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/THE FIRST WORD

Biotech Goes To Trial

Clinical trials in biotechnology tend to amplify the manic-depressive aspects of the investor personality. When the results are good, things look very, very good, and when the results are bad, or even neutral, things look totally rotten. Large pharmaceutical companies don't seem to elicit quite the same response—they can launch, abort, succeed at, or fail clinical trials without so much as a little blip registering on the big screen of investor confidence. For biotech companies, however, each clinical trial result is either the dawning of a new day or the launching of a nuclear attack. Genentech's Pulmozyme and Chiron's Betaseron brought the new dawn; the phase III falters of Magainin, MedImmune, Regeneron, and SciClone sent investors to the bomb shelters. Revelations about data alteration and suppression in National Cancer Institute-sponsored breast cancer trials haven't helped matters either. This is not an easy way to live, especially for an industry that gets 80 percent of its working capital from said investors.

What's biotechnology to do? First, perhaps, is to recognize that it has brought investor jitters down on itself through its propensity for touting every new molecule that straddles a gel as the latest and greatest cure. Rational drug design and gene therapy, to name but two, are a long way from giving to the investing public the curative results they have promised.

Second is to acknowledge that drug development is as important to biotechnology as drug research, and that planning for clinical trials is absolutely crucial to success in this area. On the 20th and 21st of this month, in Washington, D.C., *Bio/Technology* is sponsoring what we hope will become an annual conference on clinical trials, because biotechnology's future rests on its ability to approach clinical trials with knowledge and foresight. The conference features a case-study approach aimed at giving attendees real-world problems and real-world solutions [information: 212-477-9699].

Drug development is a high-risk business. Only 1 in 10,000 newly synthesized substances becomes a marketed drug. It takes 10-12 years to develop, and another 3 years or so, on average, to get through the U.S. Food and Drug Administration (FDA). This leaves little time for any company to capitalize on its drug patent and recoup a return on its investment. Rapid investor response to unsatisfactory biotech clinical trials is not simply feckless—investors know that, for smaller companies, time lost in clinical trials means depreciating patents and products.

In a commentary in this issue, David Stone offers advice to investors on biotech clinical trials—what to look for, and what to look out for, including the ever-valuable *beware of the drug in search of a disease*. Here, we would like to offer a few suggestions to those about to enter into clinical trials. If you are already there, none of this should be news to you. If it is, you're in trouble.

Everything takes much longer than it should, except failure. Find out as much as you can about clinical trials past, present, and future before you need to know about them. Leave enough time to find enough patients (Louis Lasagna's law of inclusion/exclusion criteria, that most of the time lost in clinical studies results from an overestimation of the number of patients available), assume that the trial setup will take at least a year to put together, remember that reaching consensus and writing protocols and printing forms never proceeds according to plan.

Go for quality. "Me-too" drugs will now take even longer than innovative therapies and real drug improvements to get through the FDA. This is truly a case where less is not more. Balance basic science and therapeutic needs.

In our last issue, Brandon Fradd wrote about the phase III clinical trials that are already underway this year: Advanced Tissue Sciences with Dermagraft; Amgen with granulocyte colony-stimulating factor; Creative BioMolecules with osteogenic protein-1; Gensia with Protara; Glycomed with Galardin; Scios Nova with atrial natriuretic peptide; Synergen with Antril. We wish them all the best, and urge those following in their footsteps to pay close attention to their methods, successful and otherwise.

—SUSAN HASSLER