awareness campaign and I think where disease awareness campaigns end and disease mongering begin is a very indistinct line and I think that in general if people are ill they know they are ill and they go to the doctor. Disease awareness is basically selling more drugs to people who do not necessarily have anything wrong with them.

Mr Paling: I think there are many illnesses where a patient certainly would

not know they were ill unless something was pointed out and therefore they went to the doctor. At the end of the day the doctor is in a position to decide, surely, if a patient needs treatment. If it is not a sick person the doctor is not going to give out a drug anyway.

Q652 Dr Taylor: We have heard a great deal about the length of time it takes for a drug to be developed. At what stage does a company like yours get involved with the process, with the planning of publicity?

Mr Paling: Over the years that I have been involved with the pharmaceutical industry I think it is fair to say that that time period has shortened quite dramatically. Twenty-years ago it probably would have been a year or 18 months and all sorts of development was being done relating to the product. Right now I would say it is more likely to be five or six months.

Q653 Dr Taylor: Five or six months from what stage?

Mr Paling: Five or six months from the point where an advertising agency would be appointed by a pharmaceutical company to a point where a product might be launched.

Q654 Dr Taylor: So five or six months before the launch.

Mr Paling: Yes, that would be more normal time now; six months probably.

Q655 Dr Taylor: I think we are all extremely keen to make this report fair. Something that Ms James said implied that reading through the transcripts before it has been heavily loaded against the industry. This is because we have not really had much evidence from the industry yet. Mr Paling, right at the end of your written evidence you say you have been proud to work with the pharmaceutical industry and in your opinion it does behave ethically in its dealings with the medical profession. Yet we have these tremendous criticisms coming. Would any of you like to summarise the criticisms that we have heard in a very few words?

Mr Paling: I think part of the reason I feel like that about the pharmaceutical industry - and I have been in or around it now for 35 years - is the incredible difference that the industry has brought about because of its medications. I do not think anybody would deny that and I know that this Committee does not deny it in literature and information I saw at the beginning of this inquiry. I think what is unfortunate is that starting from that base the industry does not have the best possible reputation it could have of any industry in the country. I do not think by any means the reputation is dire and there is a piece of research that MORI brought out last year which showed the reputation of the industry was much better than most people who have been in front of you in the last few months would feel. I think there needs to be a more open attitude. I think there has to be more transparency in certain areas and the way that we present ourselves to the doctor I feel is ethical and open. I feel that in the areas we work in - and I am sure Margot would say the same thing - everybody is tightly governed by a code; that code is part of how we behave as well, we are part of that process. Everybody knows the code; everybody is trained to the code and I think it is rigorously applied and is stringent and strong.

Q656 Dr Taylor: Could I ask each of you for one sentence of the main criticism? Is that fair?

Ms Rogers: I would respond to that by saying that I think the Government could help to improve the reputation of the industry by assisting the likes of us - Jenny and myself - with information when we ask for it. It recently took me ten days to get information on adverse drug reactions on a particular group of products; that is ten days of daily telephone calls. This is on a database and they obviously are withholding it from the press. That is not the first time it has happened. If you ask about adverse reactions to drugs it is sort of deeply confidential, sensitive information and the impression that you are automatically given is that somehow the Department of Health is assisting the manufacturers in withholding information. It is not conducive to us thinking that everything is all right in the pharmaceutical industry.

Ms Hope: I would completely agree with that and say that the whole point of going to the Department of Health is because we are concerned about drug safety not because we are going there to get a puff or a drug. We still find it hard to get information.

Dr Horton: In one sentence it is hard, but I would say that the practice of medicine and the delivery of healthcare have become overly dependent upon the pharmaceutical industry to the point where the integrity and validity of medicine and science is being compromised and risks being compromised further.

Ms James: Are you asking me to summarise any criticisms?

Dr Taylor: If you have one, your main one in one sentence. If you do not have one and are full of support, great.

Q657 Chairman: Can I ask a final question which might help you? In a sense Richard Horton referred to his views on this some time ago where when we try to strike a balance between the commercial imperatives and the public health good it is a tricky area and this is at the heart of this inquiry which I am sure you all understand. Richard Horton was talking about some kind lightweight oversight with legal statutory tests. I do know whether you have any thoughts on this as to what might be that key conclusion as to where this tension could be resolved and some of the issues we have picked up today addressed in a way in which the public can have some confidence.

Ms James: I think that the tension between the public good and the commercial interests have to be resolved in the regulatory process. From what I have read there is a need for a greater transparency of the regulatory process. There have been various recommendations to you of a way of tightening up the process of clinical trial publication so that absolutely every trial embarked upon has the potential for publication. Most are published and a lot of the time they are not published because they are not deemed of interest for quite genuine reasons. Where there is any scope for a trial that does not give the desired outcome to be suppressed that shocked me; it had not been in my consciousness before. If there is any potential in the system for that to occur then that should be regulated out.

Mr Paling: I would agree with that entirely. That was the point I was making

about transparency before. I think through this process I have also learned a few things and that is one that I was not aware of. I think that is important and I think there are firm moves within a number of companies - we heard that from Sir Richard Sykes - that that should happen; I am sure that will happen and I think that is a very good thing.

Ms Hope: We need to know how decisions are arrived at as to whether a drug gets licensed or not and why and what the evidence was upon which that was based.

Q658 Chairman: Transparency is crucial.

Ms Hope: Yes, exactly. Then you can market these things because we know that they do work.

Ms Rogers: I would concur with almost everything that everybody else has said. I think that the regulatory process needs to be far more transparent.

Chairman: Can I place on the record the Committee's thanks to all of you for an excellent session and for your written evidence which has been most useful. We are very grateful to you for coming along today to take part in this inquiry. Before we conclude, can I just say that after this meeting we are loosing the most important member of our Committee, Anna Browning, who is our Committee Secretary. I would like to place on record the Committee's thanks to you for your work over many years. You are a very key figure in our Committee's work and we appreciate everything that you have done. We wish you well in your retirement because you retire at Christmas. We thank you for all your work. Can I also wish everyone the compliments of the season; this is the last meeting before Christmas. Thank you very much everyone.