

Annual General Meeting

28 November 2006



The Faculty of Pharmaceutical Medicine



In this my first Presidential address, I will share some personal thoughts and recollections of the year and also touch on some particular activities for the future. Our five-year strategic plan is now being implemented and many of the activities that I will highlight in my report are areas of particular focus in this plan.

Taking over the Presidency has been a great privilege, an even greater one than I had perhaps imagined. It was also rather daunting and I wondered what I would be needed to do as the Faculty was in such good shape and of course, as with all of us in any job or role, I wanted to make my contribution.

We are a thriving Faculty, with a very active membership; we are recognised as a specialty and have substantial numbers of members undertaking higher medical training to obtain their CCT. We are a not insignificant part of the wider fraternity of our three parent colleges; I sit as the representative of Pharmaceutical Medicine at the RCP Council Meetings and at the Academy of Royal Medical Colleges. I attend the RCP London Fellows and Members Ceremonies and have the opportunity to mingle afterwards with the new Members and Fellows, offering encouragement about pharmaceutical medicine as a superb career choice and dispelling some of the adverse myths about the pharmaceutical industry. Our views and input are sought on a considerable number of very diverse healthcare related issues, for example I was invited to be one of the judges for a prestigious research prize awarded by the Medical Council on Alcohol. The list of events that I have attended and been able to contribute to on your behalf is long and I include some from the list in each of my presidential emails.

One event that I will mention here was an expert review workshop on safety where I gave a presentation. This workshop was part of a major scoping review of incident reporting systems, part of the Patient Safety Research Programme. This was a large meeting and I was very surprised and saddened at the lack of knowledge on how and when to report adverse drug reactions and the considerable ignorance about the fact that patients can now report adverse events.

One other considerable surprise – and I have to say major disappointment – has been the ignorance about our specialty within the wider health care community that I have become aware of this year. I am perhaps not surprised that patients and the public have little conception as to what pharmaceutical medicine is, but nor do many senior people within patient associations and most disappointingly of all, nor do many healthcare workers and fellow physicians at the functions I attend. I have discovered that those practicing pharmaceutical medicine are widely and frequently considered to be pharmacists. My father was a pharmacist and I have no problem being considered a pharmacist *per se* but pharmacists and doctors do have different roles, different responsibilities and different training. How do we change that perception? I do not know the answer, although I do believe that if pharmaceutical medicine is to play its critical role in the development and safe commercialism of medicines and if this contribution is to be recognised and respected more widely, then we need to be seen as physicians with the contingent standards and ethics that should pertain to all physicians and which are so well set out by the General Medical Council and Royal Colleges.

President's Address

I do also believe that medicines work best if patients have faith in them and that we have a responsibility to do all we can to increase patients' confidence in the safety and efficacy of their medicines. I do think that if there was greater knowledge about the diverse and responsible roles of physicians within pharmaceutical medicine, this would help. Despite all the bad press about doctors, studies have shown that patients still regard doctors very highly. We are doctors with the same high professional standards as other physicians and we need to leverage that fact to benefit patients. If any of you have any suggestions as to how we can change the perception of our speciality please let me know. I do believe it is important we make every effort to do so.

Although the gestation was prior to my presidency, one highlight I wish to mention is the publication by the Faculty of the report 'Ethics and Pharmaceutical Medicine' and the accompanying 'Guiding Principles'. These excellent and useful reports do much to help establish pharmaceutical medicine as a highly credible and ethical career. They are in line with our mission statement, and set the standards by which we must all work.

The formation of our own Specialist Advisory Committee (SAC) by the JCHMT, is in many ways the final step in the recognition of pharmaceutical medicine as a speciality. It will be the first committee to have open advertising of its members within the membership, applications and a transparent, accountable appointment process. For me, this is very exciting because it is how I believe boards and committees should be appointed. It will allow members with the required skills to have equal opportunities to contribute to the Faculty's work.

The achievement of our SAC is due to the hard work and commitment of many people, who so willingly give their time. This includes all the Senior Specialty Advisors and the Educational Supervisors, who have undertaken their roles so assiduously, competently and with such rigor. They should be proud of the standards they have insisted upon.

Indeed, a great privilege of presidency is to witness the huge amount of voluntary work ensuring the present and future success of our Faculty by those who serve as officers or trustees or on the various committees and working groups. This also includes those who draft responses to often complex, sometimes lengthy documents on behalf of the Faculty. It is not until one attends committee and working party meetings right across the breadth of the Faculty's work, that one realises, not just how many

members are involved but just how much they do. It is really very humbling to see the dedication given to our Faculty. This aspect is perhaps one of the most memorable for me in my first year. I am truly grateful to all those who support the Faculty in such a wide variety of ways.

Another related highlight for me has been achieving a wider involvement of our membership in the activities of the Faculty. This was certainly one of my personal objectives and the office now holds a growing list of those of you who have offered to contribute within your own area of special interest. We would like to call on your help to review papers, attend meetings or to offer guidance in response to the growing number of activities that the Faculty is now engaged. We value input from all of our members however long they have been with us and wherever in the world they are based.

The governance review must also rank as a highlight this year. So far, I have received nothing but support for the need for the Faculty to review its constitution. I believe that the proposal is the right one to take the Faculty forward and I will keep you informed about progress on this during the year ahead.

The final item I must mention is the CMO's report 'Good Doctors, Safer Patients.' It was very disappointing to find that re-licensing in this long awaited report related solely to doctors working within the NHS. It is fundamental to our work as pharmaceutical physicians, to maintaining our high standards with specialist accreditation, to attracting high calibre doctors into pharmaceutical medicine and to enabling global movement of UK trained pharmaceutical physicians that we are able to remain on the full medical register and the specialist register.

We met with the Deputy CMO in October 2006. We had, prior to this, formulated a top line model that would essentially, parallel the model proposed for NHS doctors for re-licensing and recertifying and this had received board approval in principal. The Deputy CMO confirmed that the report did only address NHS doctors and advised us that it is for the Faculty to propose a model which mirrored that for NHS doctors, or propose an alternative, or to argue for an exemption. However, an exemption is highly unlikely to be granted and a danger is that we might be the only group of doctors in this position. This would gradually, or possibly rapidly, marginalise us from our peers. We have fought long, hard and successfully to be treated as equals – I believe we cannot pick and choose where we want equality if we are to retain our place within the medical profession.

Faculty Board and Fellowship Report

As the time between this meeting and the deadline for submitting our response to the report was very short, our response was quite brief and to the point – stating that will to work alongside the CMO and the GMC to formulate a practical, acceptable model that enables pharmaceutical physicians to re-license, hopefully whether they are in the UK or overseas. We have not committed to the nature of the model – in any case, the model for NHS doctors may undergo some radical changes following the consultation period, although my view is that this is unlikely.

I know there is very considerable unrest amongst pharmaceutical physicians about the report. I hope that what I have said reassures you that it is my top priority to ensure that pharmaceutical physicians whether members of the Faculty or not, can remain on the full medical register. When re-licensing is assured then of course the Faculty will have a major role to play in the recertification for our specialisation.

When I was elected President last year the Faculty was in good shape thanks to my predecessors and officers both past and present. However, no organisation stands still and the goals I set myself for my presidency still hold. I am committed to continuing to drive these, and new ones, along with the implementation of the strategic plan. I will finish by reminding you of these objectives, in no particular order of priority, so that if we did appraisals for presidents - and maybe under the proposed new governance arrangements we will - I know what I am to be measured against.

- To ensure that pharmaceutical physicians can be re-licensed alongside the whole medical profession.
- To take forward the governance review and work up detailed proposals for approval at the next AGM.
- To continue to encourage and enable a wider membership to contribute to the work of the Faculty.
- To work with our international membership to lessen their isolation and avoid the Faculty appearing UK-centric.
- To enhance the image of pharmaceutical physicians with patients, patient associations, carers and the public, for patient benefit.

Tough goals perhaps but with the support, help and advice from our membership I do believe that next year will see yet more continued progress to achieve these.

Dr Susan Bews, President

The Faculty Board

Dr Steve Hobbiger was elected for a second term as Vice President.

Dr Jane Zuckerman was appointed Registrar as Dr Jane Barrett completed her term in this office.

Dr Keith Bragman and Dr Dominique Dubois were elected as new Board members, whilst Dr Andrew Hockey, Dr Allison Jeynes-Ellis, Dr Oswald Morton and Dr Christopher Worth were re-elected to the Board. Dr Peter Adnitt, Professor Nigel Baber, Dr Carolyn Greenwood, Dr John Posner, Dr Nadarajah Sree Haran, Dr Tim Tasker, Dr Richard Tiner and Dr John Young left the Board in 2006.

Annual Dinner

At the Annual Dinner the President took the opportunity to promulgate the mission and achievement of the Faculty to guests and members. This year's Guest of Honour was Dr Fiona Godlee, Editor of the BMJ.

Faculty Awards Ceremony

The President welcomed all the new Fellows and Members and congratulated those who had been awarded the Certificate of Completion of Training by PMETB during the year.

Honorary Fellowship

Honorary Fellowship was presented to Professor Martin Kendall.

Professor Martin Kendall

Professor Kendall is Professor of Clinical Pharmacology and Associate Dean (NHS liaison) at the University of Birmingham. He is also an Honorary Consultant Physician at Selly Oak Hospital in Birmingham.

Professor Kendall qualified in medicine at the University of Birmingham in 1965, became a member of the Royal College of Physicians in 1968, obtained his MD in 1971 and was elected as a member of the Association of Physicians of Great Britain and Ireland in 1981 and Fellow of the Royal College of Physicians (FRCP) in 1982.

During his distinguished career as a clinical pharmacologist, his main interest has been cardiovascular pharmacology, particularly in the treatment of hypertension and the prevention of ischaemic heart disease. For some time he has had an interest in beta-receptors and recently this has been



Professor Martin Kendall receiving Honorary Fellowship from the President, Dr Susan Bews

directed principally towards cardio-protective effects of beta-blockade and the metabolic consequences of beta-antagonism. He also has a broad interest in the role of drugs in the prevention of coronary artery disease.

His contribution to scientific literature is enormous. He has written three books, 16 chapters in other books and a total of 298 papers, most on clinical pharmacology with about 19 on gastroenterology and 25 papers on rheumatological topics.

Professor Kendall is an examiner for the MRCP, an examiner for the Diploma of Pharmaceutical Medicine and Senior Speciality Adviser in Pharmaceutical Medicine. He has major medical contributions at a national level in many areas. He is currently a member of the Commission on Human Medicines and served as a member on the Committee on Safety of Medicine and Chairman of the sub-committee of Pharmacovigilance. He also is the Chairman of the Joint British National Formulary and was responsible for initiating the plans to produce the National Formulary for Children, which was first published in 2005. He is also Chairman of the Formulary Development Committee and member of the BNF Board and the BNF Business Development Committee.

Fellowship by Distinction

Fellowship by Distinction was awarded to Dr Allan Gaw and Professor Pawel Januszewicz.

Dr Allan Gaw

Dr Allan Gaw is currently the Director of the Clinical Trials Unit at Glasgow Royal Infirmary. After graduating in Medicine he trained in clinical biochemistry completing a PhD which focussed on the metabolic mechanisms of cholesterol lowering medicines. He then undertook two years further study in the laboratories of Nobel Laureates, Joseph Goldstein and Michael Brown in Dallas working upon the molecular genetics of familial cholesterol disorders. Dr Gaw returned to the UK to take up a Fellowship in the Department of Pathological Biochemistry at Glasgow Royal Infirmary. Between 1997 and 2002 he was involved in the design and execution of a landmark trial of statins which brought important advances in our understanding of vascular risk management in the prevention of disease. He has also taken a major interest in clinical education and is a gifted lecturer. He is the lead author of a standard study text on clinical biochemistry and has developed interactive educational programmes in GCP. He has a vast publication list and has editorial responsibilities for a number of specialist journals.

Professor Pawel Januszewicz

Professor Pawel Januszewicz is currently Head of the Paediatric Pharmacology Unit at the National Drug Institute, Warsaw. His career uniquely combines activities in three areas – clinical paediatrics, scientific research and an expertise in the development of paediatric medicines. He is a pioneer of paediatric hypertension research in Poland



From the left: Professor Pawel Januszewicz (Fellow by Distinction), Professor Martin Kendall (Honorary Fellow), Dr Andrzej Czarnecki (Member by Distinction), Dr Brian Sanderson (Member by Distinction) and Dr Allan Gaw (Fellow by Distinction).



and he also implemented the practice of evidence-based medicine for the management of about twenty common paediatric diseases in the country. Professor Januszewicz has held many nationally recognised appointments and is considered an expert in paediatric pharmacology. He was the founder of the Central Register of Rare Adverse Drug Reactions in Children and a member of the Ethics Committee for paediatric drug trials, both in Poland. His interest in public health led to him creating an innovative private cable TV channel in Poland through which important health and disease information is presented. Amongst much recognition, Professor Januszewicz was delighted to be receive a medal awarded by the paediatric population in Poland. This award, which translates as 'Distinction of Smile' was also awarded to Pope John Paul II.

Membership by Distinction

Membership by Distinction was awarded to Dr Andrzej Czarnecki and Dr Brian Sanderson.

Dr Andrzej Czarnecki

Dr Andrzej Czarnecki is currently the Director and Deputy EU Qualified Person for Pharmacovigilance and a Medical Fellow at Eli Lilly. He has a distinguished career in pharmacology, regulation and pharmacovigilance in both the industry and as a consultant to public bodies and governments. He is a prolific contributor to professional and scientific activities related to pharmaceutical medicine and he contributes to the development of medicines policy internationally. Dr Czarnecki qualified, studied and worked in Warsaw for many years. He has also worked at the University of Cambridge, the Royal Postgraduate Medical School and at the former Medicines Control Agency. He has been advisor to the World Health Organisation, World Bank and the Governments of Slovenia and Poland. He is currently an active member of the Drug Information Association, currently Editor-in-Chief of its Forum. Dr Czarnecki holds honorary lectureships at the London School of Hygiene and Tropical Medicine and the University of Surrey and he is also involved in other educational activities related to his many areas of expertise.

Dr Brian Sanderson

Dr Brian Sanderson is Chief Executive Officer and Medical Director of Drug Development Solutions Limited, Dundee and he has a record of substantial achievement within pharmaceutical medicine. It was whilst working in general practice that his interest in therapeutics developed. He joined Inveresk Clinical Research in 1994 gaining experience there in Phase 1 clinical trials. After four years

he joined DDS Medicines Research Unit as Deputy Medical Director and assumed its headship in 2002. This unit was established to link the University of Dundee with a leading edge clinical research Phase 1 Unit. In 2005 Dr Sanderson was largely responsible for the management buy out of the unit which has ensured the continuity of its quality activity and training. Education and training has always been an important component to Dr Sanderson's contribution to pharmaceutical medicine and he has actively supported Higher Medical Training both personally and within his company. Dr Sanderson's wider contributions are also demonstrated by his position as clinical representative on the Scottish Executive's Strategy for Life Sciences Industry Advisory Group and his involvement with the Scottish ABPI.

Ordinary Fellowship

The following Members of the Faculty were awarded Ordinary Fellowship:

- Dr Graham Barker
- Dr Nina Bjarnason
- Dr Michael Bowden
- Dr Jorgen Dirach
- Dr Geoffrey Down
- Dr Ruth Hargreaves
- Dr Neil Mackillop
- Dr Donna McVey
- Dr Khurshid Alam Mridha
- Dr Robert Sands
- Dr Maria Sarno
- Dr Laurence Skillern
- Dr Siân Walker

New Fellows

- Back row from the left:*
- Dr Jorgen Dirach,*
- Dr Siân Walker,*
- Dr Graham Barker,*
- Dr Geoffrey Down.*
- Front row from the left:*
- Dr Laurence Skillern,*
- Dr Maria Sarno,*
- Dr Donna McVey,*
- Dr Ruth Hargreaves,*
- Dr Khurshid Mridha.*



Ordinary Membership

Twenty-seven doctors were granted Ordinary Membership (MFPM) in 2006.

- Dr Izabella Bossowska
- Dr Sarah Bourne
- Dr Charles Brigden
- Dr Kai Chuen Chan
- Dr Emma Dellow
- Dr Andrew Francis-Lang
- Dr Shazia Hasan
- Dr Markus Hinder
- Dr Teresa Improta-Brears
- Dr Sangeeta Jethwa
- Dr Nandan Koppiker
- Dr Kate Lyttle
- Dr Andrew Makin
- Dr E David McIntosh
- Dr Teng Jin Ong
- Dr Sheuli Porkess
- Dr Suyash Prasad
- Dr Graham Ross
- Dr Obukohwo Siakpere
- Dr Jitendra Solanki
- Dr Bernard Souberbielle
- Dr Fredric Steinberg
- Dr Sivayogan Thiagarajah
- Dr Anissa Tse
- Dr Julius Vaz
- Dr Adrian Warnock
- Dr Guy Yeoman

Certificate of Completion of Training (CCT) in Pharmaceutical Medicine

Seventeen members received their CCTs in 2006.

- Dr Graham Barker
- Dr Joanne Collier
- Dr Helen Colquhoun
- Dr Emma Dellow
- Dr Geoffrey Down
- Dr David Gordon
- Dr David Haynes
- Dr Andrew Hockey
- Dr Mark Layton
- Dr Stephen McDonough
- Dr Edwin McIntosh
- Dr Sunil Navani
- Dr Virginia Norris
- Dr Charles Phillips
- Dr Graham Price
- Dr Latha Ratnasingam
- Dr Paul Slade



Dr Latha Ratnasingam, Dr Andrew Hockey, Dr Geoffrey Down and Dr Stephen McDonough



New Members

Back row from the left: Dr Graham Ross, Dr Bernard Souberbielle, Dr Jitendra Solanki and Dr Suyash Prasad.

Front row from the left: Dr Teng Jin Ong, Dr Fredric Steinberg, Dr Teresa Improta-Brears, Dr Sarah Bourne, Dr Sheuli Porkess and Dr Guy Yeoman

Annual General Meeting 28 November 2006

Annual Symposium – Protecting Patients: The Future

This year's annual symposium was opened by Dr Susan Bews, President of the Faculty of Pharmaceutical Medicine. Dr Bews highlighted the changing external environment where patient expectations in terms of safety, efficacy and concordance were rapidly changing.

Dr June Raine, Director, Post Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), then presented 'Medicines Safety – Sharing the Challenge'. Dr Raine believed we were currently at a turning point regarding drug safety. There were various influences bringing about this change, including societal pressure and the recent UK Health Select Committee report on the influence of the pharmaceutical industry. How have Regulators been responding to these 'influences of change'? The MHRA is currently being restructured: a new vigilance and risk management division has been created and new IT systems procured to more actively monitor risk:benefit of drugs. A mind-set change was required – moving from detecting harm to demonstrating greater safety. But how is this challenge to be shared? Dr Raine explained that this could be achieved by greater collaboration with academic research (Innovative Medicines Initiative currently underway), more integration with the NHS (electronic records), greater stakeholder involvement (patient reporting of ADR's), streamlining regulation (self certification of label changes in some circumstances – type 1A variations) and building a network of EU agencies (European Commission consultation assessing pharmacovigilance resources in the EU). Change is taking place, but challenges remain - including how best to involve patients and better targeting of resource.

Dr Agnes Saint Raymond, Head of Sector for Scientific Advice Paediatric and Orphan Drugs, European Medicines Agency (EMA), then discussed the proposed new EU regulation of medicinal products for paediatric use. Historically it has been argued that to study medicines in children was unethical, however we were informed that not giving the paediatric population the chance to benefit from research was also unethical. Legislation will bring about implementation of the new paediatric regulation in early 2007. The objectives of this are to increase high quality/ethical research and availability of/information on medicines for children. This will be achieved via the creation of a paediatric committee at the EMA, incentives for pharmaceutical companies (patent protection available for extra 6 months or 10 years data protection/exclusivity if off-patent) and the use of Paediatric Investigational Plans (these will be research

and development plans to ensure the availability of data in the paediatric population. These need to be agreed with the Paediatric Committee EMA and written at around the time of the adult PK [pharmacokinetic] studies).

Free scientific advice is also being offered by the EMA who will liaise with the FDA to ensure developmental compatibility between the EU and US. In addition an EMA paediatric research network will be established to link together existing networks and facilitate the conduct of studies. All the above is aimed to encourage better medicines for the children of Europe (and the world). When asked if it was just PK studies that were required in this population Dr Saint Raymond argued that it was efficacy and safety studies too – children were different and not just small adults. It was also clarified that if a company performs studies in children and the medicine is effective, then the product must be put onto the market.

Professor Hazel Biggs, Professor of Medical Law at Lancaster University, then gave a presentation entitled 'Consent is not enough - Patient safety and data protection'. A thought provoking presentation was given which examined whether consent and data protection promoted and protected patient safety. It was argued that in terms of consent the law was failing and the implementation of the law was failing too. The Data Protection Act was an excellent premise but poorly understood.

Professor Joe Collier, Professor of Medicines Policy, Consultant in Clinical Pharmacology, St Georges Hospital, London, discussed his observations as an advisor to the UK Health Select Committee which examined the influence of the pharmaceutical industry. After describing how parliamentary select committees are formed and operate, the key findings from the 2005 report on the pharmaceutical industry were summarised. Professor Collier indicated that, with regards to health provision, the report found that the industry had enormous influence in the UK. This influence rarely breached the law, but could distort health provision. He felt that there was too much 'spin' when it came to industry responses to the report and that the industry should take pro-active action to right wrongs before reports such as these are published. There was a vigorous Q&A session after the presentation covering issues that needed addressing in relation to poor prescribing by health care practitioners.

Dr Jonathan Stewart MFPM

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

ETHICS DAY:

Clinical Research and the provision of new medicines: A crisis of confidence

TUESDAY, 15 MAY 2007

Royal College of Physicians, 11 St Andrews Place, London NW1 4LE (with the kind permission of the Treasurer)

A day of debate and discussion with speakers:

Dr Mary Baker

President European Federation of Neurological Associations

Professor Zulfiqar Bhutta

Professor and Chair, Dept. of Paediatrics and Child Health, Aga Khan University, Pakistan

Professor Sir Gordon Duff

Chairman, Commission on Human Medicines

Dr David Glover

Independent Consultant, Pharmaceuticals & Biotechnology

Professor Trevor Jones CBE

King's College London

Dr Ronald Krall

Senior Vice President and Chief Medical Officer, GlaxoSmithKline

Professor Sir Michael Rawlins

Chairman, National Institute of Clinical Excellence

Dr Ian Rubin

Medical Director, Ashfield Healthcare Ltd

Dr Richard Smith

Chief Executive, United Health Europe, former Editor, The BMJ

Booking form available from the Faculty Office or on the Faculty website www.fpm.org.uk

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