

# Annual General Meeting

## 11 November 2005



It is some nineteen years since I was first asked to sit on the shadow Board of the proposed Faculty of Pharmaceutical Medicine, and I have served continuously on the Board ever since in some capacity or other. This has, however, given me the opportunity to see the growth and development of the Faculty from close quarters. Much has happened such that the Faculty one sees now bears little relationship to the one we set up in 1989.

These last four years have seen enormous change and continued development of the Faculty. This last year alone has seen the first Certificates of Completion of Specialist Training (CCSTs) presented and a steady rate of recruitment to the Higher Medical Training programme. To date, 126 National Training Numbers have been issued and some 50 companies now have pharmaceutical physicians enrolled in the programme.

The establishment of the Postgraduate Medical Education and Training Board (PMETB) has presented us with new challenges and responsibilities. These include the revision of the curriculum, the continuing development of standards and assessments as well as the establishment of a visiting programme to sites where training is taking place.

Revalidation is an area where there has not been much activity over the past year. The medical profession is awaiting a report from the Chief Medical Officer before further progress is likely; it seems likely that many of the underlying principles that were already in discussion are set to remain.

CPD, for example, is sure to be an integral part of revalidation and we are now moving to a web based system for both recording activities and keeping reflective notes. This will hopefully make the whole process of CPD much easier to manage for our members and encourage those who are not recording data at the moment to do so. I have no doubt that most of us are active participants in CPD activity, but probably not always recording it as systematically as we should.

This past year has seen the introduction of the Faculty's Certificate of GCP examination, with 45 people sitting the examination to date. In addition, the Diploma in Pharmaceutical Medicine examination continues to attract some 45 to 50 entrants each year.

Perhaps the most important activity this year has been the development of a five-year strategy for the Faculty. I am grateful to Dr Steve Hobbiger for leading a team to produce a plan that will be challenging, but will ensure the fulfilment of the Faculty's mission. This plan could not have been conceived or any of its ambitious ideas developed unless the Faculty was in a sound financial position. Over the past four years we have seen a steady improvement in our financial strength. This has been achieved by the excellent stewardship of our Treasurer, Dr Richard Tomiak, who retires from office this year.

One of the great successes of the year is the recognition of the specialty by a second EU member state, namely the Republic of Ireland. This is a major step forward for the specialty. I am encouraged that other states are beginning to move in this direction as well.

My goal as President was to raise the profile of the Faculty and of pharmaceutical medicine in order that the organisation is more effective in the fulfilment of its charitable aims. I believe that this has been achieved through the work of many dedicated people too numerous to mention by name but I express my sincere thanks to you all. It has been a great honour and privilege to serve as President of the Faculty, and I wish my successor, Dr Susan Bews every success in her term in office.

*Dr Brian Gennery, President 2001-2005*

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## New President and Officers

At its Annual General Meeting on 11<sup>th</sup> November 2005 three Fellows of the Faculty of Pharmaceutical Medicine were elected to senior positions of Office.

Dr Susan Bews was elected President. In addition to holding positions as Medical Director with varying sized companies over twenty years, Dr Bews served on the ABPI Medical Committee for nearly twenty years, chairing this committee for ten of these. She served on the Prescription Medicines Code of Practice Authority Appeal Board for seventeen years and the Medicines Commission for five years. Dr Bews was involved in the formation of the Faculty in 1989 and was a member of its inaugural Board.

Dr Neil Hounslow was elected Treasurer. For the past 15 years Dr Hounslow has worked in a variety of senior roles in all stages of Clinical Drug Development at Parke-Davis

and Pfizer. In 1996 he joined the Faculty's Specialist Training Working Party, and subsequently served on the Education Committee as the Faculty worked towards the recognition of Pharmaceutical Medicine as a medical specialty in 2002. He joined the Board 4 years ago as Deputy Treasurer.

Dr David Galloway was elected Academic Registrar. A qualified Clinical Pharmacologist with a strong academic background, Dr Galloway has worked as a Senior Research Physician in a number of Pharmaceutical companies. He has been a member of the BMA negotiating team in Scotland leading to the new Consultant Contract, Director of the Medicines Assessment Research Unit in Aberdeen and now runs his own Research Company. He has been an active Board member of the Faculty for the past 4 years, latterly as Deputy Academic Registrar.

## First CCSTs granted in Pharmaceutical Medicine

At the Fellowship, Membership and Awards Ceremony, the Faculty acknowledged the first members who had completed the Higher Medical Training programme and had received or were awaiting receipt of their Certificates of Completion of Specialist Training:

Catherine Baxter	Brian Muller
Kevin Bridgman	Jacqueline Napier
Mireille Cantarini	Jatin Patel
Ruth Hargreaves	Juliet Roberts
Steven Hughes	Lindsey Rolfe
Pimprapa Kon	Robert Sands
Alan Lenox-Smith	Maria Sarno
Christopher Link	Laurence Skillern
Christopher Millwater	Howard Snow
Clive Morris	Michael Zaiac



*The President of the Faculty congratulates three members who had completed the Higher Medical Training programme, from the left Dr Juliet Roberts, Dr Maria Sarno, Dr Brian Gennery and Dr Alan Lenox-Smith.*

The annual reports from the Registrar, Treasurer and Academic Registrar were previously circulated to the membership and are available on the Faculty website at [www.fpm.org.uk/AGM/AGMAgenda.pdf](http://www.fpm.org.uk/AGM/AGMAgenda.pdf)

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## Faculty Board and Fellowship Report

### The Faculty Board

Dr Susan Bews was elected President of the Faculty for a two-year term.

Dr David Galloway was appointed Academic Registrar and Dr Neil Hounslow was appointed Treasurer.

Dr Philip Ambery, Dr Fergal Donnelly and Dr Simon Dando were elected as new Board members, whilst Dr Alan Boyd and Dr Pablo Fernandez were re-elected to the Board. Dr Karen Atkin and Dr Susan Griffith left the Board in 2005.

### Annual Dinner

The outgoing President, Dr Brian Gennery, took the Chair at the Annual Dinner at which the Guest of Honour was Professor Parveen Kumar. Dr Gennery formally handed over the Presidency to Dr Susan Bews at the Dinner.



*Dr Brian Gennery hands over the Presidency to Dr Susan Bews*

### Faculty Medal

Dr Gennery presented the Faculty Medal to the outgoing Academic Registrar, Professor John Griffin, in recognition of his contributions to the educational activities of the Faculty, in particular the Diploma of Pharmaceutical Medicine.



*Professor John Griffin receiving Faculty Medal from Dr Brian Gennery*

### Faculty Awards Ceremony

#### Honorary Fellowship

Honorary Fellowship was presented to Professor Nilima Kshirsagar and Professor Graham McClelland.

#### Professor Nilima Kshirsagar

Nilima Arun Kshirsagar was a student at Seth GS Medical College at a time when, in her words 'there weren't that many drugs, and often treatment would involve just talking nicely to the patient.' Inspired by Dr U K Sheth, who was the Professor of Pharmacology, the young Nilima Kshirsagar was attracted to the novel discipline of clinical pharmacology.

A brilliant student, she was awarded a training fellowship with GD Searle in the days of Geoffrey Venning. She has built on this firm foundation to become Dean of the Seth GS Medical College and King Edward Memorial Hospital, which is the largest and most prestigious of the Mumbai (Bombay) municipal teaching hospitals, and one of the largest hospitals in the world.

She is also Head of the Department of Clinical Pharmacology at the College, and one of the leading Indian Clinical Pharmacologists. Her election in 1999 as President of the Indian Society of Pharmacologists attests to that.

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## Faculty Board and Fellowship Report *continued*

She has set a clinical trials centre at KEM in close association with indigenous pharmaceutical companies. A recent success has been the commercialization of a liposomal antifungal for the treatment of Leishmaniasis. The clinical research facility will no doubt be of great value to the industry in years to come, since KEM has an unrivalled wealth of patients, and the expertise to conduct studies within Good Clinical Practice.

Her contribution to clinical pharmacology outside clinical trials has been substantial. She runs the regional pharmacovigilance centre for Maharashtra state, one of the largest in India, with a population about equal to that of the United Kingdom. She and her team have made a particular study of the treatment of epilepsy and of adverse reactions to anti-epileptic drugs. This has led to many publications, including several in *Drug Safety*.

On the international stage, Professor Kshirsagar is a member of CIOMS, the Council for International Organizations of Medical Sciences; and an advisor to the World Health Organization.

Professor Kshirsagar, by her charm, determination, and skill in pharmacological medicine, has set an example for others to follow, in an environment where resources we take for granted are often lacking. She will be an excellent ambassador for the Faculty.

### **Professor Graham McClelland**

Professor McClelland is an outstanding member of the British clinical pharmacology community who has made major contributions to pharmaceutical medicine.

By way of education Professor McClelland is both a pharmacologist and psychologist. He obtained his bachelor's degree in 1979 and his PhD, which was done on a part time basis, in 1987. This was on the topic of 'Psychometric Studies of Psychoactive Drugs in Normal Volunteers', a subject of great interest in the development of new products acting on the CNS. It was perhaps at this stage that his interest in surrogate markers and more recently biomarkers was beginning to emerge.

Between 1972 and 1987 he worked for Beecham Laboratories, during which time he was taking on more and more responsible positions, ending up with responsibility for clinical pharmacology studies on centrally and gastrointestinally acting drugs. There he developed and applied methods to measure gastric and cardiac function, psychometric tests and psychophysiological methods in volunteer studies.

Since 1987 he has been at Roche Products where he is now Global Head of Clinical Pharmacology Operations. He has been involved in the development of the antidepressant moclobemide (Manerix), the anti-AIDS drug saquinavir



*Dr Henry Pan, Fellow by Distinction; Dr Peter Jackson, Fellow by Distinction; Professor Graham McClelland, Honorary Fellow; Dr Richard Tiner, Fellow by Distinction; Dr Brian Gennery; Professor Nilima Kshirsagar, Honorary Fellow; Dr Tony Chandler, Honorary Member; Dr Fergal Donnelly, Fellow by Distinction; Professor Ann Sommerville, Honorary Member; Ms Sarah Wark, Honorary Member*

(Inivrase and Fortovase), the influenza treatment oseltamavir (Tamiflu), and the anti-obesity drug orlistat (Xenical).

Since 1999 he has been Visiting Professor, Postgraduate Medical School, University of Surrey and was responsible for the development of the part time MSc in Clinical Pharmacology at this University. Member of the Board of Studies, and the Examining Board, for the MSc and Diploma degrees in Clinical Pharmacology, and in Pharmaceutical Medicine. Member of the Post Graduate Medicine Academic Board, and Taught Board, and of the University of Surrey Senate.

Graham has served as a Member of many advisory bodies, including the Scientific Advisory Board of the registered UK charity, Ataxia, advising on the significance of research developments in related fields for Friedrich's and other cerebellar ataxias, the Clinical Pharmacology and Experimental Medicine Advisory Group, of the Association of the British Pharmaceutical Industry, the Industry Advisory Group for the University of Hertfordshire, Faculty of Health and Human Sciences and the Education and Skills Task Force of the Association of the British Pharmaceutical Industry

His commitment to the standards of this Faculty in his professional life as a clinical pharmacologist makes him a worthy candidate to receive an Honorary Fellowship.

### **Fellowship by Distinction**

Fellowship by Distinction was awarded to Dr Fergal Donnelly, Dr Peter Jackson, Dr Henry Pan and Dr Richard Tiner.

### **Dr Fergal Donnelly**

Dr Fergal Donnelly is Scientific Officer within the Biotechnology and Applied Genomics Unit at the Commission of the European Union. He has held this position since the year 2000 before which he was employed in medical roles by UCB Pharma and Pharmacia. Through these earlier appointments he gained experience in regulatory affairs, global marketing and operations and pharmacovigilance. Following Dr Donnelly's election to Membership of the Faculty by distinction in 2003 he has continued to contribute to the work of the organisation and to the speciality in a number of ways. He continues to act as advisor on European affairs to the Faculty's International Committee and is also a member of Faculty's Communications Committee. As a member of the Communications Committee he has been the lead co-ordinator for this year's annual

symposium 'Creating Effective New Medicines'.

### **Dr Peter Jackson**

Dr Peter Jackson has been a member of the Faculty's Board of Examiners for many years and is currently Secretary to the Board. After obtaining MRCP, his career in academic medicine led him into the field of therapeutics with a special interest in cardiovascular medicine. He held an MRC Clinical Research Fellowship and completed a PhD with a study of mathematical pharmacokinetic models of the effect of genetic polymorphisms of drug metabolism on drug disposition. As well as his involvement in multiple research projects, Dr Jackson provides clinical care at the Royal Hallamshire Hospital and is head of the Sheffield Clinical Pharmacology Unit. Dr Jackson is also actively involved in both undergraduate and postgraduate teaching in clinical pharmacology and therapeutics and he stands out as one who remains committed to this important aspect of medical education.

### **Dr Henry Pan**

Twenty-five years of service to pharmaceutical medicine have made Dr Henry Pan a highly respected member of the pharmaceutical community in the United States and beyond. He is currently Executive Vice President and Chief Medical Officer of Neurocrine Biosciences, a prominent biotechnology company in San Diego. Dr Pan has also held senior executive positions at two major pharmaceutical companies, one contract research organisation and an operating company. Dr Pan has been the principal physician responsible for the successful development of seven new chemical entities and he is able to offer the rare experience of taking a new entity all the way from pre-clinical development through launch to billion dollar sales. Dr Pan has been recognised by peers through the award of numerous internal and professional awards and has been nominated to receive Fellowship by Distinction by the Past President of the American Academy of Pharmaceutical Physicians. Dr Pan is described by his proposer as not only one of our most highly regarded pharmaceutical physicians but also as a natural leader, innovator and visionary.

### **Dr Richard Tiner**

Dr Richard Tiner is the Medical Director of the Association of the British Pharmaceutical Industry. Following his election to Membership by Distinction of the Faculty 1999 he has continued to work towards the improvement of standards in pharmaceutical medical

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## Faculty Board and Fellowship Report *continued*

practice. Dr Tiner has nurtured a number of areas of relevance to pharmaceutical medicine within the ABPI: licensing medicines for children, clinical trial registries, EU clinical trials directive and monitoring NHS reforms to name but a few. Dr Tiner was elected by the Faculty to its Board in 2001 and he is also a member of the Faculty's Revalidation Subcommittee. He has supported the Faculty's initiative to introduce a Certificate of Good Clinical Practice examination and the development of the Higher Medical Training Programme. His wider support of pharmaceutical medicine is demonstrated through his

involvement in the Royal Society of Medicine's Section in pharmaceutical medicine and also as a Board member of the Society of Pharmaceutical Medicine.

### **Honorary Membership**

Honorary Membership was awarded to Dr Tony Chandler, Professor Ann Sommerville and Ms Sarah Wark.

### **Membership by Distinction**

Membership by Distinction was awarded to Dr Charles Richard Jones and Dr Jennie Sykes.



*Newly elected Fellows of the Faculty, who received their certificates at the 2005 Fellowship, Membership and Awards Ceremony. From the left, Dr Timothy Paget, Dr Claire Barton, Professor Christopher Davis, Dr Kevin Bridgman, Dr Ranbir Bahra, Dr Brian Gennery, President, Dr Tsutae Nagata, Dr Peter Kleist, Dr Eiry Roberts, Dr Peter Kennerley, Dr Michael Telford*

### **Ordinary Fellowship**

The following Members of the Faculty were awarded Ordinary Fellowship:

Dr Ranbir Bahra

Dr Claire Barton

Dr Kevin Bridgman

Dr Rudolph Buirma

Dr Owen Collins

Professor Christopher Davis

Dr Robert Donnelly

Dr Andrew Hughes

Dr Peter Kennerley

Dr Peter Kleist

Dr Pimprapa Kon

Dr Paul Lacante

Dr Francois Menard

Dr Tsutae Nagata

Dr Timothy Paget

Dr Rafael Ortega

Dr Eiry Roberts

Dr Patrick Round

Dr Jean-Philippe Santoni

Dr Kim Simonsen

Dr Michael Telford

Dr Mark Watling

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## Annual Symposium – Creating Effective New Medicines

Dr Brian Gennerly, President of the Faculty, opened this year's symposium by reminding us that we were all in the business of creating effective new medicines. He also highlighted the fact that undergraduate training in pharmaceutical medicine was now available in some UK medical schools, an achievement he never envisaged occurring during his time as president.

Dr Thomas Lönngren, Executive Director, EMEA then gave an informative presentation outlining changes to European pharmaceutical legislation. This was the biggest change in legislature in 10 years. The aim was to continue the process of harmonisation within the EU that has been occurring over the past 4 decades. To explain the changes the role of the EMEA today was presented – providing scientific advice to pharmaceutical organisations, undertaking pharmacovigilance inspections and information provision to patients / health professionals. The CHMP formulates scientific opinions, with working parties involved in operational issues eg COMT (Committee on Orphan Medical Products), HMPC (committee on Herbal Medicinal Products – the newest committee). The way decisions are reached when assessing risk – benefit will be changing – new methodology will be used including outcomes research. A new senior chief medical officer will commence next year to oversee this.

The priorities for the future include an EMEA roadmap to 2010 and strengthening of the EU regulatory network. This could include utilising the best experts in a particular therapeutic area (rather than giving companies the choice of rapporteur) and perhaps establishing centres of excellence in particular member states e.g. for oncology or paediatrics depending on where the best expertise was located.

New tools would be available including a conditional market authorisation for chronic / long term diseases which would be valid for one year and be driven by risk / benefit analysis, and an accelerated evaluation process (if in the interest of public health e.g. vaccine for influenza)

We were told that the environment was challenging, especially in relation to the safety of medicines. The public demands 'zero' risk. More information should be made available to the public on risks / benefits and risk management plans will have to be formulated by pharmaceutical companies for all new drugs coming to the market.

Transparency and communication would be important as we move forward.

Professor Sir Michael Rawlins, Chairman NICE, then gave a thought provoking presentation entitled 'cutting the cost of drug development'. He highlighted the paradox that there was only a limited amount of money available for governments to spend on healthcare at the same time as healthcare costs were increasing, due to an ageing population and technological advances. These costs would continue to increase due to increasing regulatory requirements and market fragmentation. The industry needs to decrease costs and time of drug development. Highlighting areas where this could be achieved he suggested that much of preclinical development was not evidence based (except mutagenicity) and questioned if money and time spent here could be rationalised. A new paradigm for clinical research was needed with greater use of tools such as biomarkers, surrogate endpoints and HRQOL. In phase 1 perhaps patients could be utilised to a greater extent (rather than healthy volunteers) with efficacy as well as safety assessed.

In terms of trial design greater use of pragmatic and adaptive designs in place of the standard crossover or parallel paradigms could be explored. He suggested the frequentist approach to statistical analysis was too rigid and counterintuitive and that alternative (Bayesian) approaches offered benefits to conventional analysis.

Risk - benefit assessment was also touched on – the conventional approach failed to capture the judgements of the consumer. A patient orientated approach with appropriate trade-offs would increase public confidence in medicines Professor Rawlins suggested.

Dr Ian Ragan, Executive Consultant, European Scientific Affairs, Eli Lilly and EFPIA Research Directors Group, discussed the innovative medicines initiative. As a background it was pointed out that there was declining investment in R+D in Europe, with the US still dominant. In the future this may change, but with India or China emerging as powerhouses for pharmaceutical research. To improve the situation within the EU a Strategic Research Agenda (SRA) for innovative medicines has been developed. As part of this R+D bottlenecks have been identified (including predictive toxicology, patient recruitment and validation of biomarkers). Methods to improve safety and efficacy assessments are being

## Annual Symposium – Creating Effective New Medicines *continued*

developed as well as improved knowledge management systems. The SRA will enable a better understanding of disease, improve translation of lab science to clinical trials and provide partnership with regulators for innovative clinical trial designs. The SRA is a unique proposal that could offer a competitive advantage to the EU but would need the support of member states.

Professor Rory Collins, British Heart Foundation Professor of Medicine and Epidemiology, University of Oxford, outlined potential obstacles and solutions to making clinical trials work. There had been a proliferation of laws and guidelines (EU CTD, data confidentiality) over the past decade that, although well intentioned, were increasing bureaucracy and promoting too rigid an approach to drug development. To overcome these 'obstacles' Professor Collins suggested that there should be widened eligibility criteria, simplified treatment regimes and less time consuming data collections. It

was suggested that the increasing regulatory burden was due to, in part, concerns about misconduct in research – but he suggested fraud in trial development was rare and that the analysis and interpretation of trial results were more problematic and misleading. The time and resource spent monitoring trials at study site could perhaps be better deployed – central monitoring could be just as effective to assess patient eligibility and follow up outcomes. Misconduct could be prevented by relaxing eligibility criteria, assessing compliance crudely, accept that some data will be missing and limit overall data collected.

The symposium was enlightening, informative and provocative. I'm sure all who attended took something away which will influence their daily practice, creating effective new medicines.

*Dr Jonathan Stewart*

## Fellowship Elections 2006

Nomination papers will be posted to Fellows and Members of the Faculty at the beginning of February, with a closing date for receipt of papers of 18 April. The schedule is summarised below.

<b>30 January 2006</b>	Nomination packs distributed
<b>18 April 2006</b>	Closing date for return of nominations
<b>Tuesday 23 May 2006</b>	Fellowship Committee meeting
<b>Tuesday 18 July 2006</b>	List of New Fellows submitted for Board approval
<b>Friday 16 November 2006</b>	New Fellows Ceremony, Royal College of Physicians, London

Nominations forms and further information are available from the Faculty Office or the Faculty website.

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