Randall's Parliamentary Service

The Influence of the Pharmaceutical Industry

November 11, 2004

Interviewing Members:
Mr. David Hinchliffe (Chair)
David Amess
John Austin
Patsy Calton
Jon Owen Jones
Siobhain McDonnagh
Doug Naysmith

Witnesses:
Dr Iona Heath, Royal College of General Practitioners
Professor Tim Kendall, Royal College of Psychiatrists
Matt Griffiths, Royal College of Nursing
John D'Arcy, National Pharmaceutical Association
Rob Darracott, Royal Pharmaceutical Society of Great Britain
Richard Nicholson, Editor, Bulletin of Medical Ethics

The session commenced at 10:30 AM and concluded at approximately 1:00 PM.

Committee Chairman David Hinchliffe welcomed the witnesses and asked for general comments from them on the mechanisms that members of their organizations and the health provision community had to deal with the influence of pharmaceutical industry.

Dr. Heath said that many GPs faced the problem that most major conferences were funded/sponsored by pharmaceutical companies. There is also a problem in unrealistic expectations about the cost of postgraduate and continuing education for doctors.

Mr. Hinchliffe asked if she agreed that 90% of continuing education is paid for by pharmaceutical companies (as mentioned by a witness in a previous meeting of this committee).

Dr. Heath said that she did not agree with that number, there is a whole range of funding sources. The primary area of sponsorship was in funding of large conferences. Postgraduates now are not often dependent on corporate funding. This represents an improvement. Some GPs do fund continuing education from pharmaceutical industry money, but not 90%.

Mr Hinchliffe asked about dining out (mentioned as a problematic source of influence by a previous witness).

Dr. Heath said that the GP who is constantly dined by drug company representatives is an unrealistic caricature. The Royal College has guidelines that attempt to link sponsorship from pharmaceutical industry with content of educational material for GPs.

Mr Hinchliffe asked if this system worked well.

Dr. Heath said that it works to a point; dependence on the pharmaceutical industry for large conferences is regrettable, though the content influence had been limited.

Mr. Jones asked what the point of sponsorship would be if there was no influence.

Dr. Heath agreed that this is a problem and said that sponsorship had fallen from limiting influence on content. There is also less sponsorship of conferences with limited relevance to sales of pharmaceuticals.

Mr. Griffiths said that the exhibitions at conferences raise money without effecting content. He also noted that many nurses pay for continuing education themselves, or receive education through higher education institutions. He said that where pharmaceutical companies do provide continuing education it is checked for its objectivity.

Mr Hinchliffe asked if the situation had changed at all with the increasing role of nurses in writing prescriptions.

Mr. Griffiths said that there is a rising emphasis on nurses, but a great deal of work is going into limiting influence on content of educational materials for nurses from the pharmaceutical industry.

Mr. Kendall said that he noted that there is some concern that 5% of the funding for the Royal College of Psychiatrists comes from the pharmaceutical industry. Some are opposed to this funding source, but some think it is a good thing.

Ms. Calton asked, in reference to testimony from a previous witness, about the influence based on personal contacts and relationships.

Dr. Heath said that this does exist. She and her colleagues do not see pharmaceutical reps, but some doctors do.

Mr. Kendal said that he also refused to see pharmaceutical reps, but that many were obviously influenced. A problem arises from the fact that many drugs are similar and doctors will prescribe the one sold by the representative closest to him/her.

Dr. Nicholson said that the ethics committee does not take funding from the pharmaceutical industry and that interested parties are required to withdraw from discussions to avoid conflicts of interest; interests are registered and noted for reference.

Dr. Darracot said that interests are also registered in discussions at his organizations. An example of a potential conflict of interest is a pharmacist who had served as consultant to the pharmaceutical industry.

Mr Hinchliffe asked Dr. Darracot if contact is growing with the pharmaceutical industry.

Dr. Darracot said that contact is growing, but that it is still ‘early days.’ He said that there are codes for acceptable practices and codes separating sponsorship from content. His organization publishes independent advice from pharmacists.

Mr Hinchliffe asked how aware Dr. Darracot is of influence on GPs in deciding prescriptions and asked if his members had raised concerns to this effect.

Dr. Darracot responded that where there are good, joined up relationships then the pharmacist would be more aware of the decision making process of the GP. He said that his members had not raised concerns about undue influence of drug company representatives.

Mr. D’Arcy said that pharmacists keep an arms length from the pharmaceutical industry. When there are issues of attempted influence his organization took it up with the company, but issues are rare. The role of the pharmacist was to provide the right drug at the right time and that it was used properly. Now they are taking on a wider public health role as a part of a health provision team. They are bound by a code of conduct and do their own CPD, though they sometimes use industry material, but this is appropriate since the companies who produce the drugs also test them and know most about them.
He stated that there is not much ‘hospitality’ from the pharmaceutical industry, but some at conferences and events and that influence was more from general marketing. The power of prescription would create more problems of influence for the profession, but the commitment to ethics is very important to pharmacists.

Mr. Jones asked if there are examples of inappropriate influence and if there are none did this mean that the code of conduct was working perfectly or that there is no influence.

Mr. Darracot said there have been cases where pharmacists were involved in over-prescribing drugs, but that these were issues of narcotic drugs for profit, not of pharmaceutical company influence. He emphasized the point that this is early days.

Mr. Jones asked if there are mechanisms to see if information used by pharmacists is balanced.

Mr. D’Arcy said that information comes from a variety of sources including academics, industry, manufacturers and the pharmacist’s association. Some of the information from the industry is good and some is propaganda, but pharmacists are pretty good at differentiating and his organization occasionally tells pharmaceutical agency that the information they provided is not useful and would be tossed.

Mr. Jones asked if the code of conduct required that pharmacists do good, and not just avoid doing harm. He then asked that if all medications they prescribe are effective for treating a definite health problem.

Mr. D’Arcy said that pharmacists do more than sell drugs, they assess medications and do not prescribe them if they are not effective. This is expressly in the code of ethics. He also said that if medications are licensed, it meant they are effective.

Dr. Kendall responded that the licensing process is in fact more concerned with safety than efficacy and that everyone was dependent on published information and trials are not published.

Mr. Naysmith asked if pharmacists report problems.

Mr. D'Arcy responded that they are reported when seen.

Mr. Naysmith then asked if the reporting scheme is working.

Dr. Darracot responded that a quarter of all reports are now coming from pharmacists, but that further information on medications is necessary for the Yellow Card scheme to work and pharmacists should have access to information on drug trials.

Mr. Naysmith noted that the Yellow Card scheme is voluntary and asked if that is functional.

Mr. D'Arcy said that for now, in the early days, voluntary reporting is OK.

Dr. Heath mentioned that patients should be allowed and encouraged to report through the scheme as well.

Mr Hinchliffe asked if "disease-mongering", or exaggeration of the notion of abnormality, as had been discussed in earlier sessions, is in fact a problem. He noted that the generation of health anxiety is clearly in the interest of pharmaceutical companies. He asked if there is anything pharmacists can do about this problem and noted that there seems to be a growing expectation among patients that they leave health consultation with a prescription for something.

Dr. Heath said that nowhere near 100% of consultations end up in a prescription being writtten and doctors are aware that medications are as dangerous as they are beneficial. She said that she is aware that 70% of the population was taking something regularly and that in Norway 90% of the over-fifty population is in some 'disease' category. She mentioned the tension between prevention and treatment and that more investment is being made in prevention because of the illusion that all health problems (often just normal ageing) can be prevented.

Mr Hinchliffe asked if the rising fear of diseases is related to the pharmaceutical industry.

Dr. Heath responded that it is. More and more people fear diseases and a huge public debate is needed on the limits of medicines as many take drugs with no gain and the cost per increment of benefit is high and rising. Indeed, doctors seem to be making people worse.

Mr Hinchliffe asked if people leave consultations disappointed if they don't get prescriptions and if many doctors, who did not think deeply on this issue just went ahead and prescribed medications to make things easier on themselves.

Dr. Heath responded patient expectation is a concern to many doctors, but that often giving a prescription is not easy, since among older people the potential damage was

very large: there are no studies available on the effects of people taking many (ten or even more) prescriptions at the same time, as many older people do.

Mr. Naysmith asked about the inappropriate fears of cholesterol. He said that with the heightened demand for cholesterol drugs (especially statin), one solution might be to make it available over the counter, so that the costs involved in consultation of physicians would not be incurred for the vast numbers of people interested in taking it.

Dr. Heath said that this is not a good solution, since mostly fit wealthy people worry about cholesterol and would buy the drug unnecessarily. The people who need it most are poor people with poor diets and little time to worry about cholesterol. Making the drug available over the counter would only make it more expensive for poor people. She emphasized that too little emphasis is placed on non-therapeutic methods of health care.

Mr. Naysmith said that antibiotics are an area where some public education effort had been made to lower demand, but that results were small.

Dr. Heath said that there was a downward tendency in antibiotic demands and that public debate was a good thing.

Dr. Nicholson said that trials on drugs were very controlled and did not well represent the general public: a lot was being spent on drugs to not do very much at all.

Mr Hinchliffe asked rhetorically what was to be done about this problem.

Mr. Austin asked for information about osteoporosis and suggestions on what to do about it.

Dr. Heath said that with age, everyone's bones thin. There is not a direct linear relationship between thinning bones and increased likelihood of fracture. There are some people who have bones that are too thin, but problem is overstated. To call it a disease is mongering. There are many non-therapeutic measures, like stamping (impact exercise). Part of the problem arises with comparing older people to younger people and calling the difference an abnormality. The situation is similar with blood pressure. We are only just beginning to consider the health effects of worrying about our health all the time.

Mr Hinchliffe asked about the positions of pharmacists on disease mongering.

Mr. D'Arcy said that his organization has no official position, but that be believes debate is needed. People get information from many sources and health information sells. People do have a right to know about potential health problems. Politically this is an issue of how much can be spent for what benefits from drugs.

Mr Hinchliffe asked if pharmacists are honest brokers: if a patient goes to a pharmacist convinced that he needs a drug, will a pharmacist tell him he does not?

Mr D'Arcy said that if the pharmacist believes the drug is inappropriate, he would tell their clients. He said that pharmacists do not act purely commercially, but also ethically. It is not easy if the patient really wants the drug, but pharmacists give good advice when they can. He again emphasized the code of ethics.

Dr. Darracot said that disease awareness is often linked to a particular drug where there is no competition or there is only a provisional risk-benefit profile. Pharmacists add more information as they get it. In the US disease awareness campaigns evolved into direct marketing of drugs and this is a concerning trend. There is healthy debate among pharmacists, but when consumers really want a particular drug the demand on the pharmacist to provide it is high.

Mr. Austin asked how the regulatory system is immature.

Dr. Heath said that HRT (Hormone Replacement Therapy) was ineffective because women did not understand.

Mr. Austin said that evidence from the Kings Fund said that research money does not go to the right areas.

Dr. Nicholson said that there are various problems in this regard. New drugs are not tested against old drugs that hold most of the market, to see that they are more effective, but against placebo or against a drug that the company thinks will be slightly less effective. Dr. Nicholson lamented that his organization does not have the power to refuse drugs approval because it is not more affective than the most used drugs for any particular condition. He mentioned that the World Health Organization reported that 90% of drug research funding was on 10 percent of the disease demand.

Mr. Austin asked if NHS should adopt a policy for drug research.

Dr. Nicholson said that too much money for research comes from the pharmaceutical companies. In the US 50% of the money comes from the government, while only 25% comes from the government in the UK.

Mr. Naysmith asked if there was any control over what drugs are tested against to see if they really provided much public benefit.

Dr. Nicholson said no, they can only decline studies if taking only a placebo might be harmful to some of the study participants. The US still does the sort of trial where placebo takers could be at risk.
The UK rules are outdated according to international ethical standards that require non-placebo based trials and the publication of all trials.

Mr. Jones asked if, rather than specifying trials, the NHS might set a pricing scheme that bases prices on the relative effectiveness of medications (as is done in Australia).

Dr. Nicholson said that seems worth looking into.

Mr Hinchliffe asked about other problems for the ethics committees.

Dr. Nicholson said that the committees are under-supported and more training was necessary. Resources go to the central committee, which is over staffed, but do not dissipate out the other side. The US model shows better training and coordination for treatment of individuals. The UK system does not show joined up thinking or coordinated activity.

Mr. Naysmith asked if patients are well enough informed for trials and if there is evidence to support that they are.

Dr. Nicholson said that there is very little evidence to this effect. Patients receive one information sheet and one consultation before participating in studies. Pharmaceutical companies can be ineffective in this regard. One area of problems is that the information sheets are often written to too high of a level (age 19 reading level rather than 14) and patients do not understand them. If the information sheets are very inappropriate, then they will be rejected by the ethics committee. Nor is any direct contact allowed between pharmaceutical companies and the patients.

Dr. Kendall said that trials are too often not to show safety or efficacy of a drug, but to fit into an advertising campaign. There is also a problem of inappropriate recruitment of patients, sometimes through advertisement.

Ms. Calton asked if post-licensing research should be disconnected from pharmaceutical companies. She also asked about data availability from original trials for those who conduct post-licensing studies.

Dr. Heath said that all data should be available. Otherwise decisions are not made on all available information. A lot of studies are designed just to get the drug prescribed. The relation/publication of research should not be controlled by the pharmaceutical industry.

Ms. Calton asked if it is possible to change the fact that most research is not independent.

Dr. Heath said that post-approval research should be linked to pre-approval data.

Ms.Calton asked if there was any indication of what the cost of this system might be.

Dr. Heath said that she did not know.

Ms. Calton asked if the ethics committee should have power to register studies.

Dr. Nicholson said that the code is out of date. All research should be registered and the ethics committee should have power to do this. Trial techniques and results of all studies should be made available (perhaps on the internet, since you cannot force journals to publish studies). The post marketing studies should also be improved, since the Yellow Card system only picks up one fifth to one fourth of adverse effects.

Ms. Calton asked if involving patients would pick up the remainder.

Dr. Heath said she thought it would.

Ms. Calton asked if it should be a compulsory system.

Dr. Nicholson said that it would probably help. Studies also need all the pre-market trial information.

Mr. Griffiths said that the Yellow Card reporting system is now available to the public and that nurses also use it.

Several panelists agreed that further publicity of this fact is needed for it to be truly useful.

Ms. Calton said that if patient information on drugs is too complicated, should it be written independently, and if so how might this work.

Mr. D'Arcy said that there may be a benefit to more independent information. Much of the information that patients currently get is just legal defence, necessary but not sufficient. Information on the real value of medication and what it means to the patient is necessary. Information sheets could come from the company, but need to be approved independently.

Dr. Nicholson said that at least one company does a good job on patient information sheets. Novartis sheets are long, but readable and useful to patients.

Mr. D'Arcy said that another problem is that pharmacists are obliged to give out information sheets, but number given does not always correspond to number of prescriptions, so pharmacists are forced not to give them to some patients (unless they photo-copy them, but they are copyright protected).

Dr. Darracot said that the pharmaceutical association was putting some information on the internet.

Ms Caltor noted that this was good, but subject to patients' access to the internet.

Dr. Heath said that another problem is that lists of adverse effects of some drugs are frightening and that the lists were not contextualized with information about risk.

Ms. Calton asked if someone would modify an information sheet to give a model of what it would look like. She also asked to see examples of where promotional information was blurred with helpful information about a drug and how that might be edited.

Mr. Naysmith asked if the Royal College of Physicians regretted taking funding from pharmaceutical companies for in the case of SRIs. After Dr. Kendall expressed doubt about this funding relationship, Mr, Naysmith produced funding information at which point Dr. Kendall expressed his disapproval of that funding arrangement. Mr. Naysmith asked if this was the heart of disease mongering.

Dr. Kendall said that yes, the goal of information campaigns is to de-stigmatize diseases, but not sell the diseases. He also noted that patient organizations lobby for particular drugs and are influenced by drug companies.

Dr. Heath said that depression and child hyperactivity are good examples of diseases and drug therapy being oversold.

Mr. Jones asked if there should be a review of clinical trials and if so, why?

Dr. Kendall offered that the roles of doctors in patient recruitment need to be known and the results of negative trials need to be published.

Mr. Jones asked about the role of nurses in prescription.

Mr. Griffiths said that nurses enhance patient care and their involvement in the prescription community is helpful, though they must of course stay within the code of conduct.

Mr. Jones asked if there were cases of nurses getting struck off for inappropriate conduct with regards to advising drugs and asked that if there were none, did this mean that the system under the code of conduct was perfect or that there was no influence.

Mr. Griffiths said that the system is not perfect, and that nurses have been struck off for other offences, but not for inappropriately being influenced by pharmaceutical companies.

Ms. McDonagh asked if specialty training by pharmaceutical companies (as with respiratory issues) is inappropriately affecting nurses or distorting the number of nurses with specialty training in certain fields.

Mr. Griffiths said that training from pharmaceutical companies helps provide valuable information, but must of course be monitored for content. He said he doesn't think it is distorting the numbers of specially trained nurses.

Dr. Heath noted that in her experience a lot of the information that nurses have is proprietary because of trainings from drug companies.

Mr. Griffiths said that most nurses are being trained through higher education schools, not by pharmaceutical companies.

Ms. McDonagh asked if RCN has concerns about the relationship with pharmaceutical companies.

Mr. Griffiths said that while independence is important, working with these companies in partnership can be helpful.

Mr Hinchliffe asked if the percentage of money coming from drug companies was known.

Dr. Kendall said that pharmaceutical companies are a constant presence in education.

Mr. Naysmith asked about the problem of academics putting their names on studies they did not write (known as ghostwriting).

Mr Griffiths said that there are incentives for academics to do it, but he knew most of the people who wrote in his journals.

Dr. Nicholson said that he recently saw an article on the importance of selecting your ghostwriter early, so that they at least know the basic facts of the drug trial.

Mr Hinchliffe asked to get copy of this article. Mr Hinchliffe then asked how the government might make positive regulatory steps without severely damaging the pharmaceutical industry, which represents major economic value for the country.

Dr. Kendall said that working together with Europe would probably be necessary, but that better regulations are definitely needed and the pharmaceutical industry, with very high profits, can afford some.

Mr. D'Arcy said that the benefits of the industry should not be forgotten in all the conversations about how it could be better. The industry is in the difficult position of balancing public benefit in a commercial setting. Pharmacists need to work with them, but to do so credibly and objectively.

Dr. Heath said that it is clear that the amount of money spent on public relations by the industry is out of balance and needs to be brought back within a more reasonable range.

Dr. Nicholson said that the Department of Health should help run research, its failure to do so pushes studies abroad and gives it little control over what research is done. Involving the public in what research is done provides a way to systematically look at the whole disease burden of the world: an opportunity to narrow gap of funding on the 90% of the disease burden that is not being properly researched by drug companies.

Mr Hinchliffe thanked the witnesses and adjourned the session.