GOVERNMENT STUDY

# OTA TO TAKE ANOTHER LOOK AT BIOTECHNOLOGY

WASHINGTON, D.C.—The U.S. Office of Technology Assessment (OTA) has initiated a project called "New Developments in Biotechnology." The 28-month assessment, which began officially on October 1, will produce technical memoranda, background papers, and small reports, plus an overall assessment volume.

According to Louise A. Williams, who is leading the project, the first action will be a November workshop on deliberate release of genetically engineered organisms into the environment. The meeting, sponsored jointly with the National Science Foundation, will emphasize technical issues of the vector mechanics of recombinant microbes.

Throughout the assessment, OTA will examine technology with an eye to predicting its direction and importance. Although OTA has not yet selected definite topics, Williams notes that her office has received some specific requests from Congressional committees. Among the issues likely to be included are:

- Federal funding of basic, generic applied, and risk assessment research;
- Patents (including, possibly, deposit requirements);
- International concerns, such as export control;
- Social relevance of products (such as a malaria vaccine) and how to facilitate technology use by the Third World;
- Patients' rights (to what extent should people retain ownership of products derived from their tissues or fluids, and what are the ethical and legal ramifications); and
- Ethical issues of gene therapy.

OTA might also assess the quality and accuracy of biotech information reaching the general public. This could include a case study of several representative high schools to determine what students are being taught about biotechnology. Williams says that the agenda should be firmed up by the beginning of next year.

OTA intends to produce a variety of comparatively short documents, each tailored to a particular topic. This will be in sharp contrast to the Office's thorough but much delayed *Commercial Biotechnology: An International Analysis*, which came out in 1984 and stretched to 600 pages.

"We built flexibility into the project because we wanted to be able to be responsive to Congressional needs and to the directions the technology takes within the next year or two," says Williams, who was a senior analyst for OTA's 1984 report. "That is why we will be publishing several documents."

Williams reports that OTA has approximately four people working on the project now, but expects to increase staff soon. OTA also is now choosing members for the assessment's advisory panel.

**—Arthur Klausner**

RFLP TECHNOLOGY

# GETTING CLOSER TO THE CYSTIC FIBROSIS GENE

TORONTO—The recent discovery by scientists at this city's Hospital for Sick Children of a chromosome site close to the gene responsible for cystic fibrosis is the first practical application of an effort by Massachusetts scientists to construct a human gene map.

Scientists at Collaborative Research (Lexington, MA) are mapping the genome—the body of genetic material contained in every human cell—by isolating genetic markers, or segments of the genome that vary from individual to individual. Canadian scientists Lap-Chee Tsui and Manuel Buchwald have used one of the 525 markers (known as restriction fragment length polymorphisms, or RFLPs) identified so far to search for the DNA segment or segments responsible for cystic fibrosis (CF). They have analyzed DNA from 54 Canadian families with at least two children who have the disease.

The CF marker was isolated by Southern blotting, but the scientists weren't home free yet. By correlating inheritance of the disease gene from each carrier parent with inheritance of each marker, Tsui and Buchwald found a marker that is co-inherited with the disease 85 percent of the time. This indicates that the marker is some distance from the CF gene. However, there is no doubt that the marker is still quite close: the odds in favor of true linkage between the gene and the marker are 10,000:1. (By convention, 1,000:1 odds are sufficient to indicate true linkage.)

The search can now begin for the specific CF gene—a task in some ways more daunting than the search for the marker. Eighty-five percent co-inheritance means that the marker is still some 15 million base pairs *to either side* of the CF gene. Because it is unfeasible to "walk" down the chromosome to the CF gene by cloning that many base pairs, scientists must first find a marker much closer to the disease gene.

Buchwald played down any link between this discovery and a possible cure for cystic fibrosis, which affects one in every 2,000 Caucasian children. It is true, he said, that "the ultimate cure will only come when you find the gene."

"So, if this is a first step toward finding the gene, then I suppose it's a first step toward finding a cure."

But he stressed that finding the gene does not guarantee that there will be a cure. There are some diseases, such as Tay-Sachs, for which the gene has been located but for which there is still no cure.

**—Mark Timm**

# BIO/TECHNOLOGY STOCK INDEX

NEW YORK—It's been a long wait, but the *Bio/Technology* Index of Specialty Firms finally climbed back over the 1000 mark where it was set in July of 1983. In fact, the index rocketed all the way to 1192 as of November 13, up from 966 a month earlier.

In a generally record-setting market, the big biotech gainer was Genentech, which climbed 12 points to over $55 per share on news of FDA approval of its engineered human growth hormone, and on its report of higher profits for 3rd quarter 1985.

The month's other big news was that Bristol-Myers agreed to buy Genetic Systems for $294 million. Following Eli Lilly's decision to purchase Hybritech, the move leaves Centocor as the largest free-standing monoclonal antibody specialist. Centocor stock price has risen to 21½, up 30 percent since the middle of October.

**—Arthur Klausner**