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/THE FIRST WORD

Putting Value on Biotech Drugs

Drug makers, large and small, must put cost containment and global health-care reform considerations into any equation about clinical drug development. It is no longer enough to prove that your drug is safe and effective to get it through the clinic and into the market. You also need to show that it has value—that it is either a pioneer drug that meets an unmet medical need or that it is more cost effective than currently available treatments. This was one of the theme's sounded at *Bio/Technology's* meeting "Clinical Trials: New Paradigms for Success," held in Washington, D.C. at the end of June.

Australia already mandates pharmacoeconomic outcome studies in addition to demonstrations of safety and efficacy, and the United Kingdom has recently issued a 12-point guideline for the pharmacoeconomic evaluation of new products. But whether the U.S. Food and Drug Administration (FDA) and other regulatory agencies follow suit isn't the issue. Nor is whether it is fair to concentrate so much cost containment energy on drugs, which make up only about 8 percent of total medical expenses in the U.S. Biotech therapeutics are highly visible targets, with typical treatments running from \$1,000 to \$150,000 per patient per year. Those who are paying for these new therapeutics—be they government bodies, insurance companies, or managed care organizations—want to know the value of what they are paying for.

The analyses used to assign value—called outcomes analyses or outcomes research—are critical to biotech product development in a market in which the paying customers are running the show, as George Poste, president of R&D at SmithKline Beecham, and Alison Taunton-Rigby, president of Mitotix, among other speakers, made clear.

Outcomes research need not be a death knell for drug development. For while it is true that biotech therapeutics are expensive, in large part because many of the diseases they target are complex, it is also true that they are often cost effective in terms of the dramatic changes they can make in patients' lives. And pharmacoeconomic data gathered during clinical trials can be used to expedite the FDA approval process, as was the case with Pulmozyme, when Genentech was able to demonstrate that patients who received the cystic fibrosis drug spent fewer days in the hospital—one measure of cost effectiveness.

But as Taunton-Rigby pointed out, the definition of "cost effective" depends on who's doing the defining—patient, drug developer, or third party payer—and on what methods are used to calculate it. And no matter who is calculating, the data often lead to difficult questions. With Genzyme's Ceredase treatment for Gaucher's disease, it seems clear that the drug adds value even though it is enormously expensive. But what about Activase, Genentech's tPA clot dissolver for myocardial infarct patients? In the postclinical GUSTO trial, Genentech was able to show a 1 percent improvement in mortality rates for those who received Activase over those who received the traditional treatment, streptokinase. If all 200,000 annual U.S. patients receive Activase, the cost is \$400 million a year, versus \$40 million a year for streptokinase administration. If you are the insurer, that 1 percent is insignificant and streptokinase is the drug of choice. If you are the drug maker, that 1 percent represents 2,000 lives saved. If you are the patient, you want that 1 percent on your side. Who gets what treatment? Who decides?

These questions and the many more like them that will be churned up in the wake of health-care reform demand answers. Outcome research—looking at the patient, the disease, and the social consequences of treatment collectively—is one way of gathering the facts on which to base them.

—SUSAN HASSLER