

Annual Meeting

29 November 2007



Advancing the science and practice of pharmaceutical medicine for the benefit of the public

The Faculty of Pharmaceutical Medicine



President's Address

This second year of my presidency has been just as busy as my first, but equally fulfilling and enjoyable. I was therefore delighted to know in August that I was re-elected unopposed.

This for me was very exciting and gratifying. It confirmed what so many of you have so very kindly said to me in emails or in person, that you support me in the ways I want to take the Faculty forward and in the plans and visions I have. Thank you for that vote of confidence. I feel very privileged to know that I have your backing and I look forward to serving the Faculty in this capacity for

a further two years. Importantly for me, it gives me sufficient time to see some of the new initiatives come to fruition or to at least be on a secure road to progress.

As you all know, the government's White Paper on the regulation of the medical profession was issued in 2007, and I committed the Faculty to ensuring a process for revalidation for pharmaceutical physicians wherever their place of work, whatever their role.

There are two aspects which the Faculty have to consider, relicensing to stay on the GMC medical register, and, for those to whom it applies, recertification for those on the specialist register.

Progress has been excellent on both fronts. We have quite detailed proposals as to how the Faculty can assist member and non member pharmaceutical physicians in two of the aspects of relicensing which can be difficult for those working in small organisations or as independent consultants, namely the provision of an appraisal system and of a process for multi-source feedback. There will still be a lot of work to be done to define the detail of both of these, but the proposals were acceptable in principle to the GMC. In terms of the third aspect of relicensure for pharmaceutical physicians, the "GMC affiliate", this has also been discussed with the GMC and the concepts we put forward as to how this requirement could be met again received a positive response. Of course, this latter aspect is actually a GMC responsibility but as we are so different from the NHS environment we considered it prudent to be proactive in proposing a solution to what could have become a tricky problem.

In terms of recertification, we are, I believe keeping at least abreast of other colleges and faculties in developing our proposals. The Academy of Royal Medical Colleges has been an excellent forum through which ensure that our proposals for recertification onto the specialist register meet the same standards. At the moment we are proposing a collation of validated evidence to demonstrate chosen competencies from the Pharmaceutical Medicine Specialty Training curriculum but no examination. There are still however a lot of details that have to be worked through but I am confident we can meet whatever time scales the government decide upon.

Our Pharmaceutical Medicine Specialty Training, previously known as Higher Medical Training, is going from strength to strength. We have had 60 new trainees into the scheme since last year's AGM making a total of over 250 who are in or have been through their specialty training. For a relatively small Faculty this really is fantastic, mainly because it demonstrates such a real commitment from those joining pharmaceutical medicine from clinical careers. I want to thank all of the many members – some nearly 200 – who contribute in various ways to ensuring the smooth running and success of our PMST scheme.

In my presidential address this time last year, I set myself the goal of continuing to encourage and enable a wider membership to contribute to the work of the Faculty. I believe we have done this in the past year but will continue to do so as the more resources we have, the more external activities we can become involved in and there remain many areas where I would like to see some or greater Faculty participation and input.

We sent out a questionnaire earlier in the year to ascertain member's availability and interests. We received an excellent response to that and have set up a database so we can approach appropriate members directly for assistance, for example, to assist with consultation documents or to write articles. However we would like to expand that database. So, please, do let us know if you have a special interest or a little bit of extra time you can give to the work of your Faculty.

This year as part of that objective and setting the scene for the new governance arrangements we appointed the Specialist Advisory Committee chair and members by open advertising and interview. The interview panel was comprised of independent persons apart from myself. The response was gratifying and it was particularly pleasing to realise just how much thorough preparation had been put in by those applying. Another new initiative to involve more members and in this case to give our large international membership equal opportunity for involvement was the introduction of an Award for Outstanding Contribution, open to affiliates, associates and members. This award was to recognise a significant achievement to furthering the practice of pharmaceutical medicine in line with the Faculty's mission. We had a very good response from both the UK and overseas.

Another aspect of wider participation links with another goal I set myself, which was to enhance the image of pharmaceutical physicians with patients, patient associations, carers and the public for patient benefit. The Faculty have not only taken every possible opportunity to attend meetings or functions involving non-healthcare professionals but we have also been proactive in seeking such opportunities. These physicians attend under the Faculty banner and we have had feedback that such attendance has been appreciated as bringing relevant expertise but not Company associated. We hope to extend these opportunities next year.

The feedback from the pharmaceutical physicians themselves has been that this can provide a unique

opportunity which can in fact benefit their company work.

Functions and meetings that I have attended which have included patient/public attendance have been diverse. But probably the greatest opportunities for the Faculty to interact directly with the public have been provided by one of our parent colleges, the RCP London.

I have attended the majority of the membership and fellowship award ceremonies held by the college this year. As president of our Faculty, it provides a wonderful opportunity to meet, after each ceremony, the family and friends of those people.


It is a superb opportunity to talk with a wide community from both the UK and overseas about what pharmaceutical medicine is, the contribution pharmaceutical physicians make and the role of the Faculty itself. I do not use it primarily to encourage new recruits to our specialty, although obviously if anyone expresses an interest I encourage and advise. I use it more as an opportunity to explain our specialty, to correct misunderstandings, to enhance our credibility.

In the same way, when I was asked to give a short formal presentation on our specialty at one of the ceremonies itself, I tried to educate on our vital role in the provision of healthcare, to correct some of the adverse myths that circulate about pharmaceutical medicine. The level of ignorance even amongst many of our healthcare professional colleagues may not surprise some of you, but it continues to astonish and disturb me and I consider one of my – and your – important roles is to take every opportunity to lay those myths to rest.

This year the Faculty took another unique opportunity to interact with the public and healthcare professionals when we decided to have a stand at the RCP London Open Day here in September. Over 900 people attended the event and it certainly seemed as if the majority came and looked at our stand, asked questions, took part in our quiz. Certainly a very large number of people went away that day more knowledgeable.

Allied to my goal of enhancing the image of pharmaceutical medicine, I believe two activities I have recently become involved in support this goal. I mention them because I believe they reflect well on the Faculty and give me additional opportunities to promote our Faculty and specialty and its rightful standing alongside other Colleges and specialties.

These are firstly that the RCP London has set up a group under the chairmanship of Dr Richard Horton, Editor of



The Lancet, to produce a report on the relationships of the medical profession and the pharmaceutical industry. The group functions very similarly to the group the RCP established to produce that highly acclaimed report on Professionalism. It is intended that this report should provide similar constructive recommendations and be of similar value with evidence being given to the group by a wide range of stakeholders.

The second is that Dame Carol Black as Chairman of the Academy of Medical Royal Colleges has determined that there should be a thorough governance review of that organisation and has asked me to chair the review which I am doing.

A Faculty activity which is still currently in its gestation period but which should become a measurable success next year is the Diploma in Human Pharmacology which we are planning to set up. Originally designed for principal investigators in Phase I units, this has been widened to now also be available to other personnel at Certificate Level – the difference being not in the knowledge required but in the skills and competence to be demonstrated. There has been very considerable support of the proposals from Sir Gordon Duff, chair of the Expert Scientific Group, the MHRA, ABPI and from CRO's in this country and Europe.

The highly successful symposium "A Crisis of Confidence" run by our ethics committee must feature as one of the top highlights of the year. We had a packed audience who were very lively and considering the speakers included Richard Smith, Trevor Jones and Mike Rawlins it was not surprising that the stage was very lively too. We were grateful to our industry colleagues who were prepared to put their heads above the parapet and speak controversially too. It was a great day and sets a standard for the next one.

Pharmaceutical Medicine is global; unlike many aspects of clinical medicine it is practiced very similarly in very diverse countries and increasingly so as clinical research moves eastward. Our international membership has always been highly valued by the Faculty and that situation has not changed. In many ways it is becoming increasingly important for us to be seen to participate at a global level on international concepts. Of particular note this year are the activities relating to the European Innovative Medicine Initiative or IMI. The Faculty has supported a submission to the IMI as part of a call for support for pharmaceutical medicine which includes, as an integral part, the development of IFAPP's Council for Education in Pharmaceutical Medicine. It is very good news that this submission to the IMI has been approved

by EFPIA and so will be part of a set of initiatives that now go forward for public consultation.

Colleagues, all this is really only a glimpse of the work and activities of the Faculty. We have achieved a great deal in this last year, there will always remain a lot to do even just to keep up with the evolving environment but especially if we want to develop the Faculty in any way. But for next year, the priorities must be to see the new governance structure in place under transitional arrangements, to ensure we keep abreast of revalidation requirements, to ensure the successful continuation of the Diploma in Human Pharmacology project and to continue to develop the goals I referred to earlier. As well of course as continuing with all the work that is ongoing and at the heart of our mission.

My crystal ball tells me that it will be another very busy year.

Dr Susan Bews, President

Diploma and Certificate in Human Pharmacology Update

The Faculty is very pleased to report that a contribution to start-up funding has been provided by the Department of Health, Research and Development. Professor Sally Davies, Director of NHS R&D stated: 'Human pharmacology studies are a critically important step in the development of new medicines. They provide the bridge between translational medicine and clinical research, in which the Department of Health is already investing heavily. We are pleased to support the Faculty of Pharmaceutical Medicine in its initiative to provide these training programmes and qualifications.'

Professor Sir Gordon Duff, Chairman of the Commission on Human Medicines said: 'The training of human pharmacologists has become an increasing priority. This multi-disciplinary area underpins the development of new medicines and their rational use in medical practice. The Faculty of Pharmaceutical Medicine is, therefore, to be congratulated for introducing objective quality standards of training with its new Diploma and Certificate in Human Pharmacology. This important initiative will be to the benefit of the wider public health.'

Elections and Awards

The Faculty Board

Dr Susan Bews was elected for a second term as President of the Faculty.

Dr Neil Hounslow was re-appointed as Treasurer for a second term.

Following the completion of Dr David Galloway's term as Academic Registrar, Dr Kirsteen Donaldson was appointed Academic Registrar on an interim basis. This would be in addition to her duties as Chair of the Board of Examiners. As some changes to the role and method of appointment of Academic Registrar are proposed under the new governance arrangements the Board has agreed not to make a permanent appointment to this role at the present time.

Dr Richard Tiner, Dr Siân Walker and Dr John Young were elected as new Board members. Dr Philip Ambery, Dr Alan Boyd, Dr Simon Dando, Dr Fergal Donnelly and Dr Pablo Fernandez left the Board in 2007.

Faculty Awards Ceremony

The President welcomed all the new Fellows and Members and congratulated those who had been placed on the Specialist Register through the Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR) by PMETB since the 2006 AGM.

Honorary Fellowship

Honorary Fellowship was awarded to Dr Stephen Ankier

Dr Stephen Ankier's bibliography of peer-reviewed publications include a veritable Who's Who of distinguished researchers and authors from the world of pharmaceutical science and medicine which cover 43 unbroken years from 1964 to the present day. They span the pharmaceutical industry's therapeutic revolution which in the early 1960s saw the launch of psychotropic medicines, non-steroidal anti-inflammatory drugs and beta-blockers, to name but a few – and certainly it spans the development of pharmaceutical medicine, a term not coined until 1969.

Dr Ankier graduated in pharmacy at the Chelsea School of Pharmacy, and has earned a postgraduate biochemistry Diploma and a doctorate in Pharmacology in the Faculty of Medicine at University of London. From 1967, Dr Ankier was at Allen &


Hanbury's where he directed a neuropharmacological unit to evaluate novel compounds in the search for new medicines. In particular he made significant contributions to the development of new anti-migraine therapy and analgesics. In 1973 he entered clinical research in Roussel Laboratories, where he was solely responsible for characterising and developing a novel anti-dysrhythmic agent, and managed the clinical development of the company's neuropsychiatric portfolio, making a major contribution to their regulatory approval and market launch. From 1984-1992 Dr Ankier established and managed the clinical research unit and regulatory affairs function for Charterhouse, a contract clinical research organisation linked to St Bartholomew's hospital.

After obtaining a law degree, Dr Ankier has been teaching and writing on medical law as related to the pharmaceutical research. He is the principal author of *Medical Law and Research*, the first publication of its kind, which is now in its second edition. Dr Ankier has a prolific parallel career as a teacher, lecturer and tutor in many aspects of pharmaceutical medicine and research centred on the Charles West School of Nursing, University of London and Cardiff University. At the University of Surrey he made a major contribution to establishing four modules of the first Masters programme in Pharmaceutical Medicine. He is a Fellow of the Royal Statistical Society, the Royal Pharmaceutical Society of Great Britain, and the Royal Society for the Promotion of Health.

For the past 40 years Dr Ankier has been involved in preclinical and clinical pharmaceutical research, making innovative contributions to medical science as a preclinical scientist and clinical researcher, and promoting the practice of pharmaceutical science and medicine as a university teacher, tutor and author.

Honorary Fellowship was awarded to Dr Jeffrey Aronson

Dr Jeffrey Aronson is a Reader in Clinical Pharmacology at the University of Oxford and Honorary Consultant Clinical Pharmacologist and Physician at Oxford Radcliffe Hospital Trust. He is a highly distinguished clinical pharmacologist and physician, both in the UK and internationally. Within clinical pharmacology, Dr Aronson has been very active in the field of



drug safety and pharmacovigilance. He qualified in medicine at Glasgow University in 1970 and was awarded MRCP(UK) in 1973, a DPhil from Oxford University (on clinical pharmacology of cardiac glycosides) in 1977, MA (University of Oxford) in 1984, FRCP in 1985 and Fellowship of the British Society of Pharmacology in 2004. Dr Aronson's numerous achievements and awards include three visiting professorships to the University of Ceara in Brazil, University Kentucky in Louisville and the University of Colombo in Sri Lanka. He has been the Editor-in-Chief of the British Journal of Clinical Pharmacology since 2000, Editor-in-Chief of Meyler's Textbook of Side-Effects of Drugs, Editor-in-Chief of the Side Effects of Drugs Annals since 1991, Managing Editor of the European Journal of Clinical Pharmacology 1985-1993, as well as, memberships of many editorial boards and visiting editorships to important general and pharmacology journals. His public service is outstanding, including Vice Chairman of the Medicines Commission (2002-5), Member (2001-5), a Member of the Technology Appraisals Committee of NICE, Member of the Technology Assessment's Commissioning Board and a Member of the Joint Formulary Committee of the British National Formulary and President of the British Pharmacological Society (2006-7).

His responsibilities at Oxford University include his position as Head of the University Department of Clinical Pharmacology (1990-1 and 2000-1), a Fellow of Green College since 1984 and a member of several groups and committees relating to the history of medicine at the University. He has delivered numerous invited lectures, including national named lectures and has made significant contributions to the medical literature with 86 original articles, 27 editorships of books, 65 editorial and commentaries, 126 book chapters and reviews and 62 presentations to national and international learned bodies.

Dr Jeffrey Aronson was lecturing in Australia on 29 November, and he will be presented with his certificate in 2008.

Honorary Fellowship was awarded to Professor Huw Jones

Professor Huw Jones is the Postgraduate Dean for Medical and Dental Education for the Eastern Region of the United Kingdom. For the past 18 years he has been a Consultant Clinical Oncologist at Addenbrookes Hospital in Cambridge and was

appointed as the Postgraduate Dean in 2002.

The role of Postgraduate Dean is to lead the commissioning, management, monitoring and the quality assurance of postgraduate education for medical and dental trainees in both hospital and community practice. In March 2003, with the initiation of the Higher Medical Training Programme by the Faculty, Professor Jones became the Lead Postgraduate Dean with responsibility for Pharmaceutical Medicine throughout the UK and the "Virtual Deanery of Pharmaceutical Medicine" was created with Professor Jones at the helm.

Pharmaceutical Medicine has a number of unique features which are quite distinct from other more 'hands on' clinical specialities and the Faculty has been fortunate to be able to benefit from his extensive experience as our speciality training programme continues to evolve.

Professor Jones has been involved in many aspects of the programme including the training of our Senior Speciality Advisors and Educational Supervisors, where he is able to share his knowledge of good educational practice from other specialities and disciplines. Professor Jones also attends each meeting of the Specialist Advisory Committee and he was instrumental in recognising the need to establish a SAC in Pharmaceutical Medicine in its own right and he encouraged us to work for this achievement. This resulted in Pharmaceutical Medicine being recognised in 2006 as a truly independent speciality within the Joint Royal Colleges of Physicians Training Board. Finally, Professor Jones' key input has been into the RITA (Record of In Training Assessment) process which ensures that all our trainees demonstrate and achieve the standards necessary. Each trainee has to attend an annual RITA. Professor Jones chairs each RITA session and examines each trainees' progress personally. Professor Jones has probably now performed in excess of 500 individual RITAs.

It is clear that Professor Jones' firm belief in our Speciality, his adherence to the highest educational standards and his encouragement and support to all those involved in the Faculty's educational work is having a significant and long lasting impact on the development of the standards in the practice of Pharmaceutical Medicine and hence patient safety worldwide.

Honorary Fellowship was awarded to Professor Brian Kirby

Professor Kirby trained at the University of Leeds and worked as a Medical Registrar at the Central Middlesex Hospital in London. His early interest was focussed on the cardio-pulmonary effects of acute myocardial infarction and as a result of this work and a Medical Research Council grant, he was appointed to a research position at the Commonwealth of Virginia University in the United States, working with Dr Sami Said on vasoactive substances extracted from lung. On return to the United Kingdom, he was appointed to a prestigious Registrar post at the Hammersmith Hospital in Clinical Cardiology, at that time one of the centres for Clinical Cardiology, not only in the UK but in Europe.

Professor Kirby then moved to an academic appointment as Lecturer in Medicine in the Department of Medicine at the University of Edinburgh. After a short time in Edinburgh he was then appointed as Deputy Director, becoming Director, Reader and then to a personal Chair at the Postgraduate Medical School at the University of Exeter. Subsequently, his clinical commitment to acute emergency medicine continued with particular reference to cardiology. Throughout this time of academic application and research coupled to a substantial degree of university based administration, he maintained his interest and expertise in acute emergency medicine and in particular Cardiology. Professor Kirby became increasingly interested in coronary prevention and initiated a landmark study of more than 3,000 school children in Devon, which attempted to identify coronary risk factors in young people.

His committee activities at this time were no less extensive and he became a member of a number of advisory committees to the Department of Health including Vice Chair of the Committee on Review of Medicines, a member of the CSM, one of a panel of external advisors on the Safety of Medicine, a member of the Clinical Complaints Procedure Panel and numerous other national bodies of concern to the health of the UK public. Professor Kirby was also involved in the Home Office Prison Service, in the European Community, in the Coronary Prevention Group, the National Heart Forum as well as the GMC and has played an important role in a number of committees associated with the Royal College of Physicians London.


Within pharmaceutical medicine, the Faculty was fortunate to recruit Professor Kirby to its Board of Examiners and he has played an active and contributory role as an examiner for the last decade. His contribution to pharmaceutical medicine has been substantial not only in his teaching commitments both in Edinburgh and in Exeter but also in his knowledge of appropriate drug therapies in acute, sub acute and chronic medical practice. He has been recognised for these services both in terms of research, teaching and academia by National awards, among which was an OBE for services to medicine and health in the New Year's Honours List of 1997.

Honorary Fellowship was awarded to Professor James Ritter

Professor Ritter is Professor and Head of Clinical Pharmacology and Honorary Consultant Physician at Guys, Kings and St Thomas' School of Medicine and Guys' and St Thomas' NHS Foundation Trust. He has an eminent academic and clinical reputation and is a recognised expert in human cardiovascular pharmacology especially endothelial function and cardiovascular risk factors. Professor Ritter has sat on the subcommittee on safety and efficacy of the CSM and has chaired local and multi-centre research ethics committees, and he is an Editor of the British Journal of Clinical Pharmacology.

In addition, Professor Ritter has played a leading role in the development and support of postgraduate medical training in Clinical Pharmacology and Therapeutics (CPT). He is a former Chairman of his regional Deanery Training Committee and is the current Chairman of the Specialist Advisory Committees on CPT.

Professor Ritter's support of pharmaceutical medicine goes back many years. He was a member of the Faculty's Board of Examiners between 1999 and 2005 and an active contributor to this, particularly to the Viva Section. Professor Ritter was also Chairman of the Subcommittee on Pharmaceutical Medicine of the SAC on CPT from May 2005 until September 2007. From May 2006, an SAC on Pharmaceutical Medicine in its own right was established, with a new constitution and membership taking effect from October 2007. Professor Ritter's support and contribution to this achievement cannot be underestimated. Having a SAC in pharmaceutical medicine represents an acknowledgment that



specialty training in pharmaceutical medicine now operates on the same basis as the other specialties overseen by the Joint Royal Colleges of Physicians Training Board. During his time as Chairman of the SAC Subcommittee and SAC, Professor Ritter had overall responsibility to the parent Colleges for the educational aspects of our training programme. The Faculty has been extremely fortunate to have been able to benefit from Professor Ritter's wide experience in this area and his ability to adapt his knowledge to the particular requirements of pharmaceutical medicine.

Honorary Fellowship was awarded to Professor Sam Salek

Professor Salek is Professor of Pharmacy Practice and Pharmacoepidemiology at the Welsh School of Pharmacy, Cardiff, and Director of the Centre for Socioeconomic Research. He has been a member of the Faculty's Education Committee since 2005.

Professor Salek has been deeply involved in the Postgraduate Course in Pharmaceutical Medicine run in conjunction with BrAPP since 1986, and has been Director since 1991. Very many pharmaceutical physicians working in the industry today have expressed their gratitude to Professor Salek for his encouragement and nurturing.

Professor Salek has had a long and distinguished career in academic pharmacy and pharmacoepidemiology, in this country, the US, and Iran, and has current academic and professional links with nine other countries. He has published over 370 articles, abstracts, books and book chapters, is referee for 15 journals, and is on the editorial panel of four others. He is retained as external assessor of health-related quality of life trials by more than a dozen pharmaceutical companies.

Professor Salek has worked closely over many years with the Department of Health, particularly the Pharmaceutical Division and MCA/MHRA, and has been sponsored by government to carry out several projects. He is increasing his involvement with medical charities and patient organisations, particularly in the field of Parkinson's disease.

Fellowship by Distinction

Fellowship by Distinction was awarded to Dr Thomas Steinbach

Dr Thomas Steinbach practised forensic medicine for 10 years becoming head of the GAF institute of Pathology and Forensic Aviation Medicine in Germany. He was appointed lecturer in medical psychology and medical ethics at Ludwig-Maximilians University Munich in 1989. In 1991 he joined the pharmaceutical industry in the field of drug safety holding positions in Germany and the UK. During this time he has contributed to the pharmacovigilance work of numerous professional groups and has made 30 international presentations. For a distinguished career in academic and scientific medicine and international pharmaceutical medicine Dr Steinbach is awarded Fellowship by Distinction.

Honorary Membership

Honorary membership was awarded to Mr Peter Jay

Mr Peter Jay is the Chief Executive of MedicoLegal Investigations Ltd. As one of the founders (with Dr Frank Wells) of the only European organisation investigating, detecting, preventing and prosecuting clinical research fraud and misconduct, he has been responsible for training a great number of pharmaceutical company employees in the prevention and detection of research fraud. He has been pivotal in taking 26 doctors to the General Medical Council for fraud, of whom all but one were found guilty of serious professional misconduct. His company has carried out investigations not only in the UK, but also Europe, Russia and the US.

Peter Jay was formerly a career Detective Chief Inspector in the Metropolitan Police. His extensive experience of major investigations included a three-year spell at Scotland Yard's Company Fraud (now Serious Fraud) Office.

In 1984, following his retirement from the Metropolitan Police after 26 years service, he was invited to join the General Medical Council solicitors (then Messrs Field Fisher Waterhouse) as an investigator and for six years he investigated all manner of allegations against doctors including irresponsible prescribing, gross negligence, dishonesty, indecency, patient exploitation and, on rare occasions, made enquiries for the GMC Health Committee to confirm a doctor's

continuing impairment to practise for health reasons.

In 1996, he set up the independent agency MedicoLegal Investigations, in collaboration with Dr Frank Wells, former Medical Director of ABPI, to combat research fraud and misconduct. He became Chief Executive of MedicoLegal Investigations Ltd when the company was formed in February 2001.

Recent years have seen a significant decline in the number of cases of suspected fraud, which is attributed by many to Peter's passionate conviction that it is essential to keep the possibility of fraud high in the awareness of industry researchers.

Membership by Distinction

Membership by Distinction was awarded to Dr David Roblin

Dr David Roblin is Vice President, Head of Clinical Research and Development with Pfizer Global R&D. Under his leadership there has been a major expansion of Phase I capacity in Europe and he has also advanced the development of translational medicine. Dr Roblin is committed to education and training in pharmaceutical medicine at both undergraduate and postgraduate level and has created frameworks within Pfizer to facilitate both. He is also an active contributor to many professional associations and has an impressive track record of influential and successful leadership and innovation in medicines development.

Ordinary Fellowship

The following Members of the Faculty were awarded Ordinary Fellowship of the Faculty:

Dr Peter Arlett
Dr Anne Kehely
Dr Glenn Matfin
Dr Latha Parvataneni
Dr Philippa Smit-Marshall
Dr Kristina Strutt

Ordinary Membership

Nineteen doctors were granted Ordinary Membership (MFPM) since last year's AGM.

Membership

Via UK Diploma in Pharmaceutical Medicine

Dr Simon Ashworth
Dr Sandip Chaudhuri
Dr Joanne Collier
Dr Colm Galligan
Dr Paul Gandhi
Dr Matthew Goodman
Dr Annelize Koch
Dr Imran Lodhi
Dr Stuart McIntosh
Dr Rakesh Patel
Dr Jayvant Ramjee Heera
Dr Duncan Richards
Dr Koshika Soma
Dr Stephen Watt
Dr Colin Wheeler
Dr Andrew Zambanini

Via Diploma in Pharmaceutical Medicine, Free University, Brussels

Dr Hagen Krüger
Dr Irena Sassin
Dr Rafal Ziecina

Specialist Register in Pharmaceutical Medicine

Twenty members were placed on the Specialist Register since the 2006 AGM.

Dr Latif Akintade
Dr Arash Bakhtyari
Dr Alice Butler
Dr Joanne Collier
Dr Tristan Cooper
Dr Robert Lai
Dr Kate Lloyd (CESR)
Dr Christa Ulrike Lorch
Dr Oswald Morton (CESR)
Dr Richard Philipson
Dr Charles Phillips
Dr Neil Pumford
Dr Jonathan Ryland
Dr Julian Schofield
Dr Jit Solanki
Dr Martin Toal
Dr Eng Soon Teo
Dr Mark Tomlinson
Dr Christopher Worth
Dr Guy Yeoman



*Dr David Roblin (Member by Distinction)
 Professor Brian Kirby (Honorary Fellow)
 Professor Huw Jones (Honorary Fellow)
 Dr Kristina Strutt (Ordinary Fellow)
 Professor James Ritter (Honorary Fellow)
 President
 Professor Sam Salek (Honorary Fellow)
 Dr Latha Parvataneni (Ordinary Fellow)
 Dr Stephen Ankier (Honorary Fellow)
 Mr Peter Jay (Honorary Member) and
 Dr Thomas Steinbach (Fellow by Distinction)*



*Dr Eng Soon Teo (CCT)
 Dr Joanne Collier (CCT)
 Dr Kate Lloyd (CESR)
 Dr Oswald Morton (CESR)
 President
 Dr Ulrike Lorch (CCT)
 Dr Jitendra Solanki (CCT)
 Dr Christopher Worth (CCT)
 and Dr Colin Wheeler (Member)*



*New Fellow of the Faculty
 Dr Latha Parvataneni (back
 row, far right) with her sister-
 in-law Lorraine O'Sullivan, her
 sister Geetha Maheshwaran
 (back row centre), her son
 Master Jahnu Parvataneni and
 her niece Miss Sundaraama
 Maheshwaran*



*New Member and Specialist in
 Pharmaceutical Medicine
 Dr Joanne Collier
 and her husband Paul Wright
 and daughter Georgia*

Annual Dinner

Annual Dinner

Dr Susan Bews took the Chair at the Annual Dinner at which the Guest of Honour was Professor Sir Liam Donaldson, Chief Medical Officer for England. We were pleased to welcome as guests for the first time representatives from the Patients' Association, the National Patient Safety Agency and the British Medical Association.

Faculty medal

Awarded in recognition of outstanding services to the Faculty of Pharmaceutical Medicine.

Dr Frank Wells

Dr Wells came from general practice and then the BMA to join the industry association ABPI as Medical Director in 1986, and soon became familiar with the peculiarities of the pharmaceutical industry. Dr Wells realised that sound research data is at the heart of drug licensing and commercialisation and that the fabrication of data by clinical investigators could no longer be allowed to be tolerated because of the dangers to patient safety. Dr Wells was

instrumental in bringing the first cases of fraudulent clinical research data to the GMC. He trod an unenviable path, the repercussions to the industry - even of proven cases - cannot be overestimated. Ethics have continued to drive Dr Wells' passion for pharmaceutical medicine. He has played a very active part in many Faculty initiatives, having been a highly respected trustee and contributed greatly to the Faculty's Ethical Issues Committee and their publications. He now undertakes a similar role in Europe as the Co-Chairman of the Ethics Working Party of the European Forum for Good Clinical Practice.

Outstanding Contribution Award for Affiliates, Associates & Members of the Faculty of Pharmaceutical Medicine 2007

Congratulations to Paediatrician and Pharmaceutical Physician Dr Suyash Prasad, Winner of the 2007 Outstanding Contribution Award.

This award was established last year to recognise the important contribution that Affiliates, Associates and Members of the Faculty of Pharmaceutical Medicine (FPM) make towards furthering the practice of pharmaceutical medicine in line with the mission of the Faculty.

Dr Prasad's entry concerned 'Attention Deficit/Hyperactivity Disorder - ADHD,' as Faculty President Dr Susan Bews explained at the FPM Annual Dinner in November. In the view of the judges, his entry was 'an excellent account of a child-centred pharmaceutical approach to a distressing paediatric condition'.

Dr Bews was one of the three Award judges. The judging panel was chaired by Professor Sir Alasdair Breckenridge, Chairman of MHRA. The third judge was Claire Rayner, President of the Patients Association.

Two key features of the project were highlighted by Dr Bews. 'This was a UK study with both paediatric and child psychiatry sites, not just to reflect working practice in the UK but also to promote joint working and shared learning between the two specialist groups. This was the first ADHD pharmacotherapy study that formally assessed the child's viewpoint within the context of their chronic illness and both groups of specialists have started to change their clinical practice to take into account the value of regular Health-related Quality of Life assessments.'



Dr Frank Wells receiving the Faculty Medal from the President.



Dr Suyash Prasad receiving the inaugural Outstanding Contribution Award from the President.

A medal and certificate were presented to Dr Prasad at the Dinner. 'It has been a privilege to work with colleagues of exceptional quality on a project that has had considerable impact on paediatric clinical practice,' he said. 'It is especially pleasing and personally satisfying to receive such positive comment on this project by the Faculty'.

Entrants were asked to submit written summaries of projects they had played a significant role in and which contributed towards the Faculty's mission – to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the speciality for the benefit of the public. The judges were also looking for an innovative project that involved the entrant in going above and beyond what was expected as part of their job and evidence that a difference has been made.

There was a good response from both the UK and overseas. The judges commented on the high quality of the entries and the interesting range of projects submitted. A wide range of topics had been chosen, from public health research projects in underdeveloped countries, initiatives for improving education for pharmaceutical physicians, to therapy area specific research.

Following the success of the 2007 Award, entries are now sought for 2008. Dr Prasad believes that the Award represents an opportunity to 'reflect the continuing high professional standards of the Faculty' and that it is an opportunity for 'the extremely talented members of the Faculty to demonstrate the value of their scientific and medical contributions'.

The eligibility criteria for the 2008 Award are as follows:

1. Entrants must be a current Affiliate, Associate or Member of the Faculty of Pharmaceutical Medicine.
2. Entrants must have played a significant role in the project.
3. Only individual entries will be accepted.
4. The project must normally have occurred or have had an impact during the two years leading up to the closing date.
5. The written submission must be the original work of the individual entrant.

The closing date for entries is 30 June 2008. Full details are available from the Faculty website (www.fpm.org.uk).

Dr Amanda Oliver MFPM

Outstanding Contribution Award

Outstanding Contribution Award (Affiliates, Associate and Members)

Dr Suyash Prasad MBBS MRCP MRCPC MFPM

**Senior Associate Medical Director,
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Overview

ADHD (Attention-Deficit/Hyperactivity Disorder) is a neurodevelopmental disorder affecting approximately 5% of the paediatric population in the UK. Most of the research into ADHD has been conducted in the US, where there is greater recognition of this condition. Given the increasing range of treatments available, and the differences between US and UK practice, it has been important to study ADHD in a UK population.

The SUNBEAM study (Study into the Broader Efficacy of Atomoxetine^{1, 2, 4}) is a study assessing ADHD in UK children and adolescents. It is a unique study for two principal reasons. Firstly, it is the UK's largest paediatric psychopharmacotherapy study that used a Health-Related Quality of Life (HRQL) endpoint as a primary outcome measure. In addition, parent, investigator and importantly, child rated psychometric measures were assessed at baseline and throughout the study. I have been a driving force behind the origination, initiation, development, setting up, management, and scientific data dissemination of the SUNBEAM study.

The SUNBEAM study has been considered a model of performing paediatric pharmacotherapy studies in the UK, given its focus on HRQL and child-rated measures. It is of particular relevance with the increased focus on paediatric studies in light of the recently passed EU legislation on medicinal products for paediatric use.⁶

Project Timelines

The project started in early 2003 with publication of the primary manuscript in February 2007.

Objectives of the Project

- To demonstrate the impaired HRQL that exists in children with ADHD, and how this improves with appropriate treatment¹
- To demonstrate how childhood perceptions of illness and their treatment might be explored in a


formal scientific manner. This was done by applying a formal, psychometrically validated, child-rated measure of self-esteem (Harter scale), to all children at baseline and throughout the study.⁴ Although there was some discussion about the capabilities of children to provide accurate and consistent insights into their illness and treatment, given that there is increasing focus on children's rights, autonomy and viewpoints⁷, it was felt that this would yield important information of value to specialist clinicians in their management

- To educate Child Psychiatrists, Paediatricians and other child-focussed health care practitioners (groups traditionally somewhat inexperienced in performing clinical trials) on the ethical, legal and practical aspects of running pharmacotherapy studies in children. This is in keeping with the current considerable focus on performing clinical trials in children, and in alignment with recent EU legislative changes regarding medicines development in paediatric populations
- To demonstrate a model of how child focussed health care professionals and industry can work in partnership together, to develop high quality and comprehensive data that addresses key clinical questions
- To demonstrate a model of how studies in children can be performed in the UK, in alignment with recently passed European legislation
- To develop clinical trial data that would be of value in demonstrating the cost effectiveness of medication, in keeping with increasing focus on the economic evaluation of medicines in the current environment. This was done by delivering data on HRQL and functional outcomes in children from the parent and child perspective

My Role

I developed the initial concept of the SUNBEAM study, after discussion with specialist ADHD clinicians. I bid for funding from the UK senior management after convincing them of the necessity and value of supporting a long term project of this nature. Once funding was secured, we were able to start the project.

After writing the protocol, in conjunction with statistician and clinical research colleagues within Lilly, I led the SUNBEAM study over a period of approximately 3-4



years. This included driving the submission through the national and local ethics committees – such groups had concerns given that this was a study of a psychoactive compound in children.

I was involved in training the clinical investigators and sub-investigators (approx 60 in total - the majority of whom were new to clinical studies) on the practical aspects of running studies, the sensitivities of running studies in children, pertinent legal and ethical issues and details of the product. Training of investigators was accredited for CPD Points with the Royal College of Paediatrics and Child Health, in keeping with the faculty's aim of maintaining high training standards, and working in partnership with other professional bodies. This is especially important with regard to paediatric populations who represent a vulnerable group in our society, and thus any training needs to be comprehensive, of high quality and be able to withstand scrutiny.

Throughout the duration of the project I managed other issues if and when they arose. For example during the course of 2005, there were 3 safety changes to the atomoxetine label that required frequent, timely and comprehensive communication with clinical investigators and sub-investigators. Part of my role included educating the clinical investigators on the safety of medicines in paediatric populations, and on the specific safety issues that affected SUNBEAM. Accordingly all patients in the SUNBEAM study were reconsented.

I took a lead in the analysis of the data and its subsequent scientific dissemination. I presented the data for the first time at an international meeting² and am lead author on the primary manuscript.¹

What Differences has the Project Made?

ADHD in the UK is principally treated by two specialities: Paediatricians and Child Psychiatrists. It has been recognised that both specialities may have different approaches to treating ADHD. When selecting sites for SUNBEAM, we were keen to include both Paediatric and Child Psychiatry sites. This was partly to reflect working practice in the UK, but also to promote joint working and shared learning between the two specialist groups within the context of partnering with industry. This can be reflected in the authorship (and contributorship) of the primary publication¹ where industry, child psychiatrists and paediatricians are all acknowledged.

SUNBEAM has demonstrated the extremely poor HRQL (approximately 2.5 standard deviations below the mean) that exists in children with ADHD.^{1, 2} This has transformed understanding of the implications of this condition, and changed the paradigm of how it should be assessed, monitored and managed. In addition to proving or disproving a hypothesis, studies should also have clinical applicability. The SUNBEAM study has modified the clinical practice of ADHD in the UK. Several specialist Paediatricians and Child Psychiatrists, partly as a consequence of their involvement in SUNBEAM, and partly as a reflection of increasing awareness of HRQL and functional outcomes in children, have started to formally administer a HRQL assessment on a regular (usually six monthly) basis to their patients and families with ADHD.

There is increasing awareness that HRQL measures in children and adolescents are of importance in the assessment of children with chronic illness.⁹ One of the acknowledged difficulties however, is that there are few fully validated rating scales to measure HRQL in children. The primary outcome measure in SUNBEAM was the Global Score of the parent-rated Child Health and Illness Profile (CHIP), developed by Anne Riley (Professor of Psychology, Johns Hopkins University, Baltimore). I and my statistician colleague at Lilly, worked with Anne to publish the validation of the Global Score of the CHIP in UK ADHD children.³ This enables the CHIP scale to be used with confidence in future UK ADHD studies and has made a significant scientific contribution to the developing area of HRQL assessment in children.

SUNBEAM was the first ADHD pharmacotherapy study that formally assessed the child's viewpoint within the context of their chronic illness. These data were presented at the Royal College of Paediatrics and Child Health conference in April 2006.⁴ Indeed, the recent NICE guidelines for ADHD state that clinicians, when considering treatment choice in this condition, should include the child's viewpoint.⁵

SUNBEAM represents a useful model and a practical example of how paediatric studies could be run in partnership with industry in the UK. This is evidenced by invitations to a number of international Paediatric Medicines Development meetings to discuss the study,⁸ its practical management and implications in light of recent EU paediatric legislation.⁶ This demonstrates the utility of the study as an educational tool.

There was significant public interest in the SUNBEAM study and its philosophy of assessing HRQL in children with ADHD. Indeed there were several articles in national and regional press^{10, 11, 12} after the results were presented, with an estimated potential readership of 2.8 million; this may have enhanced the public perception of the pharmaceutical industry as the SUNBEAM study makes a considerable contribution to the understanding of the HRQL issues in ADHD.

Conclusion

In line with the recent EU paediatric legislation, there is recognition that high quality, comprehensive paediatric studies must be performed in order to demonstrate safety and efficacy in paediatric populations. The SUNBEAM study is a model of how child focussed health care professionals and physicians within industry, may partner to conduct such studies. It has advanced the science and practice of pharmaceutical medicine with its focus on HRQL and parent/child perception of illness, and enhanced the public profile of the pharmaceutical industry.

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Amendments to the Honorary and by Distinction categories were approved by the membership at the 2007 Annual General Meeting on 29 November 2007. Most significantly, entry to the Fellowship by Distinction category has been discontinued; however, current Members by Distinction as well as Ordinary Members can now be nominated for Ordinary Fellowship. The nomination form documentation and criteria for all categories are available on our website at www.fpm.org.uk/membership/fellowshipeclections.

The 2008 Annual Meeting will take place on Monday, 17 November, at the Royal College of Physicians London.

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