•Breakthrough technology;
•A disease focus representing major, unsatisfied markets;
•Validation through corporate alliances and/or clinical data;
•A lead, commercializable product that is already in human testing or will enter the clinic this year;
•Well-protected intellectual property position; and
•Strong management.

From the resulting pool of stocks, a basket could be selected by using the following factors:

•Disease focus/core technologies.

However confident of the highly rational basis of the novel technologies and therapeutic strategies that underlie these companies one might be, one has to recognize the risks inherent in early-stage biopharmaceutical companies. Consequently, it makes sense to diversify development risk by choosing a mix of companies using a range of core technologies to target a range of diseases.

The time is right because valuations look inexpensive and companies have a lot of cash.

•Time to "inflection point." The first hard, albeit preliminary, evidence that a company's lead product could succeed—and therefore move the stock to a significantly higher level—comes from human efficacy data. In many cases, companies with products already in the clinic or expected to begin human testing this year should be able to generate such data, which typically comes from a phase II study, by the end of 1994.

•Technology value. Assuming fundamentals have not been abandoned entirely in current valuation by the market, stocks that have retained relatively more technology value during the ongoing correction probably have the best fundamentals. This argues for a bias to the more "expensive" early-stage stocks.

Some stocks that satisfy the screening criteria outlined above are Affymax (Palo Alto, CA), Alteon (Northvale, NJ), Amylin Pharmaceuticals (San Diego, CA), Athena Neurosciences (S. San Francisco, CA), Cytel (La Jolla, CA), Genta (San Diego, CA), and IDEC Pharmaceuticals (La Jolla, CA).

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INTEREST IN CONFLICT OR...

CONFLICT OF INTEREST?

WASHINGTON, D.C.—Jeremy Rifkin and Andrew Kimbrell of the Foundation on Economic Trends (Washington, DC) recently asserted that the National Institutes of Health (NIH, Bethesda, MD)—specifically, the Recombinant DNA Advisory Committee (NIHRAC)—is not adequately guarding against conflicts of interest. They also accuse former NIHRAC chairman Gerard McGarrity of committing an "ethical breach" when he changed jobs last year. In demanding a remedy, the foundation formally petitioned NIH director Bernadine Healy to have NIHRAC members fully disclose relevant investments or other potential conflicts of interest.

In response, NIH officials say that current procedures, which require advisory committee members to file confidential disclosure statements, provide ample protection against conflicts of interest. Moreover, members of NIHRAC disagreed with the foundation over how to change current practices, arguing that NIH and other federal agencies—not the committee itself—would need to consider making any changes concerning disclosure statements or other matters affecting potential conflicts of interest. In addition, the committee staunchly defended McGarrity, asserting that he exercised great care and thus avoided the conflict of interest that the foundation claims he committed.

"Serious ethical breach"

Last year McGarrity moved from his position as president of Coriell Institute (Camden, NJ)—a cell-repository facility—to become vice president for development of Genetic Therapy Inc. (GTI, Gaithersburg, MD). As its name implies, GTI is involved in several phases of gene-therapy research, including preparing retroviral vectors for numerous NIH researchers who are conducting gene-therapy clinical protocols.

The foundation calls McGarrity's actions, including his negotiations with and subsequent move to GTI while he was NIHRAC chairman, a "serious ethical breach." Kimbrell points out that McGarrity chaired NIHRAC during a period when several critical matters involving gene therapy came before the committee, including decisions as early as 1988 to approve protocols submitted by NIH researchers who have collaborated with GTI. Kimbrell also says that GTI secured a multimillion dollar investment in November 1991, shortly after McGarrity left the committee and joined the company. He contends that McGarrity's NIHRAC ties could have helped GTI secure the investment. "That is a clear appearance of a conflict of interest," Kimbrell says, noting that federal laws deal not only with actual conflicts of interest but also the appearance of such conflicts.

McGarrity denies any wrongdoing, pointing out that in his move to GTI he was "totally open and honest" and that he has been "fully responsive to the spirit and letter of all applicable rules and regulations."

In a formal statement, GTI asserts that the company's arrangements with McGarrity "do not create any actual or apparent conflict of interest." The statement further notes that, during the October 1991 meeting of NIHRAC, McGarrity stated his pending career move and did not participate in any deliberations affecting research connected with GTI. He also notified federal officials in writing of the planned move to GTI and took other steps to formally "recuse" himself from activity that would risk a conflict of interest. Although McGarrity technically remained chairman of NIHRAC until January 1992, the title was his merely as a convenience to NIH until the appointment of his successor, Barbara Murray of the University of Texas Health Science Center in Houston, was approved.

"Shocking dismissal"

During the June meeting of NIHRAC, members of the committee strongly disagreed with the foundation's assertions about McGarrity and also concluded that it was not the appropriate forum in which to consider the foundation's petition. The committee's cool reception upset Kimbrell. The committee's "complete dismissal" of the foundation's petition is "shocking," he says.

"The issue of conflict of interest is not without merit," says NIHRAC executive secretary Nelson Wivel. However, he says, "Despite the histrionics, Kimbrell raised his allegations in an imprecise fashion and could not identify any information indicating any conflict of interest."

Moreover, the committee is the "wrong place" to deal with procedural issues affecting conflict of interest, Wivel adds. Thus, the Administration or Congress would need to consider the issue, either by changing disclosure procedures across affected federal agencies or by considering other changes that would further safeguard advisory committees such as NIHRAC and others within NIH against real and apparent conflicts of interest.

—**Jeffrey L. Fox**