/THE FIRST WORD

Managed Innovation?

Can innovation be managed, in much the same way we like to imagine we are managing information and care? At "Drug Development in the Era of Health Care Reform," a meeting of pharmaceutical executives sponsored by the Center for the Study of Drug Development last month, the answer would most likely have been yes.

Controlling the drug development future by figuring out how much everything costs down to the last centime through project and portfolio management was on many minds and tongues. Getting everything right ahead of time, factor analysis, strategic planning, streamlining, and cost containment were touted as the keys to unlocking this future.

Some speakers focused on the need to understand and respond to who are the paying customers now and what they want—and the paying customers are an expanding group that includes the government, third-party payers, physicians, nurses, pharmacists, formularies, self-insurer cartels, etc.—an innovation-on-demand approach.

The desire to make the future happen in playback fashion is not unreasonable and is based on some harsh realities—that it costs, by PhRMA estimates, $350-400 million dollars to develop a new drug; that, at the end of the day, there may be 1-3 fully integrated biopharmaceutical companies, 10-15 platform companies, and perhaps 50-100 successful research boutiques, which leaves everyone else doing something else in some other capacity; that generic drugs are annihilating the half-life of drugs still in patent; and, as Uwe Reinhardt, James Madison Professor of Political Economy at Princeton University, pointed out, that health-care maintenance organizations, whose profits rest on deep drug and medical service and supply discounts, are now very much running the show. While managed care is still largely an American phenomenon at the moment, that may not be true for much longer.

But will cutting the cost of development expedite the discovery of new drugs? It doesn't seem likely. Without a good deal more basic, nontargeted research, it's difficult to see where the new blockbuster drugs will come from.

In the midst of all the highly manageable talk of cost cutting and fiscal manipulation, a few hardy souls took the no guts, no glory approach that it is up to the companies to decide which royal research roads to follow, that innovation and the challenge of unmet medical needs, not the paying customers, must point the way. Several speakers gave examples of drugs that didn't emerge from targeted programs but were in fact designed with one indication in mind and ended up being suitable for others. Gabriel Schmergel of Genetics Institute talked about EPO and GCSF—both now billion dollar markets—both of which started out as orphan drugs and drew little initial interest because no one understood what they could or would be able to do. But that's the problem—you can't know what's a blockbuster and what's not unless you can guess what all the indications will be.

Surely things can be done to make the development of drugs less costly. The dropping of the reasonable pricing clause from the U.S. National Institutes of Health CRADA agreements was good for business. Harmonization within the EC and between the newly minted European Medicines Evaluation Agency and the U.S. Food and Drug Administration, and the creation of a common drug dossier for clinical trials, can only be helpful if they can be achieved.

Pharmaceutical companies will continue to pay top dollar for the innovations they have calculated they need. But they may not, like their biotech compatriots, be able to think of everything they need in advance and in detail.

Who then is going to pay for the nontargeted research needed for big breakthroughs to occur? A basic research fund, supported by health-care maintenance organizations and third-party payers, as well as the biopharmaceutical industry, was one suggestion that came up in Princeton.

For all the talk of the need to quantify, predict, and change the future, the most important activity may be to allow the future to happen, by continuing to fund basic research, the real innovation that drives the pharmaceutical engine. There's is no better time than the present to recognize its importance.

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