DEAR CEO: COME OUT FROM BEHIND THAT TECHNOLOGY

by Peter Dorfman

In the innocent early 1980s, the rubric of biotechnology alone seemed sufficient to attract first-class minds and money. Time-frames for commercialization were far enough out that it didn't much matter what the specific products of these technologies ultimately would be.

Those were the days. Needless to say, the financial markets are not working that way now, and many firms still waiting for their big break are rather urgently in need of cash. For anyone in this position, the ability to generate equity capital is essential to survival.

If you don't offer the market what it wants now—a good, *short-term* opportunity for capital gain—and you have the wisdom to admit it, you'll appreciate better what's happening when rapid-fire press releases don't move your share price. News has a habituating effect. Constantly issuing minor press releases will discount the importance of each bit of news. Much of it won't even be published. Worse, important announcements will be tossed along with the fluff. In short, those who live by the press release die by the press release. A key element of a genuine biotechnology public relations strategy instead should be to become identified with genuine marketing objectives and, to paraphrase a recent rallying cry from Presidential politics, come out from behind that technology.

There's technology, and then there's practical reality, which is what interests people with dollars to invest. Your company has technology. Now, how do you convince a wary and opportunistic market that you and your company also have generous helpings of practical reality?

Hence arises **Dorfman's Test of Bioesotery**: If your product or therapy were available, Food and Drug Administration (FDA)-approved for human use tomorrow, would a conservative physician in the appropriate specialty actually prescribe it? If you can look yourself in the eye and say Yes! without laughing out loud, then *you* at least are convinced your company has generous helpings of practical reality. Unfortunately, convincing the rest of the world is another problem, entirely.

Today we have a dozen-odd FDA-approved products of biotechnology to measure Dorfman's Test against, and an array of others waiting in the wings. One thing the approved products all have in common is that there is little or no controversy as to their place in the conventional practice of medicine. Nothing had to be changed about the ways physicians, hospitals, and, perhaps most important, payors behave in order to shoehorn these products into the clinical infrastructure. In at least one case—erythropoietin—it probably is fair to say most of the target prescribers were eager to get their hands on the stuff when approval came, which is rare indeed.

In other cases (recombinant insulin, human growth hormone, monoclonal antibody diagnostics), the biotech products easily substitute for conventional ones and have safety, efficacy, or cost advantages. Or, they are novel agents with clear therapeutic advantages over the existing therapy, as was the perception—at least initially—with tissue plasminogen activator and might be argued for OKT-3. Or, while the indication is clear, there is no existing therapy (alpha interferon for hairy cell leukemia).

It gets tougher to make these sorts of cases for the next crop of biotech products. Many of the biologic agents were submitted to the FDA requesting approval for clinical endpoints which are not traditional disease indications; this kind of application is not unprecedented, but no one has ever had an easy time with it. The agency typically responds with a stipulation: The research must demonstrate that the therapy causes patients with a specific disease or diseases to, for example, mend faster, live longer, or, more liberally, have a better quality of life.

The FDA will no doubt approve a number of new biomolecules on this basis in the next few years. But agency approval is a key hurdle which is followed closely by at least two other equally critical hurdles linked to attracting later stage financing: Physician adoption (read market acceptance) and approval for reimbursement. These days investors demand concrete answers to these follow-up issues. But anyone pitching adoption rates for the new biologicals in preclinical or clinical evaluation is throwing knuckleballs.

The theme of physician adoption brings us to a variation of Dorfman's Test that might be useful in valuing new projects: If the medical community is ready now to incorporate the new product into its current way of doing things, the product is likely to have a favorable adoption profile and should be considered seriously for funding. Conversely, if either the mode or site of treatment has to be altered significantly or created from scratch, the developer had better have a strong supporting rationale.

An extremely compelling modality may never find a constituency because its use requires development of a whole new treatment setting (e.g., a dedicated clinic) or a new class of specialists. Two essentially similar approaches to the same general idea thus may be distinguished by the criterion of "fit" into current medical practice.

Biotech companies need to find and articulate that fit for their products. A fortunate few already have, because their products will have inherent utility (some of the tissue growth factors and granulocyte macrophage-colony stimulating factor among them). Other companies will simply have to refine their market niches to achieve this perception. A logical first step is to establish relationships with clinicians in target specialties who are willing to become advocates not only with respect to the purported efficacy of the product, but to the readiness of physicians to adopt it now.

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