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Comparative effectiveness

All roads lead to CER...

It seems as though the term CER, or comparative effectiveness research, is in the air everywhere I turn these days — it was the subject of nine distinct sessions at the recent DIA 46th Annual Meeting (check out the Editor's Take videos recorded at the conference at pharmavoice.com) and it will be the focus of the upcoming 4th Annual Comparative Effectiveness Research Summit to be held in Philadelphia this November.

And so it is with this issue as well, which is not entirely by happenstance. As this month's Forum outlines, CER is going to have a huge impact on every stakeholder in healthcare delivery and will require everyone to take a much broader view of the healthcare system. In brief, comparative effectiveness data are geared broadly to multiple decision-makers to provide real-world evidence of the outcomes of various treatments. For physicians, CER is going to provide the ability to analyze treatment choices and pick what's best for their individual patients. For patients, it's going to provide them with more information that can help set their expectations for their treatment. For payers, comparative effectiveness will provide support for decision-making about product access and formulary placement that is based on real-world outcomes. (Please turn to the Forum in this issue, for more information.)

As a result of comparative effectiveness, the pharmaceutical business model will need to change. According to IMS Health, a more focused effort, or niche model, will address not only what patient populations to target but what populations not to target. Sydney Clark of IMS says companies will need more data to prove clinical and economic value of their drugs, and decision-making will become more complicated. Pharma companies will need to make these tough decisions earlier on in the process so they have the data to convince stakeholders that their drug will be differentiated in the marketplace. (To read more about the emerging niche model, please turn to the article on Nichebusters vs. Blockbusters).

The pressure of comparative effectiveness will also have an impact on the discovery pipeline, says Gil Bashe of Makovsky + Company. As government agencies require proof of comparative effectiveness before awarding any government reimbursement, companies will think twice about what types of drugs to bring to market. In the future, he says big pharma will take on a mass-market disease only if it can provide a big step forward in terms of treatment solutions.

This sentiment is echoed by the subject of this month's industry bio, Dr. Leon Smith, who has been practicing medicine for more than 60 years and is a pioneer in infectious disease. One of his greatest concerns is a dearth of research into new drugs, particularly antibiotics in the wake of gram-negative resistance to existing antibiotics. (To read more about his inspiring career, please turn to the feature story The Age of Excellence.)

As CER becomes more established and gains acceptance in the United States, the already astronomical cost of drug development is likely to continue to increase due to the need for ever larger studies with potentially longer duration to demonstrate superiority in end points. As Ogilvy CommonHealth thought leaders outline in their VIEW on Med Ed — Comparative Effectiveness Research: Watch and Worry or Weigh In and Leverage? — justification for healthcare choices should include effectiveness, safety, and convenience for an individual patient, in addition to cost. As such, med ed groups will have a great opportunity to partner with manufacturers to educate decision-makers and the general public about the nuanced value of CER. (To read more about the impact of CER on this sector, please reference the VIEW on Med Ed.)

Where CER will eventually take us is anybody's best guess, but the ride will no doubt be interesting.