

INFORMED CONSENT BUYER BEWARE

by Helen Lawler, M.A.

To make their investments in human genome research pay off, pharmaceutical companies need to sell the public on the superiority of gene therapy and diagnosis over other alternatives. According to a

Time magazine article, "Pharmaceutical companies stand to make incalculable billions of dollars by turning genome research into new treatments . . ."1 The Seattle Post-Intelligencer reported in August that: "Biotechnology companies in the Pacific Northwest have 240 clinical trials for new biological pharmaceuticals under way, . . ."2 Gene therapy - the insertion of genes into living patients - is the most dramatic application of genetic engineering to human medicine. But the concept of genotype-based diagnosis has the potential to affect more patients.

Gene therapy

"Gene therapy, simply defined, is the placement of beneficial genes into the cells of patients. . . ."3 Most gene therapies use genetically altered viruses, according to the same article: ". . . scientists render the virus harmless by deleting some or all of its genes, splicing the therapeutic virus into the remaining genetic material and, . . . mixing it with human cells."3

The injection of genes into a patient's heart to induce the growth of new blood vessels is an exception to the use of viruses. The "naked" genes don't remain active as long as genes spliced into viruses, but enough new blood vessels grow during that time.3

Relatively few gene therapy trials make it through Phase III testing, and many trials have failed in Phase I or Phase II.3 Scientists have difficulty explaining the first death directly related to gene therapy trials.4 The combination of adenovirus genetic material and therapeutic genes spread to unintended organs of an eighteen-year-old man's body, causing a high fever and subsequent death.

Genotype-specific diagnosis

Genome research is delving into why some individuals react differently to the same medicines. Pharmaceutical companies expect to be able to interpret individual genetic profiles "to figure out ahead of time who is most likely to suffer an adverse reaction."5 Under such conditions, it's not hard to imagine patients being persuaded to submit to DNA testing as a prerequisite to treatment. Unfortunately, results of a National Institute of Health study, reported in the Journal of the American Medical Association, cast doubt on the reliability of some current genetic tests which have been rushed to market without sufficient precautions to assure accuracy.6

At a National Institute of Health conference in early August, Jane Henney of the FDA expressed concern about bias and potential conflicts of interest by scientists who own stock in pharmaceutical companies.7 So much for the objectivity of "science-based medicine!"

In the next issue: More on genetically engineered hormone, proteins, and even vaccines.

Endnotes:

1. Lemonick, Michael D., and Thompson, Dick; "Racing to Map our DNA," Time, 1/11/99, p. 46
2. ["Clinical drug trials run by NW firms," Seattle Post-Intelligencer, August 22, 2000. Patients with questions about trials for specific diseases can call Phil Ness at Info.Resource (206_937_3620) or Sharon Schierle at Axio (206_577_0251)]
3. Jaroff, Leon; "Fixing the Gene," Time, 1/11/99, p. 68
4. Marshall, Elliot; "Clinical Trials: Gene Therapy Death Prompts Review of Adenovirus Vector," Science, 12/17/99, pp.2244_2245
5. Cray, Dan, et. al.; "Drugs by Design," Time, 1/11/99, p. 81

6. Bogardus, Sydney T., Jr, MD, et al; "Clinical epidemiological quality in molecular genetic research," JAMA, V281:20 5/26/99, pp 1919_1926

7. "Medical research methods get critical look at conference," The Associated Press, Seattle Post_Intelligencer, 8/11/2000, web site: aspe.hhs.gov/sp/coi/frcoi.htm