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Unfortunately, the balance of nature decrees that a super-abundance of dreams is paid for by a growing potential for nightmares.

Sir Peter Ustinov (1921–2004)

This special edition of *Drug Safety* is replete with examples of point and counterpoint and shifts in balance. Foremost we have the ongoing evaluation of the relationship between a medication's benefits and risks, surely the real *raison d'être* for our pharmacovigilance activities. Just how do we optimise this balance in the interest of patients? In the past several years we have seen an incremental shift in behaviours to this end whilst working in drug safety. There has been a clear move away from a reactive paradigm in which pharmaceutical companies emphasise compliance with reporting timelines and regulators take the major responsibility for identifying previously unexpected hazards, towards a world where the expected norm is that companies actively identify new risks and help in their mitigation.

The exercise of risk management spans the whole life cycle of a medicine. This edition of *Drug Safety* touches on many of these elements, from clinical pharmacology through to the periodic safety update report. Recently, we have seen additional points of focus in risk management, with recognition of the long under-estimated risks associated with medication errors and the potential for risk avoidance afforded by increased understanding of the human genome being but two prominent examples.

We see the interplay of varying perceptions of risk management demonstrated by the US FDA's Framework and concept papers, and the strategies proposed by the European Union Heads of Agencies. This edition presents specific US, European and Asia/Pacific regulatory perspectives while also illustrating how such regional approaches are brought together in harmonisation initiatives.

There is also the contrast between the perception that we should be demonstrating the relative safety of medicines, not just finding risks, yet there remains the practical necessity for managing crises when our best efforts have not succeeded as well as they might. And whilst surely all would agree that risk management and pharmacovigilance are in place to fulfil ethical medical obligations, cannot there also be commercial benefits to these undertakings?

Underpinning all the concepts of managing risk is communication – we see the pivotal requirement to communicate with health professionals and patients via product information and other means, but also the necessity for effective communication between regulators and industry utilising a common terminology that, as another counterpoint, may not lend itself so well to external communication.

In inviting the authors of these papers to contribute to a special edition, we felt that time was of the essence. To this end, we may be criticised for having sacrificed completeness of coverage in the interests of immediacy, and indeed papers on signal detection/data mining and pharmacoepidemiology will be appearing in future issues of this journal. We hope that other highly relevant and important topics not included here might be covered in a similar manner. Nevertheless, the authors in the present issue have completed their contributions in a remarkably short time and they, the peer reviewers and the publishers are to be commended for their tremendous efforts. Our watchwords in this endeavour are presented in the title – "the future is now"! We believed that there was an important gap in the published literature that needed to be filled sooner rather than later. We hope that publishing this collection of papers will stimulate others to explore and present new perspectives and ideas on this vital and rapidly evolving topic.

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