Comparative Effectiveness Research Produces Contentious Debate—To What End?

Stephen Barlas

N early everyone connected to the pharmaceutical industry agrees in principle that the kind of comparative effectiveness research on drugs, funded by the congressional stimulus bill passed in February, is a good idea. But that consensus quickly breaks apart when questions arise about how that research should be conducted and used.

Sam Muszynski, Director of the American Psychiatric Association’s Office of Health Care Systems and Financing, says:

No one would disagree that we should be looking into comparative effectiveness research. But there are always questions about how objective and reliable the data [are], and whether [they] should be tied to reimbursement and national policy. That is when the hair on the back of the neck starts to rise.

Some of those differences of opinion may get sorted out as the $1.1 billion allotted in the stimulus package, which President Obama has now signed, is deployed. But that won’t happen quickly. For one thing, the Institute of Medicine has until June 30, 2009, to make recommendations to Congress and to the secretary of Health and Human Services (DHHS) about national priorities for comparativeness research. At the same time, DHHS will be setting up a 15-member Federal Coordinating Council for Comparative Effectiveness Research that will make its own (apparently parallel) recommendations by June 30, 2009. This new federal committee will then ostensibly ride herd on research efforts.

Past history may be both instructive and cautionary here. Some readers may remember the Reagan–Udall Foundation (RUF), created by Congress in the 2007 FDA Amendments Act. The RUF was charged with advising the FDA on how to identify and address unmet scientific needs in the development, manufacture, and evaluation of the safety and effectiveness of FDA-regulated products, including postmarketing evaluation. A big name was appointed chairman: Mark McClellan, MD, PhD, former FDA commissioner and former Centers for Medicare and Medicaid Services (CMS) administrator. Members were announced in November 2007, but that was the last time anyone heard from the RUF. A spokeswoman at the FDA says that the Foundation has met many times but is still in start-up mode.

Part of the problem with the RUF was a lack of congressional funding. That won’t be the problem with the coordinating committee and comparativeness research, which has $1.1 billion to play with. The stimulus bill suggests that the money will be broken down into three streams: $300 million for the Agency for Healthcare Research and Quality (AHRQ), $400 million for the National Institutes of Health, and $400 million for DHHS at the secretary’s level. Regardless of which of these three agencies dispenses the funds, the money is to be used to determine clinical effectiveness and the development of clinical data networks.

The AHRQ has been funding comparative effectiveness research for a decade that has yielded much, and there has been some sniping at the AHRQ as a result. Judith Cahill, Executive Director of the Academy of Managed Care Pharmacy, says:

Current federal comparative effectiveness initiatives have heretofore been insufficiently funded and therefore limited and modest in their scope; they have not been coordinated across agencies and institutions.

There is clearly a strong desire on the part of employers, federal programs such as Medicare and Medicaid, and pharmacy benefit managers (PBMs) for valuable clinical insight into which drugs within the same classes work best—and comparisons across categories in a class (e.g., atypical antipsychotic agents versus typical antipsychotic medications). But pharmaceutical manufacturers oppose a program that basically gives five stars to one drug and one star to a competitor. Physicians also worry about that; sometimes a patient might require the one-star drug because of side effects with the five-star alternative or because the five-star product was tried and didn’t work. That’s why the bill includes language stating that Congress does not intend for the research money to be used to mandate coverage, reimbursements, or other policies for any public or private payer.

Congressional language aside, however, it is difficult to imagine that Medicare, for example, would not use the research results to make policy for Part D formularies. Medicare has already come under fire for a policy that forces Part D plans to make available “all or substantially all” clinically distinct drugs in six categories: antidepressants, antipsychotics, anticonvulsants, immunosuppressants, antiretrovirals, and antineoplastics. Budget-conscious observers consider that unnecessary. That’s why Congress included an amendment in a Medicare reform bill, passed last year, requiring CMS to use new standards to determine whether those six classes should remain protected and whether other classes should be added to the “protected” list. CMS starts a rule-making on that in 2010. Some of the $1.1 billion for comparative effectiveness research that is now burning a hole in the pockets of the three federal agencies that will undoubtedly be used to sort out the competing drugs in those six categories. One would think, given President Obama’s drive toward health care reform, that it will be important to get comparative drug research right. Drug company sensitivities and federal oversight inadequacies will have to be overcome if the effort is to succeed.