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Postmarketing Studies: The Work of the Drug Safety Research Unit

I write this letter because of the recent publication in *Drug Safety* of an article by Dr Fiona Jean Mackay 'Postmarketing Studies – The Work of the Drug Safety Research Unit'.[1] Dr Mackay gave welcome news of the continuation of prescription event monitoring (PEM) as the main of activity of the Drug Safety Research Unit (DSRU). She presented a clear and doubtless sound account of its recent achievements. However, the article maybe read as implying that the first PEM study was published in 1997, thereby ignoring many publications emanating from the originality and pioneering efforts of the unit's founder, in 1981 and later.[2]

The roots of PEM lie in the thalidomide diaster of the 1960s. In the hope of minimising the harm done by any future thalidomide, late Professor Dave Rutstein of the Harvard Medical School in 1962 urged me to look at ways in which statisticians might aid early detection of adverse reactions to therapeutic drugs. In 1965, I published a paper[3] that, although little more than a statisician's wild dream, contained ideas that influenced later developments. I had tried to present a logical analysis of possible organised approaches to the problem. One idea was to collect prescriptions for a new drug and, by inquiry from the prescribing physicians, to learn the subsequent medical history of each patient with special reference to any adverse event experienced, such as jaundice, stroke, nausea, bone fracture, etc. Without any assumptions on causation, correlation between drug and event could then be investigated.

Having seen a draft of my paper, the late Sir Derrick Dunlop invited me to be a member of the Subcommittee on Adverse Reactions, within the UK Committee on Safety of Drugs that he was establishing. I soon became acquainted with Dr William HW Inman, then a medical officer with Dunlop's committee and the originator of the 'Yellow Card Scheme'. He and I began to enjoy sharing concerns about the weaknesses inherent in dependence upon spontaneous reporting by general practitioners; we sought an alternative.

The Dunlop Committee achieved much, but suffered a frustrating lack of resources. In 1979, Dr Inman resigned in order to create his own concept of a drug safety research unit. With courage and by tremendous effort, he obtained funds that enabled him to make a start in Southampton. He had been attracted to my 'wild dream' and had already envisaged the possibility of implementing something of this kind. He became convinced that ascertainment of prescriptions, followed by tracking of subsequent 'adverse events', could be practicable. To this process he gave the acronymic designation PEM, making it a central principle of the DSRU operation that he initiated in 1980. He also negotiated the essential contribution to identification of prescriptions that the official Prescription Pricing Authority in the UK has subsequently provided.

The paper by Mackay[1] fails to mention a vital feature of the DSRU, that is the complete absence of any contractual relation with, or control by, the pharmaceutical industry. Much of the funding for the DSRU came by donations from the industry, but these were accepted only if there was no tie to particular drugs and no restriction on the publication of results of any DSRU investigation.

Dr Inman gathered an excellent and enthusiastic staff, people who initially had no knowledge of drug monitoring or of the PEM philosophy. From the start I was an unofficial consultant, never on his staff, but always a friend at the end of a telephone line. For him there ensued years of challenge, both on medical issues and in the never-ending struggle to obtain funds. Establishment of the Drug Safety Research Trust facilitated a status for the DSRU as a legally recognised charity; the Trustees, included several eminent medical scientists.

From the start, another important principle concerned the need to feed back to physicians information on studies in progress and completed. In addition to communications in the medical press, this was done through *PEM News*, a series of bulletins

published about once a year as reports on progress. An issue might contain several short notices or a major article on a completed investigation. Dr Inman was working under great pressure, but saw it as essential to make time for writing these, in order that good information should reach those who were taking the trouble to supply the DSRU with information on adverse events experienced by their patients. The series continued until Dr Inman retired.

In the early 1990s, Dr Inman found himself unable to continue the heavy programme of travel and lecturing that he needed in order to raise funds for the DSRU. This led him, in the interests of effective management of DSRU to retire. Dr Ronald Mann was then appointed as Director and from 1994 the unit began to approach a closer relation with the University of Southampton's Medical School.

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