



# The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom

Annual Symposium, 19<sup>th</sup> November 2010  
Royal College of Physicians, London

*The Future of Pharmaceutical Medicine:  
Industry, Academia and the NHS  
working together for the Patient*



The Annual Meeting of the Faculty of Pharmaceutical Medicine took place on the 19<sup>th</sup> November 2010 at the Royal College of Physicians London. The day included the Annual Symposium, Faculty AGM, Awards Ceremony and the Annual Dinner. Each component of the meeting was very well attended and over 250 Faculty members and colleagues from academia, industry and the public sector, invited guests and friends and family members were present throughout the day. The Annual Symposium brought together a set of renowned speakers, including voices from industry, academia and the regulatory authorities, who boldly addressed the issues of the day.

## Welcome and introduction

*Dr Richard Tiner PFPM*



The President welcomed the attendees to the Annual Symposium and introduced them to the themes of the day by drawing on the report that the Royal College of Physicians (RCP) published in 2009 *Innovating for Health: Patients, Physicians, the Pharmaceutical Industry and the NHS*<sup>1</sup>.

Professor Sir Ian Gilmore (then President of the RCP) had set up a working group called the Medicines Forum under the joint chairmanship of Dr Tim Evans and Dr Richard Horton to take on the report recommendations. The Faculty has since been a committed member of the Medicines Forum and has and will continue to be proactive in implementing the recommendations from the report that relate either directly or indirectly to the Faculty.

Consequently, this year's symposium 'The Future of Pharmaceutical Medicine: industry, academia and the NHS working together for the patient' focused on the theme of collaboration and interaction between the involved groups and the patient. The President drew attention to one challenge and recommendation from that report, which was for the Faculty to review and update its Guiding Principles for Pharmaceutical Physicians document, published originally in 2006, taking into consideration the 'Nolan Principles' of working in public life. This document has now been revised and was re-launched by the President at the meeting.

Please note that video slideshows of most of the presentations are available to view on the Faculty website: <http://www.fpm.org.uk/events/embedded-video>



*Front cover of the new Guiding Principles document*

## Call to action

*Dr Keith Bragman FFPM – Chair, FPM Advocacy Committee*

"This meeting is about opportunity. We live in tumultuous times – the pharmaceutical industry, academia, NHS are all under unprecedented pressure to serve the needs of society and patients. Tumultuous times present opportunities for those with vision and foresight and who are prepared to take risks. We clearly cannot go on working as we have been – industry is experiencing diminishing returns on investment, universities are under extraordinary pressure simply to survive and the NHS is going through reinvention. This meeting is about exploring these opportunities; what can change and what risks we are prepared to take to produce more innovative medicines and improve healthcare."



Dr Bragman introduced the two meeting chairs for the day – Professor Stephen K Smith (Pro Rector (Health) Imperial College London and Chief Executive, Imperial College Healthcare NHS Trust) and Dr Richard Barker (Director General of the ABPI) – who facilitated the subsequent discussions.

<sup>1</sup> Royal College of Physicians. *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*. Report of a Working Party. London: RCP, 2009.

# Patients, physicians, the pharmaceutical industry and the NHS: Is the cup half full or half empty?

*Dr Richard Horton – Editor of The Lancet*



Dr Horton delivered a candid and forthright presentation, focussed mainly on the need for transparency and respect in medical research and how we can boost research in the UK. He started by commenting that the editors of medical journals (himself included) can sometimes be ambivalent – on the one hand being hostile to industry but on the other hand “begging researchers to send us their best clinical research and trials”, as inevitably a journal’s success depends on high quality papers to maintain a high impact factor and revenues. He described, however, the “epiphany” that came from working on the RCP *Innovating for Health*<sup>1</sup> report, how his opinions of all parties had altered and how the need for cohesion and collaboration between the involved groups had become even more apparent and necessary to address the needs of the patient.



*Dr Richard Horton addressing the Symposium delegates*

Dr Horton called for the dependence on the “freebie culture” between doctors and pharmaceutical companies to stop and commended the new ABPI Code of Practice<sup>2</sup> with a ban on promotional aids and the disclosure of payments to doctors from 2011 and 2013, respectively. He described how he thought there is a perception of an innovation crisis across industry and this isn’t helped by the ‘speed limits’ currently slowing down medical research. Many

people believe that the European Clinical Trials Directive (ECTD) is a ‘disaster’ for research and that the MHRA’s interpretation concentrates too much on compliance rather than progress. He contemplated whether the government’s plan for a single research regulator is the best solution – on the one hand it might be possible to remove some of the impediments to research, on the other hand it may create competition between trusts, without promoting innovation.

Finally, Dr Horton expressed concern at the widespread lack of transparency in pharmaceutical research, between industry, academia, government, the media and patients. He used the *Avandia* case as an example of where communication and transparency had been negatively impacted upon and not always in the best interest of the patient.

He also called for the strengthening of the clinical trials and research culture in paediatric medicine and for continued efforts into developing treatments for the developing world, e.g. malaria vaccines.

During the subsequent discussion it was remarked that it was not necessarily the MHRA who were responsible for the problems with the ECTD – and that it was the lawyers who had drafted the regulation in the UK.

*My main thoughts about the meeting were the issues surrounding transparency within the pharmaceutical industry. Being reminded of the infamous BMJ cover early in the Symposium brought back many memories and thoughts about our industry and the issues that remain.*

Louise Levine, Honorary Fellow FPM

<sup>2</sup> Association of the British Pharmaceutical Industry. *ABPI Code of Practice for the Pharmaceutical Industry 2011*. London, 2011.

# How should the practice of pharmaceutical medicine change over the next decade?

*Professor Sir Alasdair Breckenridge – Chairman, Medicines and Healthcare products Regulatory Agency*



Sir Alasdair started his presentation by outlining what he saw as some of the current negative perceptions of industry and regulators:

- **That regulatory approval thresholds are rising**
- **There is an increased focus on safety by regulators**
- **That regulators dislike uncertainty and are becoming more risk averse**
- **The increasing cost of drug development and therefore increased price of drugs**
- **There is a demand for increased transparency**
- **How recently, development times have risen and new molecular entity outputs have fallen**

He outlined how he thought modern drug discovery is changing, with biopharmaceuticals becoming more prominent and earlier proofs of concept and small targeted clinical studies becoming the norm. The modelling of pharmaceuticals and development of biomarkers and advances in safety and risk management will also bring big changes to the discovery and development processes.



*Professor Sir Alasdair Breckenridge addressing the packed lecture theatre*

Sir Alasdair then went on to explain how he believes the interplay between drug development and regulation will be very different by 2020. In place of the traditional linear route there will be increased

knowledge of the pathophysiology of the disease, increased collaboration with the regulator, conditional approval in the context of a much shorter timeframe. He also commented on how patient registers, systematic reviews and population informatics are becoming increasingly important with respect to drug safety and how large simple clinical trials are an important adjunct to evaluating drug safety.

Sir Alasdair highlighted how risk management planning will become the central focus of safety consideration over the next decade. He highlighted the differences between EU and US risk management – whereas in the EU virtually every new product has a risk management plan (RMP), in the US there is greater flexibility. Responding to earlier comments on the role of the regulator, he remarked that over the next few years he too would like to see a shift towards benefit/risk management planning, within a formal framework, allowing increased consistency and transparency.

*The collaboration of industry and academia will largely depend on the pillars of trust, transparency and confidentiality.*

*Dr Disala Fernando*

Sir Alasdair concluded his presentation by highlighting what he sees as three areas of unmet need, these being i) patient adherence ii) multiple prescribing and iii) transparency. He challenged the Faculty to consider the issues around patient adherence of medicines.

During the discussion that followed, Professor Tim Higenbottam of the Faculty's Professional Standards Committee accepted the challenge to develop a project on patient adherence. The MHRA were asked to continue the shift from assessing 'safety' to assessing 'benefit-risk' – a more meaningful term for both the patient and the industry.

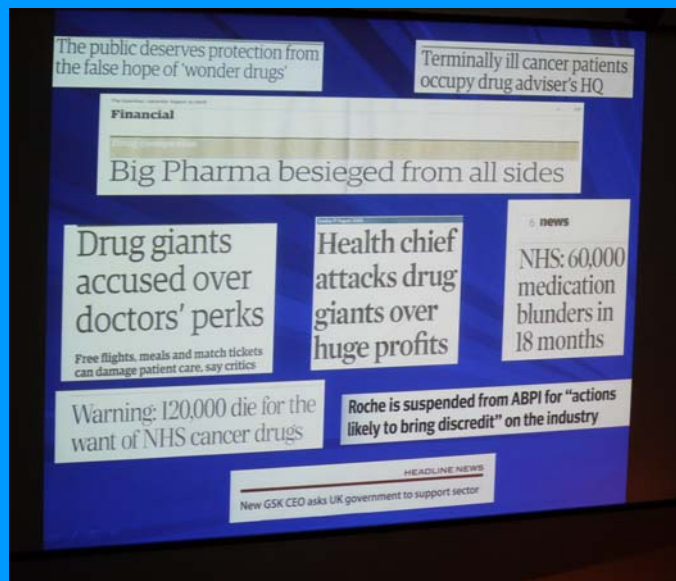
# Industry collaborating with academia and the NHS: what must change?

Dr David Gillen – Head of International Medical Affairs, Gilead Sciences



Dr Gillen started by echoing Dr Horton's remarks about how he also had come on a "journey" whilst working on *Innovating for Health*<sup>1</sup>. He reiterated the need to move to collaboration in the

real sense and gain the patient's and NHS trust. This loss of trust can partly be blamed on the fact that the doctor/industry relationship has become too entangled, with a loss of transparency. Dr Gillen then described how it was perceived that in an earlier era there was 'respectful cooperation' between doctors, academics and industry, whereas in the last decade we have seen 'all interactions considered negatively' and pharmaceutical companies viewed as being 'unscrupulous in search of profit'.



Presentation slide by Dr David Gillen giving examples of negative press relating to the pharmaceutical industry.

*[The Symposium] was a fascinating insight into the work of pharmaceutical physicians. Many medical students will not have considered this speciality as a career, but the symposium certainly highlighted just how important pharmaceutical medicine is.*

Oliver Ellis, Student Editor, Student BMJ

Dr Gillen outlined what he thought were some of the issues academics have with industry:

- Lack of clarity of mutual objectives
- Changing point of industry contact
- Early termination or change in strategy
- Restrictions imposed on publications
- Intellectual property negotiation & vice versa

And, alternatively, some industry concerns about the R&D undertaken in academic health science centres.

- Unrealistic value of IP generated in academia
- IP issues on 'own medicines'
- Poorly designed studies leading to future safety issues
- Confidentiality (academics work for multiple companies)
- Data quality issues (IP and Regulatory)
- Poor performance of clinical sites

Dr Gillen then identified some 'key ideas for change', mentioning why the public and patient support for clinical trials is conditional and how the NHS must change its attitude to research, with incentives linked to clinical practice. Industry must also be confident & open about explaining the commercial model & the benefits it brings to society.

To finish, Dr Gillen highlighted two issues that he believed needed to be urgently addressed and require appropriate collaboration between Industry, the NHS, Academia and Government.. The first is to crack down on counterfeit medicines, by ensuring that all clinicians report on the absence of efficacy of products. The second was that the industry should engage more with medical students. There should be the opportunity for student electives in pharmaceutical companies with an increased flow of career information between industry and universities. Industry employs a significant number of expert clinicians who can make a meaningful contribution to medical education.

# Integrating basic and clinical research: The academic health science centre sharing common goals with industry; an illusion or reality?

*Professor Lee Nadler – Dean for Clinical and Translational Research, Harvard Medical School*



Professor Nadler started his presentation by imploring the research community, both in industry and academia, to “think globally” and to act “less competitively”. He remarked that the ‘metrics of success’ of pharmaceuticals research are not the return on investment or the recognition of the institution, individual or team, but solely in the improvement of health.

Professor Nadler then discussed how the ‘external forces’ on both sides of the Atlantic are increasingly creating the tensions needed for academia and industry to align their efforts and how the synergy between the two groups now needs to be stronger than ever. Both groups need to share ‘common goals’ and work together in the ‘pre-competitive space’ to unravel the mechanisms of disease and develop biomarkers to anticipate clinical endpoints. He then outlined what he thought were the ‘harsh realities’ for both industry and academia today, including for industry; that the return on investment has shifted from significant profit to loss. Everyone is attacking the same targets and that the first in a new class of agents may have only a few years of market exclusivity. Academia, the academic health science centres, and hospitals are fearful of reductions in investment in research and reimbursement for clinical care and potentially also for clinical research. This is further compounded by a regulatory environment that is increasingly stringent, adding time and cost to the development of novel treatments.

Professor Nadler then went on to describe how he thought these problems could be overcome through

*Lee Nadler gave a fascinating talk on how we can integrate basic and clinical research, discussing how Harvard had registered all its scientists on a network using MeSH terms so they could form ‘dream teams’ to work on specific projects. He emphasised ‘engineering’ as the key to disease and not discovery.*

*Dr Sue Tansey MFPM*

the exploitation of the ‘pre-competitive space’ and through engineering links and consortia between basic fundamental science and clinical research in the life-sciences. Working in the pre-competitive space has led Harvard to focus on creating the Harvard Partnerships in Therapeutics. By bringing together diverse talents from academia, government and industry at a global level, Harvard believes that this is the best way to address the most difficult problems in disease management and treatment facing society.

## What is a pre-competitive consortium?

A collaborative partnership that focuses on work that increases the overall knowledge or technology base in a field, shares risks and costs, reduces duplication of effort and resource expenditure in that work, and does not ordinarily provide a competitive advantage to a specific company. The output of the consortium may be restricted or public. Unlike the competitive space, such a consortium engages in areas that are shared challenges important for progress usually involving novel and/or highly complex problems, requires a longer time-frame for resolution, and generally cannot be performed by one company.

*Speakers boldly and openly addressed the key issues, including in their own world (academia, industry, and NHS). This symposium raised hope that collaboration is not only possible but will have a big, positive impact on public health. Now it is up to us to go and make it happen through personal leadership.* Dr Lode Dewulf FFPM

# The catalytic role of informatics in competitive academic and NHS research

*Professor Andrew Morris – Director of the Biomedical Research Institute, University of Dundee*



Professor Morris provided a detailed insight into how he and his team, along with collaborators across both the private and public sector in Scotland, are working as part of the Scottish Research Networks to promote the use of informatics to improve medical research. He remarked that “informatics could and should be transformational for patient care”. In efforts to align research across Scotland, he commented on the value of “collecting data once and using it often”. He compared the process to “linking the community to the cell” and used the analogy of the three spans of a bridge to describe the activities of the networks.



*Professor Andrew Morris addressing the audience on the ‘three spans’ that link the community to the cell.*

Professor Morris went on to explain what work has been done in developing the Diabetes Audit and Research Tayside Scotland or ‘DARTS’. This project acts as a first span of the bridge and Professor Morris remarked on how everyone in the medical and research communities should champion the use of a unique patient identifier which can link the patient to different sources of information, including community pharmacies, diabetic clinics, hospital admissions and laboratories and GPs. He explained that the collection of data is made possible by all patients being nationally registered on one single register which is used in all hospitals and supported by nightly capture of data from all 1200 primary care practices across Scotland. These informatics systems have already led to significant improvements to patient care year-on-year. For example, over the last six years blindness rates amongst diabetes sufferers

have fallen by 43% and there has been a 40% reduction in amputations.

The second span can boost the participation and effectiveness of clinical trials and epidemiological research. The Scottish Diabetes Research Network has increased the numbers of patients willing to take part in trials and this has dramatically increased the efficiency of trials and research logistics and also facilitated the bilateral translation of research ideas. He used the example of how *metformin*, traditionally a diabetes drug, has become recognised as a possible treatment for cancer. He and his colleagues have also started the Scottish Health Informatics Programme to build a national system for pharmacovigilance, linking community prescribing data to electronic clinical prescribing records and other health related datasets.

Span three can see the analysis and application of biomedical informatics in the life and pharmaceutical sciences, for example in the bio-banking data programmes for type 1 and 2 diabetes, resulting in an “explosion of new knowledge”. However, Professor Morris remarked that obtaining clinical utility is the real challenge and that the genetics revolution could be accused of “great knowledge, no application”.

Finally, he described how the Translational Medicine Research Collaboration had been set up in Scotland to link universities and the NHS with industrial science and expertise. He said that the future of informatics should be about bringing research, and information systems development and innovation to the clinical community.



He remarked that informatics can be a ‘disruptive technology’ and result in “an innovation that creates a new market by applying a different set of values”.

During the discussion it was pointed out that when attempting to introduce a new computer system in UK health services, in England the approach was taken of ‘replacing all’, while Scotland took the route of ‘connecting all’, and has reaped the benefits!

# The patient's perspective: Industry, academia and the NHS working together; should we really be optimistic?

*Mr Simon Denegri – Chief Executive of the Association of Medical Research Charities (AMRC)*



Mr Denegri gave an overview of the AMRC, the membership and their contribution to life-science research, and explained how the AMRC encourages industry to think of charities as strategic partners. He first commented that the title of the conference could have been re-named ‘...Industry, Academia, **Charities** and the NHS Working Together **with** the Patient’ to emphasise the need for a broad collaboration. He described how the AMRC supports charities in implementing peer-review of research funding. How it provides leadership on issues such as collaboration and advocates on behalf of its members.

63% of AMRC members are actively seeking out partners for their research efforts and the nature of the interactions between charities and industry is becoming less about the marketing, education and sponsorship and is becoming more ‘adult’. There is a higher degree of mutual respect, in which charities are now setting research questions and strategy, and establishing opportunities for co-funding with other organisations.

He outlined the three dimensions of charity collaboration with industry as:

- **Funding development**
- **Business and market development**
- **The innovation pipeline**

Giving an example of funding development he described a project involving the Motor Neurone Disease Association and Biomedica collaborating in

the early clinical trials of a gene therapy. In many cases patients are taking the lead and becoming

## Facts and figures on the AMRC and its members:

- AMRC members contributed £1.1 billion to medical and health research in 2009-2010, a further £200 million internationally
- AMRC represents approx 94% of all available charity funding in the UK
- Over one third of all ‘public expenditure’ on research
- 80% of sector funding ‘goes to’ universities
- 83% in England, 14% Scotland, 2% in Wales, 1% in N.I.

ambassadors and drivers of research efforts. In terms of business development he used the example of the Royal National Institute for the Deaf, who are seeking to develop better treatments and therapies for deafness with industry partners. Finally Mr Denegri outlined how the members of the AMRC are working to improve the ‘innovation pipeline’. The goal is to improve the quality and relevance of research to patients and facilitate the faster uptake of new treatments across the NHS.

Mr Denegri finished with two appeals to Faculty members; to “see charities as long-term strategic partners” & “look at the evidence behind public involvement & champion it as part of what you do”.

## Conclusions from the symposium and future plans

*Dr Richard Tiner PFPM*

The RCP London Report ‘*Innovating for Health: Patients, Physicians, the Pharmaceutical Industry and the NHS*’<sup>1</sup> had set the tone for the Faculty Symposium in 2010. One of the recommendations in the Report had

specifically called for the Faculty to review its Ethical Principles document and ‘Nolanise’ it. This work had been completed and the public launch occurred at the Symposium. There were a number of key messages

from the speakers, some of which have been adopted by the Faculty as future work streams.

Dr Richard Horton reminded the meeting that we were approaching the 50<sup>th</sup> anniversary (19/2/11) of Dr. William McBride's letter on congenital abnormalities and the use of thalidomide. Although this had led to the setting up of the Dunlop Committee and thence the MCA and MHRA, it had taken 46 years before legislation had been introduced for medicines that are likely to be used in children to have specific clinical trials on children performed.

- **The issue of clinical trials in children will feature as part of the 2011 Faculty Symposium on 'Prescribing without Evidence'.**

Dr Horton also felt that the Government's proposed move to value-based pricing would not reduce the medicines bill and questioned whether it was rational to try and reduce the overall spending rather than having better targeting. His third message was on the utmost importance of reporting clinical trial results which is highlighted in the FPM Ethical Guiding Principles document and is a key responsibility for all pharmaceutical physicians involved in clinical research.

- **The Faculty has now submitted its response to the value-based pricing consultation and has been asked to lead on this for the Academy of Medical Royal Colleges.**

Professor Sir Alasdair Breckenridge's key challenge for the Faculty was to lead on patient adherence and how to improve it. He described it as the key unmet need for the future. Sir Alasdair also indicated that we should all be moving away from patient safety as the main priority for medicines and moving towards assessing the benefit-risk ratio of medicines.

- **Our Professional Standards committee will be considering how to take up this challenge.**

He could see a real future for UK medical databases as a source for researchers around the World and that the UK should be the best place in the World for database resource.

Dr David Gillen highlighted the need for mutual trust in collaborative activities and that trust can only develop in a transparent environment.

Professor Lee Nadler had two fundamental messages: there is a need for the partners in the title of the Symposium to work together in the pre-competitive space and that engineering (integrating fundamental scientific research into clinical research) is the key to treating disease, and not necessarily the discovery of new medicines.

Professor Andrew Morris continued Professor Alasdair Breckenridge's theme on the vital importance of databases and demonstrated just how Scotland is making real progress in this area.

Finally, last but certainly not least, Mr Simon Denegri on behalf of patients and medical research charities which are mainly funded by the public, pointed out that what patients really want is a National Health and Research Service.

- **The Faculty will be developing a patient friendly version of its Ethical Guiding Principles document and will be approaching patient advocacy organisations for their input and endorsement.**

A trend throughout the day was the need to reach out to doctors early on in their careers with regard to the importance of research.

- **The Faculty has set up a working party on introducing pharmaceutical medicine to young doctors via student electives, week long introductions and short term secondments for F1/F2 doctors.**

The Faculty is continuing to promote pharmaceutical medicine in the interests of both the patient and society. Over a relatively short period of time, pharmaceutical medicine is evolving into a major speciality in the United Kingdom. We want to attract excellent clinicians who will continue to take up the challenge of improving healthcare and promoting the highest standards in pharmaceutical medicine.

# Delegate and speaker feedback and analysis from the symposium...

*The symposium contained a wonderful range of speakers who covered many of the controversial interactions between the NHS, Industry and Academia. The only element that was missing [from the Symposium] was the fourth partner; the UK government, and its plans for the NHS. The informatics lecture by Andrew Morris was wonderful and shows that professional approach, especially when the ethics of accessing patient data are concerned, yields major opportunities. This needs to be urgently extended to all regions in the UK.*

Professor Tim Higenbottam  
Chair, FPM Professional Standards Committee

*How do we move research on so that it really means something for patients and their families? This seems to be the essential question with which we are all grappling. So I was delighted to be asked to give the perspective of medical research charities and their patient groups on this issue at the Annual Symposium. My members and patients will tell you that the fundamental barrier in the way of research and innovation is the lack of engagement within the NHS, and professional attitudes. Much of what I heard at the symposium echoed this. I hope the Faculty and its members will take on this challenge and strive to be an important voice in making change happen in the interests of patients and research.*

Mr Simon Denegri  
Chairman, AMRC (speaker)

*At a time when the pharmaceutical industry is suffering from a rock-bottom reputation among its "customers" i.e. patients, and clinical trial research has dropped to a third of what it once was, a reminder of the urgent need to focus on increasing high quality research in collaboration between industry, academia and the NHS was a particularly pertinent and salutary one. One key message that came through was that pharmaceutical physicians have been somewhat passive in defending the often erroneous perceptions and misconceptions about what the industry does, but equally recognising that as physicians we are also obliged to speak up when colleagues are pursuing goals which are unlikely to benefit patients and promote a healthy society.*

Dr Dipti Amin  
FPM Board Member



*This has been a very well attended and successful meeting with speakers of high calibre who brought their experience regarding coordination of efforts from academia, industry and government to a better way for drug development.*

Dr Joseph Chiesa FFPM

*Thoughts for future areas of work:*

- 1) *Active engagement between the Faculty and medical schools to define effective undergraduate training in new medicines development and therapeutics – not only lecture/seminar based learning but also including electives within pharmaceutical companies to enhance an understanding of work in pharmaceutical medicine in the UK.*
- 2) *Active engagement between the Faculty and other partners including patient organisations, prescribers, pharmacists and patient on effective translation of research findings into medical practice.*
- 3) *Increasing visibility concerning the contribution of physicians to research and development science by:*
  - i) *Effective collaboration with post graduate training and educational outreach programs*
  - ii) *Obtaining recognition of periods spent in the industry towards specialist accreditation for physicians remaining in practice*
  - iii) *Fostering effective exchange programs between academic research, NHS practice and the industry (for which the model enjoyed by our colleagues in Sweden might be an example)*

Dr Penny Ward MFPM

*This annual symposium was a brilliant example of multidisciplinary interaction and I thoroughly enjoyed it. The quality of the speakers was universally outstanding and it was particularly refreshing to hear such senior people talking in a relatively informal manner. I thought there was a real sense of purpose and looking to the future as well as a realistic appreciation of the problems in the industry and for pharmaceutical physicians in particular.*

Dr Andy Rose MFPM

*As a medical student at Guys Hospital I was first taught that Medicine is an Art and needs hands on practice and confidence between patient and doctor. Increasingly Medicine has become more and more removed from the patient and heavily dependant on Science and the symposium aimed to redress this balance. For me the apprenticeship of an idea, a target or a new molecule as it serves its time in migrating from test tube to bedside via the pre-clinical, clinical and post marketing arena serves to illustrate the Art of the pharmaceutical physician as he/she ensures that the validity of the Science is measured alongside the benefit/risk ratio for the therapy. Professor Geoffrey Barker, FPM Registrar*



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