I thank Dr Cook for raising some very pertinent issues. Unfortunately, the Therapeutic Goods Administration’s (TGA) decision on the new indication for dexmedetomidine just predated the introduction of the AusPAR system (TGA website\textsuperscript{1} and personal communication from the TGA).

I agree with Dr Cook that anaesthesia and sedation are different states and furthermore are not necessarily representative of different degrees along the same spectrum. Rather than conceptualising

\textit{Anesthesia and Intensive Care, Vol. 39, No. 3, May 2011}
sedation as a uni-dimensional phenomenon culminating in complete anaesthesia, with more drugs and drug combinations available, the profession has the exciting opportunity to explore the myriad of different states that might facilitate the tolerability of noxious procedures. Dexmedetomidine, along with ketamine, opioids, traditional GABAergic agents, etc might allow for safe, comfortable, airway-stable states with suitable anxiolysis while maintaining the ability to co-operate.

In restating the process of drug evaluation by the TGA, Dr Cook raises an important issue: “Before a prescription medicine can be made available in Australia, the company legally responsible for supplying the product must lodge a submission with the TGA. The TGA then evaluates the safety, quality and effectiveness of the product to determine if the benefits to people taking the medicine outweigh the risks”. The transparency that the AusPAR system brings might address a problem with the current system. First, in the evaluation of any drug, there are multiple indices to consider (multiple effects and side-effects) and therefore there are infinite possible overall risk/benefit ratios depending on the weight given to each index. It is accepted that within our current system of medical ethics, the weighting (or importance) of each index is based on personal opinion (although it is sometimes legitimate to override this in the cause of the ethical principle of justice). Furthermore, even the simplest of evidence assessments are influenced by human factors. In commenting on health reform legislation in the United States in the New England Journal of Medicine, the somewhat obvious was stated in relation to our colleagues in the legal profession whose raison d’être is to weigh evidence. Decisions of the US Supreme Court Justices (based on a very limited Constitution and limited case precedent) are often diametrically opposed to each other and consistent with their ideological and political preconceptions.

One solution might be for the TGA to adopt a more ‘what you get is what you see’ approach, whereby they assess and guarantee pharmaceutical quality and give an account of the basic properties of a drug and allow established clinical, medicolegal and peer-review pathways to answer the questions of harm and benefit across different patient groups and individual patients. The current medicolegal standard for assessing the appropriateness of the use of any drug renders decisions by the TGA almost irrelevant anyway, yet enormous amounts of money are required to get a license or new indication.

M. J. Keane
Berwick, Victoria

References